EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

GxP Inspections and related Inspectors Working Groups

IPA- INTRODUCTORY MEETING 1-2 February 2010

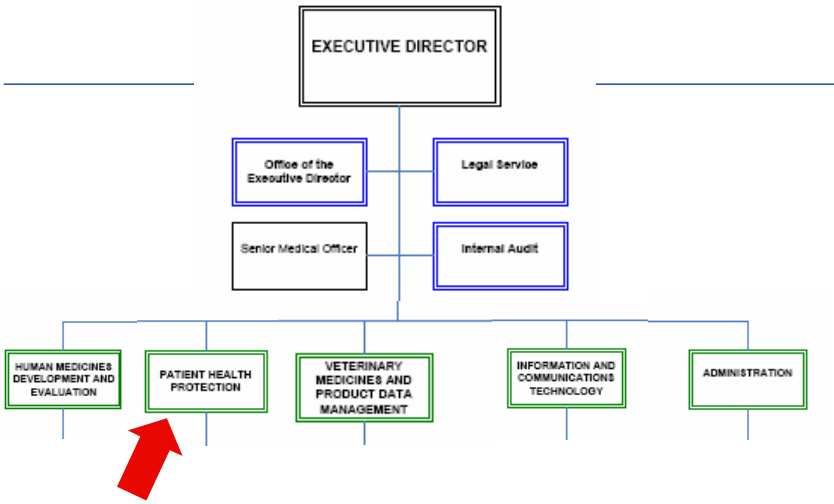
Presented by: Ana Rodriguez
Head Clinical and Non-Clinical Compliance

An agency of the European Union

EUROPEAN MEDICINES AGENCY

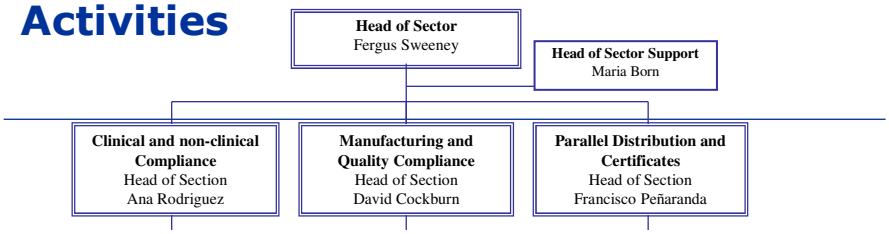
- Compliance and Inspection Sector Activities
- Coordination of GxP Inspections
- GxP Inspectors Working Groups
- Where to find relevant information

Patient Health Protection Unit



Compliance and Inspection Sector

Activities



- Coordination of GxP Inspections (GMP, GCP, GLP and PhV)
- Secretariat and Chair of GxP/PhV Inspectors Working Group meetings
- Secretariat joint CHMP/CVMP Quality Working Party (QWP)
- Mutual Recognition Agreements (MRAs)
- EMA Certification of Medicinal Products
- Parallel distribution
- Sampling and Testing (S&T)
- Product Defects i.e. Quality problems
- Business analyst for EudraCT and EudraGMPs

EUROPEAN MEDICINES AGENCY

Coordination of Inspections

- Regulation (EC) No 726/2004 Art. 57.1(i), coordinating the verification of compliance with the principles of good manufacturing practice, good laboratory practice, good clinical practice and the verification of compliance with pharmacovigilance obligations
- Specific framework and details of framework for inspections are set out in Directives for GCP, GLP, GMP and Pharmacovgilance
- EMA coordinates inspections requested in the context of Marketing Authorisation Applications to the Centralised procedure
- Inspections are carried out by the inspectors of the National Competent Authorities of the EU Member States
- These national inspections are conducted on behalf of the community
- Inspection results are shared by EU authorities

EUROPEAN MEDICINES AGENCY

Coordination of Inspections

Purpose of an inspection

- To verify if the information provided in the marketing authorization application is reliable and accurate
- To verify and confirm compliance with Good Practices and/or Community law
- To review the performance of the quality management systems of the applicants – to gather experience
- To investigate reported deficiencies/non-compliance issues

EUROPEAN MEDICINES AGENCY

Coordination of GMP Inspections

Pre-authorisation GMP inspections

- GMP compliance for sites outside the EU
- Production / process issues from assessment of application

Post-authorisation GMP inspections

- Checks on technology transfer and process validation
- Routine inspections for compliance with GMP

So far more than 900 inspections:

- USA 73%, Switzerland 6.4%, EU 7.7 %, Puerto Rico 6.7%, Japan 3%, Canada 1.6%, Israel 0.3%, South Africa 0.1%, Singapore 0.3%, Australia 0.1%, South Korea 0.3%, India 0.3%, Brazil 0.1%

EUROPEAN MEDICINES AGENCY

Coordination of GCP/PhV Inspections

Pre-authorisation GCP inspections

- Verification of GCP compliance and data validity in clinical trials submitted – triggered and routine

Post-authorisation GCP/PhV inspections

- Type II variations involving extension of indication
- Monitoring of compliance with specific obligations, follow-up measures or pharmacovigilance obligations

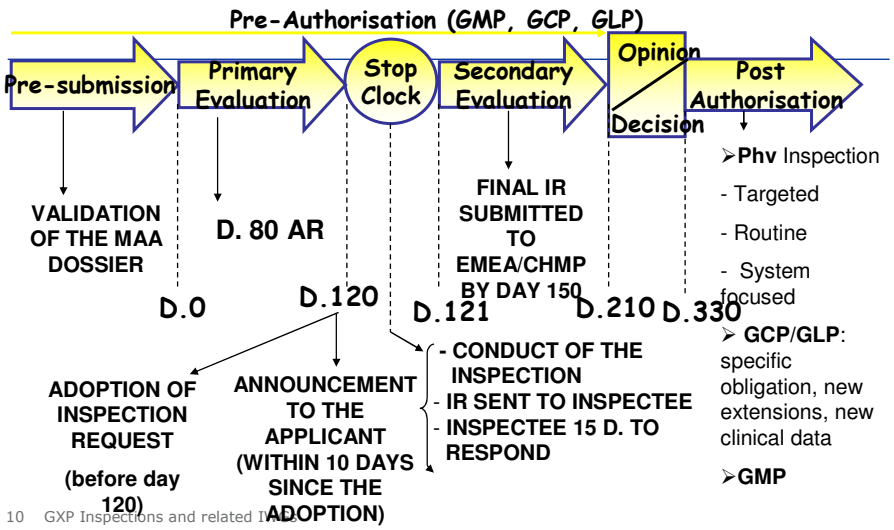
So far there have been more than 283 inspections requested

- 237 GCP (83.7%), 93.2% pre, 52.3% non-EU
- 46 PhV (16.3%); 100% post, 45.7% non-EU

Coordination of GLP Inspections

- Co-ordination of the verification of compliance with the principles of GLP.
- Procedures adopted by the CHMP/CVMP in 2004
- So far there have been 2 GLP for 1 centralised on ad hoc basis and 10 GLP for 8 centralised using new GLP SOP.

CAP Inspections Overview and Timelines



Inspectors Working Groups

Meetings

- Quarterly meetings of GMP/GCP/PhV inspectors from EU at EMA
- Joint meetings with assessors or interested parties or other WP (1-2/year)
- Ad hoc group to establish procedures for GLP inspection request

Composition:

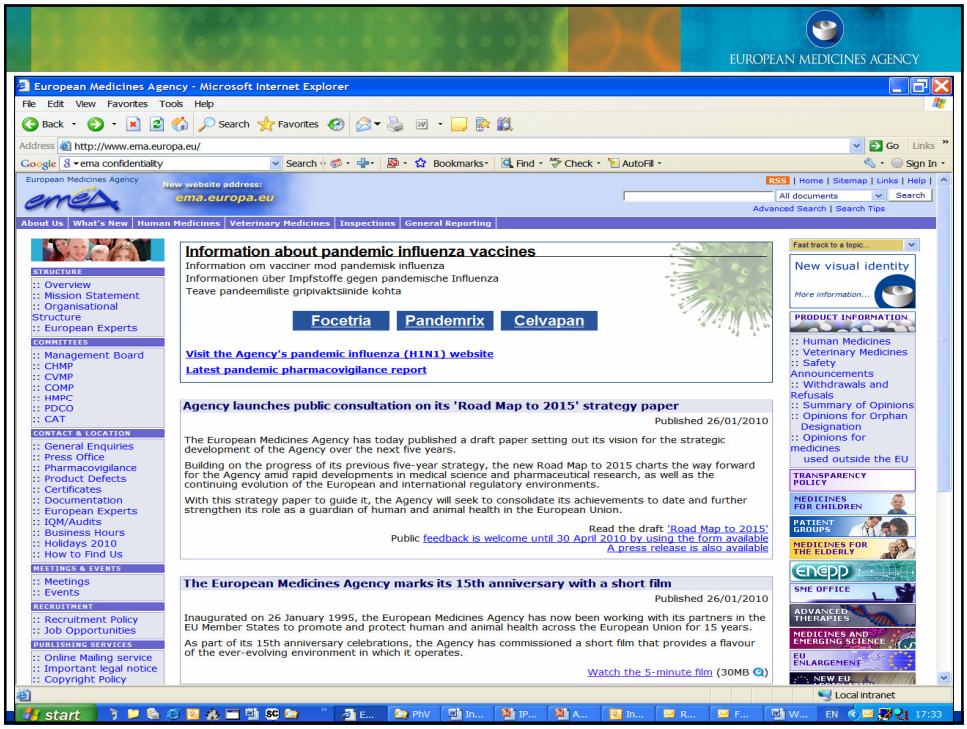
- Human and Veterinary medicinal products (GCP only Human)
- Delegates from 30 EU/EEA member states – agencies responsible for inspection H + V (GCP only Human)
- Observers from Croatia, FYRM, Turkey and Switzerland.

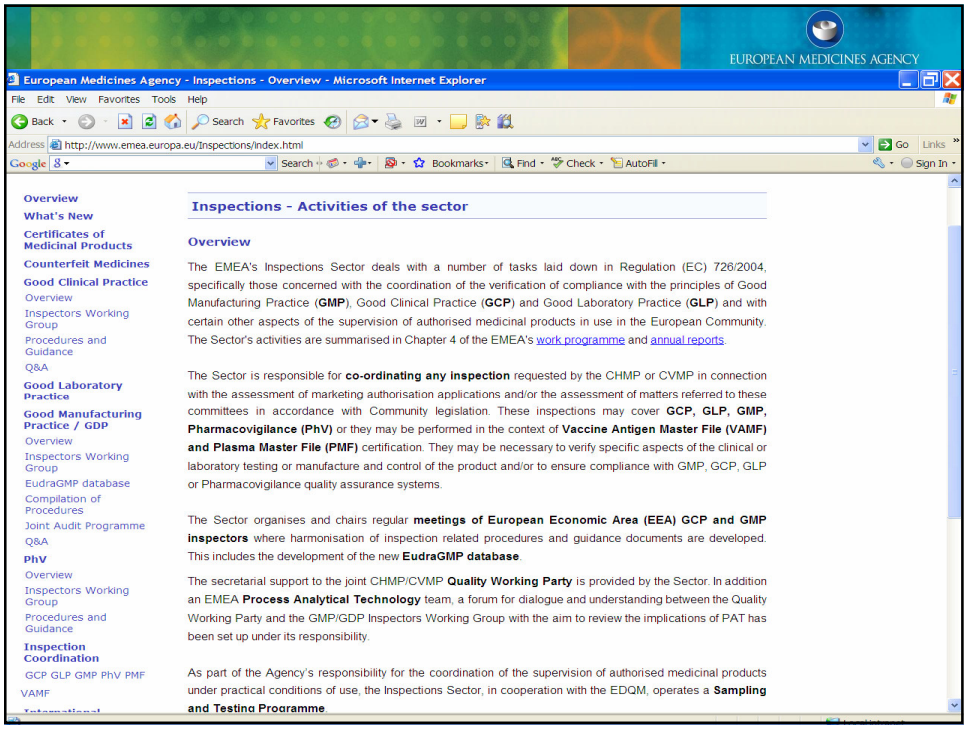
Inspectors Working Groups

Objectives

- Harmonisation through practice
- Shared experience, discussion, conclusion
- Policy/guidelines/SOPs development
- Network of contact between inspectors
- Joint inspections on most Centralised inspections

Section on EMA website – work programme and annual report from the group:
http://www.ema.europa.eu/Inspections/


EUROPEAN MEDICINES AGENCY
European Medicines Agency - Microsoft Internet Explorer
http://www.ema.europa.eu/
European Medicines Agency
New website address:
ema.europa.eu
About Us | What's New | Human Medicines | Veterinary Medicines | Inspections | General Reporting
Information about pandemic influenza vaccines
Information om vacciner mod pandemisk influenza
Informationen über Impfstoffe gegen pandemische Influenza
Teave pandeemiliste gripivaktsiinide kohta
Focetria
Pandemrix
Celvapan
Visit the Agency's pandemic influenza (H1N1) website
Latest pandemic pharmacovigilance report
Agency launches public consultation on its 'Road Map to 2015' strategy paper
Published 26/01/2010
The European Medicines Agency has today published a draft paper setting out its vision for the strategic development of the Agency over the next five years.
Building on the progress of its previous five-year strategy, the new Road Map to 2015 charts the way forward for the Agency amid rapid developments in medical science and pharmaceutical research, as well as the continuing evolution of the European and international regulatory environments.
With this strategy paper to guide it, the Agency will seek to consolidate its achievements to date and further strengthen its role as a guardian of human and animal health in the European Union.
Read the draft 'Road Map to 2015'
Public feedback is welcome until 30 April 2010 by using the form available
A press release is also available
The European Medicines Agency marks its 15th anniversary with a short film
Published 26/01/2010
Inaugurated on 26 January 1995, the European Medicines Agency has now been working with its partners in the EU Member States to promote and protect human and animal health across the European Union for 15 years.
As part of its 15th anniversary celebrations, the Agency has commissioned a short film that provides a flavour of the ever-evolving environment in which it operates.
Watch the 5-minute film (30MB)
New visual identity
PRODUCT INFORMATION
:: Human Medicines
:: Veterinary Medicines
:: Safety Announcements
:: Withdrawals and Refusals
:: Summary of Opinions
:: Opinions for Orphan Designation
:: Opinions for medicines used outside the EU
TRANSPARENCY POLICY
MEDICINES FOR CHILDREN
PATIENT GROUPS
MEDICINES FOR THE ELDERLY
enepp
SME OFFICE
ADVANCED THERAPIES
MEDICINES AND EMERGING SCIENCE
EU ENLARGEMENT
NEW EU
STRUCTURE
:: Overview
:: Mission Statement
:: Organisational Structure
:: European Experts
COMMITTEES
:: Management Board
:: CHMP
:: CVMP
:: COMP
:: HMPC
:: PDCO
:: CAT
CONTACT & LOCATION
:: General Enquiries
:: Press Office
:: Pharmacovigilance
:: Product Defects
:: Certificates
:: Documentation
:: European Experts
:: IQM/Audits
:: Business Hours
:: Holidays 2010
:: How to Find Us
MEETINGS & EVENTS
:: Meetings
:: Events
RECRUITMENT
:: Recruitment Policy
:: Job Opportunities
PUBLISHING SERVICES
:: Online Mailing service
:: Important legal notice
:: Copyright Policy


EUROPEAN MEDICINES AGENCY
European Medicines Agency - Inspections - Overview - Microsoft Internet Explorer
http://www.emea.europa.eu/Inspections/index.html
Overview
What's New
Certificates of Medicinal Products
Counterfeit Medicines
Good Clinical Practice
Overview
Inspectors Working Group
Procedures and Guidance
Q&A
Good Laboratory Practice
Good Manufacturing Practice / GDP
Overview
Inspectors Working Group
EudraGMP database
Compilation of Procedures
Joint Audit Programme
Q&A
PhV
Overview
Inspectors Working Group
Procedures and Guidance
Inspection Coordination
GCP GLP GMP PhV PMF
VAMF
Inspections - Activities of the sector
Overview
The EMEA's Inspections Sector deals with a number of tasks laid down in Regulation (EC) 726/2004, specifically those concerned with the coordination of the verification of compliance with the principles of Good Manufacturing Practice (GMP), Good Clinical Practice (GCP) and Good Laboratory Practice (GLP) and with certain other aspects of the supervision of authorised medicinal products in use in the European Community. The Sector's activities are summarised in Chapter 4 of the EMEA's work programme and annual reports.
The Sector is responsible for co-ordinating any inspection requested by the CHMP or CVMP in connection with the assessment of marketing authorisation applications and/or the assessment of matters referred to these committees in accordance with Community legislation. These inspections may cover GCP, GLP, GMP, Pharmacovigilance (PhV) or they may be performed in the context of Vaccine Antigen Master File (VAMF) and Plasma Master File (PMF) certification. They may be necessary to verify specific aspects of the clinical or laboratory testing or manufacture and control of the product and/or to ensure compliance with GMP, GCP, GLP or Pharmacovigilance quality assurance systems.
The Sector organises and chairs regular meetings of European Economic Area (EEA) GCP and GMP inspectors where harmonisation of inspection related procedures and guidance documents are developed. This includes the development of the new EudraGMP database.
The secretarial support to the joint CHMP/CVMP Quality Working Party is provided by the Sector. In addition an EMEA Process Analytical Technology team, a forum for dialogue and understanding between the Quality Working Party and the GMP/GDP Inspectors Working Group with the aim to review the implications of PAT has been set up under its responsibility.
As part of the Agency's responsibility for the coordination of the supervision of authorised medicinal products under practical conditions of use, the Inspections Sector, in cooperation with the EDQM, operates a Sampling and Testing Programme.

EUROPEAN MEDICINES AGENCY

Inspections - Good Clinical Practice

GCP Inspectors Working Group

The Sector draws on the expertise of member states' inspectorates for the fulfilment of many of its GCP related tasks. This is primarily achieved through the GCP Inspectors Working Group.
The GCP Inspectors Working Group focuses on harmonisation and co-ordination of GCP related activities at Community level. The Group activities are outlined in its work plan. It is involved in the preparation of new and revised guidance on GCP and community procedures relating to inspection. The Sector chairs and provides secretarial support to the GCP Inspectors Working Group. Members provide the expertise for the fulfillment of the group tasks and play a key role in the development of collaborative projects both within the community and externally.

The GCP Inspectors Working Group meets on a regular basis four times a year, at EMEA with representatives of the GCP inspectorates of the European Economic Area Member States, observers from candidate countries and Switzerland.

They support the co-ordination of the provision of GCP advice and provide a link with other groups such as CHMP, CVMP, EWP and PhVWP. These links include joint meetings with clinical and pharmacovigilance assessors and contributions to training of both inspectors and assessors. The Mandate of the GCP Inspectors Working Group describes the group's role and activities in more detail.

The GCP Inspectors maintain a dialogue with GMP Inspectors on areas of common interest in particular the interface between GMP for investigational medicinal products and GCP. A GCP / GMP subgroup assists in the interpretation of GMP in a number of specified areas (see workplan).

Documents of Interest:

- Annual report for GCP IWG: 2008
- Workplan for Ad Hoc GCP IWG: 2008, 2009
- Draft Reflection Paper on Expectations for Electronic Source Documents used in Clinical trials - Released for consultation until 31 April 2008.
- Mandate of the GCP Inspectors Working Group
- Draft reflection Paper on advice to applicants, sponsors, CROs of Bioequivalence Studies - Released for consultation until 31 March 2008. Many bioequivalence studies are well conducted, however, in recent years a number of cases, (including 3 referred to CHMP), have raised concerns amongst regulators leading to the preparation of this reflection paper.

EUROPEAN MEDICINES AGENCY

Recommendations and guidance related to the implementation of GCP

These recommendations and guidance documents are for the attention of sponsors, CROs, clinical investigators and other parties involved in the conduct of clinical trials. They have been prepared by the GCP Inspectors Working Group in conjunction, where needed, with other Working Groups and Committees of the European Regulatory Network.

Reflection Paper on advice to applicants / sponsors / CROs of Bioequivalence studies *Corrigendum*

Inspection procedures and guidance for GCP inspections conducted in the context of the Centralised Procedure

The GCP Inspectors Working Group has developed procedures for the coordination, preparation, conduct and reporting of GCP inspections carried out in the context of the Centralised Procedure.

These inspections are adopted by the CHMP and may be routine or may be triggered by issues arising during the assessment of the dossier or by other information such as previous inspection experience.

They are usually requested during the initial review of a Marketing Authorisation Application, but could arise post-authorisation (e.g. inspection of studies conducted or completed as part of the condition of a marketing authorisation, or because of concerns arising about the studies previously submitted).

- INS-GCP-1 Procedure for coordinating GCP inspections requested by the EMEA *Corr.*
- INS-GCP-2 Procedure for preparing GCP inspections requested by the EMEA
- INS-GCP-3 Procedure for conducting GCP inspections requested by the EMEA
- INS-GCP-3 Annex I to Procedure for conducting GCP inspections requested by the EMEA- Investigator Site
- INS-GCP-3 Annex II to Procedure for conducting GCP inspection requested by the EMEA- Clinical Laboratories
- INS-GCP-3 Annex III to Procedure for conducting GCP inspection requested by the EMEA- Computer Systems *Rev. 1*
- INS-GCP-3 Annex IV to Procedure for conducting GCP inspections requested by the EMEA- Sponsor and CRO
- INS-GCP-3 Annex V to Procedure for conducting GCP inspections requested by the EMEA- Phase I Units
- INS-GCP-3 Annex VI to Procedure for conducting GCP inspections - File structure and archiving
- INS-GCP-3 Annex VII to Procedure for conducting GCP inspections requested by the EMEA: Bioanalytical part, Pharmacokinetic and Statistical analyses of Bioequivalence Trials
- INS-GCP-4 Procedure for reporting of GCP inspections requested by the EMEA
- Principal Documents taken into account for the preparation of procedures for the GCP inspections requested by the EMEA

EUROPEAN MEDICINES AGENCY

Questions and Answers on GCP Matters

Q1. Can a sponsor prospectively approve deviations (so-called "protocol waivers") from the inclusion/exclusion criteria of the approved protocol without additional approval of the Ethics Committee and competent regulatory authority?

A1. Adherence to the protocol is a fundamental part of the conduct of a clinical study. Any significant change to the protocol should be submitted as an amendment to the competent regulatory authority and Ethics Committee. Significant changes to the protocol include any change in inclusion and exclusion criteria, addition or deletion of tests, dosing, duration of treatment etc (see the definition of a substantial amendment in the 'Detailed guidance for the request for authorisation of a clinical trial on a medicinal product for human use to the competent authorities, notification of substantial amendments and declaration of the end of the trial' published by the European Commission in Chapter I, Volume 10 of The Rules Governing Medicinal Products in the European Community). Deviations from the inclusion / exclusion criteria of the protocol might erode the scientific and ethical value of the protocol and its authorisation and might have an impact on the processes put in place for the care and safety of the study subjects.

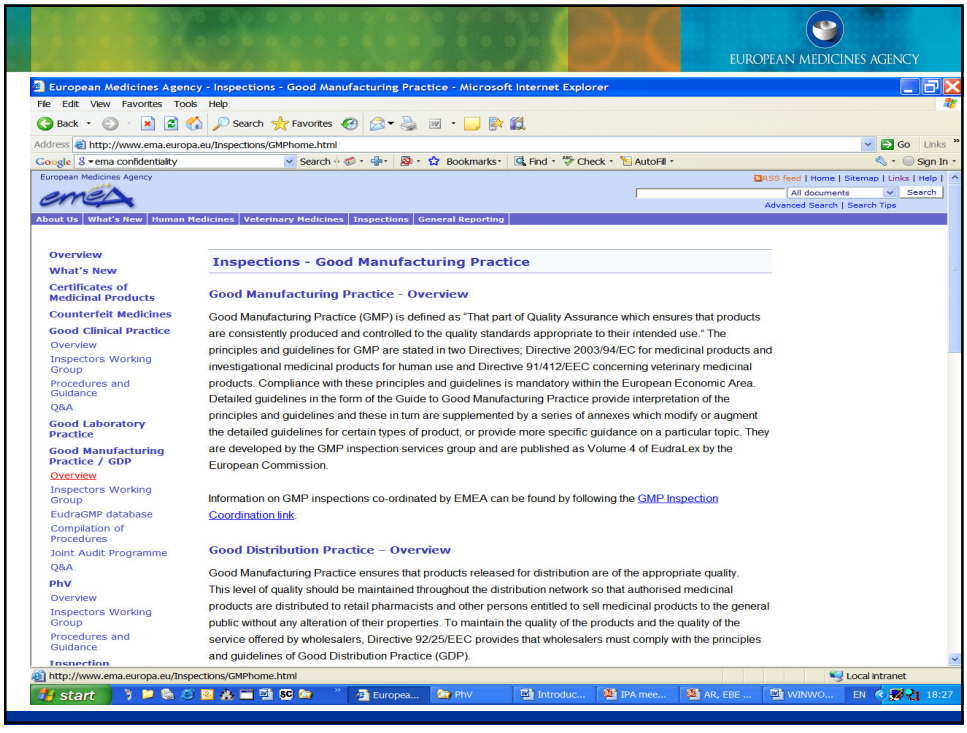
Sponsors and investigators should not use systems of prospectively approving protocol deviations, in order to effectively widen the scope of a protocol. Protocol design should be appropriate to the populations required and if the protocol design is defective, the protocol should be amended.

The GCP does permit deviations from the protocol when necessary to eliminate immediate hazards to the subjects but this should not normally arise in the context of inclusion/exclusion criteria, since the subject is not yet fully included in the trial at that point in the process GCP inspectors have observed a number of sponsors implementing systems where the investigator can contact the sponsor, usually the Medical Monitor, and request a prospective approval to deviate from the inclusion and/or exclusion criteria. The use of such systematic waiver systems in clinical trials is not considered to be appropriate and studies using such a system might be regarded as non-compliant with GCP.

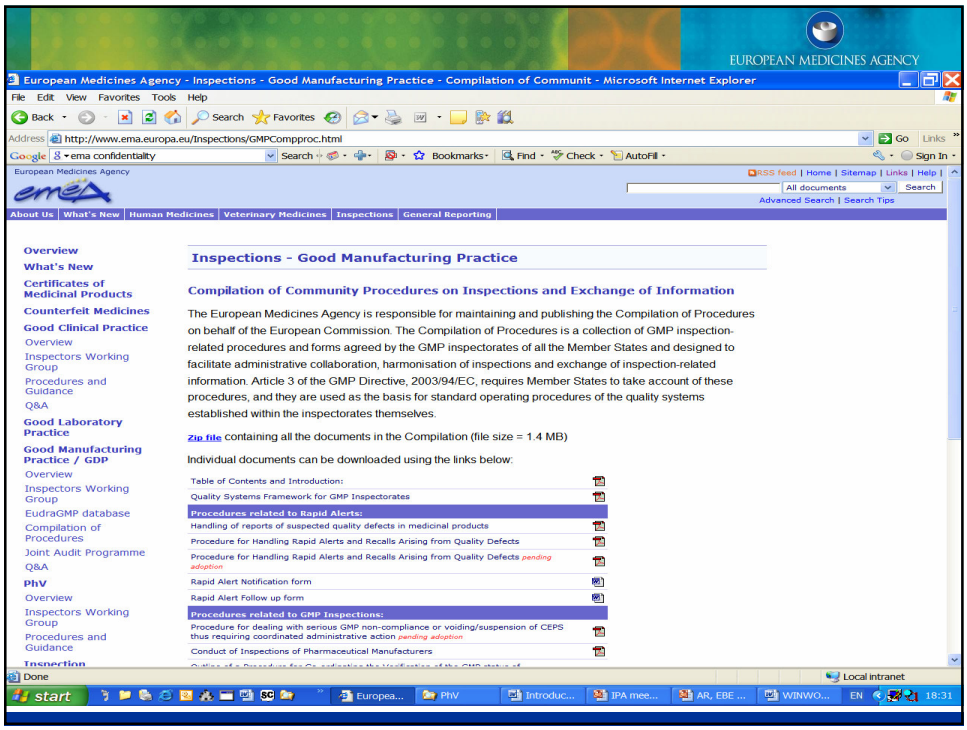
Question and Answers on records of study subject data relating to clinical trials

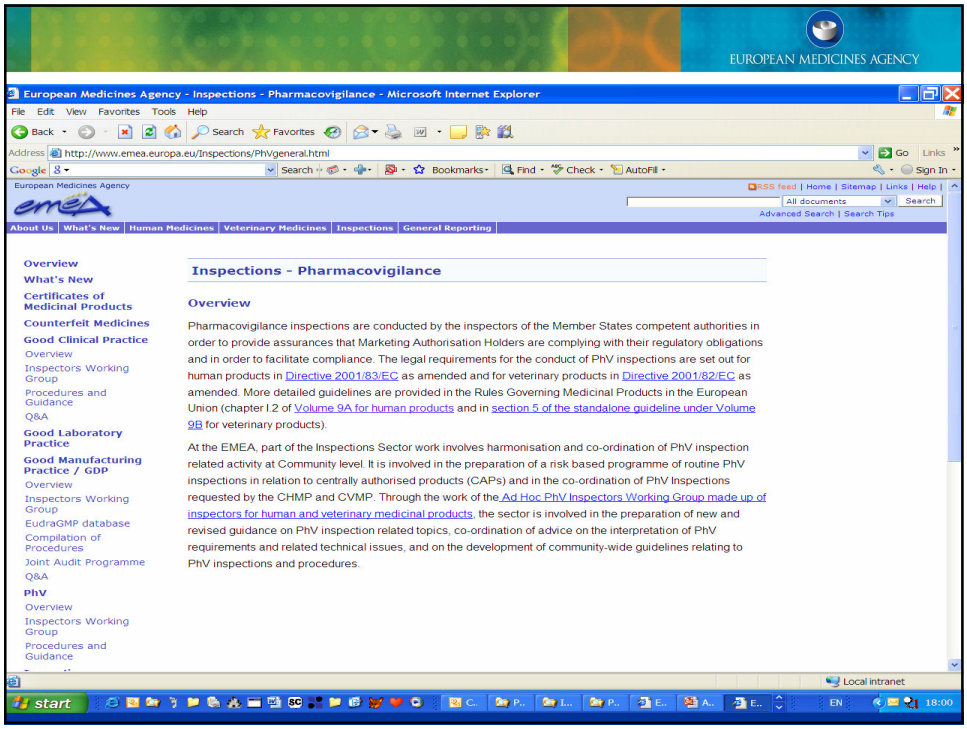
Q1. What are the roles and requirements for the study subject record (medical record) and related source documents in the context of a clinical trial?

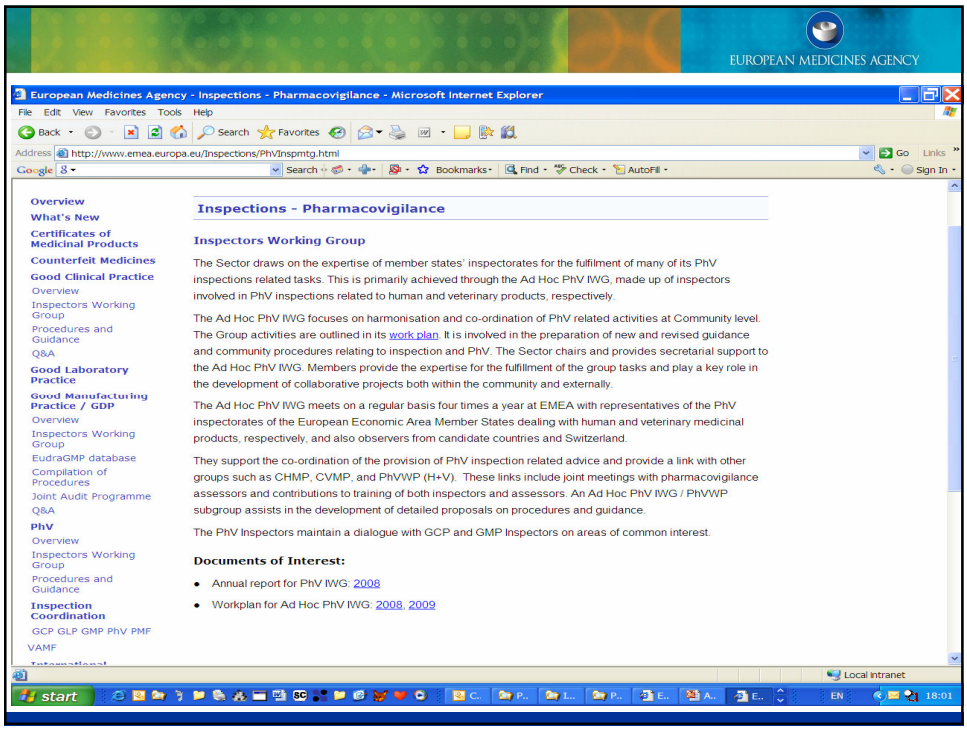
A1. Background: A variety of records is generated and maintained relating to the healthcare of clinical trial subjects (whether study subjects or healthy subjects). Some of these are general and relate to the general healthcare of the study subject before, during and after the trial. Others are specific to the trial. A clinical trial as a scientific undertaking requires careful record-keeping to ensure that

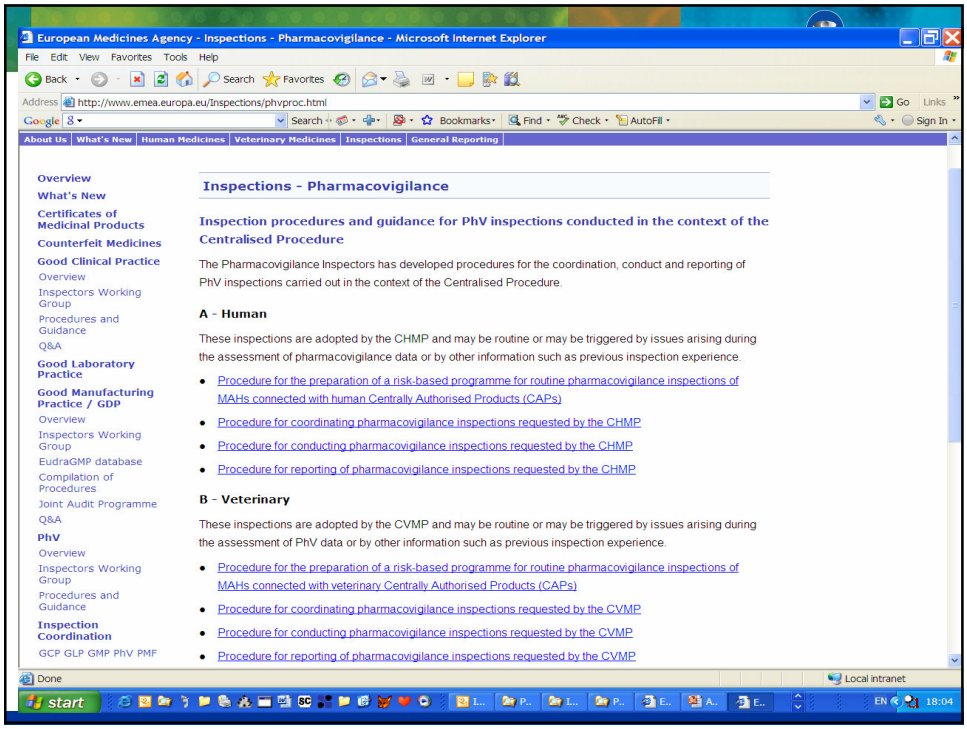



EUROPEAN MEDICINES AGENCY
European Medicines Agency - Inspections - Good Manufacturing Practice - GMP/GDP Inspectors Work - Microsoft Internet Explorer
File Edit View Favorites Tools Help
Address http://www.ema.europa.eu/Inspections/GMPInspmtg.html
representatives of the GMP inspectorates of the European Economic Area Member States, a representative from the European Commission (DG Enterprise and Industry) and observers from EDQM, the inspectorates of the countries accessing to the EU and MRA partner countries. The Sector provides the chair and secretarial support for these meetings.
The meetings consider new and revised GMP-related guidance, normally developed by drafting groups, work related to Mutual Recognition Agreements, how new legislation impacts GMP inspection activity and harmonisation of GMP inspections. It is also where community-wide procedures relating to GMP inspections, known as the Compilation of Procedures are developed. The group interacts with other bodies e.g. PIC/S and EDQM. GMP related issues concerning centrally authorised products and GMP inspections co-ordinated by EMEA in connection with these, are also considered at the meetings. The Group's work plan is published annually.
The functions of inspection and assessment have always been complementary activities and there is increasing awareness of the importance of interactions between GMP inspectors and assessors. EMEA therefore arranges a joint meeting between this group and Quality Working Party at least once a year. The group contributes to the EMEA PAT team, which is made up of representatives of Quality Working Party, Biologics Working Party as well as the GMP/GDP Working group.
GMP inspectors maintain a dialogue with GCP Inspectors on areas of common interest in particular the interface between GMP for investigational medicinal products and GCP. A GCP / GMP subgroup assists in the interpretation of GMP in a number of specified areas.
The group aims to meet with its interested parties, representatives of European industry associations and relevant professional associations, at least once a year.
Documents of Interest:
Mandate of GMP/GDP Inspectors Working Group corrected
Work plan 2010 for GMP/GDP Inspectors Working Group Updated on 12 January 2010
Information on GMP Guidance can be found on the main GMP home page
Procedures and Guidance
Q&A
Good Laboratory Practice
Good Manufacturing Practice / GDP
Overview
Inspectors Working Group
EudraGMP database
Compilation of Procedures
Joint Audit Programme
Q&A
PhV
Overview
Inspectors Working Group
Procedures and Guidance
Inspection Coordination
GCP GLP GMP PhV PMF
VAMF
International Cooperation
MRAs AU CA CH JP NZ
US
FDA
ICH-VICH
Process Analytical Technology
Overview
Q&A
Done
Local intranet
start
18:29


EUROPEAN MEDICINES AGENCY
European Medicines Agency - Inspections - Good Manufacturing Practice - Compilation of Communit - Microsoft Internet Explorer
File Edit View Favorites Tools Help
Address http://www.ema.europa.eu/Inspections/GMPCompproc.html
European Medicines Agency
RSS feed | Home | Sitemap | Links | Help |
All documents
Search
Advanced Search | Search Tips
About Us | What's New | Human Medicines | Veterinary Medicines | Inspections | General Reporting
Overview
What's New
Certificates of Medicinal Products
Counterfeit Medicines
Good Clinical Practice
Overview
Inspectors Working Group
Procedures and Guidance
Q&A
Good Laboratory Practice
Good Manufacturing Practice / GDP
Overview
Inspectors Working Group
EudraGMP database
Compilation of Procedures
Joint Audit Programme
Q&A
PhV
Overview
Inspectors Working Group
Procedures and Guidance
Inspection
Inspections - Good Manufacturing Practice
Compilation of Community Procedures on Inspections and Exchange of Information
The European Medicines Agency is responsible for maintaining and publishing the Compilation of Procedures on behalf of the European Commission. The Compilation of Procedures is a collection of GMP inspection-related procedures and forms agreed by the GMP inspectorates of all the Member States and designed to facilitate administrative collaboration, harmonisation of inspections and exchange of inspection-related information. Article 3 of the GMP Directive, 2003/94/EC, requires Member States to take account of these procedures, and they are used as the basis for standard operating procedures of the quality systems established within the inspectorates themselves.
Zip file containing all the documents in the Compilation (file size = 1.4 MB)
Individual documents can be downloaded using the links below:
Table of Contents and Introduction:
Quality Systems Framework for GMP Inspectorates
Procedures related to Rapid Alerts:
Handling of reports of suspected quality defects in medicinal products
Procedure for Handling Rapid Alerts and Recalls Arising from Quality Defects
Procedure for Handling Rapid Alerts and Recalls Arising from Quality Defects pending adoption
Rapid Alert Notification form
Rapid Alert Follow up form
Procedures related to GMP Inspections:
Procedure for dealing with serious GMP non-compliance or voiding/suspension of CEPS thus requiring coordinated administrative action pending adoption
Conduct of Inspections of Pharmaceutical Manufacturers
Done
Local intranet
start
18:31


EUROPEAN MEDICINES AGENCY
European Medicines Agency - Inspections - Pharmacovigilance - Microsoft Internet Explorer
http://www.emea.europa.eu/Inspections/PhVgeneral.html
European Medicines Agency
About Us | What's New | Human Medicines | Veterinary Medicines | Inspections | General Reporting
Overview
What's New
Certificates of Medicinal Products
Counterfeit Medicines
Good Clinical Practice
Overview
Inspectors Working Group
Procedures and Guidance
Q&A
Good Laboratory Practice
Good Manufacturing Practice / GDP
Overview
Inspectors Working Group
EudraGMP database
Compilation of Procedures
Joint Audit Programme
Q&A
PhV
Overview
Inspectors Working Group
Procedures and Guidance
Inspections - Pharmacovigilance
Overview
Pharmacovigilance inspections are conducted by the inspectors of the Member States competent authorities in order to provide assurances that Marketing Authorisation Holders are complying with their regulatory obligations and in order to facilitate compliance. The legal requirements for the conduct of PhV inspections are set out for human products in Directive 2001/83/EC as amended and for veterinary products in Directive 2001/82/EC as amended. More detailed guidelines are provided in the Rules Governing Medicinal Products in the European Union (chapter I.2 of Volume 9A for human products and in section 5 of the standalone guideline under Volume 9B for veterinary products).
At the EMEA, part of the Inspections Sector work involves harmonisation and co-ordination of PhV inspection related activity at Community level. It is involved in the preparation of a risk based programme of routine PhV inspections in relation to centrally authorised products (CAPs) and in the co-ordination of PhV Inspections requested by the CHMP and CVMP. Through the work of the Ad Hoc PhV Inspectors Working Group made up of inspectors for human and veterinary medicinal products, the sector is involved in the preparation of new and revised guidance on PhV inspection related topics, co-ordination of advice on the interpretation of PhV requirements and related technical issues, and on the development of community-wide guidelines relating to PhV inspections and procedures.
Local intranet
start
18:00


EUROPEAN MEDICINES AGENCY
European Medicines Agency - Inspections - Pharmacovigilance - Microsoft Internet Explorer
http://www.emea.europa.eu/Inspections/PhVInspmtg.html
Overview
What's New
Certificates of Medicinal Products
Counterfeit Medicines
Good Clinical Practice
Overview
Inspectors Working Group
Procedures and Guidance
Q&A
Good Laboratory Practice
Good Manufacturing Practice / GDP
Overview
Inspectors Working Group
EudraGMP database
Compilation of Procedures
Joint Audit Programme
Q&A
PhV
Overview
Inspectors Working Group
Procedures and Guidance
Inspection Coordination
GCP GLP GMP PhV PMF
VAMF
Inspections - Pharmacovigilance
Inspectors Working Group
The Sector draws on the expertise of member states' inspectorates for the fulfilment of many of its PhV inspections related tasks. This is primarily achieved through the Ad Hoc PhV IWG, made up of inspectors involved in PhV inspections related to human and veterinary products, respectively.
The Ad Hoc PhV IWG focuses on harmonisation and co-ordination of PhV related activities at Community level. The Group activities are outlined in its work plan. It is involved in the preparation of new and revised guidance and community procedures relating to inspection and PhV. The Sector chairs and provides secretarial support to the Ad Hoc PhV IWG. Members provide the expertise for the fulfillment of the group tasks and play a key role in the development of collaborative projects both within the community and externally.
The Ad Hoc PhV IWG meets on a regular basis four times a year at EMEA with representatives of the PhV inspectorates of the European Economic Area Member States dealing with human and veterinary medicinal products, respectively, and also observers from candidate countries and Switzerland.
They support the co-ordination of the provision of PhV inspection related advice and provide a link with other groups such as CHMP, CVMP, and PhVWP (H+V). These links include joint meetings with pharmacovigilance assessors and contributions to training of both inspectors and assessors. An Ad Hoc PhV IWG / PhVWP subgroup assists in the development of detailed proposals on procedures and guidance.
The PhV Inspectors maintain a dialogue with GCP and GMP Inspectors on areas of common interest.
Documents of Interest:
Annual report for PhV IWG: 2008
Workplan for Ad Hoc PhV IWG: 2008, 2009
Local intranet
start
18:01



EUROPEAN MEDICINES AGENCY

EU Legislation - Eudralex

http://ec.europa.eu/enterprise/sectors/pharmaceuticals/documents/eudralex/index_en.htm

Volume 1 - EU pharmaceutical legislation for medicinal products for human use
Volume 5 - EU pharmaceutical legislation for medicinal products for veterinary use
The basic legislation is supported by a series of guidelines that are also published in the following volumes of "The rules governing medicinal products in the European Union":
Volume 2 - Notice to applicants and regulatory guidelines for medicinal products for human use
Volume 3 - Scientific guidelines for medicinal products for human use
Volume 4 - Guidelines for good manufacturing practices for medicinal products for human and veterinary use
Volume 6 - Notice to applicants and regulatory guidelines for medicinal products for veterinary use
Volume 7 - Scientific guidelines for medicinal products for veterinary use
Volume 8 - Maximum residue limits
Volume 9 - Guidelines for pharmacovigilance for medicinal products for human and veterinary use
Volume 10 - Guidelines for clinical trial

EUROPEAN MEDICINES AGENCY

Thank you for your attention!

Questions?