ECA Academy
Your GMP/GDP Information Source

Speakers


Sinéad Cowman
Lonza


Dirk Denecke
Bayer


Hannah Greiner
Epista Life Science


Dr Philip Hörsch
Vetter Pharma-Fertigung


Maria Kladi
National Organization for Medicines, Greece


Günther Kurta
Boehringer Ingelheim RSV


Matthias Runge
Bayer


Yves Samson
ECA Data Integrity & IT Compliance Interest Group


Stefan Schoettle
Roche Diagnostics


Dr Arno Terhechte
Bezirksregierung Münster


Dr Ruud van Stigt
Curium


Francois Vandeweyer
Form. Janssen Pharmaceutica


Thomas Wibbeling
Miltenyi Biotec

Data Integrity

Part of Pharma Congress 2020

15/16 September 2020 | Düsseldorf/Neuss, Germany

Highlights

- Inspector's point of view:
  - Data Integrity in manufacturing
  - Audit Trail and Audit Trail Review
- Data Integrity by design
- Data Integrity in manufacturing and engineering
- Data Integrity and validation
- Case studies from
  - Bayer
  - Boehringer Ingelheim
  - Curium
  - Fresenius
  - Lonza
  - Miltenyi Biotec
  - Roche Diagnostics
  - Vetter Pharma-Fertigung

This conference is part of
2020 PHARMA CONGRESS Production & Technology

Objective

- You will get a deeper understanding what European inspectors expect from pharmaceutical companies in regard to Data Integrity and how they deal with Data Integrity issues during inspections
- You will learn how to prepare your company for a 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 5 years. Many US Warning Letters and EU Non-Compliance Reports deal with serious Data Integrity violations. Data Integrity questions have been and will continue 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 and 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 Interest Group

Social Event

On the evening of the first congress day, on 15 September 2020, 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 – 15 September 2020

Keynote
Annex 1 Revision – the long and winding road
Dr Bernd Renger, Immediate Past Chair, European QP Association

- The drivers of change
- New paradigms and concepts
- Contamination Control und Quality Risk Management
- Stakeholder consultation
- New expectations to Media Fills and Lyophilisation
- The big challenges – CCIT and PUPSIT

Data Integrity from an Inspector's Point of View
Maria Kladi, National Organization for Medicines, Greece

- Data integrity and Good Documentation Practice
- Principles of Data Integrity
- WHO/FDA/MHRA Data Integrity Guidances
- Examples of Data Integrity issues

Data Integrity by Design
Stefan Schoettle, Roche Diagnostics

- Systems, Processes, Organizations
- Data Lifecycle based measures
- Best practice (dos and don'ts)
- Challenges today
- Available and emerging technologies

DI as topic of GMP-inspections; an inspector's view
Dr Arno Terhechte, Bezirksregierung Münster

- Specific documents requested during preparation of an inspection
- How DI is addressed in the Quality Management resp. Data Governance system
- What is the company-specific definition of data (GxP-Data)?
- Specific activities during implementation / operation of computerized GxP systems (risk management, validation approach, backup, archiving, rolls and responsibilities)
- Data Flow in manufacturing and quality control
- Ensuring Compliance with regard to DI at service providers and contract manufacturers / labs
- Inspection findings

CASE STUDY – A risk based approach for systematic DI-assessments and -mitigation
Hannah Greiner, Epista Life Science

- How to get started with DI gap assessments
- How to set up a systematic DI assessment approach
- How to document DI assessments
- How to identify high risk DI gaps that need immediate mitigation
- How to define a risk-based mitigation strategy
- Experiences with this risk based approach during a CS inspection by Austrian Authorities (AGES)

Requirements for Operating Computerized Systems and Data Management
Dr Philip Hörsch, Vetter Pharma Fertigung

- 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)

Data Integrity Compliance Improvement: A Combined Approach to Mitigation
Matthias Runge / Dirk Denecke, Bayer

- Challenges of a gap-based approach to ensure data integrity for a large number of computerized systems
- Ensuring data integrity with a general set of mitigation measures
- General mitigation measures combined with gap-based approach
- Practical experiences

Programme – 16 September 2020

Keynote „Case Study AbbVie: The new Biologics Site in Singapore“
Dr. Rolf Ratke, AbbVie
Ronan McGarvey, AbbVie

- The Site strategy
- Products, processes & equipment
- Cooperation with EMA, blueprint to prepare for the successful pre-approval-inspection
- From start- up to realization until approval

Data Integrity implementation at Curium
Dr Ruud van Stigt, Curium

- Intro Curium, the Nuclear Medicine company
- Direct Cause for follow up the program
- Why are we doing this
- Remediation plan
- What is next, where are we standing

Practical applications of Data Integrity and Audit Trail Review
Sinéad Cowman, Lonza

With the intro of the Data Integrity guidelines and the focus on the data management and security, the audit trail has become a primary focus of inspections. Understanding your Audit trail and the ability to review the data contained in it is now essential to compliance.

- Recommendations in understanding the audit trail functionality and approaches for validation.
- Importance of details of user requirements and user acceptance testing of audit trail functionality
- Review of the audit trail: System review vs Data review & Event logs vs. audit logs
- Identify and avoid typical pitfalls

Practical Examples found and case studies on how to challenge DI potential issues
Swa Vandeweyer, form. Janssen Pharmaceutica

- Introduction and real life examples
- Practical challenges on potential DI issues in Production, Calibration, Quality Organisation,....

Data Integrity in the interaction between business departments and IT as service provider
Thomas Wibbeling, Miltenyi Biotec

- Aspects of Data Integrity and their translation into „tangible“ requirements
- Data Integrity and its implementation in SLAs between business units and IT
- IT strategy as a provider of shared services for the regulated environment

Data integrity from engineering to operations based on Comos DDMS at Boehringer Ingelheim”
Günther Kurta, Boehringer Ingelheim

- How to validate a complex engineering tool landscape according to EU GMP Annex 11 and 15
- Change management (working layer technique)
- Assisted engineering document and data management (e.g. object-oriented engineering templates, IEC document classification, flexible unique tags)
- Approval workflows and electronic signature (CFR 21 Part 11)
- Electronic plant documentation (incl. full text search, redlining)
- Plant maintenance interface
- Future scenarios (brownfield enablement, scanning solution, intelligent P&ID)

Data Integrity and Process Validation: a virtuous circle
Yves Samson, ECA Data Integrity & IT Compliance Interest Group

- How much data are needed?
- Understanding the process
- Reporting validation
- Securing data integrity

Speakers

Sinéad Cowman, Lonza

She joined Lonza in 2005 to manage their endotoxin business in Ireland and for the past 7 years has been involved in their informatics division.

Dirk Denecke, Bayer AG

Dirk has 6 years of experience in the QA department of an API manufacturer and 5 years as business consultant with a focus on CSV and implementation of GxP-compliant IT systems in the life science industry. Since 2015 he focuses on data integrity topics which lead him in 2019 to his current position as a QA specialist at Bayer's Supply Center Berlin.

Hannah Greiner, Epista Life Science

Ms. Greiner is Senior Consultant at Epista Life Science. Prior to that she was heading the Quality Assurance department of the Innovation & Development Center in Graz and was responsible for the site's GxP compliance related to development of pharmaceuticals and combination products for EU, US and PhM markets, as well as subsequent upscaling and transfer to commercial production sites.

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.

Maria Kladi,National Organization for Medicines, Greece

Maria has been working for the last 10 years as GMP Inspector at the National Organization for Medicines in Greece.

Günther Kurta, Boehringer Ingelheim RSV

More than 20 years with Boehringer Ingelheim and now Head of technical documentation.

Matthias Runge, Bayer AG

Matthias has 17 years of experience with manufacturing IT for the pharmaceutical industry. He started his career at former Schering AG and then transferred to a global function at Bayer AG. Matthias has long-term experience with managing the development, implementation and roll-out of Manufacturing Execution Systems. Since 2018 he is leading the data integrity mitigation program for computerized systems at Bayer's Supply Center Berlin.

Yves Samson, ECA Data Integrity & IT Compliance Interest Group

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.

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 October 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 he was from 1998 – 2003 in the Bezirksregierung Düsseldorf. Since 2003 he is inspector in the Bezirksregierung Münster. Arno Terhechte is head of the German expert group 11 “computerised systems” and member of the APV special interest group “Information Technology”.

Dr Ruud van Stigt, Curium

IT management with a detail understanding of GXP regulations. Responsible for EU SPECT, PET and radiopharmacies from an IT Manufacturing responsibilities.

Francois Vandeweyer, Form. Janssen Pharmaceutica

Francois Vandeweyer is Director Pharmaceutical Regulatory Compliance EMA/APAC. He has also started his own Consultancy office (VDWcGMP consulting GCV).

Thomas Wibbeling, Miltenyi Biotec

Over 15 years experience in the pharmaceutical and biotechnology industry as manager CSV in IT and QA. Among others at Schwarz Pharma, UCB, Aesica Pharmaceuticals, Grünenthal and Miltenyi Biotec.

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GERMANY

Reservation Form (Please complete in full)

Data Integrity, 15/16 September 2020, Düsseldorf/Neuss

Part of the Pharma Congress Production & Technology, 15/16 September 2020 – I would like to register for the following days:

☐ *Data Integrity Day I – 15 September 2020 (EUR 690.- plus VAT)*

☐ *Data Integrity Day II – 16 September 2020 (EUR 690.- plus VAT)*

☐ *Data Integrity Day I and Day II – 15/16 September 2020 (EUR 1,380.- plus VAT)*

☐ *I would also like to participate in the Social Event on 15 September 2020*

Title, first name, surname

Department | Company

Important: Please indicate your company's VAT ID Number | Purchase Order Number, if applicable

City | ZIP Code | Country

Phone / Fax

E-Mail (Please fill in)

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 %,
- Cancellation until 1 weeks prior to the conference 50 %
- Cancellation within 1 week prior to the conference 100 %.

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If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. CONCEPT HEIDELBERGwill not be responsible for discount airfare penalties or other costs incurred due to a cancellation.
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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)! (As of January 2012).
German law shall apply. Court of jurisdiction is Heidelberg.

Privacy Policy: By registering for this event, I accept the processing of my Personal Data. Concept Heidelberg will use my data for the processing of this order, for which I hereby declare to agree that my personal data is stored and processed. Concept Heidelberg will only send me information in relation with this order or similar ones. My personal data will not be disclosed to third parties (see also the privacy policy at http://www.gmp-compliance.org/eca_privacy.html). 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.

Date
Tuesday, 15 September 2020, 09.00 – 17.45 h
Wednesday, 16 September 2020, 09.00 – 17.00 h
Registration:
Monday, 14 September 2020, 19.00 – 20.30 h,
Tuesday, 15 September 2020, 08.00 – 09.00 h
Wednesday, 16 September 2020, 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@cphotelduesseldorfneuss.com

Fees
EUR 1,380.- for both days plus VAT
(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 15 September. 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, by e-mail or by fax message.
Or you register online at www.pharma-congress.com.

Please note
There will be no print-outs at the Pharma Congress. All documentation will be provided prior to the Congress in a download are and via the Pharma Congress app.
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.

Conference language
The official conference language will be English.

Organisation and Contact
ECA has entrusted Concept Heidelberg with the organisation of this event.

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