ECA Certified Computer Validation Manager Course*

New Requirements for the Definition of Electronic Raw Data

New EU GMP Annex 11 Regulations for Computerised Systems

What will be the Impact on Your CSV Policies and Procedures?

5 - 6 May 2011, Heidelberg, Germany

SPEAKERS:

Dr Bob McDowall
McDowall Consulting, UK

Karl-Heinz Menges
(European GMP Inspector)
Regierungspräsidium Darmstadt, Germany

PROGRAMME:

- Identifying the Main Changes to GMP Annex 11 for Computerised Systems and GMP Chapter 4 on Documentation
- Scope of Annex 11: Qualify IT Infrastructure and Validate Applications
- Impact on Computerised System Validation Policies and Procedures
- Assessing the Impact of the New Roles and Responsibilities of Annex 11
- Annex 11 Requirements for Electronic Signatures: Are they the Same as for 21 CFR Part 11?
- Electronic Records Requirements of Chapter 4:
  - Data Integrity
  - Availability
  - Confidentiality
- Batch Release – Role of the Qualified Person
- Change Control and Configuration Management
- Specific Annex 11 Requirements for the Periodic Evaluation of Computerised Systems

ECA
EUROPEAN COMPLIANCE ACADEMY

This education course is recognised for the ECA GMP Certification Programme „Certified Computer Validation Manager". Please find details at www.gmp-certification.eu

New EU GMP Annex 11 Regulations for Computerised Systems

5-6 May 2011, Heidelberg, Germany

Objectives

There are three main objectives of this education course

- To review and understand the changes that have been made in the new version of EU GMP Annex 11 before it becomes effective.
- To review and understand the impact of the changes to EU GMP Chapter 4 (Documentation) and their impact on the definition of raw data and generation and maintenance of electronic records.
- To understand how the requirements of Annex 11 and Chapter 4 interact.

These three objectives will allow organisations to plan for the changes to policies and procedures for the validation of computerised systems and management of electronic raw data that the new regulations bring.

Background

EU GMP Annex 11 for computerised systems has been an unchanged part of EU GMP since 1992. In 2008, the European Medicines Agency issued a proposed update that also consisted of a Principle and 19 clauses but the length of text was four times as long as the current version. This was a major change to the regulation that incorporated regulatory concerns noted by inspectors with all types of computerised systems. There were also consequential changes to Chapter 4 on documentation that were also issued for industry comment. Within the six month comment period, over 1,400 responses from industry were received by the Agency.

The final version of Annex 11 was issued in January 2011 and becomes effective on 30th June 2011. The structure of the released document has a Principle and 17 clauses but the text is still longer than the current version it replaces. Some of the more stringent requirements from the 2008 draft have been removed from the final version of the regulation.

Major changes in Annex 11 include:

- Applications must be validated; IT infrastructure must be qualified
- Formalisation of risk management in both computer validation and change control
- The life cycle validation phase has been extensively expanded
- Requirements traceability throughout a life cycle moves from a regulatory expectation to a regulatory requirement for the first time.
- New requirements for data integrity, availability and confidentiality
- Vendor audit reports should be available for inspectors to review
- Explicitly allows the use of electronic signatures for signing documents including records

However, it is the consequential changes to Chapter 4 that update the regulation for documentation that bring **major changes to European GMP regulations**. There are **new requirements for the definition of electronic raw data and the need to keep and manage all electronic records** that brings this portion of GMP into the 21st century. The new versions of Annex 11 and Chapter 4 combined are Europe's answer to 21 CFR 11 for electronic records and electronic signatures.

Therefore individuals involved with computerised systems as well as regulated organisations that operate them need to be aware of the changes that these updates bring and be prepared for them. Therefore, implementation of the Annex and Chapter 4 require a good understanding of the changes and how they impact existing computer validation policies and procedures, define and manage electronic records but also how we validate or revalidate computer systems in the future.

This educational course is designed, through a series of presentations, discussion and workshops, to help the understanding of the regulation and how to interpret it.

Target Audience

This education course should be attended by:

- Quality Assurance staff, especially those involved with computerised system validation
- Qualified persons
- System owners of computerised systems in manufacturing, production and the analytical laboratory
- Computerised system validation professionals
- CSV consultants
- IT staff either in-house, outsourcing organisations or hosting companies
- Suppliers of GMP software applications or systems to the pharmaceutical and allied industries
- API manufacturers
- Contract research organisations with GMP operations and contract manufacturing organisations

Moderator

Dr. Bob McDowall, McDowall Consulting, UK

Programme

Introduction to the Annex 11 Course
- Introduction to the teaching team
- Overview of the two days of the course
- Roadmap of the Course

Identifying the Main Changes to GMP Annex 11 for Computerised Systems
An overview presentation looks at a brief history of Annex 11 and its revision between 2008 and 2011 and highlights the new requirements of the regulation.
- History of Annex 11
- Structure of Annex 11
- New requirements of the regulation

Each attendee will receive a document mapping the versions of Annex 11 that will enable them to see how the regulation has changed and where there is consistency between the original and new versions.

Annex 11 Principles and Risk Management
The principles of Annex 11 and the new section on risk management will be discussed and compared with the old version to understand the impact of the changes in these sections.
- Scope of Annex 11: qualify IT infrastructure and validate applications
- Risk management in computer validation – has anything changed in the new version?

Roles and Responsibilities in Computerised System Validation
The new version of Annex 11 brings increased roles and responsibilities to supplying, implementing and operating computerised systems
- Process owners and system owners
- IT Department
- Suppliers and service providers

Workshop 1: Assessing the Impact of the New Validation Section of Annex 11
The new section on validation has been greatly expanded in the new version of Annex 11. Working in groups, attendees will discuss the changes and draw up a list of the major ones and their impact on computerised system validation policies and procedures in their organisations e.g.
- Approaches for commercial versus customised systems
- What is the project life cycle?
- User requirements need to be traceable throughout the life cycle
- User testing
- Automated testing tools

EU GMP Annex 11 Electronic Signatures
For the first time, the pharmaceutical organisations following EU GMP have the authority to use electronic signatures on regulatory documents, reports and records.
- Annex 11 requirements for electronic signatures
- Comparison of Annex 11 requirements for electronic signatures with 21 CFR 11 - are they the same?
- Implementing electronic signatures to comply with Annex 11 and Part 11

Workshop 2: Electronic Signatures
The use of electronic signatures is a key component of improving productivity in the regulated quality control laboratory to release products faster to market. This workshop, in the format of a facilitated discussion, will explore what needs to be done to comply with the new Annex 11 requirements for electronic signatures and if there will be any impact on existing validated systems validated to 21 CFR 11.

Inventory of Computerised Systems and System Descriptions
The need for an inventory of computerised systems has been introduced into Annex 11 as well as some modifications to the requirements for system descriptions. This presentation will explore these two topics.
- Inventory requirements for computerised systems
- System description – what is required?
- Linkage with Validation Master Plans outlined in Annex 15

New Requirements for Vendor Audits
Annex 11 mandates that vendor audit reports should be available for review by inspectors, this talk will explore the issues surrounding this area.
- Identifying the changes in approach from the old to the new version of Annex 11
- What will this mean for vendor audits in the future?
- Will vendor management be an undocumented requirement for software suppliers that fail audits?

GMP Chapter 4 on Documentation: What are the major changes?
The new version of Chapter 4 was revised in the light of the increasing use of electronic documents within the GMP environment and it brings requirements for the definition of raw data and the handling of electronic records.
- Types of records: Site Master File, instructions and records / reports
- Definition of electronic raw data
- Management requirements of electronic records
- Hybrid and electronic systems under EU GMP
- Retention of documents

Workshop 3:
Implementing Chapter 4 and Annex 11 Requirements for Electronic Records

The requirements for electronic records from Chapter 4 and the data integrity requirements of computerised systems will be evaluated in this workshop where attendees will develop an approach to comply with the requirements of Chapter 4 and Annex 11 in this area including archiving and data migration.

Data Integrity Requirements for Computerised Systems

The requirements for data integrity are split over several clauses of Annex 11 and we will explore the updated sections for this topic as follows:

- Accuracy checks
- Printouts of data
- Audit trail requirements

Regulatory Issues around the Information Technology Department

In addition to the need to qualify the infrastructure there are several other areas that directly impact the IT department or an outsourced IT service provider.

- In-house or out-sourced IT – what are the requirements?
- Data storage and backup
- Incident management
- Business continuity requirements

Security of Networks and Computerised Systems

Security is a key requirement of computerised systems, applications and networks; here we will review the requirements for this topic.

- Security of networks and applications
- Access control requirements in the new Annex 11
- Procedures and records for security and access control

Batch Release

Integrating the requirements of Chapter 4 and Annex 11, this presentation will focus on the role of the Qualified Person in releasing a batch using a computerised system in an electronic environment.

- Annex 11 requirements for batch release
- Chapter 4 requirements for the Qualified Person

Change Control and Configuration Management

Change control is an existing requirement of Annex 11; the clause has been streamlined in the new version. However the title also mentions configuration management but does not define the term which is confusing as there are at least two definitions used in software engineering.

- Review and interpretation of the new Annex 11 requirements
- What is configuration management?
- Issues in implementing the requirements

Periodic Evaluation of Computerised Systems

The new version of Annex 11 formalises the periodic review of computerised systems and the talk will present the regulatory requirements and practical interpretation of them.

- Requirements of the new Annex 11
- Practical interpretation of the new requirements – are all systems the same?

Speakers

DR BOB MCDOWALL

McDowall Consulting, Bromley, Kent, UK

Analytical chemist with over 35 years experience including 15 years working in the pharmaceutical industry and 18 years working for the industry as a consultant. He is Principal of McDowall Consulting, UK. Bob is an ISO 17025 assessor and he has been involved with the validation of computerised systems for over 20 years and is the author of a book on the validation of chromatography data systems. Bob is also the writer of the Questions of Quality (LC-GC Europe) and Focus on Quality (Spectroscopy) columns and is a member of the Editorial Advisory Boards of several Journals.

KARL-HEINZ MENGES *(European GMP Inspector)*

Regierungspräsidium Darmstadt, Germany

Karl-Heinz Menges is an Inspector at the Regierungspraesidium Darmstadt in Germany. Mr Menges studied Pharmacy at the University of Heidelberg and received his Approbation in 1982. Mr Menges has been an Inspector for over 25 years and he is currently Head of the German Inspectors Working Group. He is also a member of GAMP D-A-CH steering committee and the German delegate of the PIC/S Expert Circle for computerised systems. Mr Menges has also contributed to Annex 11, PIC/S document PI 011 Recommendations on Computerised Systems and several GAMP CPGs.

Social Event

On Thursday, 5 May 2011, 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

About CONCEPT HEIDELBERG

Founded in 1978, CONCEPT HEIDELBERG is the leading organiser of seminars on pharmaceutical production, quality control, quality assurance and GMP in Europe. This year more than 240 events will be organised by CONCEPT HEIDELBERG.
ECA has entrusted CONCEPT HEIDELBERG with the organisation of its events.

What Is ECA?

The European Compliance Academy (ECA) is an independent educational organisation chaired by a Scientific Advisory Board with members of the pharmaceutical industry and regulatory authorities. The ECA will provide support to the Pharmaceutical Industry and Regulators to promote the move towards a harmonised set of GMP and regulatory guidelines by providing information and interpretation of new or updated guidances.

What Are the Benefits of ECA?
First benefit:
During the membership, you enjoy a € 200 discount on the regular participation fee of any European Conference organised by ECA in co-operation with CONCEPT HEIDELBERG.

Second benefit:
The GMP Guideline Manager Software with a large number of guidelines, e.g. EC Directives, FDA Guidelines, ICH Guidelines, will be forwarded to you when you are using your membership for a conference registration.

How Do You Become a Member of ECA?
By participating in one of the European Compliance Conferences or Courses marked with ECA, you will automatically become a member of ECA for two years – free of charge. Conferences and Education Courses organised by ECA will be realised in co-operation with CONCEPT HEIDELBERG. More information about ECA can be obtained on the Website **http://www.gmp-compliance.org**

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 certification 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

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.

ECA Education Course
Computerised Systems in Analytical Laboratories
2 – 4 May 2011, Heidelberg, Germany

On 2 – 4 May 2011, i.e. from Monday to Wednesday of the same week, there will be another ECA GMP Education Course in Heidelberg about Computerised Systems in Analytical Laboratories. The objective of this course is

- to present ways of developing strategies to automate a GMP analytical laboratory to reduce overall analytical turnaround time
- to integrate existing or newly purchased software applications and leverage the business benefits of them for greater efficiencies
- to maintain or improve the integrity of data generated within a GMP analytical laboratory
- to ensure compliance with GMP regulations

Topics that will be covered are:
- Principles of the Electronic Analytical GMP Laboratory
- e-Compliance in Regulated Laboratories: Quality Assurance Principles for an Electronic Analytical Laboratory
- Developing a Strategy for the Electronic Analytical Laboratory
- What is Your Strategy for Managing the Electronic Records Produced by the Laboratory
- Involving the IT Department in Developing the Laboratory Strategy
- Designing Electronic Working practices and Incorporating Electronic Signatures
- Integrating LIMS, Electronic Laboratory Notebooks and Instrument Data Systems
- Understanding and Applying Risk-based Computerised Systems Validation to Laboratory Systems
- Users: The Human Element of the Electronic Laboratory
- Protection of Electronic Records in the Electronic Laboratory
- Quality Assurance Audit of the Electronic Laboratory
- Changing a System – What to Do with the Old Data?
- Facilitated Discussion: Options for Retention and Archiving of CDS Records
- Streamlining Automating Computerised System Validation on the Electronic Laboratory

In addition, **Workshops** are offered about:
- Designing a Electronic Laboratory Strategy
- Designing Electronic Working Practices in an Analytical GMP Laboratory
- Designing Integrated Systems for a Laboratory
- Designing Electronic Working Practices – the Devil is in the Detail

Speakers:
Eberhard Kwiatkowski, Bayer Schering Pharma AG, Germany
Dr Bob McDowall, McDowall Consulting, UK

The course on **Computerised Systems in Analytical Laboratories** (2-4 May 2011) is an ideal precursor for all those who are responsible for laboratory systems (process owner, system owner, IT department, suppliers, and service providers) to the course **New EU GMP Annex 11 Regulations** (5-6 May 2011). Further information about the course Computerised Systems in Analytical Laboratories can be received at www.gmp-compliance.org.

Participants who register simultaneously for both courses will receive a 350€ discount (not valid for EU GMP Inspectorates).

Easy Registration

Reservation Form:
CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg
Germany

Reservation Form:
+ 49 6221 84 44 34

e-mail:
info@concept-heidelberg.de

Internet:
www.gmp-compliance.org

Reservation Form (Please complete in full)

+ 49 6221 84 44 34

☐ **New EU GMP Annex 11 Regulations for Computerised Systems**
5-6 May 2011, Heidelberg, Germany

☐ **Computerised Systems in Analytical Laboratories**, 2-4 May 2011, Heidelberg, Germany

☐ Mr. ☐ Ms.

Title, first name, surname

Company Department

Important: Please indicate your company's VAT ID Number **Purchase Order No, if applicable**

Street/P.O. Box

City Zip Code Country

Phone/Fax

E-Mail (please fill in)

If the bill-to-address deviates from the specifications on the right, please fill out here:

CONCEPT HEIDELBERG
P.O. Box 101764
Fax +49 (0) 62 21/84 44 34

D-69007 Heidelberg
GERMANY

General terms and conditions
If you cannot attend the conference you have two options:
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 %,
- until 1 weeks prior to the conference 50 %
- within 1 week prior to the conference 100 %.

CONCEPT HEIDELBERG reserves the right to change the materials, instructors, or speakers without notice or to cancel an event. If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. CONCEPT HEIDELBERG will not be responsible for discount airfare penalties or other costs incurred due to a cancellation.
Terms of payment: Payable without deductions within 10 days after receipt of invoice.
Important: This is a binding registration and above fees are due in case of cancellation or non-appearance. If you cannot take part, you have to inform us in writing. The cancellation fee will then be calculated according to the point of time at which we receive your message. In case you do not appear at the event without having informed us, you will have to pay the full registration fee, even if you have not made the payment yet. Only after we have received your payment, you are entitled to participate in the conference (receipt of payment will not be confirmed)!

Date

Thursday, 5 May 2011, 09.00 – 18.30 h
(Registration and coffee 08.30 – 09.00 h)
Friday, 6 May 2011, 08.30 – 16.30 h

Venue

Crowne Plaza Hotel Heidelberg
Kurfürstenanlage 1
69115 Heidelberg, Germany
Phone + 49 / (0) 6221 917 0
Fax + 49 / (0) 6221 917 100

Fees

ECA Members € 1,490.- per delegate plus VAT
APIC Members € 1,590,- per delegate plus VAT
(does not include ECA membership)
Non-ECA Members € 1,690.- per delegate plus VAT
EU GMP Inspectorates € 845.- per delegate plus VAT
The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first day, lunch on all days and all refreshments. VAT is reclaimable.

Would you like to save money?
If you register for the ECA Education Course "Computerised Systems in Analytical Laboratories" from 2 to 4 May 2011 at the same time, you will receive a 350 EUR discount. This is not valid for EU GMP Inspectorates.

Accommodation

CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form when you have registered for the event. Please use this form for your room reservation or be sure to mention "VA 6886 ECA Event" to receive the specially negotiated rate for the duration of your stay. Reservation should be made directly with the hotel not later than 8 April 2011. 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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