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Data Integrity

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This conference is part of the
2019 PHARMA CONGRESS Production & Technology
DÜSSELDORF, 9 - 10 APRIL 2019
www.pharma-congress.com

9/10 April 2019, Düsseldorf/Neuss, Germany

SPEAKERS


IB ALSTRUP
Danish Medicines Agency


KLAUS EICHMÜLLER
Wolnzach, c/o Regional Council Darmstadt, GMP Inspectorate, Germany


DR PHILIP HÖRSCH
Vetter Pharma-Fertigung


DR GERALD KINDERMANN
F. Hoffmann-La Roche


DR THOMAS MEINDL
Labor LS


THOMAS REINER
Berndt+Partner


KNUD RYHL
Novo Nordisk


GABRIELA SCHALLMEINER
Austrian QP Association


YVES SAMSON
ECA Data Integrity & IT Compliance Interest Group


STEFAN SCHOETTLE
Roche Diagnostics


DR ARNO TERHECHTE
Bezirksregierung Münster

HIGHLIGHTS:

- Inspector's point of view:
  - Data Integrity in manufacturing
  - Audit Trail and Audit Trail Review
  - Data integrity training systems
- Data Integrity from a QP's perspective
- Data Integrity in manufacturing and engineering
- Data Integrity requirements to technical suppliers
- Case studies from
  - Labor LS
  - Novo Nordisk
  - Roche Diagnostics
  - Vetter Pharma-Fertigung

Data Integrity

Objectives

- You will get a deeper understanding what European inspectors expect from pharmaceutical companies in regard to Data Integrity.
- You will learn how to prepare your company for an successful inspection in regard to Data Integrity.
- You will learn how to investigate Data Integrity issues in your company especially in manufacturing and engineering.
- You will discuss suppliers' responsibilities in Data Integrity compliance.

Background

Even though Data Integrity has been one of the basic GMP principles for years, multiple Data Integrity citations have been reported by FDA und European inspectors during the last 3 years. Many US Warning Letters and EU Non-Compliance Reports deal with serious Data Integrity violations. Data Integrity questions have been and will continue to be the focus of many GMP inspections. As a consequence international authorities – FDA, EMA, PIC/S, WHO, MHRA - published (draft) documents to describe the regulatory expectations of Data Integrity.

Although all guidelines are not intended to impose additional regulatory burden to the regulated companies, a lot of uncertainty predominates the pharmaceutical industry how to implement these requirements into the daily business and how to integrate suppliers' experience.

Target Audience

- Managers & staff from manufacturing, QA and engineering of pharmaceutical companies and suppliers.
- Auditors (internal and external) responsible for performing self-inspections or external audits and needing to understand and assess data integrity.

Moderator

YVES SAMSON, *ECA Data Integrity & IT Compliance Group*

Programme — 9 Apil 2019

Congress Key Note

Pharmaceutical industry in digital change

- Changes in the value chains
- Opportunities and risks for production processes
- What can and will change for packaging?
- Strategies to benefit from change

THOMAS REINER, *CEO, Berndt+Partner*

Data Integrity in manufacturing and engineering environments - Another source of weaknesses or Compliance by Design?

- Identifying applicable data integrity requirements
- Design review: how to promote and to secure compliant design
  - Product, process, data, system
- Securing data integrity during the engineering and commissioning activities
- Necessity to rely on secure and robust IT infrastructure

YVES SAMSON, *ECA Data Integrity & IT Compliance Group*

Requirements in Data Integrity

- Data Integrity – Data species & ALCOA principles
- Hot topic - Myths Critical factors for DI program
- DI problems
- Case study DI in the manufacturing area System / data mgmt.
- User set up

DR GERALD KINDERMANN, *F. Hoffmann-La Roche*

Requirements for Operating Computerized Systems and Data Management

- Data Integrity: Definitions and requirements for operating computerized systems
- Risk-based evaluation of data management (data input and output during operation) and follow-up activities for application (e.g. data review)
- Application of data management evaluation in case of new system acquisition and for assessment of existing systems
- Examples from quality control and manufacturing (aseptic, secondary packaging)

DR PHILIP HÖRSCH, *Vetter Pharma-Fertigung*

Data Integrity from a QP's Perspective

- The Regulatory Pillar
  - Regulatory baseline on data integrity
  - Regulatory Impact on the Qualified Person (QP)
- The Qualified Person's "Data" Challenge
  - Quality Management (QM) System Fundamentals
  - How GMP documents/data are related
- Make Data Integrity Integral to a Qualified Person's Daily Work
  - Data Integrity Impact on the QP
  - What gives a QP the confidence to certify a batch

GABRIELA SCHALLMEINER, *Austrian QP Association*

How QA can check for data integrity in electronic systems

- A practical approach to data integrity
- Examples of where to look for applied data integrity
- How to approach data integrity when you have no clue of where to start
- Computer systems are manageable

KNUD RYHL, *Novo Nordisk*

Inspecting DI in Manufacturing – what does an inspector expect?

- Regulatory Update (Chapter 4, Annex 11, PIC/S Guidance Good Practices for Data Management and Integrity)
- Definitions of Data, Raw Data, original data in Manufacturing
  - Aggregation of Data
  - Paper Records versus Continuous Monitoring / E-Records
- Upgrade / Modernizing the QMS with regard to Data Integrity
- Self Inspection, Assessment, Data Flow Analysis
- Data Integrity with regard to Outsourced Activities
- Data Integrity during Inspection / Inspection Findings

DR ARNO TERHECHTE, *Bezirksregierung Münster*

The Social Event at the Pharma Congress is already a tradition, and is networking and relaxation at the same time.

On the evening of the first congress day, on 9 April 2019, all congress delegates and speakers are invited to a „Get together" in the Congress Center. Take advantage of this opportunity for an information exchange and enjoy the laid-back atmosphere and the entertainment programme.

Programme — 10 Apil 2019

Congress Key Note

EU GMP Inspection in Sterile/ Aseptic Production

- Main focus areas of inspections
- Frequently detected findings
- Data Integrity issues – where are possible weak spots?
- Possible new areas due to the revision of Annex 1 and further regulatory changes

KLAUS EICHMÜLLER, *Wolnzach, c/o Regional Council Darmstadt, GMP Inspectorate, Germany*
Head of Inspectorate

Data Integrity requirements to technical suppliers - Expectations to equipment suppliers and engineering service providers

- Regulatory management: knowing and understanding regulatory requirements
- Configurability to support customer process requirements
- System design expectations
- Cybersecurity requirements and constraints for equipment
- Effective support of review activities

YVES SAMSON, *ECA Data Integrity & IT Compliance Group*

Audit trail functionality and review – expectations from an inspector

- Good documentation practice
- Qualities of the audit trail functionality
- Qualification of the audit trail functionality
- Audit trail review

IB ALSTRUP, *DMA*

Expectations of an inspector on a training system with respect to data management

- Introduction
- Expectations on the system
- Expectations not met - examples

KLAUS EICHMÜLLER, *Wolnzach, c/o Regional Council Darmstadt, GMP Inspectorate, Germany*

A Paperless Lab, a Good Idea for Data Integrity, Risk Minimization and Lean Management?

- Data integrity by avoidance of human errors by use of electronic data evaluation and documentation.
- Minimization of contamination risk due to contaminated paper
- Optimization and reduction of errors by implementation of electronic workflows
- Paper management: avoidance of excessive use of prints in order to save space in physical archives

DR THOMAS MEINDL, *Labor LS*

Data Integrity Assessment Manufacturing: Preparation, Conducting and Remediation Activities

- Authorities focus
- Corporate Guidelines
- Assessment Project
- Best practises
- Challenges

STEFAN SCHOETTLE, *Roche Diagnostics*

Speakers

IB ALSTRUP, *Danish Medicines Agency*
From 2002 – 2016 with Novo Nordisk (I.e. Principal Specialist, Lead Auditor Supplier Audits / GLP and GCP Audits). Since 2017 inspector at the Danish Medicines Agency.

KLAUS EICHMÜLLER, *Wolnzach, c/o Regional Council Darmstadt, GMP Inspectorate, Germany*
He was Deputy Head of the Central Authority for Supervision of Medicinal Products in Bavaria as long as it existed and has now been Head of the Inspectorate for Drug Products, APIs, Blood Products and Tissues in Hesse since March 2014.

DR PHILIP HÖRSCH, *Vetter Pharma-Fertigung*
Between 2004 and 2015 as Project Manager Microbiology, Team and Site Manager Quality Operations at Vetter. Since 2015 Director Quality Assurance for (Process-) Validation, Risk Management, Trending, IT-Systems, IPC/Visual Inspection Systems and Specification Management Packaging Materials.

DR GERALD KINDERMANN, *F. Hoffmann-La Roche*
Dr Kindermann joined Roche in 1996. From 2001 to 2003 he led the group for the control of incoming packaging materials where he was responsible for release analysis of packaging materials and the technical control of all packaging materials. After that he was responsible for packaging materials as Quality Manager. In 2008 he joined the Global Quality group at Roche, currently working as Head Network Support, focusing on project- and knowledge management.

DR THOMAS MEINDL, *Labor LS*
Thomas Meindl is a trained biologist who performed his PhD on novel peptide receptors at the FMI (Novartis) in Basel, Switzerland. From there he moved to a drug discovery company (Sympore, Germany) in order to discover new drug entities (patent in 2002). Then he performed clinical studies for skm oncology, Germany, until he moved to Labor L+S AG, Germany, in 2005. Here he has been working as division manager of various departments (Assays, Endotoxins, R&D, Molecular biology, disinfectant testing and computerized systems) until today.

THOMAS REINER, *Berndt+Partner*
Thomas Reiner is a managing partner and has been with Berndt+Partner for over 25 years. He is also Chairman of the Board of the German Packaging Institute and a member of the Board of the World Packaging Organisation.

KNUD RYHL, *Novo Nordisk A/S*
20 years of experience from pharma industry. Knud Ryhl has worked with qualification/validation for several years, then trained to be a GMP auditor, and has gained experience with legislation being a medicines inspector for the DKMA (Danish Medicines Agency) for 7 years. As part of DKMA Knud Ryhl participated in the group formulating the current annex 11. Since 2013 Knud Ryhl has acted as a consultant, been project quality manager for a large construction project where tasks were to assure that the project when finished comply to authority expectations. For the last 2 years Knud Ryhl has been a Senior Lead Auditor for Novo Nordisk.

GABRIELA SCHALLMEINER, *Austrian QP Association*
Gabriela Schallmeiner is Qualified Person (QP) and founding member and deputy chair of the Austrian Qualified Person Association. Since 2007 she has been running her own consultancy business, and is currently active as a QP in Austria and Germany [§15(3)]. Before that she was Head of Quality Control, Head of Quality Management, Head of External Manufacturing and Qualified Person at AFFiRiS.
She started her career at Nycomed (now Takeda) as Head Microbiology, Head of Biochemical Testing and Head of Animal Testing at the Quality Control department. Since then, she has held several quality management, compliance, quality control and manufacturing leadership positions at Baxter BioScience (now Shire), Wyeth (now Pfizer), and Biotec start-ups in the fields of life sciences and medical devices. She served many years as responsible person according to GDP, as GxP auditor and as a QP.

YVES SAMSON, *ECA Data Integrity & IT Compliance Interest Group*
Automation and system engineer with over 25 years experience, including 11 years as regulated user, Yves is the founder of Kereon AG, Basel. He supports his customers as consultant, trainer, and e-compliance auditor. He is member of GAMP Europe Steering Committees, chairman and co-founder of GAMP Francophone. He edited the French version of GAMP 4 and GAMP 5. In 2017, Yves launched the e-Compliance Requirements Initiative (eCRI) with the aim to help the regulated pharmaceutical industry and its suppliers to address and to implement accurately, consistently, and effectively the regulatory e-Compliance requirements.

STEFAN SCHOETTLE, *Roche Diagnostics GmbH*
After his studies of computer science, he started his career at Roche Mannheim in 1987. Stefan has held several management positions in Diagnostics IT Mannheim before he took over the position of Head of Informatics Pharma Manufacturing Mannheim. From Oct 2016 until December 2017 he was responsible for the data Integrity assessment of all Roche/ Genentech sites as a global project manager.

DR ARNO TERHECHTE, *Bezirksregierung Münster*
After 5 years in the pharmaceutical industry Dr Terhechte was with the Bezirksregierung Düsseldorf from 1998 until 2003. Since 2003 he has been inspector in the Bezirksregierung Münster. Arno Terhechte is member of the German expert group 11 "computerised systems".

Easy Registration

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Date
Tuesday, 9 April 2019, 09.00 – 17.45 h
Wednesday, 10 April 2019, 09.00 – 17.00 h
(Registration: Monday, 8 April 2018, 19.00 – 20.00 h,
Tuesday, 9 April 2019 & Wednesday, 10 April 2019, 08.00 – 09.00 h)

Venue
Crowne Plaza Düsseldorf / Neuss
Rheinallee 1
D-41460 Neuss, Germany
Phone: +49 (0) 2131 77 - 00
E-mail: emailus.neu02@gchhotelgroup.com

Fee
EUR 690.- per delegate and day plus VAT (EUR 1,380.- for both days) (due to the special congress fees, ECA membership discounts are not applicable, and participation does not entail ECA membership).
The conference fee is payable in advance after receipt of invoice and includes lunch on that day/both days, beverages during the event and during breaks as well as the Social Event on 9 April. VAT is reclaimable.

Your registration also entitles you to participate in all other Pharma Congress conferences on either day of your registration. For the other conferences on both days please visit www.pharma-congress.com.

Registration
Via the reservation form below, by e-mail or by fax message. Or you register online at www.pharma-congress.com.

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Please note that there will **not be any print-outs** at the Congress. Instead you will receive all presentations prior to the Congress as Downloads. All Congress delegates (excluding exhibition visitors) will also receive the presentations on a USB stick at the registration center.

Please further note that there will be no room reservations via Concept Heidelberg. Please book your **hotel room directly with the reservation form** which you will receive together with your confirmation/invoice! Charges are payable after receipt of the invoice.

Organisation & Contact
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Data Integrity (9-10 April 2019)

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Düsseldorf/Neuss, Germany, 9-10 April 2019

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☐ Data Integrity (9 April 2019 – € 690)
☐ Data Integrity (10 April 2019 – € 690)
☐ Both days (9-10 April 2019 – € 1,380)*

☐ Yes, I would also like to participate in the Social Event on 9 April.

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