EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Joint BWP/QWP workshop with stakeholders in relation to prior knowledge and its use in regulatory applications

23 November 2017, European Medicines Agency, London

Welcome, Introductions & Goals of Workshop

Presented by V Jekerle / B Dooley
EMA Quality Office

Organising committee

Name	Affiliation
Mats Welin (chair)	BWP Member, Sweden
Martijn van der Plas	BWP Alternate, The Netherlands
Nanna Kruse	BWP Member / Vice-Chair, Denmark
Sean Barry	BWP Alternate, Ireland
Sol Ruiz	BWP Member / Chair, CHMP Member, Spain
Keith Pugh	QWP Member / Chair, United Kingdom
Susanne Stotter	QWP Member, Austria
Brian Dooley	Quality Office, EMA
Veronika Jekerle	Quality Office, EMA
Markus Goese	EBE / Roche
Andrew Lennard	EBE / Amgen
Ronald Imhoff	EBE / Janssen Biologics
David Tainsh (Matt Popkin since 06.10.17)	EFPIA / GSK
Isabelle Colmagne-Poulard	EFPIA / Merck group
Keith Watson	EFPIA / Abbvie
Thomas Stangler	Medicines for Europe / Novartis
Koen Nauwelaerts (Julie Marechal since 06.10.17)	Medicines for Europe
Nancy Cauwenberghs	Vaccines Europe / MSD Inc
Audrey Brussel	IPFA / LFB-Biotechnologies

Agenda

1. What is Prior Knowledge?
2. Using prior knowledge in product development/design?
3. Using prior knowledge in process development & manufacturing strategy?
4. How to use prior knowledge in defining the control strategy?
5. Experiences of accelerated access approaches (i.e. PRIME)
6. General discussion, summing up and way forward

Format

- Each session will have a general presentation from a regulator and an industry perspective
- Sessions 2-5 will be further elaborated by a number of industry case studies (including biotech, vaccine, small molecule, biosimilar examples).
- These will be followed by group discussions.
- Audience participation is encouraged and expected!

Key questions to be considered:

- What is (and isn't) considered to be prior knowledge?
- How can such prior knowledge be used in regulatory submissions?
- How to justify its use?
- How to present it in the dossier?

We will revisit these questions throughout the day, i.e. during each individual session discussion and in the final concluding session.

Meeting objective:

- To answer these 4 key questions
- To highlight points of agreement and/or disagreement
- Identify areas for further discussion

Meeting report:

- Summarise the presentations, discussions and conclusions
- Identify any next steps

Practicalities:

- Very full agenda with many presentations to get through
- Presenters please stick to time on presentations (VJ/BD will remind)
- Please return to the room on time after the coffee and lunch breaks to minimise disruption of the broadcast
- When speaking always use your microphone
- Please state your name and affiliation when you start to speak
- When not speaking please mute your microphone

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