EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA together with other EU Health Agencies

AESGP | APIC Active Pharmaceutical Ingredients Committee | efpia | EGA Making Medicines Affordable | Europe IFAH Representing the European Animal Health Industry

Joint Regulators/Industry QbD Workshop

28-29 January 2014
London, UK

europe.pda.org/EMA2014

Workshop Guide

ORGANIZED BY PDA EUROPE

Letter from the Chairs

Dear Colleagues,

Since the new "Science and QRM-based Quality Paradigm", as described in ICH Q8-Q11 guidelines, was first endorsed by industry and regulators, global understanding of Quality by Design (QbD) and the underpinning risk management approach have progressed considerably. Nevertheless, the number of submissions containing QbD elements remains relatively low, and dossiers containing enhanced development information are far from becoming a standard approach. Furthermore, ICH Q8-Q11 guidelines provide high-level concepts that may lead to a wide range of interpretations between Industry and Regulators when compared to the earlier, more prescriptive ICH guidelines. Thus, to promote a common understanding of QbD and to share the experience gained since the first workshop in 2009, there is great interest and need for an update. In this two-day workshop at the European Medicines Agency in London, both regulatory and industry representatives will share practical experiences by presenting six case studies of recent QbD submissions that have been evaluated by the Agency. Offering plenty of opportunity for discussion and networking, this event will provide attendees with valuable industry and regulatory insights.

Workshop Overview

In this joint workshop, six case studies will be presented by five industry-representing companies:

AstraZeneca GSK Novartis Novo Nordisk Pfizer

The EU PAT Team representatives and the Rapporteurs' assessment teams involved in the evaluation of the actual submissions presented as case studies here will contribute. Regulators directly involved in the six case studies are assessors (chemicals and biologicals) and inspectors from these agencies:

Danish Health and Medicines Authority, *Denmark*
District Government of Upper Bavaria, *Germany*
Federal Institute for Drugs and Medical Devices, *Germany*
French Health Products Safety Agency, *France*
Italian Medicines Agency, *Italy*
Medical Products Agency, Sweden
Medicines Evaluation Board, *The Netherlands*
Medicines and Healthcare Products Regulatory Agency, *UK*
National Health Laboratory EP, *Luxembourg*
Norwegian Medicines Agency, *Norway*
Paul-Ehrlich-Institute, *Germany*

In addition to the experts of these agencies, representatives from other European Health Authorities, Japan PMDA and others are present.

The Steering Committee wishes to thank the supporting parties for offering current and highly applicable information to the pharmaceutical industry.

We are looking forward to a successful and informative workshop and welcome you to London.

The Workshop Chairs

Jean-Louis Robert, *PhD*
Laboratoire National de Santé

Georges France, *PhD*
Novartis

Information

Scientific Planning Committee

Jean-Louis Robert, *Co-Chair, LNS*
Georges France, *Co-Chair, Novartis*
David Cockburn, *EMA*
Graham Cook, *Pfizer*
Lina Ertle, *F. Hoffmann-La Roche*
Simona Keckesova, *EMA*
Evdokia Korakianiti, *EMA*
Riccardo Luigetti, *EMA*
Sylvie Meillerais, *EFPIA*
Peter Richardson, *EMA*
David Tainsh, *GSK*
Georg Roessling, *PDA Europe*
Sylvia Becker, *PDA Europe*

Venue of the Workshop

European Medicines Agency
7 Westferry Circus
Canary Wharf
London E14 4HB
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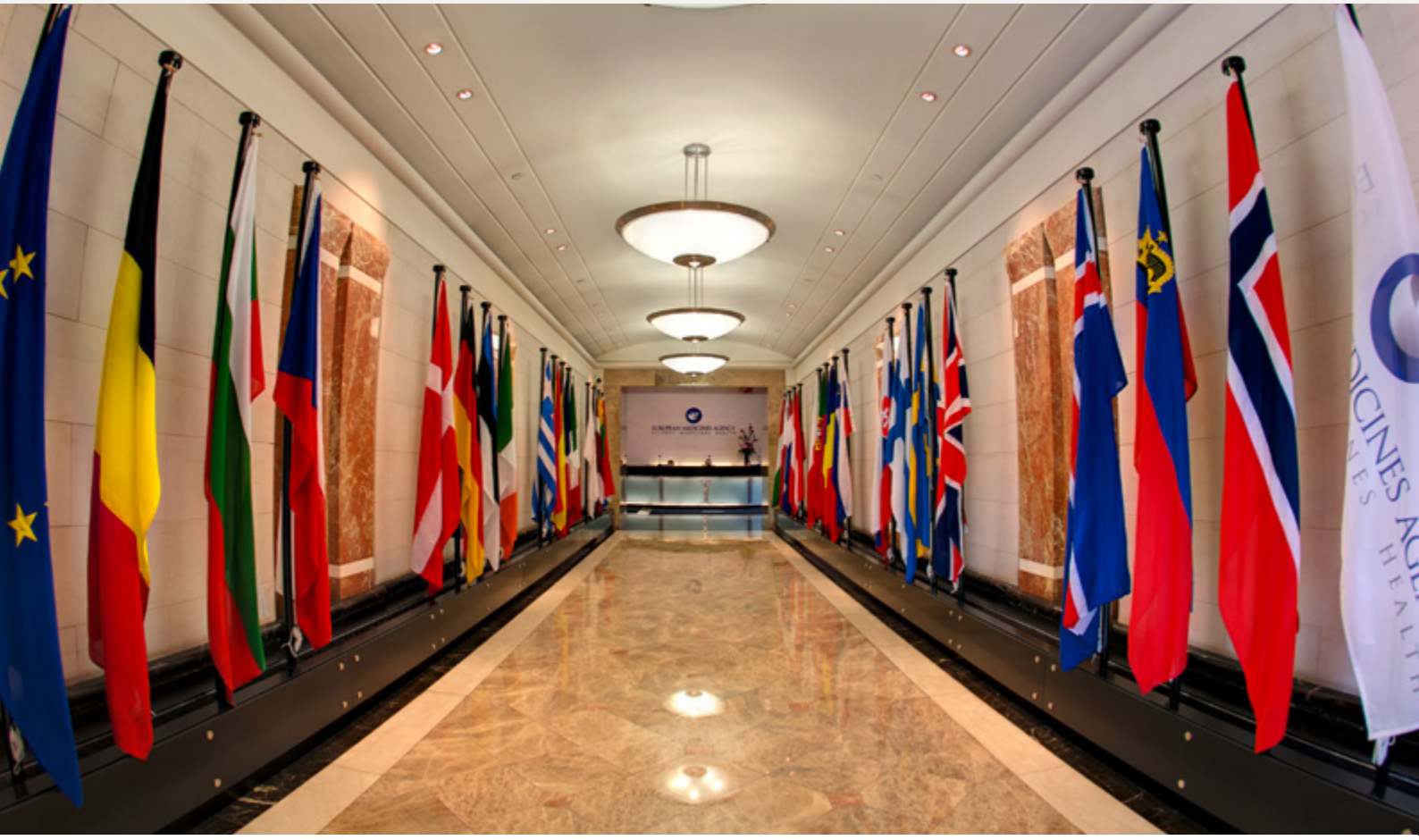
Fax. +44 (0)20 7418 8409
www.ema.europa.eu



Contact

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Workshop Agenda

Tuesday, 28 January 2014

9:00	**Welcome, Introduction & Goals of Workshop**	Jean-Louis Robert, *Laboratoire National de Santé (LNS)* Georges France, *Novartis*
	Case Study 1 & Discussion	
9:45	**Risk Assessment and Lifecycle Management Learning**	Frank Montgomery, *AstraZeneca* Olvia Lake, *Medicines Evaluation Board, The Netherlands*
10:45	**Coffee Break**	
	Case Study 2 & Discussion	
11:15	**Design Space Development and Verification**	Graham Cook, *Pfizer* Tone Agasøster, *Norwegian Medicines Agency, Norway*
12:15	**Lunch Break**	
	Case Study 3 & Discussion	
13:30	**Applying QbD for a Legacy Product and achieving Real Time Release Testing by a Design Space Approach with Supportive PAT and Soft Sensor-Based Models: Challenges in the Implementations**	Lorenz Liesum, *Novartis* Lama Sargi, *French Health Products Safety Agency, France*
	Case Study 4 & Discussion	
14:30	**Challenges in the Implementation of Model-Based and PAT-Based RTRT**	Dora Kourti, *GSK* Gorm Herlev Jørgensen, *Danish Health and Medicines Authority, Denmark*
15:30	**Coffee Break**	
	Case Study 5 & Discussion	
16:00	**Control Strategy**	Ron Ogilvie, *Pfizer* Øyvind Holte, *Norwegian Medicines Agency, Norway*
17:00	**End of Day 1 & Networking Reception**	
18:00	**Preparation of Conclusions for Day 2**	Evdokia Korakianiti, *EMA* Graham Cook, *Pfizer* Lina Ertle, *Roche* + Case Study Speakers

Workshop Agenda

Wednesday, 29 January 2014

Case Study 6 & Discussion

8:30	**Novo Nordisk Experience in the Application of QbD**	Preben Østfeldt, *Novo Nordisk* Steffen Gross, *Paul-Ehrlich-Institute, Germany*

Panel Discussion

9:30	**What is needed to further Implementation of QbD for Biopharmaceuticals?**	Moderators: Nanna Kruse, *Danish Health and Medicines Authority* Graham Cook, *Pfizer*
10:15	**Coffee Break**	

Learnings and Best Practices from the Case Studies

10:45	Questions/Issues from the Audience and Structured Discussion around Common Themes from Case Studies, e.g. - Risk Assessment and Criticality - Design Space - Use of Models - Control Strategy - Lifecycle Management - The Development Story and Presentation of Information in Submissions - Dossier – Quality System Interactions - Etc.	Moderators: Evdokia Korakianiti, *EMA* Graham Cook, *Pfizer* Lina Ertle, *Roche* + Case Study Presenters
13:00	**Lunch Break**	

International Reflections and Next Steps

14:00	• Reflections from an International perspective – USA • Reflections from an International perspective – Japan • Audience discussion – How do we progress?	Christine Moore, *FDA* Yoshihiro Matsuda, *PMDA* Jean-Louis Robert, *LNS* Georges France, *Novartis*

Innovation in Medicines and Manufacturing

15:30	**Future opportunities**	David Tainsh, *GSK* Keith Pugh, *MHRA*
16:00	**Closing Summary**	David Tainsh, *GSK* Keith Pugh, *MHRA*
16:30	**End of Workshop & Farewell Coffee**	

REGISTRATION

Joint Regulators/Industry QbD Workshop
28-29 January 2014 | London, UK

1 Your Contact Information

Name (Last, First, MI) * ☐ PDA Member ID Number

Job Title *

Company* Department

Mailing Address

City Postal Code

Country Email *

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☐ Substituting for

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* This information will be published in the conference attendee list. Should you not wish us to publish these details, please contact us.

Information about Visa Matters

- All registrations which will involve visa matters will have to be submitted to EMA EU four weeks prior to the start of the event at the latest. For later registrations, EMA Europe will be unable to assist participants in any visa affairs.
- All costs incurring in connection with visa affairs shall be borne by registrants. (This applies in particular to costs for submitting documents by courier.)
- Potential participants must be clients of UPS shipping agency and submit their UPS customer reference number to PDA EU (together with their registration).

2 Workshop Registration

All fees given in Euro and excluding VAT (20 %)

Workshop
Joint Regulators/Industry QbD Workshop
28-29 January 2014

All Participants ☐ **1.895**
(No PDA membership included)

If you like to become a PDA Member, please go to: www.pda.org/Membership Thank you.

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