2019 PharmaLab
Congress & Exhibition
Analytics•Bioanalytics•Microbiology
Düsseldorf, 12/13 November 2019

Analytical Procedure Lifecycle Management

Revisions to ICH Q2 & the proposed Q 14

ICH Press Release: Revision of Q2(R1)/(R2)/(Q14)

How to Apply Quality by Design for Analytical Methods

Laboratory Data Management Guidance APLM and APLM Workshop

Workshop Critique of a SWOT Analysis of the APLM

12-13 November 2019 | Düsseldorf/Neuss, Germany

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Analytical Procedure Lifecycle Management

12 and 13 November 2019, Düsseldorf/Neuss, Germany

Objectives & Background

Over two days, the conference will present and illuminate current developments in this field. Experts from the expert groups and from the authorities will present the contents of the guidelines and draft guidelines and discuss the consequences for analytical quality control.

On 14 November 2018, a Final Concept Paper "ICH Q14: Analytical Procedure Development and Revision of Q2(R1) Analytical Validation was published. It was proposed to develop a new quality guideline on Analytical Procedure Development and to revise the ICH Q2(R1) Guideline on Validation of Analytical Procedures: Text and Methodology. That means:

Q14 Analytical Procedure Development guideline
„The new guideline is proposed for harmonising the scientific approaches of Analytical Procedure Development, and providing the principles relating to the description of Analytical Procedure Development process. Applying this guideline will improve regulatory communication between industry and regulators and facilitate more efficient, sound scientific and risk-based approval as well as post-approval change management of analytical procedures.

Q2(R1) Revision
The scope of the revision will include validation principles that cover analytical use of spectroscopic or spectrometry data (e.g., NIR, Raman, NMR or MS) some of which often require multivariate statistical analyses. The guideline will continue to provide a general framework for the principles of analytical procedure validation applicable to products mostly in the scope of Q6A and Q6B."

Target Audience

The ECA Academy wish to actively involve analytical chemists, QC analysts, quality assurance associates & managers, R&D scientists, statisticians & managers as well as manufacturing scientists and managers, regulatory affairs specialists and contract laboratories in this critical area for analytical science. It is also useful for service providers, such as contract research organisations and contract manufacturers.

Social Event

On the evening of the first congress day, on 12 November 2019, all congress delegates and speakers are invited to a „Get together" in the Congress Center. Take advantage of this opportunity for an information exchange and enjoy the laid-back atmosphere and the entertainment programme.

Moderation

DR CHRISTOPHER BURGESS, Burgess Analytical Consultancy Limited

Speakers

ULLA BONDEGAARD, Novo Nordisk, Denmark.
Currently responsible for maintaining cross-organisational (and cross-country) laboratory processes.

PHIL BORMAN, GSK, UK.
Director Product Development & Supply. Member of various analytical teams (e.g. EFPIA, USP and BP) supporting the development of ICHQ2(R2)/Q14.

DR CHRISTOPHER BURGESS, Burgess Analytical Consultancy Limited, UK.
Chairman of the ECA Analytical Quality Control Group. Qualified Person in the EU. Member of the USP Expert Panel on Validation and Verification entrusted to revise General Chapters.

SILVIYA DIMITROVA, TEVA Bulgaria. Member of the ECA AQC Group Board and QP.
Overall responsibility for quality oversight of European TEVA suppliers as well as QC and QP Release.

DR GERD JILGE, Boehringer Ingelheim Pharma, Gemany.
Quality Control. Member of the EDQM expert group 11 and Board Member of the ECA AQC Group.

DR BOB MCDOWALL, BR.D. McDowall Limited, USA.
Director.

MARGARITA SABATER, LEO Pharma.
Principal Scientist. Board Member of the ECA AQC Group.

Programme 12 and 13 November 2019

Programme -12 November 2019

New ICH Q14 and ICH Q2 Revision – an industry view

DR JOACHIM ERMER, Sanofi-Aventis Deutschland
Head of QC Lifecycle Management Frankfurt Chemistry

Introduction to ECA AQCG

- Role of the AQCG in the ECA Foundation
- Aims and Objectives
- Current deliverables
- Work programme 2019-2020

DR CHRISTOPHER BURGESS, Chairman of the ECA AQCG Board

Overview of USP, ICH revisions & APLM Guideline; Prerequisites and approaches

- Principles of the APLM
- USP <1220> general chapter lifecycle initiative
- Prerequisites for the APLM
- Current status of revision of ICH Q2 & development of Q14

DR CHRISTOPHER BURGESS, Chairman of the ECA AQCG Board

Introduction to ATP & TMU

- Analytical Target Profile – definition and link with Product Control Strategy
- Examples of Analytical Target Profiles including combined uncertainty
- Use of ATP across the lifecycle

PHIL BORMAN, GSK

Data integrity over the Analytical Procedure Lifecycle

- Understanding the scope of data integrity via a model
- Where does analytical procedure lifecycle fit in the scope of this model?
- What are the pre-requisites needed before method development and validation begins?
- Impact of CPG 7346.832 for Pre Approval Inspections (PAIs) on lifecycle data and records?

DR BOB MCDOWAL, R.D. McDowall Limited

Stage 1: Procedure Design & Development

- Quality by Design; Application to Analytical Procedures
- Risk Management for Analytical Procedures
- Defining an Analytical Control Strategy

MARGARITA SABATER, LEO Pharma

Stage 1 in Practice

- Technique selection / Method Development – link with ATP
- Analytical Procedure risk assessment
- Use of Design of Experiments to drive method understanding

PHIL BORMAN, GSK

Analytical Control Strategy Workshop

- How can an ACS look like?

DR GERD JILGE, Boehringer Ingelheim
MARGARITA SABATER, LEO Pharma

Programme -13 November 2019

Laboratory Services - from Outsourcing to a strategic partnership

DR JÜRGEN BALLES, DR THOMAS MEINDL AND INGO GRIMM, Labor LS

Stage 2: Procedure Performance Qualification: Problems and issues?

- Strengths and weaknesses of the current ICH Q2
- Changes needed for implementation of stage 2 of the APLM
- Making best use of what we already have been doing

DR GERD JILGE, Boehringer Ingelheim

Approaches to the transfer of Analytical Procedures

- How transfer of analytical procedures is fitted into the life cycle management of the procedure
- Highlights from ISPE Good Practice Guide: "Technology Transfer", 2018
- Examples of approaches for analytical method transfer

ULLA BONDEGAARD, Novo Nordisk

Stage 3: Procedure Performance Verification

- What could/should we do? (Omitted from current ICH revisions)
- Current regulatory EU GMP requirements under Product Quality Review
- Evolving regulatory expectations
- Tools and approaches (ECA OOE & OOT Guideline)

SILVIYA DIMITROVA, Teva

Experiences in the ongoing verification of Analytical Procedures

- How to establish ongoing process verification for analytical procedures
- Which activities are relevant for which methods?
- Practical examples of ongoing process verification for analytical procedures

ULLA BONDEGAARD, Novo Nordisk

"What happens with Legacy Products?" Workshop

- What could/should we do?
- How to establish priorities
- Barriers to overcome; 2018 outcomes reviewed
- Adding value with the lifecycle approach

SILVIYA DIMITROVA, Teva
DR CHRISTOPHER BURGESS, Chairman of the ECA AQCG Board

Easy Registration

Reservation Form:
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69007 Heidelberg
Germany

Reservation Form:
+ 49 6221 84 44 34

e-mail:
info@concept-heidelberg.de

Internet:
www.pharmalab-congress.com

Dates
Tuesday, 12 November 2019, 09.00 – 18.00 h
Wednesday, 13 November 2019, 09.00 – 18.00 h
(Registration Tuesday, 12 November/Wednesday 13 November, 08.00 – 09.00 h)

Venue
Crowne Plaza Düsseldorf / Neuss
Rheinallee 1
41460 Neuss, Germany
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Fax: +49 (0) 2131 77 - 1367
emailus@cphotelduesseldorfneuss.com

Fees (per delegate plus VAT)
11 November 2019: Pre-Conference „2nd International Mycoplasma qPCR Testing User Day" € 490,-
12 November 2019 € 690,-
13 November 2019 € 690,-

The conference fee is payable in advance after receipt of invoice and includes lunch on that day/on both days as well as beverages during the event and during breaks. It also includes the Social Event on the evening of the first congress day. VAT is reclaimable.

Your registration also entitles you to participate in all other PharmaLab Congress conferences during the day of your conference/during the two days. For information on all PharmaLab conferences please visit **www.pharmalab-congress.com**.

Registration
Via the attached reservation form, by e-mail or by fax message. Or you register online at www.pharmalab-congress.com

PLEASE NOTE
Please note that there will **not be any print-outs** at the Congress. Instead you will receive all presentations prior to the Congress as Downloads. All Congress delegates (excluding exhibition visitors) will also receive the presentations on a USB stick at the registration center. Please further note that there will be no room reservations via Concept Heidelberg. Please book your **hotel room directly with the reservation form** which you will receive together with your confirmation/invoice!

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Part of PharmaLab 2019, Düsseldorf/Neuss, Germany, 12-13 November 2019
☐ Pre-Conference „2nd International Mycoplasma qPCR Testing User Day" (11.11.2019)
☐ Conferences on 12.11.2019
☐ Conferences on 13.11.2019
I would like to attend the following conference(s):
☐ **Analytical Procedure Lifecycle Management / Revisions to ICH Q2 & the proposed Q14** (12/13 November 2019)

☐ Yes, I will participate in the Social Event on 12 November.
☐ Mr ☐ Ms

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Title, first name, surname

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