The background of the slide features an abstract, overlapping pattern of blue and white geometric shapes, resembling a network or a molecular structure. The shapes are interconnected, creating a complex, web-like appearance. The colors range from light blue to dark blue, with white highlights.

An Introduction to the Pharmacovigilance System Master File

SCOTT MCCULLOCH, PHARMACOVIGILANCE SOLUTIONS DIRECTOR
TransPerfect – Life Sciences
November 5, 2013

*Pharmacovigilance exists to ensure
the safety of development for
medicinal products.*

AGENDA

- Overview - Guidelines on Good Pharmacovigilance Practices (GVP)
- Overview - Module II - Pharmacovigilance System Master File (PSMF)
- Moving Forward

GUIDELINES ON GOOD PHARMACOVIGILANCE PRACTICES (GVP)

Regulation 1235/2013
Directive 2010/84EC

- Published December 2010
- **Implantation July 2012**
- Legally enforceable legislation

Implementing
Regulation 520/2012

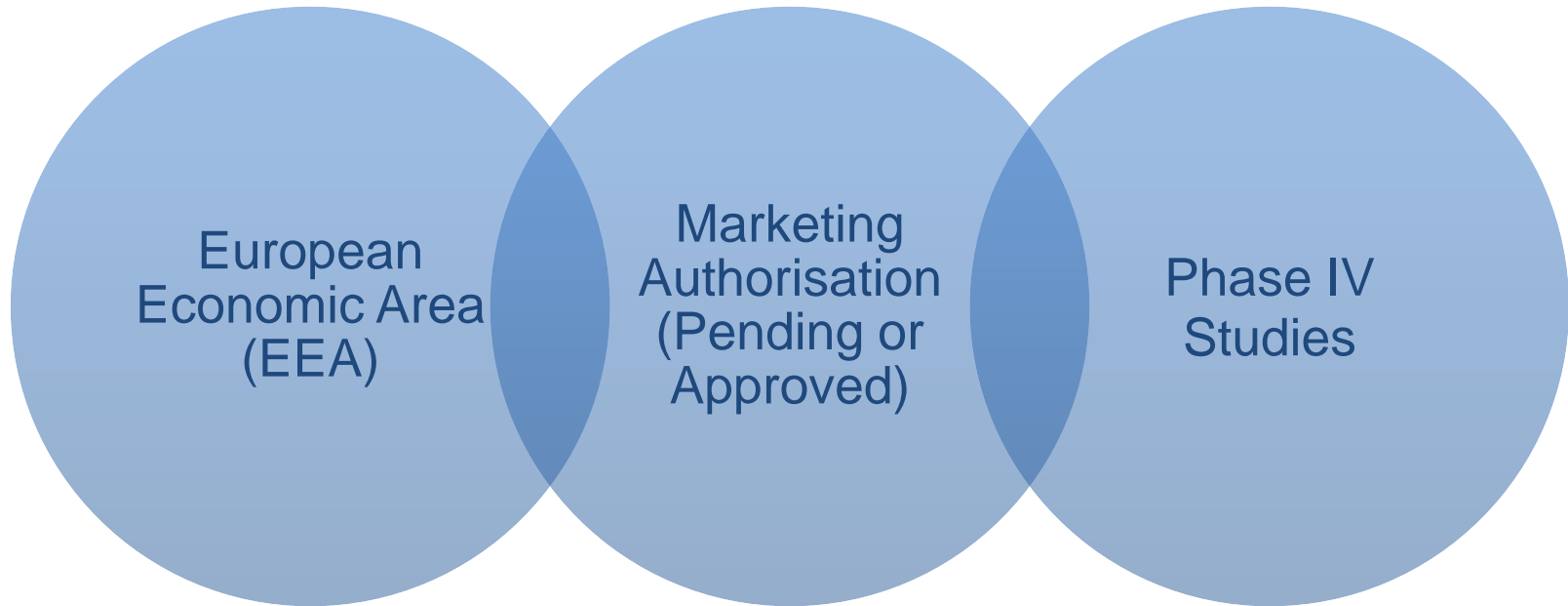
- Published June 2012
- Legally enforceable legislation

Good
Pharmacovigilance
Practices (GVP)

- Consultation & Publication 2012 & 2013
- Detailed operation guidance (day to day)
- Not legally enforceable

Transitional Provisions: Implementation 2012 - 2016

IMPACT



European Economic Area (EEA)

- European Union (28 Countries)
- European Free Trade Association (3 Countries)

GUIDELINES ON GOOD PHARMACOVIGILANCE PRACTICES (GVP)



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH



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Human medicines

- Pre-authorisation
- Post-opinion
- Post-authorisation
- Product information
- Scientific advice and protocol assistance
- Scientific guidelines
- Innovation Task Force
- Regulatory and procedural guidance
- SME office
- Paediatric medicine
- Orphan designation
- Herbal products
- Referral procedures
- Article 58 application
- Compassionate use
- Pharmacovigilance
 - 2010 pharmacovigilance legislation
 - Electronic submission

Home > Regulatory > Human medicines > Pharmacovigilance > Good pharmacovigilance practices

Good pharmacovigilance practices

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Good pharmacovigilance practices (GVP) are a set of measures drawn up to facilitate the performance of pharmacovigilance in the European Union (EU). GVP apply to marketing-authorisation holders, the European Medicines Agency and medicines regulatory authorities in EU Member States. They cover medicines authorised centrally via the Agency as well as medicines authorised at national level.

Guideline on GVP

The **guideline on GVP** is divided into chapters that fall into two categories:

- modules covering major pharmacovigilance processes;
- product- or population-specific considerations.

Each chapter is developed by a team consisting of experts from the European Medicines Agency and from EU Member States.

The guideline on GVP is a key deliverable of the [2010 pharmacovigilance legislation](#).

Modules covering major pharmacovigilance processes

GVP modules I to XVI cover major pharmacovigilance processes.

Most modules are available in their final versions. The full set of modules is scheduled to be available during 2013.

The remaining modules below are under development and are scheduled for release for an eight-week public consultation as indicated below:

Module number	Module title	Date of release for public consultation
XI	Public participation in pharmacovigilance	Third quarter 2013
	Continuous pharmacovigilance,	

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GUIDELINES ON GOOD PHARMACOVIGILANCE PRACTICES (GVP)

EEA GVP Modules

I Pharmacovigilance Systems and their Quality Systems Published 22-Jun-2012

II Pharmacovigilance System Master File Published 22-Jun-2012 Update 09-Apr-2013

III Pharmacovigilance Inspections Published 12-Dec-2012

IV Pharmacovigilance Audits Published 12-Dec-2012

V Risk Managements Systems Published 22-Jun-2012

VI Management & Reporting of Adverse Reactions to Medicinal Products Published 22-Jun-2012

VII Periodic Safety Update Report Published 22-Jun-2013 Consultation Rev 1 19-Apr-2013

VIII Post-Authorisation Safety Studies Published 22-Jun-2013 Update 19-Apr-2013

IX Signal Management Published 22-Jun-2013

X Additional Monitoring Published 19-Apr-2013

XI Public Participation in Pharmacovigilance Consultation Q3 2013

XII Continuous Pharmacovigilance, Ongoing Benefit-Risk Evaluation, Regulatory Action and Planning of Public Communication Consultation Q3 2013

XIII Void

XIV International Cooperation Consultation Q3 2013

XV Safety Communication Published 22-Jan-2013

XVI Risk-Minimisation Measures: Selection of Tools & Effectiveness Indicators Consultation Q2 2013

The background features a complex, abstract pattern of overlapping, semi-transparent shapes in various shades of blue and white. The shapes resemble a network or a cellular structure, with some areas appearing more solid and others more ethereal. The overall effect is a modern, technical, and somewhat organic aesthetic.

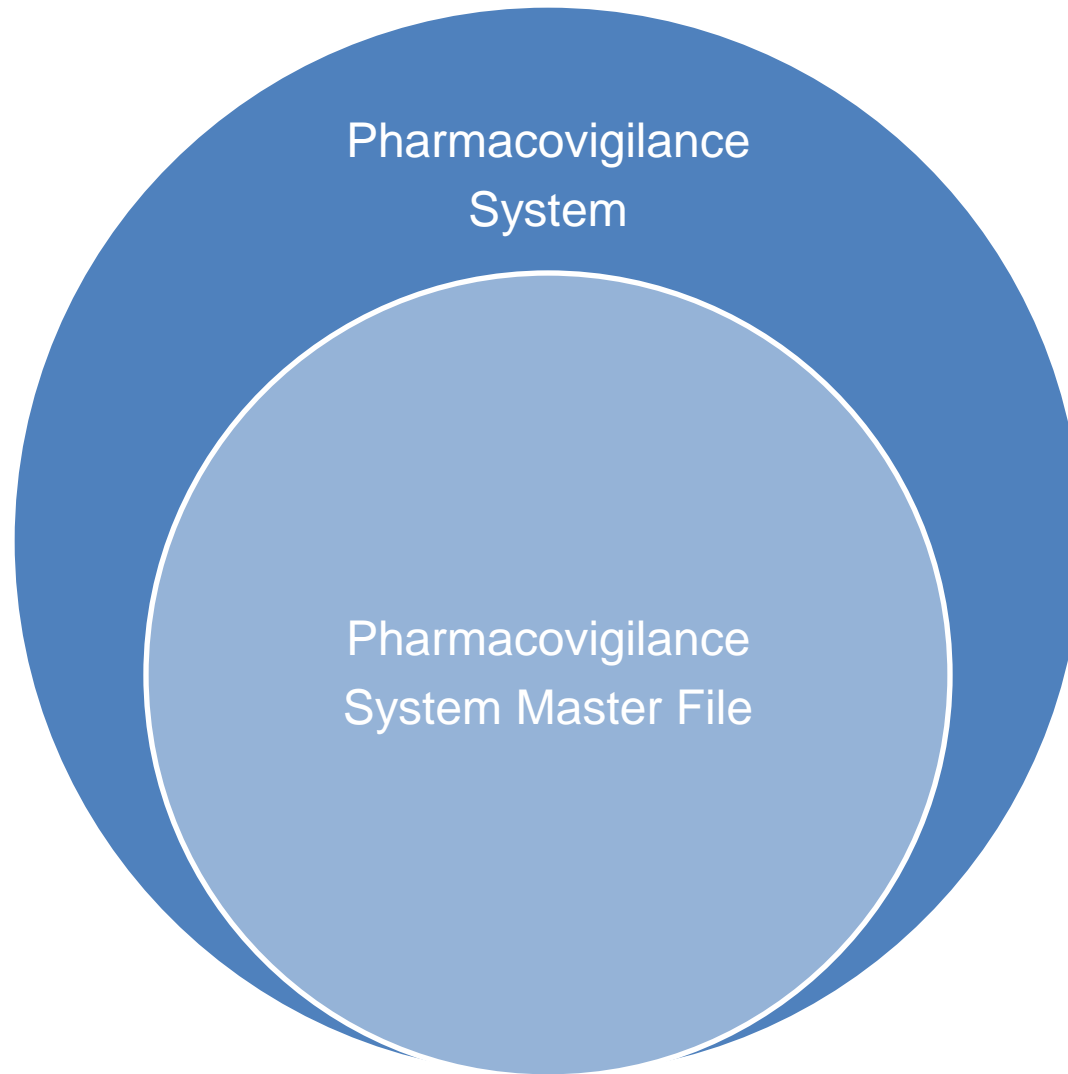
PHARMACOVIGILANCE SYSTEM MASTER FILE

PHARMACOVIGILANCE SYSTEM MASTER FILE

Describe the
Pharmacovigilance
System

Support/Document
Compliance

PHARMACOVIGILANCE SYSTEM MASTER FILE



PHARMACOVIGILANCE SYSTEM MASTER FILE



PHARMACOVIGILANCE SYSTEM OVERVIEW

Module 1.8.1 Marketing Authorisation Application Dossier

Proof of EEA QPPV Services

Country in which EEA QPPV resides & operates

Contact details for EEA QPPV (24 hour)

Statement signed by applicant that the applicant has the necessary means to fulfill the tasks and responsibilities listed in Title IX (9)

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PSMF LOCATION

Within the EEA

- Site where main Pharmacovigilance activities are performed
OR
- Where the EEA QPPV operates
 - Physical office address where the data can be directly accessed
 - Location must be entered into the eXtended EudraVigilance Medicinal
 - Product Dictionary (xEVMPD)
 - Change in location must be immediately notified to EMA
 - Location will indicate supervisory agency (centrally authorised products only)

The background of the slide is an abstract, repeating pattern of overlapping, rounded geometric shapes in various shades of blue and white. The shapes are interconnected, creating a complex, crystalline or cellular structure. The colors range from deep navy blue to light sky blue, with white highlights. The overall effect is a textured, modern aesthetic.

PSMF STRUCTURE

EEA QUALIFIED PERSON FOR PV SECTION

- Description of responsibilities guaranteeing
- EEA QPPV has sufficient authority
- Summary CV
- Contact Details
- Details of Back-Up Arrangements
- National QPPV information

PSMF – ORGANISATIONAL STRUCTURE SECTION

Organisational
structure of MAH

Sites where
Pharmacovigilance
activities take
place

Description of
delegated
Pharmacovigilance
activities

PSMF – SOURCES OF SAFETY DATA

- Who, What, How & When
- Spontaneous
- List of solicited programmes
- Patient Support Programmes, Reimbursement Programmes, Marketing Surveys, etc.
- Studies
- Literature
- Agencies
- Contract Partners

Flow Diagram / Description of Process

PSMF – DATABASES

- Location, functionality, operational responsibility for computerized systems and databases used to receive, collate, record and report safety information
- Assessment of their fitness for purpose
- Validation status
- Change control, nature of testing, back-up procedures, and electronic data repositories, nature of documentation available

PSMF – PHARMACOVIGILANCE PROCESSES SECTION

Description of Procedural Documentation

- SOPs/Manuals, etc
- Nature of data held
- Indication of how records held

Description of Process, Data Handling and Records

- Continuous monitoring of risk-benefit profile
- Risk management systems, including effectiveness of risk minimisation
- Safety data processing
- PSUR scheduling, production & submission
- Communication of safety concerns to agencies, healthcare professionals and patients
- Implementation of safety variations to product information

PSMF – PHARMACOVIGILANCE SYSTEM PERFORMANCE

- How timeliness of expedited submissions is monitored
- Description of metrics for monitoring quality of submissions, including information provided by agencies
- How timeliness of periodic submissions is monitored
- How timeliness of safety variation submissions is monitored
- How adherence to agency commitments is monitored

PSMF – QUALITY SYSTEM

- Document & record control / Archiving
- Management of procedural documents
 - Note of open SOP deviations
- Training procedures
- Auditing
 - Note of open CAPA for critical & major audit findings

PSMF – ANNEXES

- List of medicines products, authorisation & marketing status, safety monitoring requirements
- List of Ongoing Studies
- List of written policies & procedures
- List of contractual agreements
- List of tasks delegated by EEA QPPV
- List of all audits completed in last 5 years
- Audit schedule
- List of performance indicators

CHANGE CONTROL

- Main PSMF Sections
 - Formal change control process & version control
- PSMF Annexes
 - History of changes
 - Maintain inside or outside of PSMF structure
 - If maintained outside of PSMF, keep history of when generated for PSMF purposes

THE SECRETS TO SUCCESS

- Planning, planning, planning
- Identification of resources
 - People
 - Cross-functional expertise
- Technology
 - Network folder?
 - SharePoint?
 - In-house Documentation Management System?
 - Off-the-shelf IT solution?
 - Custom-built solution?
- Implementation Project Management
- Access rights
 - Who?
 - Prevention of inappropriate distribution
- Maintenance
 - Who? PSMF Administrator?
 - How frequently? Main Documents Versus Annexes?

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The background of the slide is an abstract, layered geometric pattern. It consists of overlapping, semi-transparent shapes in various shades of blue and white, creating a complex, crystalline or cellular appearance. The shapes are irregular and interconnected, forming a network of lines and voids. The overall effect is a sense of depth and movement, with the colors ranging from deep navy blue to light, almost white, tones.

THANK YOU!