ECA Academy
Your GMP/GDP Information Source

Quality Risk Management Summit

QRM over the Product Life Cycle

20/21 June 2018, Lisbon, Portugal

HIGHLIGHTS:

- The View of the Agencies
- QRM in the Light of ICH Q12
- The Link to Knowledge and Post-Approval Change Management
- How to use QRM in
  - QbD
  - GMP
  - Quality Oversight
  - GDP
- Industry 4.0

Speakers from Regulatory Agencies:


COLM REDDINGTON
MHRA, U.K.


DR KARMIN SAADAT
AGES, Austria and PIC/S QRM Expert Circle


DR FRANZ SCHÖNFELD
GMP Inspector, Germany

Speakers from Industry:


SOFIA VAN BERLEKOM
AstraZeneca, Sweden


TOR GRÅBERG
AstraZeneca, Sweden


DR BRIGITTE GÜBITZ
VTU Engineering, Austria


AIDAN MADDEN
FivePharma, Ireland


DR LISA MATZEN
Boehringer Ingelheim, Germany


PROF JOSE C. MENEZES
4Tune Engineering, Portugal


RUI PINTO
Hovione, Portugal


EMMA RAMNARINE
Genentech/Roche, USA


AUDREY SCHWEBEL
Merck, France


DR REMO STUDER
Galexis, Switzerland

.....more speakers invited

This conference is recognised for the ECA GMP Certification Programme „Certified Quality Assurance Manager". Please find details at www.gmp-certification.eu

Objectives

- Discuss how to implement integrated quality risk management principles over the life cycle of your products.
- Learn how to implement optimised Quality Risk Management (QRM) approaches to increase efficiency and to meet the expectations of the regulators.
- Take advantage to meet, listen to and interact with colleagues, regulators and industry experts.

Background

The ultimate responsibility for the performance of a medicinal product over its lifetime, its safety, quality and efficacy, lies with the marketing authorization holder (MAH). To achieve the quality objective, "there must be a comprehensively designed and correctly implemented system of Quality Assurance incorporating Good Manufacturing Practice, Quality Control and **Quality Risk Management." [EU-GMP Guidelines, Part 1, Chapter 1].**

Quality Risk Management (QRM) was formally introduced to the pharmaceutical industry in 2005 with the publication of **ICH Q9** Guideline. But QRM is not only limited to the manufacturing process. It starts much earlier in the **development phase** and lasts until the **distribution**. Even more, the new **ICH Q12** Draft Guideline (Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management) likes to facilitate risk-based regulatory oversight, e.g. for **Post-Approval Change Management (PACM).**

No matter in which area, the intent of QRM is to make data-driven and scientifically sound decisions and to support the agreed actions. Companies are currently establishing integrated risk-based thinking into their quality and regulatory affairs systems over the lifecycle of their products. This **is more than just a task of the Quality Unit**; it is bringing together knowledgeable people from different disciplines with various informed perspectives. The background and examples will be discussed in this QRM Summit.

Target Audience

This conference is designed for all persons in pharmaceutical, biopharmaceutical and API industry who establish, manage and improve quality risk management systems.

Moderator

Prof Jose C. MenezesA

Programme

▶ Part 1: The overall Importance of QRM

Changing the Habits: Value and Role of Quality Risk Management

- Regulatory requirements on risk management over the whole product lifecycle
- The Importance of QRM
- How ICH Q8-Q12 Guidelines work together from Development to Product Realisation and Continuous Improvements

PIC/S QRM Initiatives

- The Role of the PIC/S Expert Circle on Quality Risk Management
- Why QRM is more than GMP and ICH Q9
- Models for QRM systems for Inspectorates
- How to assess QRM implementation in industry
- Will there be a harmonised approach?

▶ Part 2: QRM in ICH Q12 and Life Cycle Management

Life-Cycle Risk-Management in Quality by Design (QbD)

- Status Quo of risk management in the pharmaceuticals industry
- How to implement a lifecycle risk management
- Model of Object Oriented Risk Management
- Risk communication – a key enabler for efficient risk management
- Advantages by working with innovative risk management tools

Post-approval CMC Lifecycle Management – Mitigation of global complexity?

- Agile Post-Approval Change Management within ICH Q12
- PACM Protocols & Classification of Changes
- Regulatory Flexibility & Robustness of Current Pharmaceutical Quality Systems

Risk-based Post-Approval Development and Change Management

- How to use QRM to assess criticality (minor/ major) of specific post-approval changes
- PACM protocols (access to data & info making established-conditions)

Views and Expectations of the Regulators

- ICH Q12: a way to relief burden for regulators and industry to the benefit of patients by harmonising change classifications, requirements and review timelines?
- Risk-based regulatory oversight and optimisation of resources for assessment and inspection
- What type of changes will benefit
- Concerns and implications

▶ Part 3: QRM meets Industry 4.0

Knowledge Management – a central Element of Industry 4.0 in Pharma Manufacture

- The knowledge cycle at a Pharmaceutical CMDO
- Knowledge Management and Industry 4.0 – How to make the best use of digitalized data?
- Case studies
- Challenges and next steps

QRM for agile Post-Approval Change Management

- Agility in PACM is a requirement of Industry 4.0
- QRM used over lifecycle enables risk-based decisions and knowledge excellence
- Risk management best practices for PACM
- Case Studies

▶ Part 4: QRM in GMP/GDP

Is QRM (really) a new GMP Requirement?

- The Inspector's View: Expectations
- Examples

How to effectively use QRM in the GMP Environment

- QRM –more than risk assessment
- Defining what the risk is - vital for correct and effective QRM
- How to integrate QRM in the other PQS elements
- Effort and formality – adapt QRM to your everyday business as well as major project

QRM in a complex global pharmaceutical Organisation as Enabler for Knowledge Management and Quality Oversight

- How to implement QRM oversight: harmonization as one of the key elements
- Management of risks; Risk register principles including escalation of risks in a global organization
- Example of implementation of an IT tool enabling a better overview, follow-up of overall risks and knowledge management
- Delimitation of responsibilities and interfaces over the product life cycle based on a common denominator

QRM and the new Annex 1

The term "risk management" can be found 4 times and "risk assessment" 25 times in the new Annex 1. Discuss how to establish an integrated risk assessment process within sterile manufacturing processes.

GDP: Practical Approaches to QRM using FMEA

- Examples from:
  - Inventory
  - High-level risk assessment (HLRA)
  - FMEA
- Protocols and documentation

Speakers

▶ **SOFIA VAN BERLEKOM,** AstraZeneca, Sweden
Global Business Owner QRM, Corporate Quality Operations.

▶ **TOR GRÅBERG,** AstraZeneca, Sweden
Head of External Advocacy, Global Quality, Operations, Advisory Board member of the Qualified Person Association. Former Head of the Drug Inspectorate at the Swedish Medical Products Agency and former PIC/S Chair.

▶ **DR BRIGITTE GÜBITZ,** VTU Engineering, Austria
Risk Management and Qualification Expert, PhD from Graz University of Technology on "Risk Management in Quality by Design".

▶ **AIDAN MADDEN,** FivePharma, Ireland
Managing Director and Senior Consultant.

▶ **DR LISA MATZEN,** Boehringer Ingelheim, Germany
Head of Global CMC RA Group, Global Regulatory Affairs.

▶ **PROF JOSE C. MENEZES,** 4Tune Engineering, Portugal
CEO 4Tune Engineering and Associate Professor, University of Lisbon for Bioengineering.

▶ **RUI PINTO,** Hovione, Portugal
Technical Expert Knowledge Management Group.

▶ **EMMA RAMNARINE,** Genentech/Roche, USA
Senior Director, Head Global Analytical Science & Technology (gASAT).

▶ **COLM REDDINGTON,** Medicines and Healthcare Products Regulatory Agency (MHRA), U.K.
Unit Manager, currently leading a team of experienced clinical, non clinical, pharmaceutical and scientific professionals within the licensing division of the MHRA.

▶ **DR KARMIN SAADAT,** AGES, Austria
GMP Inspector at the Austrian Agency for Health and Food Safety (AGES) and Chairman of the PIC/S expert circle on Quality Risk Management.

▶ **DR FRANZ SCHÖNFELD,** District Government of Upper Franconia, Germany
GMP Inspector and Head of the Expert Working Group for APIs at the Central Authority of the Federal States for Health Protection.

▶ **AUDREY SCHWEBEL,** Merck Consumer Health, France
Quality Manager Continual Improvement being in charge of the implementation and maintenance of the global strategy for Quality Risk Management.

▶ **DR REMO STUDER,** Galexis AG, Switzerland
Head of Quality Management and Responsible Person

Easy Registration

Reservation Form:
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Date

Wednesday, 20 June 2018, 9.30 h – 17.45 h
(Registration and coffee 9.00 h – 9.30 h)
Thursday, 21 June 2018, 8.30 h – 15.00 h

Venue

MYRIAD by SANA Hotels
Cais das Naus, Lote 2-21-01
1990-173 Lisbon, Portugal
Phone +351 211 107 600
Email info@myriad.pt

Fees (per delegate plus VAT)

ECA Members € 1,590
European QP Association Members € 1,590
APIC Members € 1,690
Non-ECA/QPA Members € 1,790
EU GMP Inspectorates € 895

The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first day, lunch on both days and all refreshments. VAT is reclaimable.

Accommodation

CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form/ POG when you have registered for the course. Reservation should be made directly with the hotel. Early reservation is recommended.

Registration

Via the attached reservation form, by e-mail or by fax message.
Or you register online at www.gmp-compliance.org.

Organisation and Contact

ECA has entrusted Concept Heidelberg with the organisation of this event
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Mr Wolfgang Schmitt (Director Operations) at +49-62 21/84 44 39, or per e-mail at w.schmitt@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation, etc please contact:
Mr Ronny Strohwald (Organisation Manager) at +49-62 21/84 44 51, or per e-mail at strohwald@concept-heidelberg.de.

Conference language

The official conference language will be English.

Social Event

On 20 June you are cordially invited to a social event. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.

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WA/16012018