

Pharmaceutical Quality Systems (ICH Q10) Conference

*A Practical Approach to Effective Lifecycle Implementation
of Systems and Processes for Pharmaceutical Manufacturing*

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Welcome

EU Regulatory Perspectives

David Cockburn

Head of Manufacturing and Quality Compliance
European Medicines Agency

Any views expressed are those of the author and should not be understood as presenting the views of the Agency or of its Scientific Committees

Agenda

- Quality Management in European Regulatory Authorities
- Quality Management in EU GMP
- Implementation of ICH Q10 in EU

Quality Management in Regulatory Authorities (GMP Inspectorates)

- Member States mutually accept inspection outcomes.
- Over 40 GMP inspectorates in EEA
- Quality System for inspectorates
 - Specified in Compilation of Community Procedures
 - Joint Audit Programme

Quality Systems Framework for GMP Inspectorates

- Organisational aspects and senior management responsibilities
- Documentation, Records and Change Control
- Inspection procedures, Administrative Actions, Quality Defects and Rapid Alerts
- Inspection resources
- Audit and Complaints
- Quality improvement, CAPA

Benchmarking of European Medicines Agencies (BEMA)

- Process of internal improvement and mutual learning for over 40 National Competent Authorities in the EU regulatory network
- Based on self assessment and peer review against a number of key performance indicators
- Two cycles completed (BEMA I and BEMA II)

Citing GMP deficiencies

- It is established practice for EU GMP Inspectors to cite references from EU GMP Guide to support inspection findings
- Actually, most GMP failures are nevertheless failures of the Pharmaceutical Quality System

EU Pharmaceutical Legislation and Guidance

- Quality systems have a legal footing in EU GMP
 - *“The manufacturer shall establish and implement an effective pharmaceutical quality assurance system, involving the active participation of the management and personnel of the different departments”*
[Art. 6 Directive 2003/94/EC and 91/412/EEC]

EU GMP Chapter 1

- Entitled “Quality Management”
- Interprets the legislation
- Outlines objectives of Quality Assurance, GMP and Quality Control
 - Product Quality Review
 - Quality Risk Management

ICH Q10

- Although published on EMA web site at step 5 it was recognised that more was needed to implement ICH Q10 in EU
 - Revision of EU GMP Chapter 1 (Quality Management)
 - Revision of EU GMP Chapter 2 (Personnel)
 - Influenced revision of EU GMP Chapter 7 (Contract Manufacture and Analysis)
 - ICH Q10 added to new Part III of EU GMP Guide

GMP in EU: Today

Principles and Guidelines of GMP
Directives 2003/94/EC and 91/412/EEC



EU GMP Guide Part 1
Detailed Guidelines for Medicinal Products

EU GMP Guide Part II
Detailed Guidelines for Active substances
ICH Q7

Supplementary Guidelines
Annexes 1 to 19

Good Distribution Practice

EU GMP Guide Part III
Miscellaneous GMP-related guidance

Revision of EU GMP Chapter 1

- Concept Paper published April 2009
 - Quality Assurance System is mandatory to comply with EU GMP
 - ICH Q10 not mandatory since it extends over whole product lifecycle beyond stages subject to GMP
 - Some terminology and concepts in ICH Q10 different from existing EU GMP
 - ICH Q10 reflects current regulatory expectations and so is an opportunity to clarify implicit EU GMP requirements

Revision of EU GMP Chapter 2 (Personnel)

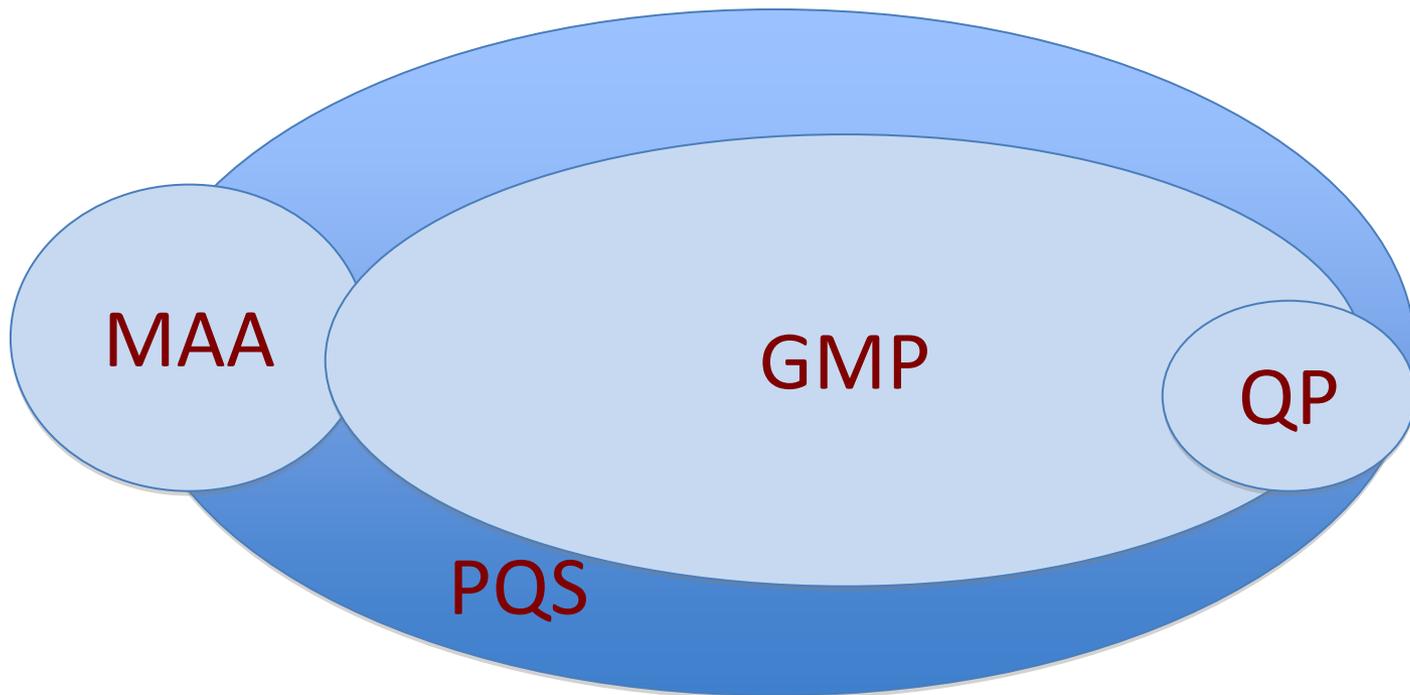
- ICH Q10 focus on senior management responsibilities has impact on Chapter 2
- Concept paper recommended revision of the chapter to emphasise this aspect
- Chapter 2 reflects organisational structures of the 1970s and is in need of modernisation

EU GMP Chapter 7 (Contract Manufacture and Analysis)

- Revised to widen scope to all outsourced activities subject to GMP
- Partly influenced by ICH Q10

PQS and the QP

The PQS enables the QP to fulfil his statutory role



Conclusions

- Quality Management applies to Regulators too
- A Pharmaceutical Quality System is mandatory to comply with EU GMP
- ICH Q10 reflects current expectations for EU GMP