Invitation to ECA's Regulatory Meeting on:

FDA 's New Quality Metrics Guideline

7 December 2015, Frankfurt, Germany

Discuss the important new FDA Guideline on **Quality Metrics** with key representatives from **FDA and EU Industry:**

Karthik Iyer, FDA
Acting Branch Chief in CDER/Office of Pharmaceutical Quality/ Office of Surveillance

Alex Viehmann, FDA
Operations Research Analyst in the Office of Surveillance – Quality Intelligence Branch

Gundeep Ahluwalia, FDA
Deputy Director (Acting),Office of Business Informatics, Center for Drug Evaluation and Research

Russell Upchurch, UCB
Director GMP Corporate QA

Richard (Dick) Bonner
ECA Foundation, ECA and European QP Association Chairman

Dr Rainer Gnibl
EU GMP Inspector

Highlights

- Update on draft Quality Metrics Guidance
- cGMP Manufacturing Statistics
- CDER Informatics – Enabling the Quality Metrics Program
- Building a Global Model for Risk Based Surveillance and Prioritization
- Quality Metrics - Current Use and Expectations
- Quality Metrics – View of an EU GMP Inspector

ECA ACADEMY

in cooperation with

QP ASSOCIATION

FDA's New Quality Metrics Guideline

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Objectives

This Regulatory Meeting is a unique opportunity for delegates from EU Industry to discuss the upcoming new FDA Guideline on Quality Metrics. The new Guideline will have a comprehensive impact on industry and authority.

FDA will use the Quality Metrics to schedule inspections based on risk assessment, improve the efficiency and effectiveness of these inspections and also reduce product-related shortages and recalls.

We invite you to discuss with FDAs experts about FDA´s expectation in all details. For this, three FDA representatives will join the Regulatory Meeting. Speakers from industry and EU Inspectorate will complement the event.

Background

In the last months, the U.S. Food and Drug Administration (FDA) has set up an initiative to use Quality Metrics for planning their risk based inspections. This development was triggered by the Food and Drug Administration Safety and Innovation Act (FDASIA; Title VII, section 706). The goal of the Guidance is to give FDA the authority to collect Quality Metrics from production sites supplying APIs, medicinal products, Biotech, OTC etc. to the US. They should provide data about the "quality level" in each manufacturing site. By this, FDA wants be able to see how well quality systems are maintained. In the future, companies will need to conduct continual monitoring, assessment and reporting on the state of quality across their drug products and facilities regulated by FDA.
The FDA Draft Guidance for Industry "Request for Quality Metrics" will be finalized soon and each company which supplies products to the US market will have to meet the demands defined in the Guidance Document.

Target Audience

All GMP and QA experts dealing with FDA requirements.

Please note: Registrations will be accepted on a first come first serve basis.

Moderator

Lance Smallshaw
UCB Belgium and ECA Co-Chair responsible for Regulatory Affairs

Programme

Update on draft Quality Metrics guidance

- Highlight key areas based on webinar and public meeting
- Common themes submitted to the public docket

• ***Karthik Iyer, FDA***
Acting Branch Chief in CDER/Office of Pharmaceutical Quality/Office of Surveillance

cGMP Manufacturing Statistics

- Overview of the statistical methods the Agency plans to utilize for model building
- Establishing a signal detection program based on quality metrics data submitted

• ***Alex Viehmann, FDA***
Operations Research Analyst in the Office of Surveillance – Quality Intelligence Branch

CDER Informatics – Enabling the Quality Metrics

Gundeep Ahluwalia, FDA
Deputy Director (Acting), Office of Business Informatics, Center for Drug Evaluation and Research,

Quality Metrics - Current Use and Expectations

- Quality Metrics in the EU GMP Pharmaceutical Quality System
- "State of control"
- Quality Management Review
- The ECA Survey on Quality Metrics – April/May 2015
- Results and Expectations

• ***Richard (Dick) Bonner,*** *ECA Foundation, ECA and European QP Association Chairman*

Building a Global Model for Risk Based Surveillance and Prioritization: Initiative Analysis and Response to FDA Draft Guidance, Request for Quality Metrics, UCB, Inc

- Introduction to UCB Inc
- Importance of a Quality Metrics Program
- Assessment of FDA Draft Guidance, Request for Quality Metrics
- Comments to Draft Guidance
- Recommendations

• ***Russel Upchurch****, UCB, Director GMP Corporate QA,*

Quality Metrics from an EU GMP Inspector's point of view

- Impact on EU-companies and how to deal with it
- EU-approach on authorities risk based inspection planning vs. US Quality Metrics approach
- Typical "Quality Metrics" an EU Inspector will look at based on EU-GMP Guideline
- Typical indicators for a lack of Quality Assurance/ Quality Culture from EU-inspectors view

• ***Dr Rainer Gnibl,*** *GMP Inspector, District Government of Upper Franconia, Germany*

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SPEAKERS

Alex Viehmann, FDA
Alex Viehmann is currently an Operations Research Analyst in the Office of Surveillance – Quality Intelligence Branch where he provides statistical support for CMC review and post-market surveillance activities. The Quality Intelligence Branch manages the CDER Quality Metrics and facility dossier program and Alex is responsible for the data analytics portion. Prior to joining the Quality Intelligence Branch, Alex worked as a statistician in the Science and Policy staff within the Office of Pharmaceutical Science where he developed policy and standards on sampling, test method evaluation and statistical quality control.

Karthik Iyer, FDA
The Quality Intelligence Branch is responsible for implementation of the quality metrics program; provide CGMP manufacturing statistics support to CDER/ORA, and creating and maintaining site intelligence dossiers for drug manufacturing sites in CDER inventory. Karthik has a BS in Chemical Engineering, an MBA, and MS in Regulatory Affairs.

Gundeep Ahluwalia, FDA
Mr Ahluwalia has over 20 years of experience building and implementing enterprise wide IT capabilities. He joined FDA in 2012 where he is responsible for defining and operationalizing the informatics strategy for human drugs. Mr. Ahluwalia's recent focus has been to implement CDER's strategic informatics capabilities to enable key regulatory processes including marketing application review, inspection management, pharmaceutical quality, and compliance. He has extensive experience leading global data exchange standards across the Life Sciences and Supply Chain industry segments. Most recently he has led FDA's ICH E2B R3 implementation working group aimed at exchange of adverse event reports across the globe.

Richard M. Bonner, ECA Foundation
Richard (Dick) M. Bonner is a Qualified Person in Europe. He is Chairman of the ECA Foundation and European QP Association Previous to his current role he was a Senior Quality Adviser for Eli Lilly and Company. He had 31 years experience within the pharmaceutical industry working in production, technical services and both Quality Control and Quality Assurance functions. He has been involved in multiple inspections from the MHRA, FDA and other authorities.

Dr Rainer Gnibl, GMP Inspector, District Government of Upper Franconia, Germany
Dr Rainer Gnibl is GMP Inspector for the District Government and the EMA and performs GMP-inspections worldwide. Before that, he was also working for the Bavarian Ministry of Environment and Health. Rainer Gnibl also holds a lectureship at the University Erlangen-Nürnberg.

Russel Upchurch, UCB
Russel Upchurch has more than 20 years experience in Pharma/Bio Pharma Industry. He has been working with Eisai as Director of Quality for Outsourced Operations and Head of Quality Control. In addition he has been working with Magellan Laboratories. In his current position at UCB he is working as Director GMP Corporate QA. He is responsible for the Corporate GxP Internal and External Audit Management Program, Corporate Recall/Investigations Process Champion and Project Lead for Internal and External Quality Metrics Program

Easy Registration

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Internet:
www.gmp-compliance.org

Date
Monday, 7 December 2015, 09:00 – 17:00 h
(Registration and coffee from 08:30 – 09:00 h)

Venue
Steigenberger Airport Hotel Frankfurt
Unterschweinstiege 16
60549 Frankfurt
Phone +49(0) 69 6975 0
Fax +49(0)69 6975 2505
info@airporthotel.steigenberger.de

Conference fees (per delegate plus VAT)
ECA and European QP Association Members: € 540
APIC Members: € 640
Non-Members: € 740
EU GMP Inspectorates: € 440
The conference fee is payable in advance after receipt of invoice and includes conference documentation, lunch and all refreshments.
VAT is reclaimable.

Conference language
The official conference language will be English.

Accomodation
CONCEPT HEIDELBERG has reserved a limited numger 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 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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Registration form (please complete in full)

FDA's New Quality Metrics Guideline
7 December 2015, Frankfurt/Main, Germany

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Company

Department

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