ECA
European Compliance Academy

Consequences for European healthcare industries

European Computer Validation Conference

First experiences with Annex 11

4 - 5 June 2013, Barcelona, Spain

SPEAKERS

FROM AUTHORITIES:

KLAUS EICHMÜLLER
Regierung von Oberbayern
Munich

DR CHRISTA FÄRBER
Staatl. Gewerbeaufsichtsamt,
Hannover

KARL-HEINZ MENGES
Regierungspräsidium
Darmstadt

KNUD RYHL
Danish Medicines Agency

AUDNY STENBRÅTEN
Norwegian Medicines Agency

FROM INDUSTRY:

FRANK BEHNISCH
CSL Behring

EBERHARD KWIATKOWSKI
Bayer Pharma

BOB MCDOWALL
McDowall Consulting

YVES SAMSON
Kereon

DR WOLFGANG SCHUMACHER
F. Hoffmann-La Roche

DR JÖRG SCHWAMBERGER
Merck

JENS SEEST
Leo Pharma

MICHAEL WEGMANN
F. Hoffmann-La Roche

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**
  - Writing testable and verifiable User Requirement Specifications
  - Cloud Computing in a GxP Environment
  - Periodic Review / Periodic Evaluation of computerised Systems

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 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, content and execution of the document.
- The interpretation of Annex 11 is provided in the PICS document PI 011. The document is now under revision. You will get first hand information about the new version from the responsible inspectors.
- Inspectors and representatives of the health care industry will discuss the influence of Annex 11 on different IT-systems and IT quality elements.
- The technological development of IT is still increasing. What are the consequences from the GxP point of view? How do you implement new trends like Cloud computing and the use of Mobile devices?

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 revised Annex 11 became effective on 30 June 2011.

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 and Dr Wolfgang Schumacher

Programme PRE-CONFERENCE WORKSHOPS

Writing testable and verifiable User Requirements Specifications - *Bob McDowall*

Annex 11 clause 4.4 states that User Requirements Specifications should describe the required functions of the computerised system and be based on documented risk assessment and GMP impact. User requirements should be traceable throughout the life-cycle. This reflects the fact that a URS is the most important document in the whole life cycle as it defines the intended use of a system.

This workshop will look at ways of writing user requirements specifications to meet the above Annex 11 regulation and will look at:

- System risk assessment and GMP impact of the system
- Overall structure of a URS document
- URS in the context of a system life cycle: one version to select an application and an updated document to validate the system
- Linking the URS to a specific version of application software
- Textual and tabular ways of writing requirements
- Writing testable and verifiable user requirements
- Functional and non-functional testing
- Impact of constraints on user requirements
- Numbering requirements for traceability and linking to the traceability matrix

The workshop will have presentations, workshops and facilitated discussions to enable attendees to gain the maximum amount of information from attending this session.

Cloud Computing in GxP Environments - *Michael Wegmann / Dr Wolfgang Schumacher*

Like in other sectors, the pharmaceutical industry considers the use of cloud computing. From a commercial point of view, it appears to be an attractive service model. However, is cloud computing an option at all in GxP environments in the pharmaceutical industry? If it is, which requirements need to be taken into account to ensure adequate quality and regulatory compliance? What is the authority's position on cloud computing?

- Overview of cloud computing and the different service models
- Comparison of internal versus external clouds
- Risks and opportunities, advantages and disadvantages of cloud computing
- Discussion of cloud computing in GxP environments; is it permissible?
- Strategies for qualification and validation of „the cloud"
- Cloud computing from a regulatory authority's perspective; what needs to be taken into account from an inspectors point of view?

Pre-Conference Workshops, cont'd

Periodic Review / Periodic Evaluation of computerised Systems - *Eberhard Kwiatkowski / Yves Samson*

Computerised systems should be evaluated periodically. Which GMP requirements must be fulfilled to show that the systems are still in a validated state? What are the time intervals for such a evaluation? You will get examples from real life which you can discuss and evaluate

- Regulatory requirements
- Responsibilities
- Evaluation scope
- Background information
- Evaluation process
  - Method
  - Frequency & triggers
  - Report

CONFERENCE Programme

Introduction - what is new?

Karl-Heinz Menges

- Upcoming new regulatory guidelines to be considered when computerized systems are involved?
- Revision of PIC/S document PI 011
- Annex 11 Questions and Answers

Review of PI 011 - the Adoption of PI 011 to the Changes in Annex 11

The Combined Impact of the new FDA Inspection Emphasis on Data Integrity and the new Annex 11 Requirements - Harmonisation or Divergence?

Bob McDowall

- Overview of the Annex 11 requirements for data integrity: e.g. security, audit trails, data entry and processing checks and data migration
- FDA's inspector training for computerised systems with the new focus on electronic records as paper output is incidental
- Compliance program guide (CPG) 7346.832 on Pre-Approval Inspections focuses on integrity of electronic records in submissions to the Agency

Management of Internal and External IT Service Providers

Klaus Eichmüller / Dr Wolfgang Schumacher

- What are the essential requirements from GMP perspective?
- Which are the differences in the management of internal and external service providers?
- Which internal departments are in the role of an IT service provider?
- Are there specific problems, if the service provider is an affiliate, the parent or the sister company?
- Examples for / content of SLAs

Definition of Raw Data regarding Annex 11

Eberhard Kwiatkowski

- Regulations
- Who defines raw data?
- Consequences of the own definition?
- What are the problems when archiving raw data?
- Are electronic data raw data even if they don't have any significance (e.g. data from HPLC detectors)?

Use of Mobile Devices in a GxP Environment

Dr Wolfgang Schumacher

- Regulations
- Tablets, I-Pad, Smartphones
- Security concepts
- I-Pad vs. Windows 8 Tablet PCs

Programme cont'd

ERP Systems and Annex 11
Karl-Heinz Menges / Dr Jörg Schwamberger
- What kind of challenges are caused by GMP-regulated and non-GMP-regulated parts of ERP?
- How to orchestrate management of business processes and enterprise data during validation?
- Local versus cross-site Validation
- Special considerations for data migration and interface validation (e.g. LIMS, MES, LLS, etc.)
- Handling of other Business Software (e.g. CRM, SRM, BI, MDM Systems)
- Regulatory expectations – what's inspections practice?
- GMP-compliant operation – what is expected?
- Tips for the usage of tools (e.g. Test Tools, Document Management)

Audit Trail Review – Annex 11 Requirements
Karl-Heinz Menges / Frank Behnisch
- Technical prerequisites?
- What's written in Annex 11?
- What to check?
- How often is regularly?
- Who should do the review?
- How to check?
- Could tools be used? If yes, which are suitable?

Track and Trace / Serialisation from the IT Point of View
Frank Behnisch
- History serialisation
- Different demands
- Serialisation
- Track & Trace
- Perspective

IT Infrastructure
Jens Seest / Knud Ryhl
IT infrastructure covers a variety of technologies and solutions. IT infrastructure is also an area where the technological development is changing in a rapid pace. As pharmaceutical companies at the same time are changing business models to become more patient centric this sets new challenges for how to stay in compliance and maintain record integrity, availability and confidentiality. How to manage the challenges as a regulated company and stay in control when more and more activities are taking place outside the regulated company ?
- IT infrastructure examples and cases
- Technological development, what are the trends going from the past years and into the future?
- The challenges operating in a complex and integrated environment
- The controls necessary to have in place for a regulated company - how to enforce them towards the suppliers ?
- The expectations from a regulatory point of view - what if the regulated company cannot explain all the technical details ?
- The regulatory development within this field - will there be IT infrastructure inspection experts?

Change Management
Audny Stenbraten / Yves Samson
- PQS and change control system
- Types of change (planned/unplanned/temporary/permanent)
- Registration and handling of changes (responsibilities)
- Risk impact and consequences of a change (QRM) (prospective or retrospective)
- Paper or electronic change control system
- Implementation of a change
- Evaluation of a change

Simulation of a real Inspection with Focus on an electronic Deviation Tool
Dr Christa Färber / Eberhard Kwiatkowski
- Golden rules – how to behave in an inspection
- Responsibilities
- Preparing an inspection
- Recommendations for conducting an inspection
- Presentation of the electronic deviation tool
- Simulation of the inspection

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).

MICHAEL WEGMANN, *F. Hoffmann-La Roche Ltd., Basel, Switzerland*
Since 1989, Michael Wegmann has been working as IT expert in the pharmaceutical industry. From 2000 to 2011, he was globally responsible for IT security in the Roche Pharmaceuticals Division. In his current role as Global Head of Integration Competency Center, he is responsible for system integration (EAI), interfaces and middleware in the Roche Diagnostics Division.

Easy Registration

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CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg, Germany

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info@concept-heidelberg.de

Internet:
www.gmp-compliance.org

Date Pre-Conference Workshops
Tuesday, 4 June 2013, 09.00 – 12.00 h
(Registration and coffee 08.30 – 09.00 h)

Date Conference
Tuesday, 4 June 2013, 13.15 – 18.00 h
(Registration and coffee 12.30 – 13.15 h)
Wednesday, 5 June 2013, 08.30 – 17.00 h

Venue
nh-Hotel Constanza
C/Deu i Mata, 66-69
08029 Barcelona, Spain
Phone +34 93 2811500
Fax +34 93 2811525

Fees Workshop*
ECA Members € 290.-
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The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first day, lunch on both days 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 when you have registered for the event. Please use this form to receive the specially negotiated rate for the duration of your stay. 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.

*per delegate plus VAT

Conference language
The official conference language will be English.

Organisation and Contact
CONCEPT HEIDELBERG
P.O. Box 10 17 64
D-69007 Heidelberg, Germany
Phone +49 (0) 62 21/84 44-0
Fax +49 (0) 62 21/84 44 34
info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content:
Dr Andreas Mangel (Operations Director)
at +49-62 21/84 44 41, or per e-mail at
mangel@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc.:
Ms Marion Grimm (Organisation Manager)
at +49-62 21/84 44 18, or per e-mail at
grimm@concept-heidelberg.de.

Social Event

On 4 June, 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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4-5 June 2013, Barcelona, Spain

☐ **Pre-Conference Workshops**
4 June 2013, Barcelona, Spain

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☐ Writing testable and verifiable User Requirements Specifications
☐ Cloud Computing in GxP Environments
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