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

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

28 – 29 October 2015, European Medicines Agency, London

## 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.

## Location

European Medicines Agency

30 Churchill Place

Canary Wharf

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*The workshop will be recorded and broadcast live on EMA website.*

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# Agenda

## *Wednesday, 28 October 2015*

| Timings | Topic | Speaker |
|---|---|---|
| 09:00–09:15 | Welcome, Introductions & Goals of Workshop | *Jean-Louis Robert (EU)*<br>*Graham Cook (EFPIA)*<br>*Peter Richardson (EMA)* |
| **Product Lifecycle Management and Status of ICH Q12** | | |
| 09:15-11:00 | ▪ Product Lifecycle Management<br>▪ ICH Q12 – progress to date and issues<br>▪ Presentation of process flow<br>*Setting the scene*<br>▪ Design of Q12 Tools and Enablers<br>• Advantage of Risk-based Variations system<br>• Regulatory commitments/Established conditions<br>• Post-Approval Change Management Protocols<br>▪ PQS elements – Change management and knowledge management<br>*Participants discussion* | *Moderator: G. Cook*<br>*Presenter: J-L. Robert* |
| ***11:00 – 11:30 Coffee break (Posters)*** | | |
| **Application of ICH Q12 Tools and Enablers** | | |
| 11:30-13:00 | **Established Conditions:**<br>Presentation of 1-2 examples for discussion with stimuli questions<br>*Participants discussion* | *Moderators:*<br>*F. Montgomery/*<br>*N. Kruse/K. Pugh* |
| ***13:00 – 14:00 Lunch break*** | | |
| 14:00-15:30 | **Post-Approval Lifecycle Management Protocols:**<br>Presentation of 1-2 examples for discussion with stimuli questions<br>*Participants discussion* | *Moderators:M. Goese/*<br>*S-E Hillver /T. van der Stappen* |

| Timings | Topic | Speaker |
|---|---|---|
| | ***15:30 – 16:00 Coffee break (Posters)*** | |
| 16.00-18:00 | **Pharmaceutical Quality System and Assessment-Inspection Interactions:**<br>Presentation of 1-2 examples for discussion with stimuli questions<br>*Participants discussion* | *Moderators: G. France/ D. Cockburn* |
| 18:00-18:30 | **Introduction to Posters and Wrap-up Day 1**<br>Poster presenters to summarize the poster content | *Posters: P. Richardson/ D. Tainsh*<br>*Wrap-up:*<br>*Jean-Louis Robert/ Graham Cook* |
| | ***19:00 Networking Reception and Posters*** | |

## *Thursday, 29 October 2015*

| Timings | Topic | Speaker |
|---|---|---|
| 08:45-09:00 | Introduction to Day 2 | *Jean-Louis Robert/ Graham Cook* |
| 09:00-10:30 | **Lifecycle Strategy:**<br>Presentation of 1-2 examples for discussion with stimuli questions<br>*Participants discussion:*<br>Is there value in the proposal of a lifecycle strategy or plan, how would this facilitate lifecycle management and what should be in ICH Q12? | *Moderators: G. Cook/ M.Goese* |
| | ***10:30 – 11:00 Coffee break*** | |
| 11:00-12:30 | **Points arising from the Poster Presentations**<br>Feedback from poster presenters and delegates<br>*Participants discussion:*<br>What additional items for consideration by the EWG were identified? | *Moderators:*<br>*P. Richardson/D. Tainsh* |

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| ***12:30 – 13:30 Lunch break*** | | |
| 13:30-14:45 | **Considerations for Q12 Development**<br>*Statements from FDA and MHLW*<br>Consideration of Workshop findings and ICH Q12 sections<br>*Participants closing discussion:*<br>How well is ICH Q12 meeting the core expectations for a framework to facilitate the management of post-approval CMC changes?<br>Where are the opportunities for enhancements in version 2 of the Technical Document? | *Moderator: M. Nasr* |
| ***14:45 – 15:15 End of Workshop and Coffee break*** | | |