EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Medicinal Product Shortages

GMP update and ICH Q12

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An agency of the European Union

Contribution from GMP/GDP IWG (1)

Regulators have been asked to reflect on what they can do to support the implementation of the 3 industry association guidelines

- Site Master File update
  - Intent is to encourage manufacturers to focus on supply continuity by seeking a summary of their approach in the Site Master File
  - A proposal has been made to add supply continuity to the section on Quality Risk Management
  - Although a minor change this is being made in cooperation with PIC/S

Contribution from GMP/GDP IWG (2)

Very recent proposal made to integrate some principles into the Pharmaceutical Quality System by small additions to Chapter 1 of the EU GMP Guide.

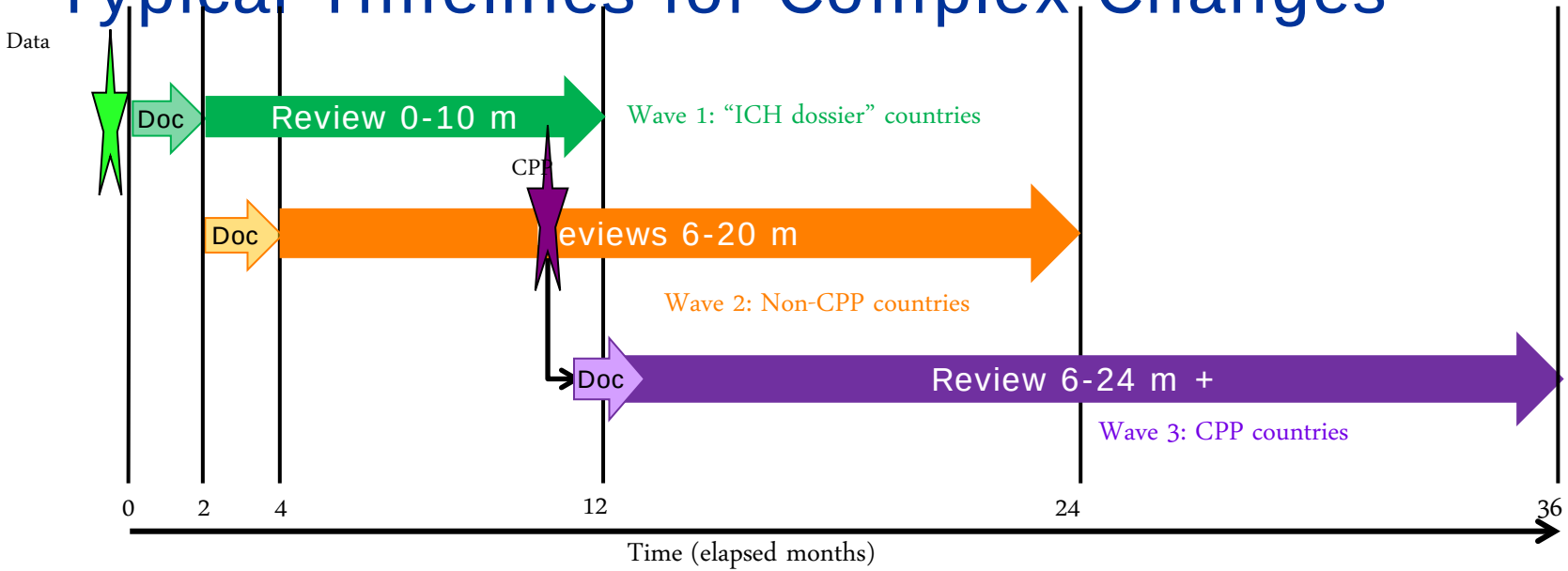
Chapter 1 already talks about "…the consistent delivery of products with appropriate quality attributes."

- Product Quality Review is proposed as the best home for these
- PQR also makes a link between manufacturer and MAH which is vital in this context

ICH Q12: Product Lifecycle Management – current situation

- Lack of incentive for proactive implementation of manufacturing improvement
- Inefficient use of industry and regulatory resources addressing less important issues
- Recent ICH Guidelines did not produce the full expected benefits and operational flexibility
- **At times leading to disruption in supply chain and drug shortage**

Challenges within and outside ICH - Typical Timelines for Complex Changes



*CPP= Certificate of Pharmaceutical Product

Acknowledgement: IFPMA

How can Q12 help to solve this problem without changing regulations?

- Clarifying “Established Conditions” for manufacture and control based on risk, product type, development approaches, manufacturing experience, GMP status
- Provide harmonised tools to facilitate prospective changes over the product lifecycle
- Establish ICH expectations of assessment and implementation of frequent manufacturing changes
- Development of product lifecycle strategy

Thank you for your attention

Further information

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