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External Service Providers (ESP) for Software Applications

Open Invitation to Tender EMEA/2008/71/PM-IT

Version 1.0

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1 About this document

This document contains all the necessary information for tenderers interested in preparing and submitting a bid for tender EMEA/2008/71/PM-IT.

1.1 Glossary

Term	Description
Application domain	The technical type of the system to be built. The currently identified types are: • On-line transactional processing systems; • On-line analytical processing systems • Document and records management, content management and web-publishing systems • Enterprise resource planning • Oracle products
Architecture & Products	These terms are used in the Skills Lists to describe (a) the structure or structures of a system which comprise software components, the externally visible properties of those components, and the relationships between them; and (b) software that facilitates the accomplishment of a task via development.
Benchmark	In the context of this tender a benchmark is not a minimum requirement, rather it is a point of reference for a measurement:
Business domain	The business context in which the system is to be built. The currently identified types are: • Medicines information • Pharmacovigilance • Regulation
Charges	The amount payable covering all the services provided, exclusive of VAT
Contractor	A tenderer to which a framework contract has been awarded.
Effort	The amount of work required to complete a task.
Elapsed time	The actual time between starting and ending an activity
Evaluation Committee	A committee made up of EMEA staff which is tasked with evaluating the tender responses. The committee may call upon technical experts for assistance; such experts may be non-EMEA staff.
Pharmacovigilance	The detection, assessment, understanding and prevention of the adverse effects of medicines
Staff turnover	Turnover refers to the number of employees who have left the company within a given period of time – normally expressed as a percentage of the total staff employed and calculated annually
ICH E2B	A data exchange standard for the submission of information on adverse reactions in connection with the use of pharmaceuticals for human use.

ICH	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use.(www.ich.org)
IT consultancy	The provision of expert advice in the area of IT
IT services provider	The provision of individuals and/or services in the area of IT to companies
Methodology & Techniques	These terms are used in the Skills Lists to describe (a) the principles, methods, rules and procedures employed by discipline; and (b) procedures used to accomplish a particular task.
Recruitment consultancy	A company which advises other organisations about recruitment, as well as providing personnel.
Standards	A rule or set of rules or requirements which are widely agreed upon and supported by an organisation regarded as authoritative.
Tenderer	An organisation or group of organisations which is submitting a response to this invitation to tender.
Tools	This term is used in the Skills Lists to describe software that facilitates the accomplishment of a task via simple deployment and configuration.

2 Executive summary

This tender aims to put into place contractual arrangements, on a time and materials or fixed price basis, that will enable EMEA to specify and acquire services and artefacts provided by resources not employed directly by EMEA. These resources will contribute expertise directly to the design, construction, implementation and maintenance of applications developed or implemented in house in both the Corporate and EU Telematics communities.

EMEA estimates, without this being binding, that the contract value for each lot over a four-year period will be:

Lot No.	**Description**	**Estimated Contract value over 4 years = €**
Lot 1	Provision of resources on a time and materials basis for on-line transactional processing systems	€30,000,000
Lot 2	Provision of resources on a time and materials basis for on-line analytical processing systems	€4,000,000
Lot 3	Provision of resources on a time and materials basis for document and records management, content management and web-publishing systems	€4,000,000
Lot 4	Provision of resources on a time and materials basis for an enterprise resource planning system	€4,000,000
Lot 5	Provision of resources on a time and materials basis for Oracle products	€4,000,000
Lot 6	Provision of ICT systems on a fixed price basis	€8,000,000

Publishing Authority	European Medicines Agency
Purpose	The selection of one or more companies for the provision of services, on a time and materials or fixed price basis, that will enable EMEA to specify artefacts and acquire resources not employed directly by EMEA in the domains of the development and maintenance of information and communication technology systems. These resources will contribute expertise directly to the design, construction, implementation and maintenance of internally developed applications.
Tender	• External Service Providers (ESP) for Software Applications
Contracts	European Medicines Agency, hereinafter referred to as EMEA, intends to sign multiple, cascading framework contracts for Lots 1, 2, 3, 4, and 5. The framework contracts lay down the legal, financial, technical and administrative provisions governing the relations between EMEA and the Contractor during their period of validity. A maximum of three contracts ranked in order of priority are expected to be signed for each Lot. For Lot 6, the framework contracts lay down the administrative

	provisions governing the relations between EMEA and the contractor during their period of validity. Framework contracts do not constitute orders. Orders are placed through Specific Contracts. The framework contract for Lots 1-5 will define the unit costs (for work at both on the Contractor's and/or EMEA premises as appropriate) of the personnel to be used to undertake the services provided as described in this Invitation to Tender. Based on these costs, Specific Contracts may be concluded according to the Terms and Conditions of this Invitation to Tender and of the corresponding financial proposal of the Contractor. For Lot 6, EMEA intends to sign multiple framework contracts under which competition can be re-opened. The framework contracts in this instance will not lay down all the terms and conditions and a system of priority will not be established. In this case, EMEA may re-open competition and ask the parties to compete on the basis of more precisely formulated terms. EMEA will consult the Contractors in writing, fixing a time limit which is sufficiently long to allow tenders to be submitted in writing. EMEA would then award each Specific Contract to the Contractor which has submitted the best tender on the basis of and following a further evaluation against at least the award criteria set out in this specification. Tenderers should be aware that the incumbent suppliers of these services currently employ significant resource in situ at EMEA's premises which includes the supplier's employees carrying out exclusive functions for EMEA. Any change of service provider may, therefore, be subject to the Transfer of Undertakings (Protection of Employment) Regulations 2006 (sometimes known as "TUPE") which apply in the UK. See ***Annex D: Draft Framework Contracts***.
Duration of framework contracts	Two years with two possible extensions of one year each. Maximum possible duration: Four years
Place of delivery	EMEA's premises at 7 Westferry Circus, Canary Wharf, London E14 4HB, United Kingdom and/or the Contractor's premises.
Particulars of delivery	Delivery of services must be in conformity with the placed orders, which, depending on the Lot, may be either Fixed Price or Time and Materials based Specific Contracts. Unless otherwise specified in the Specific Contract, services will be carried out by the Tenderer during normal working days and normal working hours, as specified in the *Draft Service Framework Contract* – see ***Annex D: Draft Framework Contracts***
Volume (indicative)	The resulting framework contracts will replace multiple framework contracts in respect of which the financial envelopes have been exhausted and/or the defined periods of validity are soon to expire. The total annual resource requirement over all the Lots involving time and materials services is expected to represent approximately 643 man-months per annum.

Joint Offers	Permitted.
Variants	Not permitted.
Subcontracting	Permitted. The Contractor may subcontract to another contractor but no further levels of subcontracting will be permitted. Information on all subcontractors must be included in the Tenderer's response to this Invitation to Tender – for details see Section ***5 The tendering process***.
Closing Date for receipt of Tenders	12.00 BST, Friday 25 July 2008. *(For full terms and conditions, see **section 5.1.2 Submitting a tender**)*
Opening of Tenders	EMEA, London, 14.00 BST, Wednesday 30 July 2008. (*For further details, see **Section 5.2.4.10 Opening of Tenders***
Presentations by shortlisted tenderers	It is unlikely that all the Lots will be evaluated at the same time. Tenderers will be given at least 7 working days' notice of the requirement to attend and give a presentation at EMEA if required. It is anticipated that the first of these presentations, in respect of the first lot evaluated, would take place during lateAugust /September 2008. Tenderers should note that any such visit is a mandatory part of the evaluation process and that refusal of an invitation may result in the exclusion of the Tenderer from any further part in the procurement procedure.

3 Background

3.1 Introduction to EMEA

3.1.1 Who we are

In accordance with EU Regulation 2309/93 which laid down the Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and the establishment of a European medicines agency, the European Medicines Agency[1] (EMEA) began its activities in 1995 with funding from the European Union. EU Regulation 2309/93 was repealed by EU Regulation 726/2004, which now governs the activities of EMEA. The Agency is a decentralised body of the European Union and is based in London, United Kingdom. The Agency has a staff of around 500, in addition to which there are a number of people working at the Agency as contractors, mainly on IT projects. The Agency staff consists of nationals from the majority of EU member states.

EMEA is headed by the Executive Director, Thomas Lönngren, and governed by a supervisory body, the Management Board, which is responsible, in particular, for budgetary matters.

3.1.2 What we do

EMEA's Mission is to foster scientific excellence in the evaluation and supervision of medicines, for the benefit of public and animal health.

Legal role

The European Medicines Agency is the European Union body responsible for coordinating the existing scientific resources put at its disposal by Member States for the evaluation, supervision and pharmacovigilance of medicinal products.

The Agency provides the Member States and the institutions of the EU the best-possible scientific advice on any question relating to the evaluation of the quality, safety and efficacy of medicinal products for human or veterinary use referred to it in accordance with the provisions of EU legislation relating to medicinal products.

Principal activities

Working with the Member States and the European Commission as partners in a European medicines network, the European Medicines Agency:

- provides independent, science-based recommendations on the quality, safety and efficacy of medicines, and on more general issues relevant to public and animal health that involve medicines;
- applies efficient and transparent evaluation procedures to help bring new medicines to the market by means of a single, EU-wide marketing authorisation granted by the European Commission;
- implements measures for continuously supervising the quality, safety and efficacy of authorised medicines to ensure that their benefits outweigh their risks;

[1] Then known as the European Agency for the Evaluation of Medicinal Products

- provides scientific advice and incentives to stimulate the development and improve the availability of innovative new medicines;
- recommends safe limits for residues of veterinary medicines used in food-producing animals, for the establishment of maximum residue limits by the European Commission;
- involves representatives of patients, healthcare professionals and other stakeholders in its work, to facilitate dialogue on issues of common interest;
- publishes impartial and comprehensible information about medicines and their use;
- develops best practice for medicines evaluation and supervision in Europe, and contributes alongside the Member States and the European Commission to the harmonisation of regulatory standards at the international level.

Guiding principles

- The Agency is strongly committed to public and animal health.
- The Agency makes independent recommendations based on scientific evidence, using state-of-the-art knowledge and expertise in its field.
- The Agency supports research and innovation to stimulate the development of better medicines.
- The Agency values the contribution of its partners and stakeholders to its work.
- The Agency assures continual improvement of its processes and procedures, in accordance with recognised quality standards.
- The Agency adheres to high standards of professional and personal integrity.
- The Agency communicates in an open, transparent manner with all of its partners, stakeholders and colleagues.
- The Agency promotes the well-being, motivation and ongoing professional development of every member of the Agency.

Central Authorisation Procedure
This procedure results in a single marketing authorisation (called a 'Community marketing authorisation') that is valid across the European Union. The centralised procedure is compulsory for human medicines that are:

- derived from biotechnology processes, such as genetic engineering;
- intended for the treatment of HIV/Aids, cancer, diabetes or neurodegenerative disorders;
- officially designated 'orphan medicines' (medicines used for rare diseases).

For medicines that do not fall within these categories, companies may submit an application for a centralised marketing authorisation to the EMEA, as long as the medicine concerned is a significant therapeutic, scientific or technical innovation, or if its authorisation would be in the interest of public health. This option may be extended to generic medicinal products authorised by the Community, provided that this in no way undermines either the harmonisation achieved when the reference medicinal product was evaluated or the results of that evaluation.

Applications through the centralised procedure are submitted directly to the EMEA. Evaluation by the Agency's relevant scientific committee takes up to 210 days, at the end of which the committee adopts an opinion on whether the medicine should be marketed or not. This opinion is then transmitted to the European Commission, which issues a formal decision on the authorisation of the product.

Once a Community marketing authorisation has been granted, the marketing-authorisation holder can begin to make the medicine available to patients and healthcare professionals in all EU countries.

Pharmacovigilance
The safety of medicines is constantly monitored by the Agency through a pharmacovigilance network. The decision to approve a drug is based on it having a satisfactory balance of benefits and risks within

the conditions specified in the product labelling. This decision is based on the information available at the time of approval. The knowledge related to the safety profile of the product can change over time through expanded use in terms of patient characteristics and the number of patients exposed. In particular, during the early post-marketing period the product might be used in settings different from clinical trials and a much larger population might be exposed in a relatively short timeframe.

Once a product is marketed, new information will be generated, which can have an impact on the benefits or risks of the product; evaluation of this information should be a continuing process, in consultation with regulatory authorities. Detailed evaluation of the information generated through pharmacovigilance activities is important for all products to ensure their safe use. The agency takes action if adverse drug reaction reports suggest changes to the benefit-risk balance of a medicinal product. The benefit-risk balance can be improved by reducing risks to patients through effective pharmacovigilance that can enable information feedback to the users of medicines in a timely manner.

Innovation
The Agency supports innovation and research by providing scientific advice and special support for small and medium-sized enterprises developing new medicinal products and is active in the field of advanced therapy medicinal products such as gene therapy and human tissue engineered products. It also supports the development of orphan medicinal products (drugs for the treatment of rare diseases or for a disease not likely to generate sufficient profit to justify research and development).

Network
The Agency works with a network of experts provided by the national competent authorities of the EU member states as well as those from the EEA countries. The experts serve either as members of the scientific committees, working parties or scientific assessments teams. They are not permitted to have any direct financial or other interests in the pharmaceutical industry which could affect their impartiality.

International Co-operation
In the international area, the Agency works with the World Health Organisation, the World Organisation for Animal Health and the US Food and Drug Administration, amongst others, on a number of initiatives.

3.1.3 Future

In the short term, EMEA's work is being shaped by a number of factors in the rapidly developing medicines regulation environment, most notably the entry into force of the legislation on paediatric medicines and the new legislation on advanced therapy medicinal products due to come into force at the end of 2008. In order to undertake the implementation of the paediatrics regulation, the Agency has established a new scientific committee (the Paediatric Committee) and instigated the related processes. A new Committee on advanced therapies will start work at the beginning of 2009.

The Agency is facing a steady growth in activities relating to the evaluation and supervision of medicinal products bringing with it an increased workload.

3.2 Introduction to IT systems at the EMEA

3.2.1 Communities served

Information Technology at EMEA serves staff and contractors within the Agency in support of their daily activities. In addition, in line with the overarching EU Telematics implementation strategy, EMEA is putting into place systems in support of the European Medicines Regulatory Network as a

whole. This network comprises the competent authorities in the domain of the regulation of medicinal products. In the context of the provision of information, patients and healthcare professionals are also stakeholders, as is pharmaceutical industry in connection with the development and authorisation of medicinal products.

3.2.2 EMEA Corporate Applications

EMEA terms the systems and infrastructure that directly support the Agency in its day to day activities 'Corporate IT Systems'. In addition to systems made available by the European Commission or acquired off the shelf and implemented, the Agency has designed and built systems tailored to its requirements.

Corporate applications are designed and implemented to support the core activities of the Agency, namely the evaluation of marketing authorisation applications, pharmacovigilance, and specific tasks allocated by legislation. In addition, the administrative functions necessary to enable the Agency to execute these core activities are also facilitated by information technology.

The systems supporting the operations of the Agency comprise:

3.2.2.1 SIAMED (Sistema de informacion Automatizada sobre MEDicamentos)

SIAMED is a system developed jointly with WHO[2] for computer assisted medicines registration.

A new version (SIAMED II) of this application is under development, which aims to:

- reflect - and integrate into – the workflows, current and future, in use at the Agency;
- maintain a history of products from "cradle to grave" through the use of a unique identifier, allowing easy cross-referencing amongst the various systems;
- integrate with - and take advantage of - electronic submission;
- communicate with other systems, including - but not limited to - EudraVigilance, EudraPharm, EUTCT[3], ECD[4] and ERP[5];
- provide a flexible and adaptable tracking system, able to cope with regulatory changes;
- provide flexible and user-friendly reporting;
- provide selective access to part of the information to external stakeholders.

3.2.2.2 Paediatrics Database

The Paediatrics Database is used to receive, process and store applications accompanying paediatric implementation plans submitted to the Agency.

[2] World Health Organisation
[3] EU Telematics Controlled Terms
[4] Eudra Common Directory
[5] EMEA Resource Planning

3.2.2.3 EDMS (Electronic Document Management System)

EMEA has implemented Documentum, a central controlled electronic repository for documents providing file management functionality, as its document management system. The system comprises a central vault linked to a desk-top client that is made available to all working at the Agency. The system has been customised to meet key requirements of the Agency's operations. The desktop client is to be phased out and replaced with a web client.

The workflow capabilities of the product have been implemented only to a very limited extent. In implementing its document management system the Agency sought to:

- Increase the overall efficiency of document management and handling within the EMEA
- Provide better control of EMEA documents
- Enable more efficient publishing of documents via the internet
- Provide an underlying platform which can support the improvement of the EMEA's business processes and meet the Agency's needs as these change.

3.2.2.4 MMD (Management of Meeting Documents System)

In the interests of increasing efficiency and reducing the use of paper, the Agency has implemented the MMD system for collaborative working on meeting documents enabling meeting participants to access these documents both on and off EMEA premises. The system is based on Documentum and uses its web client. This implementation enables:

- Better control of documents submitted to and worked on at EMEA meetings
- Secure electronic access to current versions of documentation inside and outside the Agency
- Improved editing of meeting documents

3.2.2.5 MMS (Meetings Management System)

MMS is a system developed by EMEA to control meetings organised by the Agency and the logistics associated with those meetings.

MMS controls the room booking process, the process for inviting reimbursed and non-reimbursed meeting participants and includes a workflow to assure appropriate authorisations. The system also provides summarised finance-related information as an input into the Agency's budgetary control system. The system was implemented in order to:

- Automate meeting room bookings
- Increase overall efficiency of the invitation process and reduce use of paper
- Automate input into the financial systems and hence increase control efficiency

3.2.2.6 SI2 (Sincom 2)

SI2 is a system written for and in use at the European Commission to control and manage annual budgets. It will be phased out by EMEA over the coming two to three years, as the current version ceases to be supported. It will be replaced by ERP.

3.2.2.7 ERP (EMEA Resource Planning System)

The Agency is implementing an enterprise resource planning system to interface with operational systems and provide integrated support for financial and administrative purposes. The product being implemented is SAP. The ERP system will enable administrative and financial gains in efficiency to

be realised, allowing the increased administrative workload arising from the growth of the Agency to be absorbed while reducing duplication of data-entry and barriers to inter-operability.

3.2.2.8 ECD (Eudra Common Directory)

The ECD is a directory of individuals and organisations relevant to the operations of the Agency. The central directory is used both as a contacts management database and as the repository of information underlying user management for information technology purposes.

3.2.2.9 Experts Database

The Experts Database is a list of European Experts that may participate in the Agency's work. This includes members of the CHMP[6], CVMP[7], COMP[8], HMPC[9], PDCO[10] and their working parties. It also includes any expert who is taking part in any other scientific activity of the EMEA.

3.2.2.10 eRMS (Electronic Records Management System)

The formal electronic system to manage records at EMEA is being introduced to replace existing manual systems. It will be a module based on the existing EDMS in the Agency.

3.2.2.11 Activity specific databases

A number of such databases (e.g. scientific memory, orphan drugs database) have been built in response to specific business requirements across the areas of interest of the Agency. The medium term strategy is to integrate these with SIAMED II.

3.2.2.12 ActiTrak

ActiTrak is an internally developed application for the recording of time for costing purposes. The system is also used to support the Agency's flexible working arrangements.

3.2.3 EU Telematics

As part of the implementation of the European pharmaceutical policy and legislation, the Agency was given responsibility to implement the EU Telematics Strategy. This strategy aims to increase efficiency and transparency and to facilitate the operation of procedures electronically as established by legislation.

The EU Telematics systems have been conceived as a central set of pan-European systems and information repositories for use by all stakeholders, access by the different classes of stakeholder being limited by legislative provision or by well-founded confidentiality requirements. In addition, a secure means of communication between regulators (EudraNet) is in place and a set of tools enabling the exchange of information between regulators and industry is available.

The EU Telematics systems are being designed to be separate from local systems in each agency (including EMEA), but to be able to exchange information with these local systems. These systems will support regulatory activities in the areas of manufacturing (EudraGMP), the monitoring of post-authorisation risk-benefit balance of medicines (EudraVigilance), clinical trials (EudraCT) and

[6] Committee for Human Medicinal Products
[7] Committee for Veterinary Medicinal Products
[8] Committee for Orphan Medicinal Products
[9] Herbal Medicinal Products Committee
[10] Paediatric Committee

marketing authorisation applications (electronic submissions). EudraPharm will provide information on medicinal products to all stakeholders and will be used in support of different regulatory activities.

The implementation and operation of the systems is aimed at supporting the monitoring of post authorisation risk-benefit balance of medicines in the European Union, increasing efficiency across the European Medicines Regulatory Network, and increasing transparency and the availability of high quality information on medicinal products to the general public. In most cases the system responds to a requirement laid down in legislation. The systems are described individually below.

3.2.3.1 EudraNet

EudraNet is a secure, private electronic network used by EMEA and linking the members of the European Medicines Regulatory Network. It is used to channel electronic mail between members of the European Medicines Regulatory Network in a secure manner. In addition, it is used as a channel for members of the European Medicines Regulatory Network to access the EU Telematics systems securely.

3.2.3.2 EudraLink

EudraLink is the European Medicines Regulatory Network's secure file transfer system for the exchange of information for regulatory purposes. It operates independently of the EudraNet, and can thus be used by applicants and marketing authorisation holders, as well as the regulatory organisations within the network, to transfer files.

3.2.3.3 EudraVigilance

EudraVigilance is the European Community's system monitoring the safety of medicines through safety reports. It is designed to receive, process, store and make available information submitted electronically using the E2B format agreed at ICH[11]. Reports are received via the gateway.

EudraVigilance supports in particular the:

- Electronic exchange of suspected adverse reaction reports (referred to as Individual Case Safety Reports) between the European Medicines Agency (EMEA), national Competent Authorities, marketing authorisation holders, and sponsors of clinical trials in the EEA;
- Early detection of possible safety signals associated with medicinal products for human use;
- Early detection of possible safety signals associated with medicinal products for veterinary use;
- Continuous monitoring and evaluation of potential safety issues in relation to reported adverse reactions;
- Decision making process, based on a broader knowledge of the adverse reaction profile of medicinal products especially in the frame of Risk Management.

Further information is available on the following website: http://eudravigilance.emea.europa.eu

3.2.3.4 EudraPharm

EudraPharm is the Community's database of authorised medicinal products and is under development. It contains the information currently published by means of the summary of product characteristics, the package leaflet and the labelling, but stored in structured format to enable advanced searching and presentation in contexts suitable for the person consulting the database. This information will eventually be made available via the data warehouse.

[11] In the case of veterinary medicinal products, the international forum is VICH.

The information will be collected from marketing authorisation holders by means of the Product Information Management (PIM) system by national competent authorities and EMEA, and imported into EudraPharm. The information exchange between the PIM system and EudraPharm makes use of a data exchange standard and the gateway infrastructure.

Further information can be found on the following website: www.eudrapharm.eu

3.2.3.5 EudraCT

EudraCT is the Community's electronic database containing registrations of clinical trials. It contains the information submitted by sponsors (both commercial and non-commercial) in the Clinical Trials Application Form. It informs national competent authorities of ongoing clinical trials in all member states and EEA countries thereby enabling an overview of multi-state trials. The system is also able to alert national competent authorities in case of early interruption or termination for reasons of safety or lack of efficacy; suspension or prohibition; the refusal of the national competent authority or a negative opinion of the Ethics Committee in a given Member State.

EudraCT is currently envisaged as the base system upon which the information collection, storage, processing and publication requirements of Regulation no. 1901/2006 on Medicinal Products for Paediatric Use will be built. The database for paediatric clinical trials is under development.

Further information can be found on the following website: http://eudract.emea.europa.eu/

3.2.3.6 EudraGMP

EudraGMP is a system that

- allows the submission of GMP certificates and manufacturing and importation authorisations by national competent authorities on-line and via an XML22-based interface using the gateway;
- enables the submission of non-compliance with GMP information that results from inspection activity;
- allows the sharing of information on planned inspection activity on manufacturing sites in third countries;
- permits the consultation of the GMP, authorisation, non-compliance and inspection coordination information that results from the above submissions; and
- supports the exchange of information constituting "rapid alerts" arising out of faulty manufacture.

This system is used by inspectors of good manufacturing practice. Further information can be found on the following website: http://eudragmp.eudra.org

3.2.3.7 Product Information Management (PIM)

PIM is a system that permits applicants and marketing authorisation holders to submit the information contained in the summary of product characteristics, the package leaflet and the labelling (collectively the product information) in a highly structured format to EMEA and national competent authorities using the PIM Data Exchange Standard. The PIM system is used to process, store and make that

information available for review by staff at EMEA and national competent authorities, who use the PIM system to comment upon the submitted information. Once consolidated within the PIM system, those comments are exported to the applicant or marketing authorisation holder, again using the PIM Data Exchange Standard. The amendment, exchange and review processes continue until the product electronic Common Technical Document information is finalised. The same system and processes are used for both initial applications and variations.

The information originally prepared by the applicant or marketing authorisation holder is the information that is reviewed and then made available to EudraPharm and to the Medical Product Dictionary, the latter in a highly coded format for the purposes of identification described in the section on EudraVigilance.

The following website contains further information on the system: http://pim.emea.europa.eu

3.2.3.8 European Review System (EURS)

The European Review System is a system that enables national competent authorities and EMEA to receive, validate, store and make available for review marketing authorisation applications submitted in eCTD23 format. The system's key benefit is its ability to take advantage of the lifecycle management functionality built into the eCTD exchange standard, and display a series or sequence of submissions in respect of a single product in such a way as to enable the reviewer to see immediately the full extent of the currently valid documentation, as well as the submission history showing what has changed.

3.2.3.9 Eudra Data Warehouse

The Eudra Data Warehouse is under development. The systems making up the EU Telematics applications contain between them data relating to the development, authorisation and manufacturing of medicinal products across Europe. In order to derive the greatest possible benefit from this information, the data warehouse is implemented to enable users to collate and query this information across all the systems to maximum effect.

3.2.3.10 EUTCT (EU Telematics Controlled Terms)

EUTCT is a central repository and publication system under development for controlled term lists used in the European Medicines Regulatory Network.

Controlled term lists may be defined as lists of terms that have been enumerated explicitly. All terms in a controlled term list should have an unambiguous, non-redundant definition.

Work on controlled terms has been undertaken in the European context, notably by the European Directorate for the Quality of Medicines & Healthcare as well as the Nordic Council on Medicines. In the international arena, the European Union has participated in the development of MedDRA[12] through ICH.

The implementation for EU Telematics is the support system known as "EU Telematics Controlled Terms", or EUTCT. It comprises:

- An agreed set of controlled term lists (including, for example, country code, route of administration, ATC (Anatomic Therapeutic Chemical) code);

[12] Medical Dictionary for Drug Regulatory Activities

- A central repository of controlled terms that serves the entire European Medicines Regulatory Network:

- For each controlled term list, a list of agreed terms translated into all official languages of the European Union as appropriate, with agreed definitions and a unique identifier for each term;

- A process and an infrastructure enabling the controlled update of the controlled term lists with agreed terms in a timely manner. These are likely to include a new committee that meets regularly, sets of domain experts to propose terms and definitions, and a mechanism for assuring translation into all the official languages in an accurate and timely manner; and

- A process to provide, wherever possible, the controlled term lists to the participating stakeholders.

3.2.3.11 Standards for Electronic Submission

Published standards are available within vol. 2B of Notice to Applicants- http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/homev2.htm. Information on standards being developed in the context of the electronic submission of information in support of marketing authorisation applications, or variations thereto is available on the website of the TIGes (Electronic Submissions Telematics Implementation group) - http://esubmission.emea.europa.eu/tiges/.

3.2.4 For further information on EMEA

Please refer to our website: http://www.emea.europa.eu/

3.3 ICT Standards

3.3.1 EMEA Information and Communication Technology Standards

EMEA develops and implements information systems in accordance with a defined set of technology standards. These technology standards are collected together in a formal document which is updated regularly via the Agency's ICT Standards Committee. The current version of the document is in **Annex A**.

The expertise sought in this Invitation to Tender is explicitly that which is set out in the Skills Lists which are themselves an instantiation of the Information and Communication Technology Standards.

3.3.2 Reference Data Model

Once complete, the reference data model will be used as a prescription for the definition of the concepts for modelling of data during the design of new or old systems and to generate required exchange standards between systems and institutions. It

- Defines the concepts that underlie the meaning of
    - Individual data elements; and

  - Constructs built up through the structured linking of individual elements;

- Sets out the parameters that constrain the way in which each element is used;
- Describes the relationships between elements to form the required constructs; and thus
  - Provides pre-defined elements and constructs for systems within the European Medicines Regulatory Network;
  - In a manner that supports the information needs and processes of the business of regulation of medicinal products in the EEA.

For EU Telematics, it is being established in the form of:

- A conceptual data model that includes information elements used in relation to all aspects of regulatory activity throughout the lifecycle of a medicinal product;
- A physical implementation of the conceptual data model that defines the individual information elements in sufficient detail to ensure that any information system built to deal with any aspect of regulatory activity at any stage of a medicinal product's lifecycle would be able to draw the definitions of the elements, and the relationships between them, from the reference data model;
- A physical implementation of the conceptual data model that includes the controlled terms, appropriately used in each context;
- A physical implementation of the conceptual data model that is compatible with international standards agreed for implementation in the European Medicines Regulatory Network and
- Confirmation from all stakeholders that the reference data model is the reference point for systems and exchange standards used in the European Medicines Regulatory Network.

4 Description of the Lots

The services required are divided into six lots, five of which are on a time and materials basis and one of which is on a fixed price basis.

Lot No.	Description
1	Provision of resources on a time and materials basis for on-line transactional processing systems
2	Provision of resources on a time and materials basis for on-line analytical processing systems
3	Provision of resources on a time and materials basis for document and records management, content management and web-publishing systems
4	Provision of resources on a time and materials basis for an enterprise resource planning system
5	Provision of resources on a time and materials basis for Oracle products
6	Provision of ICT systems on a fixed price basis

Tenderers may apply for all six lots or for one or more individual lots. Tenderers must clearly indicate in their covering letter and also in their response to the tender for which lot(s) they are applying. Each lot will be evaluated as a separate entity.

For each of lots 1-5, information on the following aspects is provided in the individual lot descriptions:

- Services to be provided
- Provision of persons of a given profile
- Working *intra* and *extra muros*
- Availability of people on an *ad hoc* basis
- Service Level Agreements (SLAs)

4.1 Lots for the provision of services on a time and materials basis

The services consist of the provision of appropriately skilled individuals to participate in the teams further developing the above systems. Please note however that the above list represents only currently ongoing projects and new systems are anticipated. Where new systems are introduced the services will include the provision of appropriately skilled individuals to participate in systems development project teams. The services may be provided either at the Contractor's premises or at premises designated by EMEA, being normally the EMEA headquarters in London. The services may be requested on a full-time or *ad hoc* basis (i.e. the requirement may be for work to be carried out on the basis of a limited number of days to be supplied non-consecutively). These services will be subject to conditions that are set out in the form of a Service Level Agreement (SLA), annexed to the draft Framework Contract in ***Annex D: Draft Framework Contracts***.

In order to facilitate the assessment of the appropriateness of the skills relating to individuals, a description of the expected skill combinations for given roles within a team are provided below (See section 4.1.7). These descriptions are known as profiles and are used as the basis for requesting services once the Framework Contract is effective. A request for services will comprise a given

number of days of an individual fulfilling the requirements set out in one of the profiles described below.

4.1.1 Lot 1: On-line transactional processing systems

The services to be provided are in connection with the following on-line transactional processing systems that are currently in production and subject to enhancement, as well as other systems yet to be specified:

- SIAMED
- SIAMED II
- MMS
- SI2
- ECD
- Activity-specific databases
- ActiTrak
- Experts Database
- Paediatrics Database
- EudraNet
- EudraLink
- EudraVigilance
- EudraPharm
- EudraCT
- EudraGMP
- PIM
- EURS
- EUTCT

4.1.2 Lot 2: On-line analytical processing systems

The services to be provided are in connection with the following on-line analytical processing systems that are currently in production and subject to enhancement, as well as others yet to be specified:

- Eudra Data Warehouse
- EudraVigilance Data Analysis System
- Business intelligence requirements linked to the on-line transactional processing systems set out in Section 4.1.1.above.

4.1.3 Lot 3: Document and records management, content management and web-publishing systems

The services to be provided are in connection with the following document and records management, content management and web-publishing systems that are currently in production or under development or have yet to be specified:

- EDMS
- MMD
- Records management system
- EudraPortal

- Document and records management, content management and web publishing requirements linked to the other systems within the Agency.

4.1.4 Lot 4: EMEA resource planning system

The services to be provided are in connection with the Agency's planned implementation of an enterprise resource planning system. The Agency is adopting a phased approach to implementation. EMEA has decided to build this system on the basis of SAP software modules.

4.1.5 Lot 5: Oracle products

The services to be provided are in connection with the Agency's existing implementation of these products as well as requirements that have yet to be specified. The services will involve routine activities and support of projects and systems. For the list of Oracle products used by EMEA, see the Skills Lists in Annex C: Response questionnaires.

4.1.6 Details of the profiles to be provided on a time and materials basis

The profiles have been designed to standardise the assessment of the various characteristics that are considered important in the context of the services to be provided under this tender. Below is the format used in this description which categorises the relevant characteristics. Some characteristics are mandatory across all the profiles. The mandatory nature of other characteristics is dependent upon the profile sought and where the characteristic is not mandatory, it is categorised as either desirable or very desirable. This categorisation forms the basis of EMEA's assessment of candidates' suitability for the desired role.

Profile		
Candidate characteristics		Requirement
➢ Languages		
o EN		Mandatory
o Other EU 1		Desirable
➢ Third level qualifications		
o Relevant doctorate		Desirable
o Relevant degree		Desirable
o Relevant professional qualifications		Very desirable
➢ Experience		
o Years relevant IT experience		Mandatory
o Years relevant business experience		
▪ Medicines information		Desirable/Mandatory
▪ Pharmacovigilance		Desirable/Mandatory
▪ Regulation		Desirable/Mandatory
o Years in multicultural organisations		Desirable
o Years in the public sector		Desirable
➢ Project experience		
o In the application domain		Mandatory
▪ Number of years		
• Minimum		Mandatory
• Minimum plus 1		Desirable
• Minimum plus 2		Very desirable
o In the profile role		

▪ Number of years • Minimum • Minimum plus 1 • Minimum plus 2 o In relation to the relevance of the project ▪ In the business domain ▪ Meeting a similar vision ▪ Complexity in relation to envisaged		 Mandatory Desirable Very desirable Desirable Desirable Mandatory
➢ General characteristics o Competences in the role o Communication abilities o Characteristics within a team o Time management capabilities o Supervisory experience ▪ Number of years • Minimum • Minimum plus 1 • Minimum plus 2 o Leadership capabilities		 Mandatory Mandatory Mandatory Mandatory Mandatory Desirable Very desirable
➢ Specific knowledge o Mandatory software per list o Desirable software per list o General trends in the application domain o General trends in IT as a whole o Experience of PM methodologies ▪ RUP ▪ Other (e.g. Prince 2; PMBOK) o Experience of relevant tools for the role o Specific skills identified for each profile		 Mandatory Desirable Mandatory Very desirable Mandatory/Very desirable Very desirable/Desirable Mandatory Mandatory

A list of the various profiles required in order to carry out the services in the lots relevant to the provision of services on a time and materials basis is given below, with an indication of which profiles relate to which lot. Full descriptions of each profile can be found later in this Invitation to Tender document.

Profile	**Lot 1**	**Lot 2**	**Lot 3**	**Lot 4**	**Lot 5**
Project Manager (PM)	Yes	Yes	Yes	Yes	
Business Analyst (BA)	Yes	Yes	Yes		
Software Architect (SWA)	Yes	Yes	Yes		
System Analyst (SSA)	Yes	Yes	Yes		
Developer (DVR)	Yes	Yes	Yes	Yes	
Testing Manager (TM)/Senior Testing Engineer (STE)	Yes	Yes	Yes	Yes	
Testing Engineer (TE)	Yes	Yes	Yes		
Trainer (TR)	Yes	Yes	Yes	Yes	
Technical Writer (TW)	Yes	Yes	Yes	Yes	
Lead consultant (LC)	Yes	Yes	Yes	Yes	
Technical Consultant (TC)	Yes	Yes	Yes	Yes	Yes
Database Administrator (DBA)					Yes
Application Server Administrator (ASA)					Yes
Project Officer (PO)	Yes	Yes	Yes	Yes	

Profile Specifications

4.1.7.1 Project Manager

Languages

- English is required at level 3 (fluent)
- A second EEA[13] language is very desirable

Third level qualifications

- Relevant third level qualifications are desirable

Relevant professional qualifications

- Relevant professional qualifications (e.g. PMI; Prince 2) are very desirable

General experience

Years of relevant IT experience: Minimum of 10 years required

Relevant business experience is desirable in the following domains:

- Medicines information
- Pharmacovigilance
- Regulation

Experience in multicultural organisations is desirable.

Experience in the public sector is desirable

Project experience

In the application domain:

- For Lot 1: On-line transactional processing systems;
- For Lot 2: On-line analytical processing systems
- For Lot 3: Document and records management, content management and web-publishing systems
- For Lot 4: Successful delivery of SAP projects from inception to delivery across multiple modules
- For all lots: Experience of tracking systems[14]
    - Number of years: 6 years minimum

In the profile role:

- Number of years: 6 years minimum

In relation to the relevance of the project:

- Number of years in the business domain: No minimum
- Demonstrable experience of projects meeting visions similar to those set out in sections 3.2.2 EMEA Corporate Applications and 3.2.3 EU Telematics and relevant to either Lot 1, or Lot 2 or Lot 3 or Lot 4 or any combination of the four lots is desirable.
- With regard to Lot 4, demonstrable experience of implementing at least ERP, finance and controlling and supply chain management using SAP modules.

[13] European Economic Area
[14] Systems that record the status of transactions at pre-defined points in a process.

- Demonstration that the execution of projects and/or the outcome of projects have been of a complexity similar to that set out in sections 3.2.2 EMEA Corporate Applications to 3.2.3 EU Telematics of this invitation is required.

General characteristics

- Competences in the role
  - Demonstrable competences in the role are mandatory. These include:
    - Planning;
    - Definition of tasks and deliverables;
    - Review of project deliverables;
    - Quality control
    - Risk assessment and management
    - Status and problem reporting;
    - Follow-up of decisions and activities;
    - Organisation of teams and work;
    - Human resource management;
    - Prepare and maintain quality plans;
    - Estimate costs, timescales and resource requirements;
    - Manage execution of projects against time, quality and cost criteria;
    - Manage the change control process gaining agreement for revisions to the project from project owners;
    - Ability to give presentations;
    - Capability of integration in an international/multi-cultural environment, rapid self-starting capability and experience in team working, understanding the needs, objectives and constraints of those in other disciplines and functions.

- Communication abilities
  - Receive and understand instructions
  - Deliver messages clearly
  - Interact at executive and team levels
  - Use both written and oral channels

- Time management capabilities
  - Ability to manage one's own time, even in the face of stressful situations;
  - Ability to prioritise between competing tasks on a rational basis and in a decisive manner.

- Supervisory experience
  - Number of years: 6 years minimum

- Leadership capabilities
  - Demonstrable leadership capabilities are mandatory.
  - Management of change capabilities should be demonstrated.

Specific knowledge

- Expertise per list
  - Ability to use the project management tools and methodologies as specified in the Individual Skills List in this Invitation to Tender

- General trends in the domain of expertise

- Knowledge and understanding of general trends in the domain of expertise are mandatory

- General trends in IT as a whole
  - Knowledge and understanding of general trends in IT as a whole are mandatory.

4.1.7.2 Business analyst

Languages

- English is required at level 3 (fluent)
- A second EEA[15] language is very desirable

Third level qualifications

- Relevant third level qualifications are desirable

Relevant professional qualifications

- Relevant professional qualifications (e.g. Membership of the Royal Pharmaceutical Society, Pan-Cyprian Pharmaceutical Association, Union Nationale des Pharmaciens Luxembourgeois) are very desirable

General experience

Years of relevant business analysis experience: Minimum of 5 years required

Relevant business experience is mandatory in at least one of the following domains:

- Medicines information
- Pharmacovigilance
- Regulation

Experience in multicultural organisations is desirable.

Experience in the public sector is desirable

Project experience

In the application domain:

- For Lot 1: On-line transactional processing systems;
- For Lot 2: On-line analytical processing systems
- For Lot 3: On document and records management, content management and web-publishing systems
- For all lots: Experience of tracking systems (see footnote to the Project Manager profile)
    - Number of years: 6 years minimum

In the profile role:

- Number of years: 5 years minimum

In relation to the relevance of the project:

- Number of years in the selected business domain(s): 2 years are mandatory.
- Demonstrable experience of projects meeting visions similar to those set out in sections 3.2.2 EMEA Corporate Applications and 3.2.3 EU Telematics and relevant to either Lot 1, or Lot 2 or Lot 3 or any combination of the three lots is very desirable.
- Demonstration that the analysis of projects and/or the outcome of projects have been of a complexity similar to that set out in sections 3.2.2 EMEA Corporate Applications and 3.2.3 EU Telematics of this invitation is mandatory.

General characteristics

- Competences in the role

[15] European Economic Area

  - Demonstrable competences in the role are mandatory. These include:
    - Definition of the business architecture;
    - Definition of the business use cases and actors and how they interact;
    - Business process analysis and definition;
    - Gathering of user requirements;
    - Critical review of user requirements;
    - Documentation of the user requirements;
    - Expertise on integration of information systems into the business environment;
    - Ability to achieve consensus or optimal solution in the face of conflicting requirements and objectives;
    - Formal business analysis methods and techniques;
    - Good interpersonal skills both one to one and in small and large committees
    - Ability to link non-IT users and IT technical staff in a way that both clearly understand;
    - Willingness to understand and learn the business aspects that are unique to EMEA, and also to communicate the constraints of IT (within budget) to the users;
    - Willingness to use EMEA's requirements management tool and work within the Agency's project management methodology.

- Communication abilities
  - Receive and understand instructions
  - Deliver messages clearly, including via formal presentations
  - Interact at executive and team levels
  - Use both written and oral channels

- Time management capabilities
  - Ability to manage one's own time, even in the face of stressful situations;
  - Ability to prioritise between competing tasks on a rational basis and in a decisive manner.

- Supervisory experience
  - Number of years: No minimum

- Leadership capabilities
  - Demonstrable leadership capabilities are mandatory.

Specific knowledge

- Expertise per list
  - Ability to use the business analysis tools and methodologies as specified in the Individual Skills List in this Invitation to Tender

- General trends in the domain of expertise
  - Knowledge and understanding of general trends in the domain of expertise are mandatory

- General trends in IT as a whole
  - Knowledge and understanding of general trends in IT as a whole are mandatory

4.1.7.3 Software architect

Languages

- English is required at level 3 (fluent)
- A second EEA[16] language is very desirable

Third level qualifications

- Relevant third level qualifications are desirable

Relevant professional qualifications

- Relevant professional qualifications (e.g. Sun Certified Enterprise Architect (SCEA) for the Java Platform) are desirable.

General experience

Years of relevant IT experience: Minimum of 10 years required

Relevant business experience is desirable in any one or more of the following domains:

- Medicines information
- Pharmacovigilance
- Regulation

Experience in multicultural organisations is desirable.

Experience in the public sector is desirable

Project experience

In the application domain:

- For Lot 1: On-line transactional processing systems;
- For Lot 2: On-line analytical processing systems
- For Lot 3: On document and records management, content management and web-publishing systems
- For all lots: Experience of tracking systems (see footnote on Project Manager profile)
    - Number of years: 6 years minimum

In the profile role:

- Number of years: 5 years minimum

In relation to the relevance of the project:

- Number of years in the selected business domain(s): 2 years are desirable.
- Demonstrable experience of projects meeting visions similar to those set out in sections 3.2.2 EMEA Corporate Applications and 3.2.3 EU Telematics and relevant to either Lot 1, or Lot 2 or Lot 3 or any combination of the three lots is desirable.
- Demonstration that the analysis of projects and/or the outcome of projects have been of a complexity similar to that set out in sections 3.2.2 EMEA Corporate Applications and 3.2.3 EU Telematics of this invitation is mandatory.

General characteristics

- Competences in the role
    - Demonstrable competences in the role are mandatory. These include:

[16] European Economic Area

- Architectural analysis, including definition of a candidate architecture for the system and of the architectural patterns, key mechanisms and modelling conventions of the system in line with EMEA's Information and Communication Technology Standards
- Use case analysis including:
  - Identification of the classes which perform the flow of events in a use case.
  - Distribution of the use case behaviour to those classes, using use-case realisations.
  - Identification of the responsibilities, attributes and associations of the classes.
- Sub-system design.
- Class design.
- Construction of architectural proofs-of-concept.
- Prototyping
- Identification of design mechanisms.
- Identification of design elements.
- Design of the user interface in conjunction with a user-interface specialist
- Structuring of the implementation model
- Production of the relevant technical documentation and documentation for the support team.
- Capacity to assist the support team with training the users of the system
- Capacity to assist with evaluating and testing products delivered by external system suppliers to ensure that they conform to the EMEA requirements and methodology

- Communication abilities
  - Receive and understand instructions
  - Deliver messages clearly, including via formal presentations
  - Interact at executive and team levels
  - Use both written and oral channels

- Time management capabilities
  - Ability to manage one's own time, even in the face of stressful situations;
  - Ability to prioritise between competing tasks on a rational basis and in a decisive manner.

- Supervisory experience
  - Number of years: No minimum

- Leadership capabilities
  - Demonstrable leadership capabilities are mandatory.

Specific knowledge

- Expertise per list
  - Ability to use the software architecture tools and methodologies as specified in the Individual Skills List in this Invitation to Tender
  - Three years of programming experience in the programming technologies currently used at EMEA
  - Experience with CASE tools (e.g. IBM Rational Rose)

- OOA&D[17] with UML

- General trends in the domain of expertise
  - Knowledge and understanding of general trends in the domain of expertise are mandatory

- General trends in IT as a whole
  - Knowledge and understanding of general trends in IT as a whole are mandatory

[17] Object-oriented Analysis and Design

4.1.7.4 System analyst

Languages

- English is required at level 3 (fluent)
- A second EEA[18] language is very desirable

Third level qualifications

- Relevant third level qualifications are desirable

Relevant professional qualifications

- Relevant professional qualifications or recognised training courses are very desirable

General experience

Years of relevant IT experience: Minimum of 5 years required

Relevant business experience is very desirable in at least one of the following domains:

- Medicines information
- Pharmacovigilance
- Regulation

Experience in multicultural organisations is desirable.

Experience in the public sector is desirable

Project experience

In the application domain:

- For Lot 1: On-line transactional processing systems;
- For Lot 2: On-line analytical processing systems
- For Lot 3: On document and records management, content management and web-publishing systems
- For all lots: Experience of tracking systems (see footnote to Project Manager profile)
    - Number of years: 4 years minimum

In the profile role:

- Number of years: 3 years minimum

In relation to the relevance of the project:

- Number of years in the selected business domain(s): 2 years are desirable.
- Demonstrable experience of projects meeting visions similar to those set out in sections 3.2.2 EMEA Corporate Applications and 3.2.3 EU Telematics and relevant to either Lot 1, or Lot 2 or Lot 3 or any combination of the three lots is desirable.
- Demonstration that the analysis of projects and/or the outcome of projects have been of a complexity similar to that set out in sections 3.2.2 EMEA Corporate Applications and 3.2.3 EU Telematics of this invitation is mandatory.

General characteristics

- Competences in the role

[18] European Economic Area

- Demonstrable competences in the role are mandatory. These include:
  - Tailored implementation of EMEA's requirements management plan;
  - Gathering and documentation of stakeholder requests and systems requirements;
  - Development of Vision;
  - Analysis of requirements;
  - Finding and defining actors and use cases;
  - Creation and structuring of use case models;
  - Data analysis;
  - Cost/benefit analyses;
  - Ability to link non-IT users and IT technical staff in a way that both clearly understand;
  - Willingness to understand and learn the business aspects that are unique to EMEA, and also to communicate the constraints of IT (within budget) to the users;
  - Willingness to use the EMEA's requirements management tools and work within the Agency's project management methodology.

- Communication abilities
  - Receive and understand instructions
  - Deliver messages clearly, including via formal presentations
  - Interact at executive and team levels
  - Use both written and oral channels

- Time management capabilities
  - Ability to manage one's own time, even in the face of stressful situations;
  - Ability to prioritise between competing tasks on a rational basis and in a decisive manner.

- Supervisory experience
  - Number of years: No minimum

- Leadership capabilities
  - Demonstrable leadership capabilities are not specifically required.

Specific knowledge

- Expertise per list
  - Ability to use the system analysis tools and methodologies as specified in the Individual Skills List in this Invitation to Tender
  - Good interpersonal skills both one to one and in small and large committees

- General trends in the domain of expertise
  - Knowledge and understanding of general trends in the domain of expertise are mandatory

- General trends in IT as a whole
  - Knowledge and understanding of general trends in IT as a whole are mandatory

4.1.7.5 Developer

Languages

- English is required at level 3 (fluent)
- A second EEA[19] language is very desirable

Third level qualifications

- Relevant third level qualifications are desirable.

Relevant professional qualifications

- Relevant professional qualifications (e.g. Higher National Diploma) are mandatory.

General experience

Years of relevant IT experience: Minimum of 5 years required.

Relevant business experience is desirable in any one or more of the following domains:

- Medicines information
- Pharmacovigilance
- Regulation

Experience in multicultural organisations is desirable.

Experience in the public sector is desirable

Project experience

In the application domain:

- For Lot 1: On-line transactional processing systems;
- For Lot 2: On-line analytical processing systems
- For Lot 3: Document and records management, content management and web-publishing systems
- For Lot 4: EMEA resource planning systems
- For all lots: Experience of tracking systems (see footnote to the Project Manager profile)
    - Number of years: 3 years minimum

In the profile role:

- Number of years: 2 years minimum

In relation to the relevance of the project:

- Number of years in the selected business domain(s): 2 years are desirable.
- Demonstrable experience of projects meeting visions similar to those set out in sections 3.2.2 EMEA Corporate Applications and 3.2.3 EU Telematics and relevant to either Lot 1, or Lot 2 or Lot 3 or any combination of the three lots is desirable.
- Demonstration that the development of projects and/or the outcome of projects have been of a complexity similar to that set out in sections 3.2.2 EMEA Corporate Applications and 3.2.3 EU Telematics of this invitation is mandatory.

General characteristics

- Competences in the role

[19] European Economic Area

- Demonstrable competences in the role are mandatory. These include:
    - Assistance with design activities;
    - Prototyping;
    - Writing, maintenance and unit testing of programs which reflect the specifications based on user requirements;
    - Optimisation of programs;
    - Preparation of scripts for database migrations;
    - Preparation of scripts for application installation (to be used by the support team);
    - Assistance with the testing of such programs together with the other programs making up the system;
    - Production of the relevant technical documentation and documentation for the support team;
    - Capacity to assist the support team with training the users of the system;
    - Assistance with operational support of programs produced;
    - Capacity to assist with evaluating and testing products delivered by external system suppliers to ensure that they conform to EMEA requirements and methodology.

- Communication abilities
    - Receive and understand instructions
    - Deliver messages clearly
    - Interact at executive and team levels
    - Use both written and oral channels

- Time management capabilities
    - Ability to manage one's own time, even in the face of stressful situations;
    - Ability to monitor progress against plan;
    - Ability to recognise the need to escalate issues as they become apparent;
    - Ability to prioritise between competing tasks on a rational basis and in a decisive manner.

- Supervisory experience
    - Number of years: No minimum

- Leadership capabilities
    - Demonstrable leadership capabilities are not required.

Specific knowledge

- Expertise per software Individual Skills List
    - Ability to use the development tools and methodologies as specified in the Individual Skills List in this Invitation to Tender
    - Two years of programming experience in the programming technologies currently used at EMEA

- General trends in the domain of expertise
    - Knowledge and understanding of general trends in the domain of expertise are mandatory

- General trends in IT as a whole
    - Knowledge and understanding of general trends in IT as a whole are mandatory

4.1.7.6 Testing manager/Senior testing engineer

Languages

- English is required at level 3 (fluent)
- A second EEA[20] language is very desirable

Third level qualifications

- Relevant third level qualifications are desirable

Relevant professional qualifications

- Relevant professional qualifications (e.g. Higher National Diploma) are desirable.

General experience

Years of relevant IT experience: Minimum of 7 years required

Relevant business experience is desirable in any one or more of the following domains:

- Medicines information
- Pharmacovigilance
- Regulation

Experience in multicultural organisations is desirable.

Experience in the public sector is desirable

Project experience

In the application domain:

- For Lot 1: On-line transactional processing systems;
- For Lot 2: On-line analytical processing systems
- For Lot 3: Document and records management, content management and web-publishing systems
- For Lot 4: EMEA resource planning systems

- For all lots: Experience of tracking systems (see footnote to Project Manager profile)
    - Number of years: 6 years minimum

In the profile role:

- Number of years: 5 years minimum

In relation to the relevance of the project:

- Number of years in the selected business domain(s): 2 years are desirable.
- Demonstrable experience of projects meeting visions similar to those set out in sections 3.2.2 EMEA Corporate Applications and 3.2.3 EU Telematics and relevant to either Lot 1, or Lot 2 or Lot 3 or Lot 4 or any combination of the four lots is desirable.
- Demonstration that the testing aspects and/or the outcome of projects have been of a complexity similar to that set out in sections 3.2.2 EMEA Corporate Applications and 3.2.3 EU Telematics of this invitation is mandatory.

[20] European Economic Area

General characteristics

- Competences in the role
  - Demonstrable competences in the role are mandatory. These include:
    - Identification and definition of the required tests;
    - Monitoring of detailed testing progress and results in each test cycle;
    - Evaluation of the overall quality experienced as a result of the testing activities;
    - Definition of the test approach and ensuring its successful implementation;
    - Identification of the appropriate techniques, tools and guidelines to implement the required tests;
    - Provision of guidance on the corresponding resource requirements for the test effort;
    - Creation of the validation[21] plan;
    - Creation of the test plan;
    - Creation of the test scripts;
    - Implementation of tests;
    - Automation of tests;
    - Execution of tests;
    - Analysis of test failure;
    - Preparation of the test reports;
    - Preparation of the validation reports.

- Communication abilities
  - Receive and understand instructions
  - Deliver messages clearly, including via formal presentations
  - Interact at executive and team levels
  - Use both written and oral channels

- Time management capabilities
  - Ability to manage one's own time, even in the face of stressful situations;
  - Ability to monitor progress against plan;
  - Ability to recognise the need to escalate issues as they become apparent;
  - Ability to prioritise between competing tasks on a rational basis and in a decisive manner.

- Supervisory experience
  - Number of years: 2 years are mandatory.

- Leadership capabilities
  - Demonstrable leadership capabilities are mandatory.

Specific knowledge

- Expertise per software Individual Skills List
  - Ability to use the testing tools and methodologies as specified in the Individual Skills List in this Invitation to Tender
  - 5 years of testing experience in the technologies currently used at EMEA

[21] Validation in this context is as derived from the GxP rules. For an example, see [21CFR Part 11].

- Experience with CASE tools

- General trends in the domain of expertise
  - Knowledge and understanding of general trends in the domain of expertise are mandatory

- General trends in IT as a whole
  - Knowledge and understanding of general trends in IT as a whole are mandatory

4.1.7.7 Testing engineer

Languages

- English is required at level 3 (fluent)
- A second EEA[22] language is desirable

Third level qualifications

- Relevant third level qualifications are desirable

Relevant professional qualifications

- Relevant professional qualifications or recognised training courses are desirable.

General experience

Years of relevant IT experience: Minimum of 3 years required

Relevant business experience is desirable in any one or more of the following domains:

- Medicines information
- Pharmacovigilance
- Regulation

Experience in multicultural organisations is desirable.

Experience in the public sector is desirable

Project experience

In the application domain:

- For Lot 1: On-line transactional processing systems;
- For Lot 2: On-line analytical processing systems
- For Lot 3: On document and records management, content management and web-publishing systems
    - Number of years: 3 years minimum
- For all lots:
    - Experience of tracking systems (see footnote to Project Manager profile)

In the profile role:

- Number of years: 2 years minimum

In relation to the relevance of the project:

- Number of years in the selected business domain(s): 2 years desirable.
- Demonstrable experience of projects meeting visions similar to those set out in section 3.2.2 EMEA Corporate Applications and 3.2.3 EU Telematics and relevant to either Lot 1, or Lot 2 or Lot 3 or any combination of the three lots is desirable.
- Demonstration that the testing aspects and/or the outcome of projects have been of a complexity similar to that set out in sections 3.2.2 EMEA Corporate Applications and 3.2.3 EU Telematics of this invitation is required.

General characteristics

- Competences in the role
    - Demonstrable competences in the role are mandatory. These include:

[22] European Economic Area

- Assistance in the creation of the validation plan;
- Assistance in the creation of the test plan;
- Creation of test scripts;
- Implementation of tests;
- Execution of tests;
- Analysis of test failure;
- Preparation of the test reports;
- Assistance in the evaluation of the overall quality experienced as a result of the testing activities;
- Preparation of the validation reports.

- Communication abilities
  - Receive and understand instructions
  - Deliver messages clearly
  - Interact at team levels
  - Use both written and oral channels

- Time management capabilities
  - Ability to manage one's own time, even in the face of stressful situations;
  - Ability to prioritise between competing tasks on a rational basis and in a decisive manner.

- Supervisory experience
  - Number of years: No minimum

- Leadership capabilities
  - Demonstrable leadership capabilities are not required.

Specific knowledge

- Expertise per list
  - Ability to use the testing tools and methodologies as specified in the Individual Skills List in this Invitation to Tender
  - One year of testing experience in the technologies currently used at EMEA
  - Experience with CASE tools is desirable

- General trends in the domain of expertise
  - Knowledge and understanding of general trends in the domain of expertise are mandatory

- General trends in IT as a whole
  - Knowledge and understanding of general trends in IT as a whole are mandatory

4.1.7.8 Trainer

Languages
- English is required at level 3 (fluent)
- A second EEA[23] language is very desirable

Third level qualifications
- Relevant third level qualifications are desirable

Relevant professional qualifications
- Relevant professional qualifications in the training subject and in teaching are desirable.

General experience

Years of relevant IT literacy: Minimum of 2 years required

Relevant business experience is desirable in any one or more of the following domains:
- Medicines information
- Pharmacovigilance
- Regulation

Experience in multicultural organisations is desirable.

Experience in the public sector is desirable.

Project experience
In the application domain:
- For Lot 1: On-line transactional processing systems;
- For Lot 2: On-line analytical processing systems
- For Lot 3: Document and records management, content management and web-publishing systems
- For Lot 4: EMEA resource planning systems
    - Number of years: 1 year minimum
- For all lots:
    - Experience of tracking systems

In the profile role:
    - Number of years: 3 years minimum

In relation to the relevance of the project:
    - Number of years in the selected business domain(s): 2 years desirable
    - Demonstrable experience of training courses related to systems similar to those set out in sections 3.2.2 EMEA Corporate Applications and 3.2.3 EU Telematics and relevant to either Lot 1, or Lot 2 or Lot 3 or any combination of the three lots is desirable.
    - Demonstration that the training aspects and/or the outcome of projects have been of a complexity similar to that set out in sections 3.2.2 EMEA Corporate Applications and 3.2.3 EU Telematics of this invitation is required.

[23] European Economic Area

General characteristics

- Competences in the role
  - Demonstrable competences in the role are mandatory. These include:
    - Assistance in the creation and maintenance of suitable training materials;
    - The ability to clearly explain potentially difficult and complex technical and scientific concepts;
    - The ability to cope with a multi-cultural and multi-lingual audience;
    - Training sessions for internal personnel and external stakeholders;
    - Follow-up on outstanding issues from training courses;
    - Set up a training feedback process and integrate the lessons learned into the training course and material;
    - Preparation of training reports, as required.

- Communication abilities
  - Receive and understand instructions;
  - Deliver messages clearly, including via formal presentations;
  - Interact at executive and team levels;
  - Explain and impart information at a level and in a manner easily comprehended by an interlocutor;
  - Use both written and oral channels.

- Time management capabilities
  - Ability to manage one's own time, even in the face of stressful situations;
  - Ability to prioritise between competing tasks on a rational basis and in a decisive manner.

- Supervisory experience
  - Number of years: No minimum

- Leadership capabilities
  - Demonstrable leadership capabilities are not required.

Specific knowledge

- Expertise per list
  - Ability to use the training tools and methodologies as specified in the Individual Skills List in this Invitation to Tender

- General trends in the domain of expertise
  - Knowledge and understanding of general trends in the domain of business expertise are mandatory

- General trends in IT as a whole
  - Knowledge and understanding of general trends in IT as a whole are desirable

4.1.7.9 Technical writer

Languages

- English is required at level 3 (fluent)
- A second EEA[24] language is desirable

Third level qualifications

- Relevant third level qualifications are very desirable

Relevant professional qualifications

- Relevant professional qualifications (e.g. Cambridge Certificates of English.) are desirable.

General experience

Years of relevant IT literacy: Minimum of 2 years required

Relevant business experience is desirable in any one or more of the following domains:

- Medicines information
- Pharmacovigilance
- Regulation

Experience in multicultural organisations is desirable.

Experience in the public sector is desirable.

Project experience

In the application domain:

- For Lot 1: On-line transactional processing systems;
- For Lot 2: On-line analytical processing systems
- For Lot 3: Document and records management, content management and web-publishing systems
- For Lot 4: EMEA resource planning systems
    - Number of years: 2 years minimum
- For all lots:
    - Experience of tracking systems (see footnote to Project Manager profile)

In the profile role:

- Number of years: 2 years minimum of documentation authoring experience, of which 1 year of technical documentation authoring.
- Minimum 1 year of experience with the office automation tools used in EMEA

In relation to the relevance of the project:

- Number of years in the selected business domain(s): 2 years desirable.
- Demonstrable experience of projects meeting visions similar to those set out in sections 3.2.2 EMEA Corporate Applications and 3.2.3 EU Telematics and relevant to either Lot 1, or Lot 2 or Lot 3 or Lot 4 or any combination of the four lots is desirable.

General characteristics

- Competences in the role

[24] European Economic Area

- Demonstrable competences in the role are mandatory. These include:
    - Production of end-user support and training material, such as user guides, help texts, release notes and so on;
    - Writing of end-user support and training documentation regarding information systems;
    - Preparation of reference and maintenance manuals and other technical documentation in consultation with Developers, System Architects and Software Architects.

- Communication abilities
    - Receive and understand instructions
    - Deliver messages clearly, including via formal presentations
    - Interact at executive and team levels
    - Use both written and oral channels
    - Written communication must be clear, concise, unambiguous and easy to read.

- Time management capabilities
    - Ability to manage one's own time, even in the face of stressful situations;
    - Ability to prioritise between competing tasks on a rational basis and in a decisive manner.

- Supervisory experience
    - Number of years: No minimum.

- Leadership capabilities
    - Demonstrable leadership capabilities are not required.

Specific knowledge

- Expertise per list
    - Ability to use the office automation and document management tools and methodologies as specified in the Individual Skills List in this Invitation to Tender
    - Ability to use a help-authoring tool.

- General trends in the domain of expertise
    - Knowledge and understanding of general trends in the domain of expertise are mandatory

- General trends in IT as a whole
    - Knowledge and understanding of general trends in IT as a whole are mandatory

4.1.7.10 Lead consultant

Languages

- English is required at level 3 (fluent)
- A second EEA[25] language is desirable

Third level qualifications

- Relevant third level qualifications are desirable

Relevant professional qualifications

- Relevant professional qualifications (e.g. SAP Master Certificate etc.) are desirable.

General experience

Years of relevant IT experience: Minimum of 10 years required

Relevant business experience is desirable in any one or more of the following domains:

- Medicines information
- Pharmacovigilance
- Regulation

Experience in multicultural organisations is very desirable.

Experience in the public sector is desirable.

Project experience

In the application domain:

- For Lot 1: On-line transactional processing systems
- For Lot 2: On-line analytical processing systems
- For Lot 3: Document and records management, content management and web-publishing systems
- For Lot 4: EMEA resource planning systems
    - Number of years: 7 years minimum

In the profile role:

- Number of years: 3 years minimum

In relation to the relevance of the project:

- Number of years in the selected business domain(s): 2 years desirable
- Demonstrable successful experience of projects meeting visions similar to those set out in sections 3.2.2 EMEA Corporate Applications and 3.2.3 EU Telematics and relevant to either Lot 1, or Lot 2 or Lot 3 or Lot 4 or any combination of the four lots is mandatory.

General characteristics

- Competences in the role
    - Demonstrable competences in the role are mandatory. These include:

[25] European Economic Area

- Rapid assimilation of facts and capacity to comprehend complex circumstances;
- Provide tailored and relevant advice based on a complete understanding of the circumstances and an extensive and detailed knowledge of both the business and application domains;
- Widely recognised high level expertise in aspects of the application domain to be specified at the time of conclusion of the relevant Specific Contract;

- Communication abilities
  - Receive and understand instructions
  - Deliver messages clearly, including via formal presentations
  - Interact at executive and team levels
  - Use both written and oral channels

- Time management capabilities
  - Ability to manage one's own time, even in the face of stressful situations;
  - Ability to prioritise between competing tasks on a rational basis and in a decisive manner.

- Supervisory experience
  - Number of years: No minimum

- Leadership capabilities
  - Demonstrable leadership capabilities are desirable.

Specific knowledge

- Expertise per list
  - Ability to use the relevant tools and methodologies as specified in the Individual Skills List in this Invitation to Tender.

- General trends in the domain of expertise
  - Knowledge and understanding of general trends in the domain of expertise are mandatory

- General trends in IT as a whole
  - Knowledge and understanding of general trends in IT as a whole are mandatory

4.1.7.11 Technical consultant

Languages
- English is required at level 3 (fluent)
- A second EEA[26] language is desirable

Third level qualifications
- Relevant third level qualifications are desirable

Relevant professional qualifications
- Relevant professional qualifications (e.g. SAP Professional Certificate etc.) are desirable.

General experience

Years of relevant IT experience: Minimum of 6 years required

Relevant business experience is desirable in any one or more of the following domains:
- Medicines information
- Pharmacovigilance
- Regulation

Experience in multicultural organisations is very desirable.

Experience in the public sector is desirable

Project experience
In the application domain:
- For Lot 1: On-line transactional processing systems
- For Lot 2: On-line analytical processing systems
- For Lot 3: Document and records management, content management and web-publishing systems
- For Lot 4: EMEA resource planning systems
- For Lot 5: Oracle products
    - Number of years: No minimum[27]

In the profile role:
- Number of years: No minimum

In relation to the relevance of the project:
- Number of years in the selected business domain(s): 2 years
- Demonstrable successful experience of projects meeting visions similar to those set out in sections 3.2.2 EMEA Corporate Applications and 3.2.3 EU Telematics and relevant to either Lot 1, or Lot 2 or Lot 3 or Lot 4 or Lot 5 or any combination of the five lots is mandatory.

General characteristics

- Competences in the role
    - Demonstrable competences in the role are mandatory. These include:

[26] European Economic Area
[27] For this profile, the principal criterion is expertise rather than experience.

- Rapid assimilation of facts and capacity to comprehend complex circumstances;
- Provide tailored and relevant advice based on an understanding of the circumstances and excellent technical expertise;
- In depth expertise in aspects of the application domain to be specified at the time of conclusion of the relevant Specific Contract.

- Communication abilities
  - Receive and understand instructions
  - Deliver messages clearly, including via formal presentations
  - Interact at executive, team and technical levels
  - Use both written and oral channels

- Time management capabilities
  - Ability to manage one's own time, even in the face of stressful situations;
  - Ability to prioritise between competing tasks on a rational basis and in a decisive manner.

- Supervisory experience
  - Number of years: No minimum

- Leadership capabilities
  - Demonstrable leadership capabilities are not required.

Specific knowledge

- Expertise per list
  - Ability to use the relevant tools and methodologies as specified in the Individual Skills List in this Invitation to Tender.

- General trends in the domain of expertise
  - Knowledge and understanding of general trends in the domain of expertise are mandatory

- General trends in IT as a whole
  - Knowledge and understanding of general trends in IT as a whole are mandatory

4.1.7.12 Database Administrator

Languages

- English is required at level 3 (fluent)
- A second EEA[28] language is desirable

Third level qualifications

- Relevant third level qualifications are desirable

Relevant professional qualifications

- Relevant professional qualifications (e.g. Oracle Database 10g Administrator Certified Associate etc.) are mandatory.

General experience

Years of relevant IT experience: Minimum of 8 years required

Relevant business experience is desirable in any one or more of the following domains:

- Medicines information
- Pharmacovigilance
- Regulation

Experience in multicultural organisations is very desirable.

Experience in the public sector is desirable.

Project experience

In the application domain:

- For Lot 5: Oracle database and products
    - Number of years: 5 years minimum

In the profile role:

- Number of years: 5 years minimum

In relation to the relevance of the project:

- Number of years in the selected business domain(s): No minimum
- Demonstration that the administration of databases has been of a complexity similar to that resulting from the project set out in section 3.2.2 EMEA Corporate Applications and 3.2.3 EU Telematics of this invitation is required
- Demonstration of successful database administration (including tuning) on the platforms in use at EMEA.

General characteristics

- Competences in the role

[28] European Economic Area

  - Demonstrable competences in the role are mandatory. These include:
    - Expert knowledge of databases and the types of applications, infrastructure and all related components with which they interact. Expert monitoring and consequent proactive reporting of all potentially occurring damaging events

- Communication abilities
  - Receive and understand instructions
  - Deliver messages clearly, including via formal presentations
  - Interact at executive and team levels
  - Use both written and oral channels

- Time management capabilities
  - Ability to manage one's own time, even in the face of stressful situations;
  - Ability to prioritise between competing tasks on a rational basis and in a decisive manner.

- Supervisory experience
  - Number of years: No minimum

- Leadership capabilities
  - Demonstrable leadership capabilities are not required.

Specific knowledge

- Expertise per list
  - Ability to use the relevant tools and methodologies as specified in the Individual Skills List in this Invitation to Tender.

- General trends in the domain of expertise
  - Knowledge and understanding of general trends in the domain of expertise are mandatory

- General trends in IT as a whole
  - Knowledge and understanding of general trends in IT as a whole are mandatory

4.1.7.13 Application Server Administrator

Languages

- English is required at level 3 (fluent)
- A second EEA[29] language is desirable

Third level qualifications

- Relevant third level qualifications are desirable

Relevant professional qualifications

- Relevant professional qualifications (e.g. Oracle Application Server 10g Administrator etc.) are mandatory.

General experience

Years of relevant IT experience: Minimum of 5 years required

Relevant business experience is desirable in any one or more of the following domains:

- Medicines information
- Pharmacovigilance
- Regulation

Experience in multicultural organisations is very desirable.

Experience in the public sector is desirable.

Project experience

In the application domain:

- For Lot 5: Oracle application server and products
    - Number of years: 3 years minimum

In the profile role:

- Number of years: 3 years minimum

In relation to the relevance of the project:

- Number of years in the selected business domain(s): No minimum
- Demonstration that the administration of application servers has been of a complexity similar to that resulting from the project set out in sections 3.2.2 EMEA Corporate Applications and 3.2.3 EU Telematics of this invitation is required.
- Demonstration of successful application server administration (including tuning) on the platforms in use at EMEA.

General characteristics

- Competences in the role
    - Demonstrable competences in the role are mandatory. These include:

[29] European Economic Area

- Expert knowledge of application servers and the databases and types of applications, infrastructure and all related components with which they interact
- Expert monitoring and consequent proactive reporting of all potentially occurring damaging events

- Communication abilities
  - Receive and understand instructions
  - Deliver messages clearly, including via formal presentations
  - Interact at executive and team levels
  - Use both written and oral channels

- Time management capabilities
  - Ability to manage one's own time, even in the face of stressful situations;
  - Ability to prioritise between competing tasks on a rational basis and in a decisive manner.

- Supervisory experience
  - Number of years: No minimum

- Leadership capabilities
  - Demonstrable leadership capabilities are not required.

Specific knowledge

- Expertise per list
  - Ability to use the relevant tools and methodologies as specified in the Individual Skills List in this Invitation to Tender.

- General trends in the domain of expertise
  - Knowledge and understanding of general trends in the domain of expertise are mandatory

- General trends in IT as a whole
  - Knowledge and understanding of general trends in IT as a whole are mandatory

4.1.7.14 Project Officer

Languages

- English is required at level 3 (fluent)
- A second EEA[30] language is desirable

Third level qualifications

- Relevant third level qualifications are desirable

Relevant professional qualifications

- Relevant professional qualifications (e.g. Secretarial / Office Skills or Project Management Basics etc.) are desirable.

General experience

Years of relevant IT literacy: Minimum of 3 years required

Years of relevant Project Management Support experience: Minimum of 2 years required

Relevant business experience is desirable in any one or more of the following domains:

- Medicines information
- Pharmacovigilance
- Regulation

Experience in multicultural organisations is very desirable.

Experience in the public sector is desirable.

Project experience

Demonstration that the support activities carried out have been on projects of a similar complexity to those described in sections 3.2.2 EMEA Corporate Applications and 3.2.3 EU Telematics of this invitation

General characteristics

- Competences in the role
  - Ability to take minutes of meetings
  - Ability to use recognised project planning tools
  - Ability to monitor and report against pre-defined criteria
  - Fast
  - Efficient
  - Friendly
  - Sense of humour
  - Stress-resistant
  - Accurate
  - Methodical
  - Pro-active
  - Self-starting

[30] European Economic Area

- Communication abilities
  - Receive and understand instructions
  - Deliver messages clearly, including via formal presentations
  - Interact at executive and team levels
  - Use both written and oral channels

- Time management capabilities
  - Ability to manage one's own time, even in the face of stressful situations;
  - Ability to prioritise between competing tasks on a rational basis and in a decisive manner.

- Supervisory experience
  - Number of years: No minimum

- Leadership capabilities
  - Demonstrable leadership capabilities are not required.

Specific knowledge

- Expertise per list
  - Ability to use the relevant tools and methodologies as specified in the Individual Skills List in this Invitation to Tender.

- General trends in IT as a whole
  - Knowledge and understanding of general trends in IT as a whole are desirable

4.2 Lot 6: provision of ICT artefacts on a fixed price basis

In certain circumstances EMEA instructs third parties to undertake work on a fixed price basis. EMEA describes the deliverables from Specific Contracts by means of its software development methodology. The Contractor undertakes to deliver as specified for a given price within a given timescale. Specific Contracts can be let in relation to any system which can be developed with the tools listed in the EMEA ICT Standards document in Annex A: EMEA ICT Standards (EMEA/C/20738/02)

Examples of ICT artefacts that are envisaged within this lot are:

- Feasibility study for a system, consisting of a Vision document, Risk Assessment and a Business Case
- Development and delivery of a complete system on the basis of specifications provided by EMEA
- Development and delivery of a self-contained iteration of a system on the basis of specifications provided by EMEA
- Specific maintenance deliverables for bespoke software
- Training programme in respect of specific systems

Precise timings will be dependent upon budgetary constraints and project interdependencies. It is anticipated that Specific Contracts will be let under this lot according to a consistent rhythm over the period of the framework contract. It is further anticipated that the total volume of contracts to be let will be in the region of € 8 million.

5 The tendering process

5.1 Reply procedure

The electronic version of the complete set of tender documents can be found and downloaded from the "Calls for Tender" section of the following website: http://www.emea.europa.eu/

If you are interested in participating in this tender, please submit a tender in three copies[31] (one original on paper, clearly marked "Original", and two copies, clearly marked Copy 1 and Copy 2, plus three copies[32] in electronic form on CD or DVD (in case of doubt, the paper version will prevail). EMEA cannot accept tenders submitted by e-mail. Any tender submitted by e-mail shall be eliminated immediately from the procurement procedure.

In the paper copy, the financial proposal (worksheets in Sections 10 and 11 of the Lots 1-5 Response Questionnaire in Annex C: Response questionnaires), should be contained in a separate binder or folder and should be clearly marked. In the electronic copy, they may remain a part of the workbook.

Where CVs are submitted, the name of the person must not appear on the CV. Each CV should be given a unique identifier, which should then be cross-referenced to a list of names, which should be submitted in a separate, sealed envelope, clearly marked. One list may be submitted to cover all the Lots but should be split into sections for each Lot where the Tenderer is applying for more than one.

The tender must include a covering letter signed by the person(s) empowered to represent the Tenderer and entitled to sign the contract if the tender is successful.

5.1.1 Labelling and sealing the tender

Tenders must be submitted in one or more sealed envelopes, each enclosed inside a second sealed envelope.

The **outer** envelope must read **exactly** as follows:

EMEA
Procurement Procedure – Reference: EMEA/2008/71/PM-IT – Lot(s) X

7 Westferry Circus
Canary Wharf
London E14 4HB
UK

[31] Please note that if the complete tender is presented on electronic media, then the requirement for the additional two paper copies is waived. The tenderer warrants that the electronic version is identical to the version presented on paper.
[32] The electronic copy must be a complete and exact electronic version of the paper submission..

The **inner** envelope must read **exactly** as follows:

> Tender from: (insert company name)
>
> Procurement Procedure – Reference: EMEA/2008/71/PM-IT- Lot(s) X
> Attn: Communications & Networking Unit – Project Office
>
> **NOT TO BE OPENED BY THE INTERNAL MAIL SERVICE**

If self-sealing envelopes are used, they must be sealed with adhesive tape and the sender must sign across the tape. Boxes may be used instead of envelopes if the size or weight of the tender so requires.

5.1.2 Submitting a tender

A tender may be submitted in one of the following ways. Tenderers should be aware that each of these ways has different implications as regards the observance of deadlines.

5.1.2.1 Delivery by hand

The Tenderer or an authorised representative may deliver the tender in person at EMEA's premises. The tender must be **deposited** at EMEA's premises no later than **the final time and date for submission of tenders.** Tenderers should note that in the case of delivery by hand, the envelopes must be addressed as set out under the heading "Labelling and sealing the tender" above, but **delivery** must be made to:

European Medicines Agency (EMEA)
1-7 Westferry Loading Bay
Ontario Way
Canary Wharf
London E14 4HA

At the time of writing, EMEA is open to receive tenders from Monday to Friday from 08.30 to 17.30. However, EMEA cannot guarantee that the information given will continue to be accurate in the future and cannot therefore be held liable in the event of any change. Tenderers alone are responsible for ensuring that their tender is delivered on time.

If requested, an EMEA staff member taking delivery of the tender will issue a receipt stating the date and time of delivery. This receipt will serve as proof of compliance with the deadline.

5.1.2.2 Delivery by recognised postal or courier service

Tenderers may send tenders by mail via a recognised postal service or by courier service.

If using a postal service, Tenderers must use a **registered or recorded** mail service and their tender must be **posted in time for a postmark to be added referring to the final date for the submission of tenders or earlier. Proof of compliance will be the postmark.** Exceptionally, if no postmark has been stamped or if the postmark is not legible, EMEA may accept alternative

evidence, such as a receipt issued by the postal service, provided that this clearly indicates the date and has been filled in by the post office and not by the Tenderer.

If using a courier service, the tender must be **deposited** with the courier service **on the final date for the submission of tenders or earlier**. **Proof of compliance with the deadline will be the date specified on the deposit slip with the courier service.** Please note that the tender must be delivered to:

European Medicines Agency (EMEA)
1-7 Westferry Loading Bay
Ontario Way, Canary Wharf
London E14 4HA

Format of Replies
It is important that all replies follow the guidance set out below and in section 5.1 Reply procedure in order to facilitate a fair and consistent assessment. Failure to comply may impair EMEA's ability to judge the completeness or competitiveness of a tender offer. It should also be noted in this context that the selection and award process will be influenced by the quality of the reply to this Invitation to Tender.

A standard costing table for those lots involving time and materials and a separate table for the lot involving fixed price is included in Annex C: Response questionnaires.

Tenderers must

- draw up their offer using the EMEA's questionnaires as contained in these tendering specifications. The response questionnaires (Annex C) include instructions in the first tab, entitled "Instructions", for completion of the questionnaires.

- give a YES answer to a MANDATORY requirement. Failure in this respect will result in elimination of the offer. Exceptionally, however, with regard to mandatory requirements in the CVs provided in response to the profiles, offers will not be eliminated if these requirements are not met precisely. Tenderers must, however, endeavour to fulfil these mandatory requirements, as they will be penalised for not doing so through their technical score for the award criterion Expertise proposed (see section 5.4.3 Award).

- provide complete information; any lack of an answer or a supporting document may be considered as a negative answer.

- ensure that the tender offer is perfectly legible in order to rule out any doubt whatsoever concerning the words or figures;

- where possible, responses should be given in the space provided. If more space is required, the response should be made separately and annexed to the questionnaire. Such a response should be clearly referenced or identified and this reference should be noted on the questionnaire in place of the actual response. In addition to completing the questionnaire, the Tenderer may also include any other information which he considers relevant;

- where CVs are submitted, exclude the name of the individual from the CV form. A unique identifier should be given to each CV and a separate list of names corresponding to these identifiers should be included in the tender.

- include with their tender a statement to confirm that information provided in response to this tender is accurate and complete as at the date of submission and that the electronic version is identical to the paper submission and an acknowledgement that the provision of false information in response to this tender could result in the Tenderer being excluded from future tenders for contracts with EMEA;

- include with their tender an undertaking to inform EMEA promptly following any matter which would alter or add to any of the information given in response to this tender.

A tender may be drawn up in any of the official languages of European Union. EMEA prefers, however, to receive documentation in English.

The Tenderer warrants that the information contained in the electronic copies of the tender is precisely the same as that submitted on paper.

5.2 General terms and conditions

Submission of a tender in response to this Invitation to Tender automatically implies the Tenderer's acceptance of all the terms and conditions stipulated in the Invitation to Tender, the current technical specifications and annexes, including the draft framework contract (see Annex D: Draft Framework Contracts). It also implies that the Tenderer renounces his own terms and conditions. This is binding on Tenderers to whom a contract is awarded for the duration of the contract.

Tenders are received on the understanding that the Tenderer accepts full responsibility for all statements made therein.

Until the contract is signed, EMEA may cancel the tender procedure without any compensation to Tenderers. In such a situation, a decision to cancel would be notified to all Tenderers.

EMEA will not reimburse any costs incurred in the preparation and submission of a tender. Any such costs must be paid by the Tenderer.

5.2.1 Validity

All prices, terms, conditions and stipulations contained within the response to the Invitation to Tender (ITT) should be valid for a minimum period of **12 months** from the closing date of the ITT and during which the Tenderer may not modify the terms of the tender in any respect.

5.2.2 Joint Offers

If a tenderer intends to submit a tender in conjunction with a partner or partners and has already set up a consortium or similar entity for this purpose, this should be mentioned in the tender, together with any other relevant information in this regard. If tenderers intend to submit a joint tender but have not yet established a consortium or similar entity, they should be aware that they will be required to provide formal confirmation as to the status of their collaboration before a contract can be signed.

Tenderers must also ensure that the documentation required under the exclusion and selection criteria sections of this invitation to tender are provided for **each member** of the consortium or similar entity, as well as for the main tenderer. The award criteria will be considered in relation to the tender as a whole.

5.2.3 Subcontracting

Subcontracting is permitted for this tender. However, the main Contractor retains full liability towards EMEA for performance of the contract as a whole. EMEA will treat all contractual matters (e.g. payment) as being exclusively with the main Contractor, whether or not the tasks are performed by a subcontractor. Under no circumstances can the main Contractor avoid liability towards EMEA on the grounds that the subcontractor is at fault.

The Contractor may subcontract to another contractor but no further levels of subcontracting will be permitted. If a tenderer envisages subcontracting, the tender submitted must include the names, addresses and statutory registration number of each subcontractor and a document mentioning the reasons why subcontracting is envisaged and which clearly states the roles, activities and responsibilities of subcontractor(s) and specifies the volume/proportion of the tender being subcontracted to each subcontractor. A letter of intent must also be provided by each subcontractor, confirming its intention to collaborate if the tenderer wins the contract.

5.2.4 Other Contractual Conditions

5.2.4.1 Payment

Payment shall be made on completion of the services subject to certification by an authorised staff member of EMEA that the services have been satisfactorily performed and submission of any reports required in line with the Specific Contract, on the basis of an invoice to be established by the Contractor, giving a breakdown of the fees, and verified by the EMEA, by bank transfer to the Contractor's bank account.

Payments shall be made within 45 days of receipt of the request for payment and shall be deemed to have been made on the date on which they are debited to the EMEA's account. EMEA may, however, after giving notice to the Contractor, defer payment if the products or services covered by the request for payment are contested by the EMEA or if the vouchers in support of the request are incomplete. Where payment is so deferred, the EMEA shall not be liable to pay interest or indemnities of any kind. All requests for payment and any complaints shall be sent to the following address:

European Medicines Agency
7 Westferry Circus
Canary Wharf
London
E14 4HB
United Kingdom

EMEA shall be bound to comply with payment periods only if requests for payment are properly presented at the above address.

The Contractor is required to give the following information on all invoices:

- The breakdown of fees or quantities of goods supplied, the contract price and the amount of VAT applied, if any, or, whenever appropriate, a note that the services

rendered under the contract are exempted from VAT in accordance with the national tax law by which the Contractor is governed.

- A reference to the tender number as shown on the first page of the Invitation to Tender.

- A reference to the framework contract number and specific contract number.

5.2.4.2 Tender procedure

This invitation to tender does not constitute any contractual obligation on the part of EMEA. Such an obligation only commences upon signature of a contract with the successful Tenderer.

EMEA may, until the contract is signed, withdraw from the contract or cancel the procurement procedure without any compensation to tenderers. In such a situation a decision to cancel would be notified to all Tenderers.

5.2.4.3 Personal Data

Processing your reply to the invitation to tender may involve the recording and processing of personal data (such as names, addresses and Curricula Vitae). Such data will be processed pursuant to Regulation (EC) No. 45/2001 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data. Unless indicated otherwise, your replies to the questions and any personal data requested are required to evaluate your tender in accordance with the specifications of the invitation to tender and will be processed solely for that purpose and, if necessary, for any other relevant purposes which may be specified by EMEA. You are entitled to obtain access to your personal data on request and to rectify any such data that is inaccurate or incomplete. If you have any queries concerning the processing of your personal data, you may address them to the EMEA Data Protection Officer. You have the right of recourse at any time to the European Data Protection Supervisor for matters relating to the processing of your personal data.

You are informed that, for the purposes of safeguarding the financial interest of the Communities, your personal data may be transferred to internal audit services, to the European Court of Auditors, to the Financial Irregularities Panel and/or to the European Anti-Fraud Office (OLAF).

Data of economic operators which are in one of the situations referred to in Articles 93, 94, 96(1)(b) and 96(2)(a) of the general Financial Regulation[33] may be included in a central database and communicated to the designated persons of the European Commission, other institutions, agencies, authorities and bodies mentioned in Article 95(1) and (2) of the general Financial Regulation. This refers as well to the persons with powers of representation, decision making or control over the said economic operators. Any party entered into the database has the right to be informed of the data concerning it upon request to EMEA. EMEA will obtain the requested information from the accounting officer of the European Commission.

[33] Council Regulation (EC, Euratom) No. 1605/2002 of 25 June 2002 (OJEU L 248 of 16.09.2002), as amended by Council Regulation (EC, Euratom) No. 1995/2006 of 13 December 2006 (OJEU L 390 of 30.12.2006)

5.2.4.4 Confidentiality Undertakings

At the time of signature of the contract, Contractors will be required to sign the EMEA's confidentiality undertaking for Contractors (see Annex F: Confidentiality Statement).

In addition, prior to commencing work, each individual allocated by the Contractor to work on a project will be required to sign the confidentiality undertaking set out in Annex F: Confidentiality Statement.

5.2.4.5 Additional documentation available to tenderers

We strongly recommend that Tenderers read EMEA's 'Guidebook for Tenderers', which can be downloaded from:
http://www.emea.europa.eu/pdfs/general/admin/contractspecs/GuidebookforTenderers0906.pdf

Further information about the work of EMEA can be obtained from its website:
http://www.emea.europa.eu

The EU Telematics strategy and implementation plan for Pharmaceuticals is available at http//pharmacos.eudra.org/F2/telemat/index.htm

Further information on Eudra projects can be found on the following websites:-

- EudraVigilance http://eudravigilance.emea.europa.eu; http://eudravigilance.emea.europa.eu/veterinary/
- Electronic submissions http://esubmission.eudra.org/
- EudraPharm http://eudrapharm.eu/eudrapharm/
- PIM http://pim.emea.europa.eu/
- EudraCT http://eudract.emea.europa.eu/
- EudraGMP http://eudragmp.eudra.org

Information on standards agreed at the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) is available in the section of the ICH website (www.ich.org) devoted to the work of the second multidisciplinary group (M2) dealing with Electronic Standards for Transmission of Regulatory Information (ESTRI). Publicly available information with regard to earlier tenders in the field of information technology may be consulted through the Calls for Tender section of the EMEA's website at
http://www.emea.europa.eu/htms/general/admin/tenders/contracts.htm

5.2.4.6 Registration and Questions

Tenderers are strongly advised to register for this Invitation to Tender by sending an e-mail to sherryll.eady@emea.europa.eu and quoting the tender reference number, either before or after downloading the tender specifications from the EMEA website or having received them through other channels. Registering an interest will mean that Tenderers will receive timely information as the tender procedure progresses. In particular, updated tender specifications, answers to questions of general interest raised during the tender period and any other important information relating to the Invitation to Tender (e.g. changes to deadlines), will be sent to registered Tenderers directly by e-mail. All such information will also be published on the EMEA external website at the address shown above.

Please note that a request for information or documents sent to EMEA does not constitute registration for the tender and registration should be specifically mentioned in the e-mail if a company wishes to register for the bid. Registration does not involve any commitment to submit a tender.

Contacts between EMEA and Tenderers are prohibited throughout the procedure save in exceptional circumstances and under the following conditions only:

Before the final date for submission of the tender:

At the request of the Tenderer, EMEA may provide additional information solely for the purpose of clarifying the nature of the contract. Should a Tenderer have a question, this should be submitted in writing quoting the reference "EMEA/2008/71/PM-IT" (by letter, fax or e-mail) to:

EMEA
Attn. Ms Sherryll Eady
Communications & Networking Unit
Project Management Sector
7 Westferry Circus
Canary Wharf
London E14 4HB

Fax: +44 207 418 8670
E-mail: sherryll.eady@emea.europa.eu

EMEA will, where appropriate, answer such requests. Should this lead to a written addendum to the Tender dossier, this will be posted on the EMEA external website under Calls for Tender and will also be sent by e-mail to registered Tenderers. EMEA will endeavour, as far as possible, to provide such an addendum within three working days of receipt of the written request.

Requests for additional information received less than six calendar days before the closing date for submission of tenders will not be processed for practical reasons.

EMEA may also, on its own initiative, inform Tenderers of any error, inaccuracy, omission or other clerical error in the text of the contract notice, Invitation to Tender dossier and annexes.

Any additional information including that referred to above will be posted on EMEA's external website under the heading Calls for Tender and sent to registered Tenderers by e-mail.

After the opening of tenders

If clarification is required or if obvious clerical errors in the tender need to be corrected, EMEA may contact the Tenderer provided the terms of the tender are not modified as a result.

5.2.4.7 Information visit

Information visits are not foreseen for this tender.

5.2.4.8 Prices

EMEA estimates, without this being binding, that the contract value for each lot over a four-year period will be:

Lot No.	Description	Estimated Contract value over 4 years = €
Lot 1	Provision of resources on a time and materials basis for on-line transactional processing systems	€30,000,000
Lot 2	Provision of resources on a time and materials basis for on-line analytical processing systems	€4,000,000
Lot 3	Provision of resources on a time and materials basis for document and records management, content management and web-publishing systems	€4,000,000
Lot 4	Provision of resources on a time and materials basis for an enterprise resource planning system	€4,000,000
Lot 5	Provision of resources on a time and materials basis for Oracle products	€4,000,000
Lot 6	Provision of ICT systems on a fixed price basis	€8,000,000

a. Prices must be quoted in **Euro.** They must be clearly stated and, where appropriate, they should indicate all pricing elements.

b. Prices must be fixed and not subject to revision for specific contracts concluded during the first year of performance of the framework contract. From the beginning of the second year of performance of the contract, the charges may be revised upwards or downwards each year, where such revision is requested by one of the contracting parties by notice served no later than three months before the anniversary of the date on which the contract became effective. Specific Contracts shall be concluded on the basis of the charges in force on the date on which they become effective. Such charges shall not be subject to revision.

c. This revision shall be determined by the trend in the European Index of Consumer Prices (EICP) published by the Statistical Office of the European Communities in its monthly bulletin under the theme of Economy and Finance: Harmonized Indices of Consumer Prices (http://epp.eurostat.ec.europa.eu/

Revision shall be calculated in accordance with the following formula:

$$A_r = A_o \frac{I_r}{I_o}$$

Where

A_r = revised total amount;
A_o = total amount in the original tender
I_o = index for the month in which the validity of the tender expires
I_r = index for the month corresponding to the date of receipt of the letter requesting revision of prices

d. For Lots 1 and 2 only, all prices are exclusive of expenses, which will be reimbursed (*see Article II.21 of the Lots 1-5 Draft Framework Servics Contract in* Annex D: Draft Framework Contracts). For the remaining Lots, all prices are inclusive of expenses.

e. EMEA is, as a rule, exempt from all taxes and duties, including Value Added Tax (VAT), pursuant to the provisions of Articles 3 and 4 of the Protocol on the Privileges and Immunities of the European Communities. Tenderers must, therefore, give prices which are exclusive of any taxes and duties and must indicate the amount of VAT separately if applicable.

5.2.4.9 Participation in the tender

Participation in this tendering procedure shall be open on equal terms to all natural and legal persons coming within the scope of the Treaties and to all natural and legal persons in a third country which has a special agreement with the European Communities in the field of public procurement under the conditions laid down in that agreement.

Where the Plurilateral Agreement on Public Procurement concluded within the World Trade Organisation applies, the tendering procedure shall also be open to nationals of the countries which have ratified this agreement, under the conditions laid down in that Agreement. In that connection, it should be noted that the services under Annex I-B to Directive 92/50/EEC and the R&D services listed in category 8 of Annex I-A to that Directive are not covered by the Agreement.

5.2.4.10 Opening of Tenders

All tenders will be opened at **14:00 BST** on **Wednesday 30th July 2008** at EMEA's offices (7 Westferry Circus, Canary Wharf, London E14 4HB, United Kingdom). The Tenderer, or one person representing it, as authorised by the EMEA, may attend the opening.

Tenderers wishing to send a representative to this meeting should submit a request in writing by e-mail or fax to Sherryll Eady at EMEA (sherryll.eady@emea.europa.eu or fax +44 20 7418 8670) no later than **14.00 BST** on **Tuesday 29th July 2008**.

5.3 Tender assessment procedure

5.3.1 Procedure of assessment

The assessment of Tenderers and offers will take place in four main phases:-

1. Exclusion of Tenderers
   The purpose of this phase is to determine whether a tenderer is qualified to participate in the tender procedure.

2. Selection of Tenderers
   This phase consists of two sections:
   i. Financial and economic capacity
   ii. Professional and technical capacity

The purpose of this phase is to assess whether a tenderer has the financial, economic, professional and technical capacity necessary to perform the services.

3. Evaluation of Offers
   This phase consists of two sections;
   i. Technical evaluation of the offer
   ii. Financial evaluation of the offer

   The purpose of this phase is to choose the best offers of those submitted by tenderers which are not excluded and which meet the selection criteria.

4. Award of Contract(s)

The assessment will be based on the Tenderer's answers to the questionnaires in Annex C: Response questionnaires. In addition, EMEA reserves the right to use any other information from public or specialist sources. All the information will be assessed against the criteria specified in the following section.

5.4 Exclusion, selection and award

5.4.1 Exclusion

Tenderers should refer to Annex C: Response questionnaires in order to respond to this section.

Tenderers will be excluded, with reference made to Article 93(1) of EMEA's Financial Regulation (EMEA-MB-22-03 (EN)) where:

1. they are insolvent (or the subject of bankruptcy proceedings if an individual) or being wound up, are having their affairs administered by the courts, have entered into an arrangement with creditors, have suspended business activities, are the subject of proceedings concerning those matters, or are in any analogous situation arising from a similar procedure provided for in national legislation or regulations;
2. they have been convicted of an offence (if an individual) or judgment has been made against them concerning their professional conduct by a judgment which has the force of *res judicata*;
3. they have been guilty of grave professional misconduct proven by any means which the contracting authority can justify;
4. they have not fulfilled obligations relating to the payment of social security contributions or the payment of taxes in accordance with the legal provisions of the country in which they are established or with those of the country of the contracting authority or those of the country where the contract is to be performed;
5. they have been the subject of a judgment which has the force of *res judicata* for fraud, corruption, involvement in a criminal organisation or any other illegal activity detrimental to the Community's financial interests;
6. following another procurement procedure or grant award procedure financed by the Community budget, they have been declared to be in serious breach of contract for failure to comply with their contractual obligations;
7. they are subject to a conflict of interests. There is a conflict of interests where the tenderer and a person who is involved in the implementation of the Community budget or an internal auditor share interests (including, for example, family, emotional life, political or national affinity and economic interests) which compromise the impartial and objective exercise of that person's functions
8. they knowingly or negligently make a misrepresentation in supplying the information required by the contracting authority.

All Tenderers are required to provide a signed and dated declaration upon honour that they are not in any of the situations of exclusion listed above (see Annex C: Response questionnaires). For joint applications, a declaration is required from each member of the grouping and each declaration will be considered individually.

As this is an open tender procedure, only successful Tenderers to whom a contract is to be awarded will, in addition to the signed declaration submitted with the bid documentation, be required to show that they are not in one or more of the situations listed above by providing evidence in relation to items mentioned above within a time limit to be defined by EMEA and prior to the signature of any contract. For consortia or similar entities, the documentation is required for each member of the group.

The evidence which may be required from the successful Tenderers is as follows:

1. In relation to points 1, 2 and 5 above, relevant extract(s) from the judicial record or, failing that, equivalent documentation issued by a judicial or administrative authority in the country where the tenderer is established. The extract(s) or equivalent documentation must be the most recent reasonably available. Depending on the national legislation of the country in which the tenderer is established, these documents must relate to entities with legal personality and/or natural persons; in the latter case, they must relate to the person(s) empowered to represent the tenderer and sign the contract if the tender is successful.

2. In relation to point 4 above, the most recent certificates issued by the competent social security and tax authorities of the country where the tenderer is established.

3. Where no such document or certificate is issued in a particular country, this can be replaced by a sworn and solemn statement made before a judicial or administrative authority, a notary or a qualified professional body of the country in which the tenderer is established. The statement provided must be dated less than four months before the final date for submission of tenders. Depending on the national legislation of the country in which the tenderer is established, these documents must relate to entities with legal personality and/or natural persons; in the latter case, they shall relate to the person(s) empowered to represent the tenderer and sign the contract if the tender is successful.

4. In relation to points 3, 6, 7 and 8 above, a sworn and solemn statement made before a judicial or administrative authority, a notary or a qualified professional body of the country in which tenderers are established stating that:

    - The Tenderer has not been found liable for any professional misconduct
    - The Tenderer has not been declared in serious breach of contract following a procurement procedure or grant award financed by the Community budget
    - As far as is known, the Tenderer is not subject to a conflict of interest
    - The Tenderer is supplying all the information required for the procurement procedure in good faith and without misrepresentation either knowingly or negligently.

    This sworn or solemn statement should be signed by the person(s) empowered to represent the Tenderer and sign the contract if the tender is successful and should be dated less than four months before the final date for submission of tenders.

EMEA may waive the obligation of a Tenderer to submit the documentary evidence referred to above if such evidence has already been submitted for the purposes of another EMEA procurement procedure and provided that the issue date of the documents is within 12 months of the date of submission of the tender and that they are still valid. In such a case, Tenderers must declare on their

honour that the documentary evidence has already been provided in a previous procurement procedure and must confirm that no changes in their situation have occurred.

5.4.2 Selection

Specific documentation is required from all Tenderers with regard to all the points listed in the two sections below. For consortia or similar entities, the documentation requested in Section 5.4.2.1 is required for **all** members of the group. Companies which have previously supplied similar documentation in response to another EMEA Invitation to Tender are required to supply the documentation again for this ITT.

5.4.2.1 Financial and Economic Capacity

Tenderers should refer to Annex C: Response questionnaires in order to respond to this section.

The Tenderer's financial and economic capacity will be evaluated on the basis of:

1. a brief description of the Tenderer's economic activity relating to the submission involved in this contract
2. balance sheets or extracts from balance sheets, where publication of the balance sheet is required under the law of the country in which the economic operator is established, for the past three financial years
3. interim accounts for the quarter preceding that in which the Invitation to Tender was published
4. evidence of relevant professional risk indemnity insurance
5. statement of overall turnover and, where appropriate, of turnover carried out by the Tenderer in the area attributable to the activities covered by this invitation to tender.

5.4.2.2 Professional & technical

Tenderers should refer to Annex C: Response questionnaires in order to respond to this section.

The Tenderer's professional and technical capacity will be evaluated on the basis of:

1. proof of authorisation to perform the contract under national law, as evidenced by inclusion in a trade or professional register, or a sworn declaration or certificate, membership of a specific organisation, express authorisation, or entry in the VAT register
2. staff turnover during the last financial year: total staff turnover and percentage of staff that have worked within the relevant business area for over 3 years. .
3. details of at least 3 projects per lot.
   - For Lots 1-5, in respect of which professional IT staff were supplied;
   - For Lot 6, that were commissioned
4. each project being for a different client (departments, divisions, directorates etc. are regarded as the same client)
5. a statement of the Tenderer's policy on the use of subcontractors, and of the means of ensuring quality when subcontractors are used. A confirmation whether or not subcontractors will be used for this contract and if so the full name and address of the subcontractor(s). The role, activities and responsibilities of each subcontractor should be described and an estimate given of the volume/proportion of the contract to be subcontracted. A letter of intent must also be provided by each subcontractor, confirming its intention to collaborate if the Tenderer wins the contract.
6. quality assurance accreditation(s) held by the Tenderer. If no accreditations are held, an outline of the Tenderer's quality assurance policy should be provided.

7. experience of the Tenderer in the business domain, including the number of years of activity in the domain and the staff involved
8. a statement of the Tenderer's account management policy
9. a statement of the Tenderer's policy on operational support
10. a statement on how the Tenderer ensures that contracts are operated efficiently and how it tests its charges in the marketplace
11. Tenderer's Skills List to be completed by the Tenderer (see Annex C: Response questionnaires
12. confirmation that the Tenderer is able to develop in and for an environment that replicates the architecture of EMEA at its own premises (**Lot 6** only)

5.4.3 Award

Tenderers should refer to Annex C: Response questionnaires in order to respond to this section.

Award Criteria	**Lot 1**	**Lot 2**	**Lot 3**	**Lot 4**	**Lot 5**	**Lot 6**
1. Expertise proposed	28	28	28	28	28	0
2. Skills Assurance	8	8	8	8	8	0
3 Quality of Service	28	28	28	28	28	85
4 Business Domain	4	4	4	4	4	0
5 Overall quality of the tender submitted	12	12	12	12	12	15
6 Price	20	20	20	20	20	0
TOTAL	100%	100%	100%	100%	100%	100%

The technical evaluation will consist of an initial assessment against the technical award criteria. Tenders not meeting the minimum score of 60% in any one of the award criteria numbered 1, 2 3 and 5 will be excluded.

The contracts will be awarded to the economically most advantageous offers. For Lots 1-5, evaluation of price will be conducted according to the following formula:

$$\frac{\text{Lowest price x weighting for price}}{\text{Tenderer's price}}$$

Prices to be evaluated will be based on the scenarios per Lot in the pricing scenario worksheets contained in the Lots 1-5 Response Questionnaire in Annex C: Response questionnaires. Tenderers are required to cost a given number of days for each profile over a four year period. Please note that this scenario is for evaluation purposes only and does not constitute any commitment by EMEA to procure profiles according to these figures. Up to 5 Tenderers will be short-listed for each lot, based on the rankings achieved following initial evaluation of the award criteria, including price. For Lots 1 and 2, a scenario for expenses is also outlined in the expenses scenario worksheets in the Lots 1-5 Response Questionnaire in Annex C: Response questionnaires. Tenderers are required to price expenses according to the scenarios described in the worksheets for business trips to be made by the Contractor's personnel to various locations to attend meetings or conferences. These scenarios are for

evaluation purposes only. Tenderers should also refer to the EMEA reimbursement rules contained in the Draft Framework Contract (Lots 1-5) in Annex D: Draft Framework Contracts

For Lot 6, framework contracts will be awarded to a pool of Tenderers in order to assure expertise in each of on-line transactional systems, analysis systems, document and content management and web publishing systems, enterprise resource planning systems and Oracle products. A technical merit score will be awarded for each tender. Tenders not meeting the minimum score of 60% in either of the award criteria will be excluded. Each Tenderer will be required to provide, in respect of **one** of the domains listed above, actual documentation used in a recent fixed price project that the Tenderer considers representative of the company's capabilities. A list of the documents required can be found in Section 6.4.1.2.1 Quality of the service delivery and an example of a list of documents is contained in the worksheet entitled Example document list in the Lot 6 Response Questionnaire in Annex C: Response questionnaires. Tenderers will also be required to indicate if they have expertise relevant to the other domains and, if so, which ones. It is anticipated that up to 10 framework contracts will be concluded for this Lot.

Specific contracts under Lot 6 will be awarded based on quality (70%) and cost (30%). Tenders not meeting the minimum score of 60% in the quality award criterion will be excluded. Evaluation of price will be conducted according to the same formula as the framework contract:

$$\frac{\text{Lowest price x weighting for price}}{\text{Tenderer's price}}$$

Expertise proposed

For Lots 1-5 the expertise proposed is that which relates to the individuals put forward in respect of each of the profiles. The Tenderer will be required to ensure that the skill sets of each individual proposed in the response to this invitation to tender match those specified in the profiles described in Section 4.1.7 Profile Specifications. The responses in the workbook entitled "Curricula Vitae" in Annex C: Response questionnaires will be used to evaluate this award criterion.

Skills Assurance

For Lots 1-5, the Contractor will be required to ensure that the skills levels of personnel assigned to EMEA projects are maintained throughout the period that they are working at EMEA. EMEA may require the Contractor to provide for the maintenance or enhancement of such skills levels of the individuals allocated to EMEA activities through formal training. Such training is likely to require an average of 5 man-days per person per annum. The Contractor will be expected to clear any proposed training with EMEA prior to commencement and to agree timings with the individual and with the individual's Project Manager before proceeding.

EMEA will provide, at EMEA's expense, any relevant introductory training at their premises for the Contractor's personnel with regard to the details of the project on which they will be working and with regard to generally relevant topics, such as general IT systems in use in the Agency, health and safety, business continuity, emergency procedures and so on.

Tenderers should complete the worksheet entitled Skills Assurance in the Lots 1-5 questionnaire in Annex C: Response questionnaires

Quality of Service

For Lots 1-5, the main constituent of quality of service relates to the delivery of the provision of external services. These aspects are further described in the section on Quality of the service delivery.

For these lots, Tenderers should complete the worksheet entitled Quality of Service contained in the Lots 1-5 Response Questionnaire in Annex C: Response questionnaires

For Lot 6, quality of service relates to the manner, completeness and richness with which specified deliverables are made available. These aspects are further described in the section on Quality of the service delivery within the part of this invitation to tender describing the operation of the contracts.

Tenderers should complete the worksheet entitled Quality of Service contained in the Lot 6 Response Questionnaire in Annex C: Response questionnaires.

Business Domain

For Lots 1-5, business domain knowledge takes the form of experience of individuals in relation to the building of systems or the carrying out of studies that required in-depth knowledge of medicines information, pharmacovigilance and regulation.

Tenderers should complete the worksheet entitled Business Domain contained in the Lots 1-5 Response Questionnaire in Annex C: Response questionnaires.

Overall quality of the tender submitted

The overall quality of the tender submitted will be assessed on the basis of the clarity of the tender submitted and the demonstrated understanding of the requirements set out in this invitation to tender.

Presentation at the EMEA

Tenderers should be prepared to support the written response with a visit to the EMEA in order to present their expertise and to provide answers to additional questions that EMEA's Evaluation Committee might have as part of the evaluation process. It is anticipated that such a visit, if required, will take place, in respect of the first lot to be evaluated, in late August/September 2008. As the lots may be evaluated at different times and by different Evaluation Committees, Tenderers should be prepared to present their expertise more than once if they apply for a number of lots. Should Tenderers be required to attend a presentation, an invitation to attend will be issued giving Tenderers no less than 7 working days notice. Following the presentation, the Evaluation Committee will review the technical scores for each Tenderer short-listed and will amend scores accordingly.

Tenderers should note that any such visit is a mandatory part of the evaluation process and that refusal of an invitation may result in the exclusion of the Tenderer from any further part in the procurement procedure.

6 Operation of the contracts

6.1 General description of framework contracts

A framework contract lays down the basic terms governing the relations between EMEA and the Contractor during the period of validity of the contract, particularly as regards duration, subject, price, implementing conditions and the overall quantity of services required.

It is EMEA's intention to sign multiple cascading framework contracts for each of Lots 1, 2, 3, 4 and 5 as a result of this Invitation to Tender. A framework contract will be awarded for each lot to a first priority Contractor and up to two other Contractors ranked in order following the evaluation procedure. If, for example, the first priority Contractor is unable to fulfil the requirements of an order within the requisite timelines or provides an unsatisfactory service, EMEA has the option to go to the second priority Contractor in such a cascade and then to the third until the order is fulfilled.

It is EMEA's intention to sign multiple framework contracts in a pool arrangement for Lot 6 as a result of this Invitation to Tender. Framework contracts will be awarded to a maximum of 10 Contractors each of whom may then be requested to tender on a fixed price basis for each Specific Contract to be let.

Framework contracts will be concluded for an initial period of two years, with two possible extensions of one year each, giving a maximum possible duration of four years.

Signature of a framework contract imposes no obligation on EMEA to order services. Only the implementation of the framework contract through Specific Contracts is binding for EMEA.

A draft Framework Contract, containing full terms and conditions, is included in Annex D: Draft Framework Contracts.

Tenderers should be aware that the incumbent suppliers of these services currently employ significant resource in situ at EMEA's premises which includes the supplier's employees carrying out exclusive functions for EMEA. Any change of service provider may, therefore, be subject to the Transfer of Undertakings (Protection of Employment) Regulations 2006 (sometimes known as "TUPE") which apply in the UK."

6.2 Specific contracts implementing framework contracts

The conclusion of a framework contract does not in itself constitute a confirmed order to a supplier. Orders are placed by means of Specific Contracts, which are contractual documents that contain the specific conditions for concluding and executing selected programmes of work between EMEA and the Contractor. The framework contracts for lots 1, 2, 3 4 and 5 will define the unit costs (for work both at the Contractor's and/or at EMEA's premises as required) of the personnel to be used to undertake the work required in this Invitation to Tender. Based on these costs, orders will then be placed and Specific Contracts concluded to confirm those orders according to the Terms and Conditions of this Invitation to Tender and of the corresponding financial proposal of the Contractor.

For Specific Contracts under Lot 6, please refer to Section 6.3.2 Fixed Price below.

Draft Specific Contracts can be found as an annex to the draft Framework Contracts in Annex D: Draft Framework Contracts.

6.3 Process for ordering services

6.3.1 Time and Materials

The ordering process for time and materials orders is as follows:

1. A profile specification for each profile required will be drawn up by EMEA and a sample is included in Annex G: Standard Profile Specification & Request Form:

2. A Request Form is completed by EMEA, in which the request for services is summarised and timelines are given for responses from the Contractor. An example is included in Annex G: Standard Profile Specification & Request Form. The form is accompanied by the profile specifications and any other relevant documentation and is sent by e-mail to the first priority Contractor in the cascade.

   If the first priority Contractor has already been given the opportunity to provide these services and has failed to comply with the relevant timelines or is unable to provide the services or has provided services unacceptable to EMEA, EMEA will send the documents to the next Contractor in the cascade and the process will continue until the request is satisfactorily fulfilled.

3. The Contractor is required to acknowledge receipt of the Request Form and associated documents by e-mail to EMEA within two working days of the date on which the Request Form was sent out by EMEA.

4. The Contractor is then required to indicate willingness to make an offer or to decline to make an offer by the date specified in the Request Form, which will be a maximum of 3 working days from the date on which the Request Form was sent out by EMEA. If the Contractor declines to make an offer or fails to respond by the due date indicating its willingness to make an offer, EMEA will then forward the Request Form to the next Contractor in the cascade.

5. Having confirmed willingness to make an offer, the Contractor is required to propose to EMEA by e-mail the CVs of candidates matching the requirements given in the profile specification form(s) accompanying the Request Form. The response must be sent to EMEA by the final offer date specified in the Request Form. All candidates proposed must be available for interview at EMEA in the two weeks following the sending of the CVs. If the Contractor does not comply with the timelines specified, the Contractor will be deemed to have not respected the requirements and EMEA will forward the Request Form and documents to the next Contractor in the cascade.

6. If EMEA accepts a candidate(s) as a result of interviews, EMEA will send an e-mail to the Contractor indicating that the candidate(s) has been accepted and will request a formal offer from the Contractor.

7. If a candidate(s) is found to be unacceptable to EMEA, EMEA will advise the Contractor by e-mail and will give feedback, wherever possible, on the reasons why the candidate(s) has been rejected. If the final offer date in the Request Form has not yet been reached, EMEA may permit the Contractor to forward more CVs for consideration. If the final offer date has been reached, the Contractor will be deemed not to have fulfilled the requirements and EMEA will forward the Request Form to the next Contractor in the cascade.

8. Once a candidate has been confirmed and a formal offer received from the Contractor, EMEA will draw up the Specific Contract which will include the details of the work to be carried out, the start date, the duration in man-days and any other relevant information. The Specific

Contract will be signed in the relevant number of copies by the EMEA signatory and then forwarded to the Contractor for signature. The Specific Contract becomes effective from the date of the last signature. The Contractor will return one copy of the signed contract to EMEA, retaining the other copies for its own files.

9. The Contractor's personnel will commence work on a mutually convenient date and time and at the location stipulated in the Request Form. For time and materials contracts, this will normally be at EMEA's premises.

The Contractor will be expected to present proposals which meet the requirements specified in the Request Form and associated documents. Personnel proposed must match the requested profile description and persons whose CVs have been proposed in the tender should be available to work on the Specific Contracts concluded with EMEA. The Contractor must present to EMEA at least two suitably qualified candidates for each profile required and these persons must be available for interviews, which are attended at the cost of the Contractor. Persons proposed must be available at the start date as identified in the Request Form.

6.3.2 Fixed Price

The ordering process for fixed price orders is as follows:

1. EMEA draws up a specification of the services required and decides on the timelines for the responses from the Contractors.

2. EMEA sends a mini-call for tenders to all Contractors in the pool.

3. The Contractor is required to reply with a tender in response to the mini-call for tenders by the deadline indicated in the documentation.

4. The submitted responses are opened and evaluated by an Evaluation Committee according to the award criteria stipulated in the documentation.

5. EMEA confirms to the successful Contractor by letter that the offer is accepted and will form the basis of a Specific Contract.

6. EMEA will advise the unsuccessful Contractors by letter.

7. EMEA will draw up the Specific Contract which will include the details of the services to be provided, the start date, the duration, deliverables, price and any other relevant information. The Specific Contract will be signed in the relevant number of copies by the EMEA signatory and then forwarded to the Contractor for signature. The Specific Contract becomes effective from the date of the last signature. The Contractor will retain the relevant number of copies for their files and return one copy to EMEA.

8. The Contractor's personnel will commence work on a mutually convenient date and at the location stipulated in the Request Form. For Fixed Price contracts, this would normally be at the Contractor's own premises.

The Contractor must prepare proposals meeting the requirements as specified in the invitation to tender and associated documents. Deliverables must be on time and conform to the specifications as described in the Specific Contract.

6.3.3 Languages

The required services must be provided in English.

6.3.4 Place of work

Work can be executed on EMEA's premises, or those of its partners (*intra muros*) or can be executed on the Contractor's premises (*extra muros*). There may be an occasional requirement for meetings outside the European Union (EU) and the European Economic Area (EEA) to be attended by Contractors' staff. EMEA will indicate on all Request Forms where the work has to be undertaken.

Intra muros work will be undertaken mainly at EMEA's premises at 7 Westferry Circus, Canary Wharf, London E14 4HB, UK. There may be a need for work to be carried out on the premises of national competent authorities within the EU and the EEA, or at the premises of one or more of the Agency's industry partners. The infrastructure will be provided by EMEA.

Personnel providing the service will use only the standard software packages in use at EMEA, the named national competent authority in the EU or EEA or industry partner and no other software may be installed or used without the written authorisation of EMEA.

Extra muros work will be performed primarily at the Contractor's premises. Project meetings are typically held at EMEA premises. Deliverables must be formally delivered at EMEA's premises.

The Contractor must provide all deliverables in the form and format specified in the order and shall guarantee their integration into the target informatics environment.

For Fixed Price orders, the Contractor shall provide all the necessary infrastructure on the Contractor's premises for the successful execution of the work. Official acceptance of the work carried out will take place at milestones during and at the end of each order execution, using a procedure agreed to at the beginning of the order. Invoices may be issued only for executed orders and tasks that have been completed and duly accepted.

6.4 Contract management

6.4.1 Quality monitoring

6.4.1.1 Lots 1-5

6.4.1.1.1 Quality of the service delivery

Monitoring of the quality of service delivery will measure whether the Contractor is delivering a standard of service in line with expectations. CVs should meet the profile specifications in terms of the characteristics requested in the context of that which is described per profile in this invitation to tender and should be delivered in a timely manner. In addition, administrative activities in connection with setting up and maintaining the arrangements with individuals should be carried out in a timely and efficient manner.

The mechanism for the monitoring will involve the periodic execution of the following:

- measurement of acceptability by means of invitations to an interview
- measurement of timely delivery of CVs
- measurement of the timely arrangement of interviews

- measurement of the efficiency with which contractual arrangements are finalised with selected profiles in the context of known notice periods

Benchmarks

- Benchmark 1 for acceptability will be an average of three CVs per profile.
- Benchmark 2 for timely delivery will be three weeks per profile.
- Benchmark 3 for timely arrangement of interviews will be one week per CV.
- Benchmark 4 - formal arrangements will have been concluded in such a way that availability of the resource, following EMEA's notification of intention to proceed, is no later than the known notice period, or two weeks where there is none.

For the purposes of this section, a benchmark is a point of reference for the measurement of the performance of an activity against which the successful Tenderer will be assessed. The cascade will be invoked where the successful Tenderer either fails to meet expectations either by a substantial margin in a single instance or consistently over a period of time.

6.4.1.1.2 Quality of the work delivered by time and materials resources

Monitoring of the quality of work delivered by resources will measure the delivery of the services required in respect of their timeliness and the extent to which they meet the qualitative expectations of the Agency.

Monitoring will be carried out in the following manner:

- Before commencing a task, the Contractor will agree on the scope of the task, the technical approach and the workload estimate with EMEA staff.
- Progress monitoring. All resources will report on a weekly basis via timesheets showing the number of hours spent per agreed task and progress on the task.
- Monitoring of deliverables. Upon delivery of a deliverable, EMEA staff will review the quality of what is delivered on the basis of its fitness for purpose.

Where the resource either fails to meet expectations by a substantial margin in a single instance or consistently over a period of time, EMEA may terminate the collaboration with this resource immediately. The Contractor will be required to replace the affected resource immediately.

6.4.1.2 Lot 6

6.4.1.2.1 Quality of the service delivery

Monitoring of the quality of service delivery will measure whether the Contractor is delivering a standard of service in line with expectations.

Where the deliverable from the fixed price specific contract is to be a system or part thereof, the specifications to the specific contract will include at least the vision and system use cases prepared in accordance with the principles of RUP@EMEA, as well as the requirements for documentation to be delivered with the system.

The monitoring of the quality of such fixed-price projects for software development will be carried out as follows:-

- At the outset of the project, a detailed software development plan will be drawn up by the Contractor following the principles of EMEA's RUP@EMEA software development

methodology. The deliverables of each iteration will be agreed between the Contractor and EMEA in the software development plan. This plan will be used by EMEA to measure the progress and quality of the project. .

- At the end of each iteration specified in the software development plan EMEA will test and approve the deliverables.
- During the project, the Contractor will be required to provide regular progress reports containing:
    - An executive summary of the status of the project
    - Status of all the milestones.
        - Where there are delays, the reason(s) for the delay
        - Where there are delays, a revised end date
    - Risk list, including:
        - Description of the risk
        - The probability, severity and consequence of the risk occurring
        - The mitigation plan for the risk
        - The current probability, severity and consequence of the risk occurring
    - List of issues

- During the project, the system analysis and design documentation using UML must be reviewed and approved by the EMEA Software Architects. No deliverable will be accepted by EMEA without prior approval of the analysis and design documentation. The exact format of this documentation will be agreed in an annex to the relevant Specific Contract. An example of the type of documentation required is given below:

    - System use cases (where not provided by EMEA as part of the initial specifications)
    - Sequence diagrams for every use case and showing the interaction of all classes towards the realisation of that use case
    - Class diagram
    - Data model
    - Activity diagrams to illustrate the functioning of the important functionality of individual classes or of the system
    - Architectural diagrams

- During the project, the Contractor will be required to provide a test plan, test scripts and the results of the execution of the test scripts, offering EMEA sufficient assurance that the deliverables have been appropriately tested.

- After delivery and acceptance of the system, the Contractor will be required to finalise all the documentation to EMEA's satisfaction.

- On completion of the project, the measure of quality will be the number of defects in the deliverable against the relevant use cases for the system, taking into account the relative size and complexity of each use case.

Monitoring of the quality of fixed-price projects that are not software development projects will be undertaken using a combination of the above methodologies as applicable and as agreed in the relevant Specific Contract.

6.4.2 Change management in relation to fixed price contracts

Changes to the scope will be reflected in amended requirements (e.g. use cases) supplied by EMEA which will result in agreed amendments to the relevant Specific Contract.

6.5 Reporting requirements

6.5.1 Reporting requirements for Lots 1 to 5

The Contractor must provide the following reports to EMEA in English:-

- Individuals' timesheets as required by the Project Manager
- A monthly report to be provided to the Project Office detailing the number of man-days worked by each individual contractor working on time and materials contracts in the preceding month, including cumulative totals from preceding months and the number of man-days remaining on the individual's current assignment. This report must be provided by the end of the second calendar week of the month following the month to which the report refers.
- A quarterly report to be provided to the Head of Sector, Project Management, detailing the number of requests received from EMEA, the number of requests fulfilled and those outstanding at the end of the quarter, including the number of candidates proposed for time and materials orders, the amount of time between the proposed candidates being put forward and the acceptance of a suitable candidate for the position.

The content and layout of the respective reports shall be agreed between EMEA and the Contractor following signature of the Framework Contract.

Contractors will be required to attend a quarterly meeting at EMEA premises in London to review performance, the status of the contract and the planning for the next period.

6.5.2 Reporting requirements for Lot 6

Please refer to section 6.4.1.2.1 Quality of the service delivery

7 Annexes

7.1.1 Annex A: EMEA ICT Standards (EMEA/C/20738/02)

7.1.2 Annex B: Draft Service Level Agreement

7.1.3 Annex C: Response questionnaires

- Lots 1-5 Response questionnaire
- Lot 6 Response questionnaire
- Response questionnaire Curricula Vitae

7.1.4 Annex D: Draft Framework Contracts

- Lots 1-5 Draft Framework Services Contract
- Lot 6 Draft Framework Services Contract

7.1.5 Annex E: Standard Timesheet

7.1.6 Annex F: Confidentiality Statement

- Confidentiality undertaking (Contractor)
- Public Declaration of Interest and Confidentiality Form - Consultants

7.1.7 Annex G: Standard Profile Specification & Request Form

7.1.8 Annex H: Standard Expense Form

7.1.9 Annex I – Financial Identification Form

- Financial Identification Form
- Privacy Statement for Bank Account Validation

8 Document History

Version	Who	When	What
1.0	TB	19/06/08	Published version