9 September 2013
EMA/552750/2013

Technical specifications for open invitation to tender: Procurement Procedure EMA/2013/23/FI for high level business consultancy services

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Technical specifications for open invitation to tender

1. Title of the invitation to tender

This document contains the technical specifications for the open invitation to tender no. EMA/2013/23/FI for high level business consultancy services.

The contract notice for this open tender has been published in the Official Journal of the European Union OJ S 176 of 11 September 2013.

2. Executive summary

Item	Summary
Contracting authority	European Medicines Agency hereinafter referred to as "the Agency".
Purpose	This call for tender aims to put into place contractual arrangements with a maximum of three economic operators in priority order for the provision of services, on a time and materials basis, quoted time and materials or fixed price basis that will enable the Agency to acquire resources not employed directly by the Agency in the domain of the consulting services listed in Section 4 of this document.
Contracts	A maximum of three framework contracts in order of priority is expected to be signed. The framework contracts lay down the legal, financial, technical and administrative provisions governing the relations between the Agency and the contractors during their period of validity. Framework contracts do not constitute orders. Orders are placed through specific contracts. The framework contract will define the types of consultant and their corresponding prices to undertake the services provided. Based on these costs, specific contracts may be concluded according to the terms and conditions of the framework contract and of the corresponding financial and technical tender of the contractor.
Duration of framework contracts	Two years with two possible extensions of one year each (2 + 1 + 1). Maximum possible duration: four years.
Place of delivery	Mainly at the Agency's premises at 7 Westferry Circus, Canary Wharf, London E14 4HB, United Kingdom. However services might also be provided at the contractor's premises and/or a third party's premises or a combination of both.
Particulars of delivery	Delivery of services must be in conformity with the placed orders. Unless otherwise specified in the specific contract, services will be carried out by the contractor during the Agency's normal working days and normal working hours.
Volume (indicative)	The Agency estimates, without this being binding, that the total requirement for consulting services is expected to represent a maximum of 15,000 person-days over the four-year framework contract period.

Item	Summary
Joint Offers	Permitted.
Variants	Not permitted.
Subcontracting	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.
Closing date for receipt of tenders	17 October 2013
Opening of Tenders	23 October 2013 at 1100H (London time)
Tender evaluation procedure	The evaluation of tenderers and their tender will take place in four phases: <u>Exclusion of Tenderers</u>: The purpose of this phase is to determine whether a tenderer is not in a situation of exclusion which would prevent it from participating in the tender procedure. <u>Selection of Tenderers</u>: This phase consists of two stages: 1. Financial and economic capacity 2. 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. <u>Evaluation of tenders</u>: This phase consists of three stages: 1. Qualitative evaluation of the tender 2. Financial evaluation of the tender (price) 3. Addition of points for stages 1 and 2 to arrive at a ranking of tenderers. The purpose of this phase is to identify the most economically advantageous tenders (quality and price). <u>Signature of framework contracts in priority order according to ranking.</u>

3. Objectives and context of the invitation to tender

3.1. Introduction to the European Medicines Agency

The European Medicines Agency ("the Agency") is a decentralised body of the European Union based in Canary Wharf in the Docklands area of London (E14). Its main responsibility is the protection and promotion of public and animal health, through the evaluation and supervision of medicines for human and veterinary use.

The Agency was established in 1995 and operates under Council Regulation No 726/2004 to provide a system for the authorisation of medicinal products. The Agency is an Agency of the European Union and has its own legal personality. The Agency's budget is subject to checks and audits by the Court of Auditors.

The Agency has a staff of around 800, in addition to which there are a number of people working at the Agency as contractors, mainly on ICT projects. The Agency's staff consists of nationals from the majority of EU member states.

The Agency is headed by the Executive Director, and governed by a supervisory body, the Management Board.

3.2. The role of the Agency

The Agency'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 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;
- 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 on-going professional development of every member of the Agency.

Central Authorisation Procedure

This procedure results in a single marketing authorisation that is valid across the European Union, as well as in Iceland, Liechtenstein and Norway.

The centralised procedure is compulsory for:

- human medicines for the treatment of HIV/AIDS, cancer, diabetes, neurodegenerative diseases, auto-immune and other immune dysfunctions, and viral diseases;
- veterinary medicines for use as growth or yield enhancers;
- medicines derived from biotechnology processes, such as genetic engineering;
- advanced-therapy medicines, such as gene-therapy, somatic cell-therapy or tissue-engineered medicines;
- officially designated 'orphan medicines' (medicines used for rare human diseases).

For medicines that do not fall within these categories, companies may submit an application for a centralised marketing authorisation to the Agency, 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 EU 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 Agency. 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 an EU 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.

Future

In the short term, the Agency’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 new pharmacovigilance legislation and anti-falsification legislation and the new ISO standards on individual case safety reports and identification of medicinal products.

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

4. Subject of the tender

The subject of the tender is to assist the Agency with ensuring it is best prepared for future challenges. Having just concluded a major re-organisation effort, the Agency wishes to continue to pursue the efficiency of its operational and administrative activities and to engage with and support its stakeholders and partners in an optimal way.

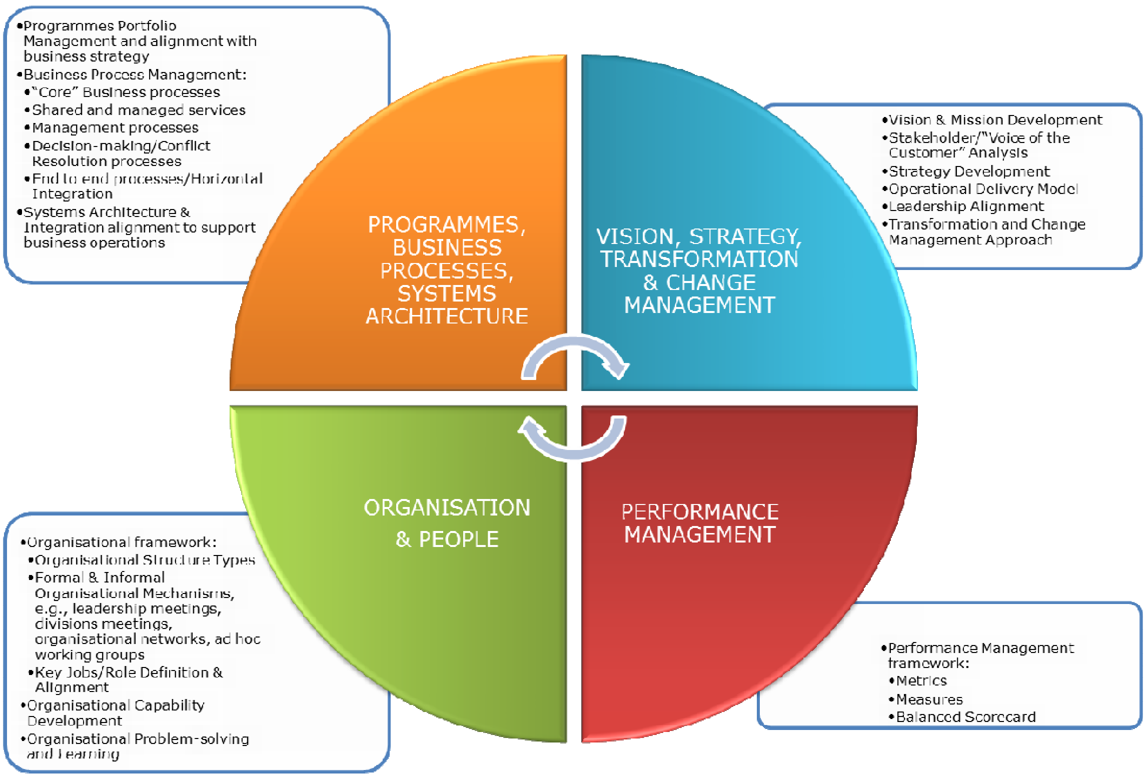
The Agency is tendering for high level consultancy services in the following domains: strategy development and performance management, operational excellence and performance improvement, business programme and project management, business and technology alignment, change management, quality management, human capital development, stakeholder communication, corporate finance and information management.

As a result of this consultancy there might be a subsequent need to develop the Agency's ICT systems. Tenderers are informed that such development is not covered by the scope of the present framework contract.

The successful contractor(s) must be able to carry out several individual orders in parallel and able to provide the required services rapidly and with a high degree of quality.

All services must be provided in English and the successful contractor(s) shall be required to work during the Agency's normal working days and normal working hours. Tenderers should note that the Agency operates on some UK Bank Holidays and contractor(s) may be required to work on these days without any increased charges applying.

The diagram below identifies possible needs for high level consultancy services.



The table below lists services which are either included or excluded by the scope of the framework contract.

Consulting Services	Incorporates	Excludes	Definition
1. Strategy development and performance management	• Corporate strategy • Business unit strategy • Operating model strategy • Communication strategy • Reputation management • Balanced scorecard • Management control systems • Planning and budgeting • Financial reporting • Key Performance Indicators (KPI)		Focuses on the formulation, articulation and validation of business strategies including their impact on the IT strategy. It includes the identification and prioritization to balance investments and risk. It includes Return on Investment (ROI) assessment, monitoring and measurement. Operating model strategy focuses on realigning the operating model to enable the agency to achieve its regulatory, financial and business objectives. In-sourced versus outsourced services, centralised versus localised service provision and other means of enhancing the existing operating model. The area also focuses on establishing a structured and consistent method to follow-up on business objectives and Agency vision implementation. It covers forecasting, planning, control and reporting, efficient meeting and reporting structure and performance measurement. Develop balanced score cards to monitor and sustain improvements. Establish Key Performance Indicators (KPIs) linked to the overall strategic targets of the Agency.
2. Operational Excellence and performance improvement	• Business Process Management (BPM) • Business Process Improvement (BPI) • Business process Reengineering (BPR) • Shared services/managed services • Operating model implementation • KPI roll down • Performance improvement • Meeting efficiency • Lean • 6 sigma • Total Quality Management (TQM)		Reduce operating costs and improve operational and organisational efficiencies whilst maintaining the desired service level quality. Focuses on creating visibility and synchronisation across an organisation whilst focussing on reducing complexity and creating a lean environment to operate within. Focuses on pragmatic ways of doing day-to-day activities and align organisational and individual behaviours to deliver according the corporate strategy. It is about continuously improving operations in a structured way in order to improve value for money, quality, efficiency and effectiveness. Also focuses on the definition of requirements and design to establish and/or improve business processes to meet the objectives of the future business state.
3. Business programme and project management	• Programme Management • Project Management • Business project delivery Framework • Business		Focuses on the management of projects or programmes as groups of strategically related but discrete projects as an integrated Programme to maximize the realisation and the delivery of real, quantifiable and sustainable business benefits according to agreed time, quality and financial investments.

Consulting Services	Incorporates	Excludes	Definition
	Programme Management Office (PMO)		
4. Business and technology alignment	• Project portfolio management and project prioritisation • Business requirements gathering • Business analysis • Software selection management • Manage business resources involvement in in projects	IT system implementation	Focuses on the business side of the implementation of the enterprise wide applications for finance, human resources, customer relationship management or specific operations management. Act as a bridge between business and IT. It includes Enterprise Resource Planning (ERP) or Customer Relationship Management (CRM) business applications. It is also applicable to any Commercial Off the Shelf (COTS) business applications. The area supports localized rollout of a common global business process design and configuration. It also includes selection of COTS business applications. This area also focuses on managing business resources limitation by aligning projects with each other to reduce redundancy / duplication.
5. Change Management	• Change management		Focuses on the assessment, design, communication and implementation of business changes on both the organizational transitions (tangible changes in structure, process and technology) and individual transitions (processes individuals go through to adjust to the new way of working, including formal training) required to enable and sustain change. Collective set of activities that provides a comprehensive, pragmatic, and action-oriented approach to address the people and organizational risks inherent in any project. The ultimate goal is to optimize business benefits realisation/return on investment (ROI), and sustain long-term performance.
6. Quality Management	• Quality management strategy • Quality assurance • Quality control	External audit Financial audit	Determines that deliverables and processes meet requirements by conducting reviews and audits, and subsequently recommending adjustments. It is also the purpose of Quality Management to support continuous process improvement. Focuses on Quality Assurance and Quality Control. Quality Management provides the overall strategy for these activities, Quality Assurance provides insight into the degree of compliance with established processes, and Quality Control substantiates that these processes produce compliant deliverables.
7. Human capital development	• Leadership development and coaching • Efficient chairing • Team management • Decision making • Communication	Headhunting General or specific training courses and related materials Coaching relating to training contracts Agency staff assessments	In coordination with HR, support Agency's staff with skills development in areas relevant to operational activities (including programme and project management and methodologies for process optimisation) in order to support the operating strategy and sustain operational excellence improvements through enhancing key staff competencies.
8. Stakeholder communication	• Stakeholder management • Communication strategy • Reputation management	Internal communication Newswire services	Consultancy supporting communication between the organisation and external third parties (including the media, EU Commission, patients, healthcare providers and industry etc.)
9. Corporate finance	• Activity based costing • Activity based budgeting		Consultancy focused on delivering the Agency accountant's agenda, both in terms of implementation and technical advice

Consulting Services	Incorporates	Excludes	Definition
	• Advisory in VAT regulation		
10. Information management	• Information Asset Management strategy and governance • Records management • Information security and access control • Business intelligence • Corporate performance management • Knowledge management • Access, search and delivery of information • Content and Data Management (unstructured and structured data	IT system design IT system implementation and development IT support or maintenance BI development Databases development and management Data recording and monitoring	Focuses on establishing a common Agency Information Management Strategy and governance; to implement a more effective Information Lifecycle management and to manage information as a business asset. Establish information governance policies and information life cycle strategy and improve information quality, consistency and security across the Agency's scientific network. Support the creation, control, distribution, retention and final disposition of information in accordance with legislations, regulations and leading business practices to manage information with the same priority and security as other business assets. To review processes and systems that can provide better access to the increasing amount of documents, emails, and other unstructured information

4.1. Provision of services on a Time and Means basis

The consulting services to be provided consist of the provision of appropriately skilled individuals to participate in the teams further helping the Agency improving performance through analysis, implementing process improvements, improving corporate governance, providing the link between the "core business" and ICT, supporting change management, supporting capability development, providing the Agency Accountant with technical advices, consulting support reviewing operational activities or any other type of consulting service that could relate to the lists services provided in the table in Section 4 above.

Time & Means orders are mainly executed on the Agency's premises (i.e. on-site).

In a Time & Means order the Agency specifies the workload (e.g. person-days) and its specific needs or services for requested profiles.

The following conditions relating to Time & Means orders apply:

- The contractor must present offers meeting the requirements as specified in a "Request for Services Form" and associated documents sent by the Agency to the contractor. The contractor's proposed staff must match the requested profile description and the specific needs indicated in the Request for Services Form.
- The contractor must be able to propose per requested profile at least two qualified consultants to choose from.
- Europass Curriculum Vitae (CV) forms should be used. All information indicated in the CV has to be true, complete and certified by the contractor.

- Consultants proposed must be available for interviews (to be held at the Agency's premises or by tele/videoconference). The objective of these interviews will be to validate the technical competences of the expert according to the requirements of the Agency's request.
- Consultants proposed must be available at the start of the project.
- At the Agency's request, the contractor must replace personnel who prove incapable of carrying out the specified services to the required standards. The replacement candidate will be given sufficient training during an adequate handover period of at least 10 working days, so that he/she may be immediately operational when the original candidate is withdrawn. Any such replacement and training, if required, will be carried out at no additional cost to the Agency.
- The contractor shall give a month's notice to the Agency of any personnel changes in the team. The prior written approval of the Agency must be obtained. This approval shall only be granted where there are imperative reasons.
- If the original consultant is no longer able to carry out the services, the contractor is obliged to immediately inform the Agency, provide a competent replacement candidate and arrange sufficient training (during a handover period where possible) to guarantee continuity of the service provided to the Agency. Any such replacement will be effected at no additional cost to the Agency.
- At the Agency's request, during holidays or other periods of planned absence by the personnel employed, the contractor may be required to provide an adequate replacement. The replacement person will be given sufficient training and provided with all information necessary to guarantee continuity of the service provided to the Agency. All such training and handover work will be carried out at the contractor's expense.
- The contractor shall ensure the continuity of service necessary for performance of the Specific Contract. Under no circumstances shall the contractor invoke a change in personnel to justify any failure to comply with contractual obligations, in particular compliance with deadlines and quality of service.
- The invoicing is based on the number of days delivered. The minimum unit chargeable to the Agency is a half-day. The Agency may only be charged for half days or full days (4 or 8 hours of work). Where an excess of 8 hours has been worked, no additional charge may be made to the Agency or for working at weekends (unless exceptionally authorised).
- The contractor's offer shall be based on unit prices per profile in its tender.

4.2. Provision of services on Fixed Price basis

Fixed Price orders are generally executed outside the Agency's premises (i.e. off-site or third party premises) but could also be executed on-site (e.g. study, pre-inception phase).

In a Fixed Price order the Agency specifies the deliverables corresponding to the work to be delivered within defined timeframes.

The following conditions relating to fixed price orders apply:

- The contractor must present a proposal meeting the requirements as specified in the "Request for Services" Form and associated annexes (specifications, work packages, deliverables, activities, deadlines, constraints, etc.).
- The offer must include an analysis based on the requirements.

- The services are usually performed off-site, in general on the contractor's premises. The contractor shall provide all necessary infrastructures on his premises for the successful execution of the services.
- The deliverables must be on time, and conform to the specifications as described in the specific contract.
- The contractor's offer shall be inclusive of all costs when the services are delivered off-site.
- The offer must include a project and work organisation plan indicating the proposed activities, the team structure, the complete list of profiles and their names, responsibilities and workload (person-days), the place of work of the team members and the professional relationship with the contractor (permanent / non-permanent), etc.
- The Agency can ask the contractor to provide CVs of the proposed team-members and may ask to meet or interview them.
- A defined methodology has to be used for the calculation of the workload of the different tasks. As result, the financial offer is based on the estimation of the number of days for each profile and for each service element (e.g. documents to be delivered, workshops, etc.). Prices included per profile should be in line with those tendered.
- In its offer, the contractor should indicate if any subcontracting is foreseen.
- Meetings with members of the contractor's team at the location of delivery or by videoconference can be required by Agency without additional costs and with short notice, i.e. 48 hours.
- The invoicing is based on the acceptance of the deliverables by Agency at the agreed fixed price.

4.3. Provision of services on Quoted Time and Means basis

Quoted Time & Means Orders are generally executed outside the Agency's premises (i.e. off-site or third party premises) but could also be executed on-site (e.g. completion of specific project phase).

In a Quoted Time & Means order the Agency specifies the activities to be executed.

The following conditions relating to Quoted Time & Means orders apply:

- The contractor must present offers meeting the requirements as specified in the "Request for Services" Form and associated documents (e.g. technical annex with description of activities, etc.).
- The offer must include a technical proposal based on the requirements.
- Upon request, the offer shall include a project plan.
- The contractor's offer should detail the profiles, roles, activities, responsibilities and workload (activity-days and/or person-days).
- The contractor's offer shall be based on unit prices per profile proposed in the tender.
- The contractor's staff must match the requested profile description.
- The services are usually delivered off-site, in general on the contractor's premises. The contractor shall provide all necessary infrastructures on his premises for the successful execution of the services.

- Meetings at the location of delivery with members of the team can be required without any additional cost by the Agency.
- The Agency can ask the contractor to provide Curricula Vitae of the proposed team members and may ask to meet or interview them.
- In its offer, the contractor should indicate if any subcontracting is foreseen.

4.4. Overview of the Profiles Required

Six consulting profiles have been identified in accordance with their business experience and technical qualifications. The required Typical Client Facing Roles that will carry out the services on a time and materials basis or quoted time basis is given below with a summary of the required experience in number of years. Unless explicitly stated, the required experience is mandatory.

Due to the nature of the Agency, experience in the following business domains is desirable:

- Medicines information
- Public sector
- Regulatory environment

In addition, experience in a multicultural organisation and public sector would be an advantage.

The table below gives a summary of the roles required.

Consulting Profile	Minimum Years of Consulting/ Business Experience	Technical Qualifications	Typical Client Facing Role	Role Profile
Analyst	0 – 2 years	Bachelor and equivalent experience or Master's degree (MBA/ MSc)	Analysis, market research	Analytical, structured and committed professional. Able to carry out research, interviews and to develop an organisation's operational and culture understanding. Able to present finding to clients and the consulting team.
Consultant	1 – 3 years	Bachelor and equivalent experience or Master's degree (MBA/ MSc)	Junior business analyst, functional architect, team leader or senior analyst	Very hands on professionals with good operational and functional knowledge. Capable of assisting with project design and project work stream planning, trained project manager with junior experience (reporting, risks, plans etc.).
Senior Consultant	3- 7 years	Bachelor and equivalent experience or Master's degree (MBA/ MSc)	Project manager, business analyst, subject matter expert, team leader	Deep hands on experience with very good and proven operational, functional knowledge. Capable of being work stream lead. Has a specific experience in a business domain (medicines evaluation, public health, risk, team management, project management etc.)
Managing Consultant/Manager	6 – 10 years	Bachelor and equivalent experience or Master's degree (MBA/ MSc)	Project manager, senior business analyst, subject matter expert	Expert in a specific functional/operational area or project management. Capable of leading multiple work streams. May also be a subject matter expert in a particular business domain
Senior manager	10+ years	Bachelor and equivalent experience or Master's degree (MBA/ MSc)	Strategic and relationship manager, programme and project manager, senior subject matter expert	Many years of experience in programme and project management. In charge of day to day client relationship management. Capable of being a subject matter expert externally recognised in their field.
Partner/Managing director	14+ years	Master's degree (MBA/ MSc)	Strategic and relationship management, contractual management	Very senior professional responsible for overall project and programme delivery, contract management and client satisfaction. Must have many years of experience in the organisation business domain. Can act as a subject matter expert but would rather focus and strategic relationship management with the organisation.

5. Participation in the tender

5.1. Agreements on public procurement

Participation in the Agency's tendering procedures is 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 Union in the field of public procurement under the conditions laid down in that agreement.

The Agency can therefore accept offers from and sign contracts with tenderers from the EU Member States, EEA countries and any other country which has an international agreement with the Union in the field of public procurement. The tender procedures of the Agency are not, however, open to tenderers from countries which have ratified the Multilateral Agreement on Government Procurement ("GPA").

5.2. Subcontracting

If the tender envisages subcontracting any part of this contract, the following documents must be provided with the tender submission:

(i) A document signed by the tenderer stating clearly the identity, roles, activities and responsibilities of subcontractor(s) and specifying the volume/proportion for each subcontractor.

(ii) A letter of intent by each subcontractor stating its unambiguous undertaking to collaborate with the tenderer if it wins the contract and the extent of the resources that it will put at the tenderer's disposal for the performance of the contract.

(iii) If requested under points 12, 13 and 14 any documents regarding the exclusion and/or selection criteria for any subcontractors.

If such documents are not provided, the Agency shall assume that the tenderer does not intend subcontracting.

The contractor may subcontract to another contractor but no further levels of subcontracting will be permitted.

6. Additional documentation available to tenderers

Further information about the work of the Agency can be obtained on its website: http://www.ema.europa.eu.

7. Information visit – not applicable

8. Variants – not applicable

9. Estimated contract volume

The Agency estimates, without this being binding, that the volume of services required under the framework contract over a four year period is as shown below:

	Estimated number of person days 2014	Estimated number of person days 2015	Estimated number of person days 2016	Estimated number of person days 2017	Total sum of estimated person days
Grand total	6 000	4 000	2 500	2 500	15 000

The estimates are based on current planning and budget estimates for the four-year period of the framework contract and include on-going projects as well as new projects to be started during the period of the contract as well as project which have already started which require completion. All these factors may lead to variations in the annual requirement for persons/days over the lifespan of the contract and therefore the estimates are not binding on the Agency as a future purchase but purely indicative for the purpose of the tender.

10. Price

10.1. Currency of tender

Prices should be submitted in Euros. The costing sheet attached to these specifications must be used to submit a tender.

Please note that any financial costing sheet must be submitted in separate binders or folders and on a separate CD, which must be clearly labelled.

Tenderers should not indicate ranges of rates. Should a tenderer do so, the highest price in the range shall be used for the purposes of evaluation as part of the award criteria.

Tenderers must only submit <u>one</u> completed costing sheet.

10.2. All-inclusive prices/reimbursement of expenses

Services to be provided intra muros (at the Agency): prices should be submitted exclusive of any expenses for travel, accommodation and subsistence but inclusive of any other costs. Expenses for travel, accommodation and subsistence may be reimbursed **<u>only under the conditions set out in Annex V and up to the capped amounts indicated.</u>**

Services to be provided extra muros (outside the Agency): prices should be submitted inclusive of all costs involved in the performance of the contract (e.g. to include travel, subsistence etc.). No expenses incurred in the performance of the services will be reimbursed separately by the Agency.

10.3. Price revision

Prices submitted in response to this tender shall 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 framework contract, prices 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 framework contract became effective. Specific contracts shall be concluded on the basis of the prices in force on the date on which they are signed. Such prices shall not be subject to revision.

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

Revision shall be calculated in accordance with the following formula:

$$Ar = Ao * \frac{Ir}{Io}$$

Where

Ar = revised total amount

Ao = total amount in the original tender

Io = index for the month in which the validity of the tender expires

Ir = index for the month corresponding to the date of receipt of the letter requesting revision of prices

10.4. Costs involved in preparing and submitting a tender

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

10.5. Period of validity of the tender

Tenderers must enclose a confirmation that the tender (including prices) is valid for nine months from the final date for submission of the tender.

10.6. Protocol on the Privileges and Immunities of the European Union

The Agency is, as a rule, exempt from all taxes and duties, and in certain circumstances is entitled to a refund for indirect tax incurred such as value added tax (VAT), pursuant to the provisions of Articles 3 and 4 of the Protocol on the Privileges and Immunities of the European Union. Tenderers must therefore give prices which are exclusive of any taxes and duties and must indicate the amount of VAT separately.

11. Payment arrangements

Payment shall always be made in arrears by the Agency by bank transfer to the contractor's bank account following receipt of an invoice and completion of services. Invoices must be submitted no later than four months following completion of the services. For further details of payment modalities, please see Article I.4 of the draft framework contract (Annex IV).

12. Contractual details

A draft framework contract is attached to these Technical Specifications as Annex IV. Tenderers must confirm acceptance of the draft contract and terms and conditions of the tender as part of their tender response.

The Agency wishes to conclude a framework contract to provide services, as and when required, for a period of four years. A framework contract will establish the terms governing specific contracts to be awarded during a given period, in particular with regard to price.

Signature of the framework contract imposes no obligation on the Agency to order services. Only the implementation of the framework contract through specific contracts is binding for the Agency.

Each specific contract will contain details of deliverables and timelines for particular services to be provided as appropriate.

It is the Agency's intention to sign multiple cascading framework contracts with a maximum of three suppliers ranked in priority order. If the first priority contractor is unable to fulfil the requirements of an order within the requisite timelines or provides an unsatisfactory service, the Agency may go to the second priority contractor in such a cascade and then to the third until the order is fulfilled.

Furthermore, once the framework contract has been signed, should a contractor not be eligible for consultancy in the requested domain, for example because it is unable to supply the service or fails to fulfil the minimum requirements set out in a request for services, or in the case of a conflict of interest, the contractor shall be considered as unable to fulfil the request for services and the cascade may be invoked.

Service performance level (Quality Indicators)

The quality indicators defined below relate to the proper execution of the framework contract. They are used in order to assess the overall compliance of the contractor with the required ordering, delivery and general framework contract follow-up. Non-compliance with most of the indicators will result in automatic exclusion of the contractor from the next three specific contracts, and activation of the cascade. Regular non-compliance for a number of specific contracts could lead to more severe measures due to under-performance, as described below.

A weight from 5 to 20 is given to all the specific Quality Indicators. The "Global Service Management Value" is the weighted average of all specific indicators and should be no less than the "Minimum Service Acceptable Value".

The following table gives measurements, limit values and weights for the Quality Indicators and the related actions when an issue occurs. The Agency's appointed contract manager shall conduct the measurement and make the relevant calculations.

Quality Indicator	**Quality Indicator values (Ratio)**	**Minimum acceptable value (percentage)**	**Weight (weight)**	**Result/Fault**	**Immediate action**
Ordering Process					
OP-1. Accepted proposals	Number of accepted proposals / Number of conform accepted proposals submitted	0,80	5	Proposal accepted or cascade mechanism activated / None	The request is sent to another contractor (cascade)

Quality Indicator	Quality Indicator values (Ratio)	Minimum acceptable value (percentage)	Weight (weight)	Result/Fault	Immediate action
OP-2. Compliance of the offer with the requirements	Number of conform offers / Number of offers submitted	0,95	10	Formal offer submitted / No formal offer sent on time.	The request is sent to another contractor (cascade)
OP-3. Compliance with formal offer deadline	Number of formal offers compliant with the deadline / Total number of accepted offers	0,95	10	Requirements or specifications with fixed deadline / None or not respecting the deadline.	The request can be sent to another contractor (cascade)
Delivery Process					
DP-1. Compliance with the starting date	Number of specific contracts compliant with the starting date / Total number of specific contracts	0,90	10	Project starting on time / delays or unavailable profiles on due time.	The contractor needs to justify any delay and delay be accepted by Agency
DP-2. Compliance with the delivery dates	Number of specific contracts with compliant delivery dates / Total number of specific contracts	0,80	10	Successful completion of the project within the deadlines / Deliverables are not provided on time or postponed due to delays at the starting date.	The contractor needs to take necessary measures at its charge. Liquidated damages may apply as defined in the framework contract.
DP-3. Acceptance and compliance of the service delivered with agreed requirements	Number of conform specific contracts / Total number of specific contracts	0,98	20	Acceptance based on the conformance of the deliverables with the specifications described in the specific contract / Deliverables do not conform to the specifications.	The contractor needs to take necessary measures at its charge. Liquidated damages may apply as defined in the framework contract.
General Framework contract follow up					
GF-1. Respect of deadlines for reports	Number of reports sent within the deadlines / Total number of reports	0,90	5		
GF-2. Compliance of reports	Number of conform reports / Total number of reports	0,90	5		

The "**Global Service Management Value" (GSMV)** measurement is the weighted average of the individual Quality Indicators values:

GSMV = (SUM (value*weight)/SUM (weight))

The **"Minimum Service Acceptable Value" (MSAV)** is the weighted average of the minimum acceptable values (percentage) of individual Quality Indicators:

MSAV = (SUM (percentage*weight)/SUM (weight))

Measures in case of underperformance

If the GSMV for the last 12 months is lower than the MSAV during 3 consecutive months, the Agency may decide to authorise its services to bypass the contractor for the next three service requests leading to three specific contracts and to address all new requests for services to the next contractor in the cascade.

These measures will be applicable when the underperformance is materialised.

The measures above may be applied in the following conditions:

- The period of measurement is the last 12 months;
- The minimum number of requests must be 10 (during the last 12 months).

At the end of the application of the measures, a new period of measurement of the Quality Indicators will be initiated.

Liquidated damages

The contractual provisions for liquidated damages are set out in Article II.16 of the draft framework contract (Annex IV).

Tenderers are informed that special conditions for liquidated damages may be also defined at specific contract level. Financial penalties might also apply in projects of particular importance to the Agency, as defined in particular specific contracts.

Framework contract execution reports

The contractor offering services must provide periodical reports to the Agency contracting authority. The reports are quarterly or at least yearly if there are few activities on the contract (e.g. less than 5 specific contracts during a quarter).

The report, with complete and accurate information at the end of the previous quarter, must be delivered at least on the beginning of current quarter.

The periodical report includes:

- A summary of the services provided.
- Data on the request processing and specific contracts from the start of the framework contract using the template set out in Annex X.
- The risks identified, the problems encountered the solutions founded and lessons learned.

13. Exclusion criteria

All tenderers and subcontractors shall provide a declaration on their honour (see Annex II), duly signed and dated by an authorised representative, stating that they are not in one of the situations of exclusion listed in this Annex.

The successful tenderer shall provide the documents mentioned as supporting evidence in Annex II before signature of the framework contract and within a deadline given by the Agency. This requirement applies to all members of the consortium in case of joint tender and to subcontractors.

The Agency may waive the obligation of a tenderer to submit the documentary evidence referred to above if such evidence has already been submitted to it for the purposes of another procurement procedure and provided that the issuing date of the documents does not exceed one year and that they are still valid. In such a case the tenderer shall declare on its honour that the documentary evidence has already been provided in a previous procurement procedure and confirm that no changes in its situation have occurred.

14. Selection criteria: financial and economic capacity

Requirements:

Tenderers must be in a stable financial position and have the economic and financial capacity to perform the contract. The annual turnover of the tenderer must be of a minimum value of 11.25 million Euros for each of the last three financial years.

The documentation supplied in response to this section will be reviewed to assess the general financial health of the tenderer (or all tenderers in the case of joint tenders whereby a consolidated assessment shall be made) and parent companies where the parent company is providing a guarantee. In addition to verifying that the financial turnover meets the required minimum amounts, as listed above and in the Official Journal notice, the on-going economic capacity will be assessed including financial independence and liquidity.

Evidence required:

The documents or information listed below must be presented as evidence of compliance with the economic and financial capacity. If subcontracting is envisaged, documentation must be provided in relation to any subcontractors unless 10% or less of the total volume of services is expected to be subcontracted and in this case documentation for any subcontractor is not required.

If the tenderer is a company and is otherwise required under the law of the State in which it is established to publish its accounts, the following information is requested:

1. appropriate statements from banks or, where appropriate, evidence of relevant professional risk indemnity insurance;
2. financial statement for the last three years for which accounts have been closed;
3. a statement of overall turnover and turnover concerning the services covered by the framework contract for the last three financial years;
4. if the tenderer relies on the capacities of other entities (e.g. a parent company), a written undertaking on the part of those entities confirming that they will place the resources necessary for performance of the contract at the disposal of the tenderer for the period of the contract. In such case the Agency may require that the successful tenderer(s) and such entities are jointly liable for the execution of the contract.

The Agency may waive the obligation of a tenderer to submit the documentary evidence referred to above in points 1, 2 and 3 if such evidence has been submitted to it for the purposes of another procurement procedure and if it still complies with the requirements of the Agency. If, for some exceptional reason which the contracting authority considers justified, the tenderer is unable to provide the documentation mentioned in points 1, 2 and 3, it may prove its economic and financial capacity by any other means which the contracting authority considers appropriate.

15. Selection criteria: legal status and technical and professional capacity

Requirements:

The criteria for this contract are:

1. Authorisation of the tenderer to perform the contract under national law.
2. Sufficient manpower with suitable qualifications and experience to perform all the services covered by this tender.
3. Relevant previous experience of the tenderer in the provision of services in the fields covered by this tender.
4. Quality assurance.

Tenderers must meet **all** of the above requirements otherwise they shall be deemed not to meet this criterion.

Evidence required:

The documents or information listed below must be presented as evidence of compliance with these selection criteria. For joint tenders the Evaluation Committee will assess the combined capacities of all members, including sub-contractors.

1. 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 of entry in the VAT register. For this purpose, tenderers should provide a duly signed and dated Legal Entity Form. The Form is available in all EU languages at the following website: http://ec.europa.eu/budget/contracts_grants/info_contracts/legal_entities/legal_entities_en.cfm
2. Proof of the educational and professional qualifications of the tenderer and/or those of the tenderer's managerial staff and, in particular those of the person or persons responsible for providing the services. Tenderers must provide **two Curricula Vitae for each of the profiles listed in Section 4.4**. Each Curriculum Vita must **all** match the requirements set out in Section 4.4, otherwise tenderers shall be considered not to have the minimum capacity to fulfil this criterion.

   Curricula Vitae submitted should bear **no indication of name or date of birth, only a number**. A separate list should be included showing the association between these numbers and actual names.

   Curricula Vitae should be submitted using the Europass template:

   http://europass.cedefop.europa.eu/europass/home/vernav/Europass+Documents/Europass+CV.csp

   Tenderers should also provide a statement of the average annual manpower and the number of staff of the tenderer who are able to fulfil the requirements of this tender in the last three years.

3. A list of the principal services provided in the past three years for similar contracts, with the sums, dates and recipients, public or private, **where projects have been completed,** using the Project Reference form provided in Annex VII.

4. Description of the tenderer's quality procedures for delivery of services relevant to this tender confirming adherence to ISO9000 – quality management – or equivalent, and a copy of the relevant certificate.

16. Award criteria

Stage 1

Qualitative award criteria

Only tenderers which have passed the exclusion and selection criteria stages shall be assessed against the award criteria in order to determine the most economically advantageous tenders. For joint tenders the award criteria shall be evaluated in relation to the tender as a whole.

The award criteria, the points available and minimum scores which must be achieved are listed below. No other award criteria, sub-criteria or weightings shall be used by the evaluation committee. Any tender not achieving the minimum points score indicated below for each subcriterion shall be eliminated and not evaluated for price.

The following qualitative award criteria shall be used. They shall account for a total of 60% of the weighting for this tender.

The questions referred to are set out in Annex VIII, Award criteria questionnaire.

Award criteria	Weighting %	Maximum points available	Minimum points which must be achieved
1. Planning and methodology	**24%**	**400**	
Question 1.1		50	30
Question 1.2		50	30
Question 1.3		50	30
Question 1.4		50	30
Question 1.5		50	30
Question 1.6		50	30
Question 1.7		50	30
Question 1.8		50	30
2. Delivery of services	**30%**	**500**	
Question 2.1		50	30
Question 2.2		50	30

Award criteria	Weighting %	Maximum points available	Minimum points which must be achieved
Question 2.3		50	30
Question 2.4		50	30
Question 2.5		50	30
Question 2.6		50	30
Question 2.7		50	30
Question 2.8		50	30
Question 2.9		50	30
Question 2.10		50	30
3. Management of services	**6%**	**100**	
Question 3.1		50	30
Question 3.2		50	30

Each evaluation committee member shall score each tender out of the maximum points available for each subcriterion. The total score to be awarded to each tenderer for each subcriterion shall be the average score of the points of all the members, calculated to two decimal places. A check shall then be made if the tenderer has met the minimum score required for each subcriterion. If this has not been achieved, the tenderer shall be eliminated at this stage.

Where the minimum score has been achieved in each subcriterion, the total points shall then be converted to the weighting percentage for the three criteria mentioned above (Project planning and methodology: 24%, Delivery of services: 30%, Management of services: 6%). The final score out of 60% shall be given to two decimal places.

Stage 2

Financial award criteria - price

Following completion of Stage 1, price shall be evaluated using the following formula:

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

For the purposes of evaluation, ”price” in this formula shall be the grand total of the scenario (intra muros + extra muros) in costing sheet in Annex I calculated to two decimal places. Price shall account for 40% of the weighting for this tender.

This scenario is indicative only for the purposes of evaluation and is not binding on the Agency as a future purchase but uses prices which shall be those charged by the tenderer if a contract is awarded.

Tenderers’ attention is drawn to Article 151 of the Rules of Application of Regulation (EU, Euratom) No. 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union concerning abnormally low tenders.

Following evaluation of price, the points for price and the points for the qualitative award criteria shall be added together (Stage 1 and Stage 2) to arrive at a grand total to two decimal places and to determine the ranking of tenderers.

17. Tender to be submitted

In order to assess each tenderer according to the above-mentioned criteria, the following information must be submitted by the tenderer:

1. Letter enclosing the tender on the official letter headed paper of the tenderer and signed by an authorised representative of the tenderer.
2. Tender in one original paper copy with one copy of all documents on CD-ROM, containing the following elements:

- Completed declaration in Annex II relating to Exclusion Criteria.
- Completed Legal Entity Form.
- Documentation requested to enable assessment of Selection Criteria (points 13 and 14 above) including completed Project Reference form in Annex VII.
- Documentation requested to enable assessment of Award Criteria (point 15 above) by completing the Award criteria questionnaire in Annex VIII.
- Tenderer information form in Annex VI.
- A statement to confirm that information provided in response to this tender is accurate and complete as at the date of submission and acknowledgement that the provision of false information, either knowingly or negligently, in response to this tender could result in the tenderer being excluded from future tenders for contracts with the Agency.
- Confirmation of acceptance of the draft contract and terms and conditions of tender.
- An undertaking to inform the Agency promptly following any matter which would alter or add to any of the information given in response to this tender.
- Documents as requested in relation to proposed subcontracting.
- Tenders submitted by consortia or by groups of service providers must indicate the role, title and experience of each member or of the group.
- **To be submitted in separate binders or folders and on a separate CD, which must be clearly labelled**, a detailed financial tender using the costing sheet attached in Annex I, and exclusive of VAT, signed by an authorised representative of the tenderer.
- Tenderers are requested to make use of the checklist given in Annex III to ensure that no enclosure has been omitted in their tender.

Annexes

Annex I Costing sheet
Annex II Exclusion criteria statement and detail of supporting documentation required – to be completed by tenderers
Annex III Summary checklist of documents which tenderers must submit
Annex IV Draft framework contract
Annex V Reimbursement of expenses
Annex VI Tenderer information form – to be completed by tenderers

Annex VII	Project Reference form – to be completed by tenderers
Annex VIII	Award criteria questionnaire – to be completed by tenderers
Annex IX	Ordering process
Annex X	Framework contract execution template