ECA
European Compliance Academy

Consequences for European healthcare industries

European Computer Validation Conference – The new Annex 11

15-16 May 2012, Copenhagen, Denmark

SPEAKERS

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HIGHLIGHTS:

- New requirements on computerised systems: what are the consequences for the European pharmaceutical industry?
- How to interpret these regulations and how to implement them pragmatically?
- What do inspectors expect from industry in the future?
- 3 pre-conference workshops
  - Qualification of virtual servers
  - Impact of Annex 11 on the Laboratory
  - Electronic Batch Record (EBR)

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

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Objectives

- The new Annex 11 and Chapter 4 set targets and provide a lot of flexibility in interpretation. Inspectors who played a major role in the development of Annex 11 will inform you about the background and content of the new document.
- Representatives of the pharma industry will interpret and give their opinion on these regulations.
- Together with the participants, the new regulations will be assessed and their practical implementation into practice will be discussed.

Background

Binding European requirements regarding computerised systems and their validation are laid down in Annex 11 „computerised systems" of the EU GMP Guide. With regard to current regulatory developments (e.g. on the risk management topic (ICH Q 9 and EU-GMP Guide part III Q 9) and new technological developments (electronic signature, etc.), it had become necessary to revise the Annex. Together with Chapter 4 „Documentation", the new Annex 11 became enforceable on 30 June 2011.

Regulatory compliance objectives have been set simply and briefly and provide enough flexibility for industry to implement them according to its own needs.

Target Audience

The conference is directed at executives in the pharmaceutical industry - suppliers and service providers - who need to implement current European requirements.

Moderators

Karl-Heinz Menges
Dr Wolfgang Schumacher

Programme
PRE-CONFERENCE WORKSHOP

Qualification of virtual servers - *Eberhard Kwiatkowski, Yves Samson*
The virtualisation of computerised systems offers a multitude of advantages; for example simultaneous use of several operating systems, simple and cost-effective installation of test environments and improved utilisation of multi-core processors. During the workshop, qualification and the principles of today's virtualisation technology will be elaborated:

- What is a virtual machine?
- Life cycle of virtual machines
- Regulations regarding the qualification of virtual machines
- Responsibilities
- Areas of application
- Creation of virtual machines
- Configuration and management of virtual machines
- Qualification plan / configuration plan

Impact of Annex 11 on the Laboratory - *Bob McDowall*
Annex 11 and Chapter 4 bring the challenge of meeting new regulation tor the analytical laboratory, for both standalone and networked systems. We will look at:

- Are there any differences between Annex 11 and Part 11 regulations for electronic signatures?
- How should we document the review of audit trails?
- How to define raw data for laboratory computerised systems
- Impact of Annex 11 on spreadsheet design and validation
- What does integration of risk management with computer validation mean for the laboratory?
- What are the implications that the IT network must be qualified and under control for networked laboratory applications?

Electronic Batch Record (EBR) - *Frank Behnisch / Dr Christa Färber*

- Process description
- Definitions (types of „signatures")
- Legal basis
- Requirements on electronic signatures
- New Chapter 4 of the EU GMP Guide „Documentation"
- EFG 11's vote on electronic signature
- Special features concerning Configuration Management and Incident Management
- Process control through electronic batch recording (EBR)
- Electronic batch recording and electronic release
- Challenges relating to the introduction

Programme CONFERENCE

Conference structure:

Inspectors and industry representatives will present and discuss all parts of Annex 11 in shared presentations.

Introduction: History of the Document

- Reasons for the Change
- Development of Annex 11
- The draft document from 2008

Principle / General

1. Risk Management

- What can elements from risk management contribute to determine the scope of inspections to be done on certain specific aspects (like validation, data integrity)?
- What does "determine the scope of a validation through risk management" actually mean? Does it relate to the number of test cases or the depth of testing?

2. Personnel

- What is meant by "close co-operation between all relevant personnel..."? Which formal requirements must be complied with?
- What training is required?
- Are there formal qualifications required (e.g. ITIL certification or something similar)?
- What role does the QP have to play in the validation process?
- Does the QP replace the QS in the validation process?

3. Suppliers and Service Providers

- Why do inspectors want to see suppliers audit reports? Is this acceptable with confidentiality agreements in place with suppliers?
- According to inspectors, what criteria shall be considered in suppliers assessments?
- Do requirements concerning auditing underlying suppliers exist?
- Which requirements apply to COTS (Commercial Off-The Shelf) products?
- What are the formal requirements regarding the selection of a supplier? Shall the process of selection be documented and justified?
- Have external suppliers/internal IT departments to implement and manage their own QMS? If so, which requirements are subject to this QMS?

Project Phase

4. Validation

- What is the definition of "relevant systems"?
- Is there any definition for "critical'?
- How should GMP functionalities in inventory lists be described?
- Can a URS based on risk analysis be created?
- Data flows – do they mean system-internal interfaces (e.g. interfaces between different modules in ERP systems)?
- Must all User requirements be traceable or is a GMP relevant classification enough?
- What "Level of Control" is expected when using automated test tools?
- What do test scripts and test results have to look like to be accepted by inspectors?

Operational Phase

5. Data

- What control mechanisms (e.g. MD 5) are expected?
- Are certain file formats (e.g. XML) preferred?
- Why are "built-in checks" for the electronic interface required when the interface has been validated?

6. Accuracy Checks

- To what extent must data entry checks be controlled in the validation?
- How do inspectors handle with risk observation when a residual risk remains during the control?

7. Data Storage

- How often should readability and accessibility of data be checked?
- What are the requirements with regard to physical protection?

8. Printouts

- Are paper printouts required or are electronic documents sufficient?
- What distinguishes "clear printed" printouts from normal printouts?

Operational Phase (continued)

9. Audit Trail
- What are the essential components of an Audit Trail?
- What are the requirements in the regular assessment of Audit Trails?
- How to handle "legacy systems" without Audit Trail?
- Is a "paper-based" Audit Trail conceivable?
- What is meant by "GMP relevant data"?

10. Change and Configuration Management
- What controls are necessary for changing configuration?
- Must changes without GMP relevance be controlled?

11. Periodic Evaluation
- How often is "periodic"? What periods/intervals are expected?
- Can or must such periodical assessments be presented in annual reports or PQR?
- Who is responsible for the performance of periodic evaluation? Can responsibility be transferred to the service provider?

12. Security
- Does the notion "Operators" refer to the users of the system? If so, what is the difference with Audit Trail accounts?
- The identity of users from "Management Systems for data and for document" must be recorded. What are "Management Systems" and doesn't this requirement apply to control systems too?
- How often do users have to change their passwords? How often must user profiles be reviewed?

13. Incident Management
- What is exactly meant with "all incidents"? Do they also refer to service requests (i.e. resetting passwords)?
- Are work-arounds accepted as preventive actions?

14. Electronic Signatures
- Is it intentional that "meaning" (like in Part 11) isn't mentioned?
- How long data on electronic signatures must be archived?
- How important is legal commitment with regard to internal rights and duties?
- What is meant with "have the same impact as hand-written signatures within the boundaries of the company"?

15. Batch Release
- Is electronic release permitted?
- Does the paragraph also apply to hybrid systems with paper release but electronic recording of the release?
- Does "real time" release enable an automated release?

16. Business Continuity
- Is high availability required for all critical processes regardless of whether availability is important?
- Must system availability be tested for each single system or is a general test sufficient?

17. Archiving
- How often must readability of archived data be checked?
- Is a single test sufficient to prove readability of the archived data?

Chapter 4: Documentation
- How to interpret the connection between Annex 11 and Chapter 4?
- Which changes affect the management of electronic documents?
- What has become of the proposed regulations about aggregation of data in Draft Annex 11?

Conclusion: "Annex 11 – The Good, the Bad, the Ugly"
- Implementation approach
- Critical chapters
- New challenges - What's at the horizon?

Speakers

FRANK BEHNISCH, *CSL Behring GmbH, Marburg, Germany*
Frank is Senior Manager Project Engineering at CSL Behring GmbH in Marburg, Germany. He is member of the GAMP® D-A-CH „steering committee“ and chairman of a GAMP® Special Interest Group (SIG) for “Small manufacturing devices”

KLAUS EICHMÜLLER, *District Government of Upper Bavaria Munich, GMP Inspectorate, Germany*
After working in the pharmaceutical Industry Klaus Eichmüller joined the District Government of Upper Bavaria in Munich. Since 1996 he is working in the field of GMP Inspections of manufacturer of medicinal products and importers. He is Deputy Head of the Central Surveillance of Medicinal Products in Bavaria

DR CHRISTA FÄRBER, *Staatliches Gewerbeaufsichtsamt Hannover, Germany*
Since 2005, after several years in the industry, Dr Färber has been working for the Staatliches Gewerbeaufsichtsamt Hannover where she is responsible for GMP monitoring. She is a member of EFG „Computerised Systems“.

EBERHARD KWIATKOWSKI, *Bayer Pharma AG, Elberfeld, Germany*
Since 2000 he has been in charge of the computerised system validation for the entire Bayer Schering Pharma plant in the "GMP-Referat" for the API production in Wuppertal. He is a co-author of the ISPE Good Practice Guide for the Audit of external suppliers and he is a member of the GAMP-DACH Forum and he is also a member of APV's expert group on computerised systems.

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.

KARL-HEINZ MENGES, *Regierungspräsidium Darmstadt, Germany*
He is Inspector at the Regierungspräsidium Darmstadt in Germany. 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.

KNUD RYHL, *Danish Medicines Agency, Copenhagen, Denmark*
He is inspector at The Danish medicines Agency. Mr Ryhl has been an inspector for 6 years. Prior to joining the inspectorate he worked in industry with programming, qualification and validation. Mr Ryhl is a delegate of the PIC/S Expert Circle for computerized systems, and is the responsible for the computerized systems area within the Danish Medicines Agency.

YVES SAMSON, *Kereon AG, Basel, Switzerland*
Yves is founder of Kereon AG, Basel. He is member of GAMP Europe Steering Committees, chairman and co-founder of GAMP Francophone and edited the French version of GAMP 4 and GAMP 5. Within ISPE he was an active member of the working group "IT Infrastructure Compliance and Control".

DR WOLFGANG SCHUMACHER, *Hoffmann-La Roche, Switzerland*
Dr Schumacher studied chemistry and pharmacy. After entering Asta Medica, he headed different positions. In 2001 he joined F. Hoffmann-La Roche, Basle, where he is now Head of the department of Quality Computer Systems. He is a member of the ECA Advisory Board.

JÖRG SCHWAMBERGER, *Merck KGaA, Darmstadt, Germany*
Jörg Schwamberger studied chemistry in Darmstadt. In 1998, he entered Merck KGaA in the department API production. Between 2001 and 2008, he headed the QS and central IT auditing unit. Since 2009, he is in charge of IT Risk Management and Enterprise Architecture.

JENS SEEST, *Leo Pharma A/S, Ballerup, Denmark*
Jens Seest, a BScME from Danish Technical University, has accumulated over 15 years pharmaceutical experience with process automation and corporate computer systems. He has worked in numerous positions as IT-manager, project manager, QA, Validation responsible and IT-governance. In his current position as Head of Department for Quality Assurance IT Compliance with LEO Pharma,. He has contributed to GAMP5 and is currently chairman of the GAMP Nordic Board.

AUDNY STENBRÅTEN, *Norwegian Medicines Agency, Oslo, Norway*
With over 30 years of experience, Audny Stenbråten works as pharmaceutical inspector since 2003 at the Norwegian Medicines Agency. She performs inspections amongst others in the areas of GDP/GMP/GCP. She is member of the PIC/S Expert Groups on Quality Risk Management (QRM) and on GDP (wholesaling).

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with colleagues from other companies in a relaxed atmosphere.

Easy Registration

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Date Pre-Conference Workshops
Tuesday, 15 May 2012, 09.00 – 12.00 h
(Registration and coffee 08.30 – 09.00 h)

Date Conference
Tuesday, 15 May 2012, 13.15 – 18.00 h
(Registration and coffee, 12.30 – 13.15 h)
Wednesday, 16 May 2012, 08.30 – 17.30 h

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Conference language
The official conference language will be English.

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