Electronic GMP Systems

Specification - Implementation – Validation

18 – 20 March 2015, Prague, Czech Republic

SPEAKERS:

Kai Kiefer
fme AG, Germany

Dr Bob McDowall
McDowall Consulting, UK

LEARNING OBJECTIVES:

- Impact of the updated legislation and guidance
- How to identify the best system
- Management of costs and risks
- Efficient and compliant implementation
- How to integrate the user in the implementation of a new Electronic System
- How to achieve the benefits promised
- Business Benefits with GMP Compliance
- Auditing Electronic Systems
- Ensuring Data Integrity in Electronic Systems
- GMP Systems and the Cloud

ECA ACADEMY

This course is recognised for the ECA GMP Certification Programme „Certified QA Manager“. Please find details at www.gmp-certification.eu

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Objectives

During this Master Class you will get to know benefits and risks using electronic solutions for GMP and Quality Assurance systems. You will learn how they work and interact, and what needs to be considered when specifying, implementing and validating them.

Experts will show you possibilities to improve your systems and how to use them efficiently and in compliance with the (c)GMP regulations.

Background

Computerised systems have been used for many years in pharmaceutical industry. Their use increases product safety, improves speed of processes, ensures data integrity and saves time and costs in manufacturing. However, these benefits only come if the system has been implemented and validated correctly. Over the last years, electronic solutions for GMP- and QA-Systems have been getting more and more sophisticated and popular for the same reasons. They are able to remove much of the paper work that is still used in quality assurance, manufacturing and quality control.

But while implementing those systems, a lot of factors have to be considered and questions to be answered both from a technical and compliance point of view:

- Ensuring your system is correctly specified
- How to identify the best system for your needs
- Strategic design of electronic solutions
- How to manage the project
- Management of costs and risks
- Effective and efficient computer validation
- Efficient and compliant implementation

Increasing cost pressures on pharmaceutical companies mean that internal efficiencies are essential to ensure profitability from manufacturing operations but also in R&D. And implementing electronic systems first of all needs a lot of resources: people, money, time. Therefore it is of utmost importance to do the right things: choose the right systems, implement them quickly and efficiently and get the most out of them.

In June 2011, the new versions of EU GMP Annex 11 and Chapter 4 became effective. The course will look at how these requirements have impacted the validation and operation of electronic solutions.

Moderator
Dr Bob McDowall

Target Audience

This Education Course is designed for all persons in pharmaceutical, biopharmaceutical and API industry who are involved in projects establishing, implementing and improving electronic solutions for GMP Systems:

- Quality Assurance
- Project Management
- Business Development
- IT
- Production
- Quality Control

Programme

Why Use Electronic Systems Not Paper?

- Business and regulatory drivers for working electronically
- Benefits of electronic working locally and globally
- Ensuring product quality and supply chain integrity through end-to-end traceability
- The human element of electronic systems
- Agility in responding to changed product and production requirements
- Ensuring product quality through end-to-end traceability
- Effort required to maintain state-of-the-art electronic process support

User involvement in Electronic Systems Projects

- Understand impact of IT systems on organizations
- Strategies to identify and ensure evolvement of stakeholders & users
- Techniques to develop common project vision
- Techniques to motivate and manage user involvement in all project phases

Workshop I: How to Propose a Project

The first of five linked workshops will focus on how to propose a project to management. There will be two streams, one focussing on a Quality Assurance system and a second one using a QC laboratory application. Attendees will be able to select which group they want to be in for the duration of the education course.

Role of Specification Documents in the selection and implementation of new Electronic Systems

- User requirements specifications – essential for system selection and defining what to validate
- Configuration specifications – how is an application changed to match your requirements?
- Functional specification – is one essential
- Essentials of traceability in the life cycle
- Design specification – when custom additions are required

Effective and Efficient Implementation and Use of Electronic GMP Systems

- Process mapping and redesign as an essential part of understanding the business process and an essential pre-requisite for implementation of an electronic solution
- Techniques for process analysis and design
- Applying Total Quality Management principles for process design

Workshop II: How to optimize a process

Implementing an electronic solution on a paper based process is a waste of time and money. Therefore the attendees will look at the QA and Laboratory workflows and redesign them to work electronically for the selected applications. Their choices will be discussed with the whole course.

Impact of the new GMP Regulations including Annex 11 on Electronic Systems Design and Validation

- EU GMP Annex 11 and Chapter 4 requirements
- Impact of the new clause of US GMP: 21 CFR 211.68(c)
- Impact of Compliance Programme Guide 7346.832 on Pre-Approval Inspections on Computerised Systems
- Impeding an FDA inspection?
- Impact of the FDA's new Post Inspection Response programme – are you inspection ready?
- GAMP®5: flexibility not constraint?

Principles of Project Management

- Fundamentals of Project Management
- Overview of current Project Management Practices
- Typical breakdown of a classical Project
- Key roles in a project: project manager and project sponsor
- Project team members – where do they come from and what do they do
- Interactions of line management (organisation) versus the project team (matrix management)

Specification of User Requirements

- Why are user requirements essential: business and regulatory reasons
- Who is involved writing requirements?
- Why traceability of requirements is critical for both regulatory and business reasons
- Methodology for writing requirements
- The Homer Simpson requirements analysis tool

Workshop III: Specifying Requirements

Defining user requirements are essential for selecting a commercial system and for defining the tests to be carried out in the user acceptance testing. This workshop will look at two ways of writing user requirements in a facilitated discussion and then the attendees working in their teams will write requirements for review by the rest of the course. The course will apply the Homer Simpson requirements analysis tool to the requirements generated by the teams.

How to Decide on a Solution

- Understand the process of evaluating solutions
- Case Studies: Effectively evaluate a solution and a solution provider by example
- How to audit suppliers quality of IT suppliers efficiently

Implementing and Rolling out a System

- Typical breakdown of a classical Project
- Compare Roll-out Approaches on Case Studies: Document management vs. Complaint management Roll-outs
- Managing Validation, Change & Training on site level
- How to deal with global implementation teams

Workshop IV: Planning the Roll-out to Users

The two systems have already been selected, implemented and now they need to be rolled out to the users. Given the scenarios of the two environments, the teams will discuss and decide how the QA and laboratory example systems will be rolled-out to the users.

Going to the Cloud with a GMP System?

- What is the Cloud?
- Types of cloud offering: IaaS, PaaS or SaaS
- Criteria for selecting a hosting company
- Is the IT infrastructure qualified?
- Annex 11 requirements for service providers: agreements and assessments

Ways to Ensure Data Integrity in Electronic Systems

- Ten commandments for data integrity and regulatory compliance when using electronic systems e.g. ensure that you have enough user licenses to uniquely identify users

Efficient and effective validation of Electronic Systems

- How effectively manage the key elements of GAMP
- Understand importance of applying good Application Management Practises for validation
- How deal with challenges in managing agile projects
- How to validate Interfaces, Data Migrations & Reports

Easy Registration

Reservation Form:
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69007 Heidelberg
Germany

Reservation Form:
+ 49 6221 84 44 34

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info@concept-heidelberg.de

Internet:
www.gmp-compliance.org

Date

Wedesday, 18 March 2015, 9.00 – 18.00 h
(Registration and coffee 8.30 – 9.00 h)
Thursday, 19 March 2015, 8.30 – 18.00 h
Friday, 20 March 2015, 8.30 – 13.00 h

Venue

Corinthia Hotel Prague
Kongresova 1
14069 Prague 4, Czech Republic
Phone +420 (261) 191 111
Fax +420 (261) 225 011

Fees (per delegate plus VAT)

ECA Members € 1,790
APIC Members € 1,890
Non-ECA Members € 1.990
EU GMP Inspectorates € 995
The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first day, lunch on the first and second day 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 with all further information when you have registered for the event. 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.

Conference Language

The official conference language will be English.

Organisation and Contact

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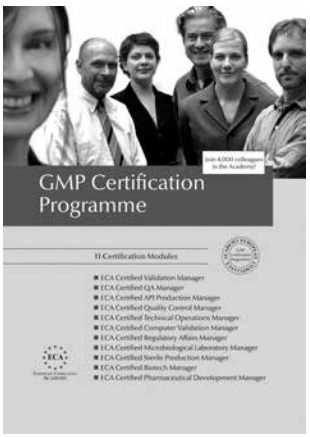
For questions regarding reservation, hotel, organisation etc.:
Mr Ronny Strohwald (Organisation Manager) at
+49-62 21/84 44 51 or at strohwald@concept-heidelberg.de.

GMP Certification Programme

This seminar is recognised within the GMP Certification Programme. By attending selected seminars, the participant can acquire an additional certificate. We offer the following modules:

ECA Certified Validation Manager
ECA Certified QA Manager
ECA Certified API Production Manager
ECA Certified Quality Control Manager
ECA Certified Technical Operations Manager
ECA Certified Computer Validation Manager
ECA Certified Regulatory Affairs Manager
ECA Certified Microbiological Laboratory Manager
ECA Certified Sterile Production Manager
ECA Certified Biotech Manager
ECA Certified Pharmaceutical Development Manager
ECA Certified GMP Auditor
ECA Certified GDP Compliance Manager

On the internet at www.gmp-compliance.org you will find a text explaining which seminars are recognised for which certificates. Or you send an e-mail to info@gmp-compliance.org or a fax to +49-6221- 84 44 64 with the request for information about the GMP Certification Programme. We will then send you our brochure on the topic.



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As an ECA course or conference attendee, you will receive up to 20% discounted travel fares (according to availability). And as Lufthansa German Airlines offers a comprehensive global route network linking major cities around the world you will most likely be able to benefit from these special prices and conditions.
And this is how it works: Once you registered for a course or conference you will receive a link together with your registration confirmation. Opening that link will take you to the Mobility Partner Program website where you can enter a code in the "Access to Event Booking" area you will also receive. This will take you into an online booking platform* that will automatically calculate the discount offered or provide you with an even better offer if another promotional fare is available.

We look forward to welcoming at one of our next events – and we already wish you a pleasant flight!

*Please note: You may have to enable pop-ups on the Mobility Partner Program website – other-wise the booking platform window will not open.

Workshop V: Reviewing Plans for a System Validation

Validation of GMP systems is a regulatory requirement but how much is enough? Using the example systems and the roll-out plans from Workshop 3, the teams will develop plans for the validation of their systems and decide the level of documentation required to support their work. The results of their deliberations will be presented and discussed with the rest of the course.

Electronic Systems: Conducting Audits and Periodic Reviews

- The impact of working electronically will change the way that we audit and review manufacturing facilities, laboratories and computerised systems
- Periodic reviews versus audits – are they the same?
- What do we need from the systems?
- What do we need from the auditors / inspectors?
- The future of audits and inspections? Remote access and video conference discussion?

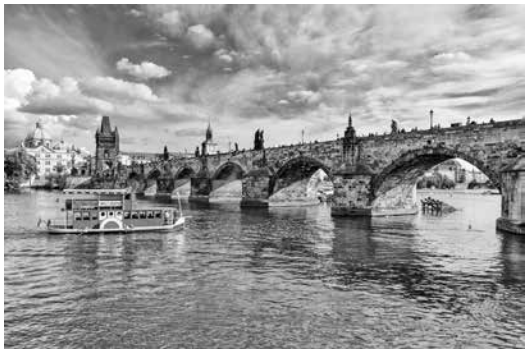
Speakers

Kai Kiefer, fme AG, Germany
Managing Consultant, Life Science. He has been implementing and managing IT systems over 15 years in life science. For nearly 10 years he has been managing implementations, validations and roll-outs of local and global computerized systems for quality, regulatory, risk management or safety functions at pharmaceutical and medical device companies.

Dr Bob McDowall, McDowall Consulting
Principal of McDowall Consulting, UK. He has been involved with the validation of computerised systems for over 25 years and is the author of a book on the validation of chromatography data systems as well as numerous articles on the validation of computerised systems. He is a trained auditor.

Social Event

On 18 March 2015, 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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Company Department

Important: Please indicate your company's VAT ID Number **P.O. Number (if applicable)**

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General terms and conditions
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1. We are happy to welcome a substitute colleague at any time.
2. If you have to cancel entirely we must charge the following processing fees: Cancellation
- until 2 weeks prior to the conference 10 %,
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I note that I can ask for the modification, correction or deletion of my data at any time via the contact form on this website.