CASSS CMC Strategy Forum EU 2016 - Introduction to EBE Satellite Session

Paris - May 9, 2016

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WELCOME TO THE EBE SATELLITE SESSION 2016!

source: http://quartier-latin.education
OUTLINE – THE EBE BIOMANUFACTURING WORKING GROUP AT A GLANCE

- Activities Update 2015-2016

- Program for the 2016 CASSS EU CMC STRATEGY FORUM EBE Satellite Session
Focus 2015: Lifecycle Management / ICH Q12

22 October 2015
EMA/468878/2015 Rev.1
Human Medicines Evaluation Division

Joint BWP/QWP/GMDP IWG – Industry European workshop on Lifecycle Management

Purpose

Product Lifecycle Management is the focus of the ICH Q12 guideline that is currently in development. This guideline is intended to build on ICH Q8 – Q11 guideline principles and provide a framework to facilitate the management of post-approval CMC changes in the pharmaceutical and biotechnology sectors in a more predictable and efficient manner, thereby promoting innovation, continual improvement and assurance of supply of medicines.

This workshop is intended to gather input from European stakeholders with invited observers, including EWG members, on the core expectations for the ICH Q12 guideline, the design of the proposed ICH Q12 tools and enablers, and their application to typical post-approval changes. The output from the workshop will be used to inform the further development of the ICH Q12 Technical Document.

Together with EFPIA, very active participation of EBE BioM WG in developing agenda and presenting at workshop
EMA LCM Workshop 2015: take-aways

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<th>High-level Agenda Topics</th>
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<td>Product Lifecycle Management and Status of ICH Q12</td>
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<th>Application of ICH Q12 Tools and Enablers:</th>
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<td>Established Conditions</td>
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<td>Post-Approval Lifecycle Management Protocols</td>
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<td>Pharmaceutical Quality System and Assessment-Inspection Interactions</td>
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<td>Lifecycle Strategy/ Lifecycle Management Plan</td>
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<th>Considerations for ICH Q12 Development</th>
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<td>All participants (approx. 90; industry and regulators) very committed to optimize ways of working</td>
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<td>Some concepts were well understood: Established Conditions (EC); Post-approval change management protocols (PACMPs)</td>
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<td>Other concepts still need more clarity, concrete examples: Lifecycle management plan (LCMP); Interaction inspectors – assessors; Role of the Pharmaceutical Quality System (PQS) in reducing regulatory burden</td>
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Update 2015: Concept papers remain foundation of our work

1. Promote consistent application of technical & regulatory standards by industry and authorities, defining industry position and best practice:

- Industry Concept/ position papers published:
  - Forced Degradation Studies
  - Visible Particle Inspection Practices for Biotech-derived drug products incl. MAbs
- Industry Concept paper in final consultation:
  - Bioburden (presented last year)

- next topics under development:
  - Drug/device combination products
  - Management & control of raw materials
  - Antibody-Drug Conjugates

- EBE/ EFPIA Topic Group established on biotech products and the role of the Ph.Eur.:
  - Further dialogue with EDQM after industry hearing in 2015; next important checkpoint: publication of draft infliximab monograph in Pharmeuropa
Update 2015 cont’d: increasing scope beyond biomanufacturing

2. Raise awareness of biotech manufacturing in technical & quality areas

Key objectives include:

- Consolidate relationship with EMA-BWP in order to encourage the development of appropriate regulatory guidance:
  - Support BWP interested parties meeting in 2016
  - Continue to work with BWP in identifying topics for future industry-agency workshops (eg. use of prior knowledge)

- Support appropriate manufacturing standards for accelerated development and regulatory approvals:
  - EBE input into EFPIA-TDEG White paper on CMC Challenges & Opportunities for MAPPs (version 1 just finalized)

- Encourage global convergence of regulatory standards:
  - Focus: ICH Q12 (see previous slides)
Program for the 2016 CASSS CMC FORUM EBE Satellite Session (1/2)

08:30 – 08:45  Welcome and Introduction to the European Biopharmaceutical Enterprises (EBE) Ongoing Activities and Initiatives in the Forum Rooms E-J
Markus Goese, F. Hoffmann-La Roche Ltd., Switzerland

Concept Paper 2016 Update: New Initiatives
In the Forum Rooms E-J
**Session Chairs:** Ronald Imhoff, Janssen Biologics BV and Karin Sewerin, MedImmune Limited (consultant)

08:45 – 09:00  Antibody Drug Conjugates
Fred Jacobsen, Genentech, a Member of the Roche Group, USA

09:00 – 09:15  Management and Control of Raw Materials
Annick Gervais, UCB Biopharma sprl, Belgium

09:15 – 09:30  Drug Device Combination Products
Serge Mathonet, Sanofi Pasteur, France

Medicines Adaptive Pathways to Patients (MAPPs) Initiative Workshop
In the Forum Rooms E-J
**Session Chairs:** Ronald Imhoff, Janssen Biologics BV and Karin Sewerin, MedImmune Limited (consultant)

09:30 – 09:45  Introduction to CMC Challenges and Opportunities for MAPPs / Accelerated Pathways
Ronald Imhoff, Janssen Biologics BV, Netherlands

09:45 – 10:00  Use of Prior Knowledge: A Regulatory Agency Perspective
Mats Welin, Medical Products Agency, Sweden

10:00 – 10:30  Networking Break in the Forum Foyer, Level 1
Monday, 9 May continued...

Use of Prior Knowledge Panel Presentations and Discussion
In the Forum Rooms E-J

Session Chairs: Ronald Imhoff, Janssen Biologics BV and Karin Sewerin, MedImmune Limited (consultant)

10:30 – 11:45  Panel Discussion – Questions and Answers
Ciro Cottini, Chiesi Pharmaceutici, Italy
Earl Dye, Genentech, a Member of the Roche Group, USA
Chana Fuchs, CDER, FDA, USA
Alistair Kippen, IPSEN Biopharm Ltd., United Kingdom
Yasuhiro Kishioka, Pharmaceuticals and Medical Devices Agency (PMDA), Japan
Mats Welin, Medical Products Agency, Sweden

10:30 – 10:55  Prior Knowledge in Drug Substance Process Validation
Earl Dye, Genentech, a Member of the Roche Group, USA

Alistair Kippen, IPSEN Biopharm Ltd., United Kingdom

11:20 – 11:45  Drug Product Modeling in Scale-up and Transfer of Lyophilization Processes
Ciro Cottini, Chiesi Pharmaceutici, Italy

11:45 – 12:00  Concluding Remarks
Barbara Freischem, European Biopharmaceutical Enterprises (EBE), Belgium
THANK YOU!