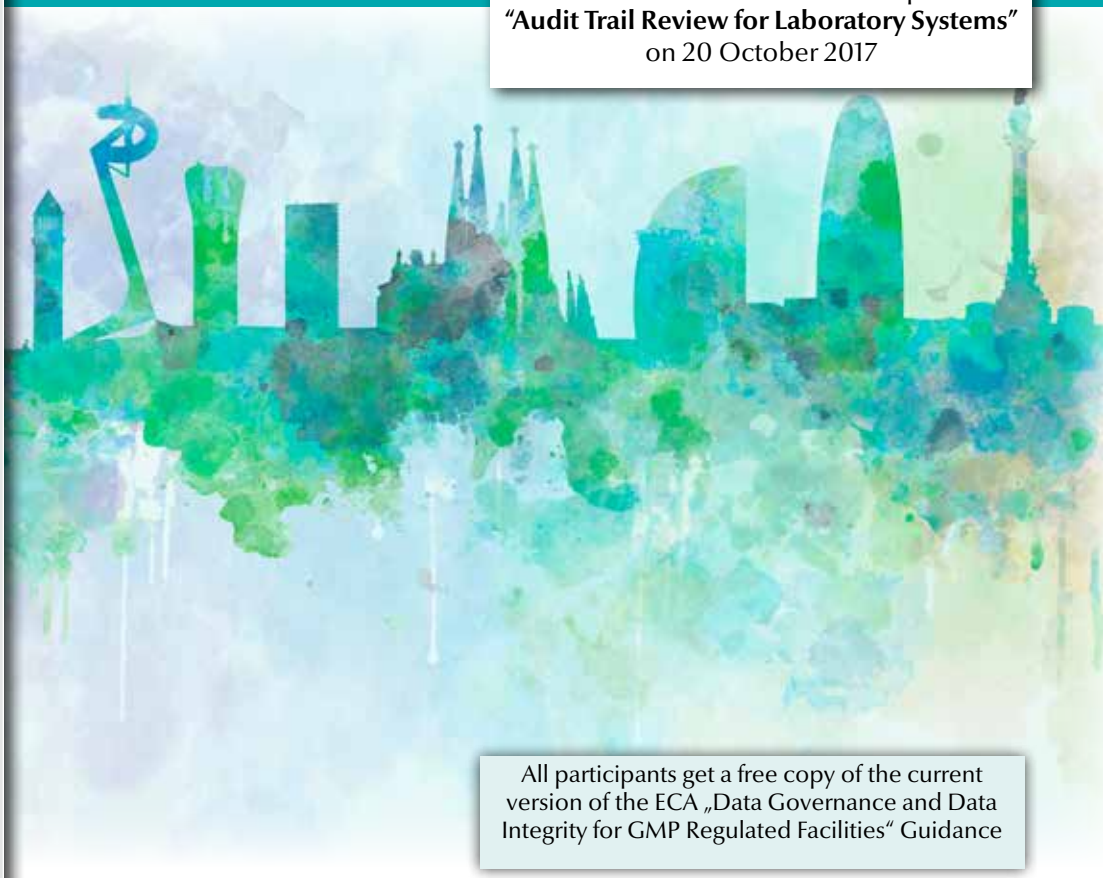
Lab Data Integrity Conference

Post-Conference Workshop
"Audit Trail Review for Laboratory Systems"
on 20 October 2017



All participants get a free copy of the current version of the ECA „Data Governance and Data Integrity for GMP Regulated Facilities" Guidance

18-19 October 2017, Barcelona, Spain

Highlights

- Introduction – Laboratory Data Integrity: Where Are We Now?
- Regulatory Requirements and Expectations of a European GMP Inspector
- Mitigating Data Integrity Risks in Pharmaceutical Manufacturing
- Metrics for Laboratory Data Integrity
- Case Study: Data Integrity from Research to Manufacturing: Balancing Analytical Science and Regulatory Compliance
- Instruments with Integrated Software and Data Integrity
- Scope and Detail of a Second Person Review
- Using Data Flow Mapping to Identify Data Integrity Concerns
- Data Integrity: An Instrument Suppliers Perspective
- Data Integrity Audits – An Analytical Perspective
- Laboratory Control Systems: how to prevent Data Integrity Violations
- Review of the GAMP Guide: Records and Data Integrity

Speakers:

Gunnar Danielson
Mettler Toledo GmbH, Switzerland

Dr Markus Dathe
F. Hoffmann-La Roche, Switzerland

Travis Frick
GlaxoSmithKline Vaccines, Belgium

Dr Bob McDowall
ECA Data Integrity Working Group, R D McDowall Ltd

Dr Danilo Neri
PQE, Italy

Dr Siegfried Schmitt
PAREXEL International, UK

Dr Franz Schönfeld
GMP Inspector, Government of Upper Franconia, Germany

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

Background/ Objectives

Data integrity in the GMP analytical laboratory continues to be **THE** major global topic amongst both regulatory agencies, pharmaceutical companies and suppliers. Although the headlines are still gabbed by warning letters and non-compliances involving cases of falsification and fraud from a minority of organisations this is the tip of the iceberg. The majority of data integrity issues seen in warning letters and 483 observations are still due to poor data management practices where records created are not adequately documented, electronic records that are poorly protected or not protected at all and / or there is still a reliance on paper printouts from computerised systems as raw data.

Since 2015 there has been a tsunami of regulatory guidance and advice from MHRA, FDA, WHO, PIC/S, EMA and even the Chinese FDA. In addition, ECA have issued a draft guidance for comment and the April 2017 release of the GAMP guidance on Records and Data Integrity that is a companion to GAMP® 5. Do these guidances say the same things or are there contradictions? How should laboratories and suppliers respond to the WHO suggestion that „replacement of hybrid systems should be a priority"?

The second Laboratory Data Integrity conference is designed to present, from a practical perspective, the following areas:

- Laboratory data integrity where are we now?
- Regulator talk
- Review of the GAMP Guide on Records and Data Integrity
- Scope of the Second person review
- Instruments with integrated software – quo vadis?
- Data integrity audits
- Data integrity from research to manufacturing
- Developing metrics for laboratory data integrity
- Using data flow mapping to identify data integrity concerns
- Instrument Supplier's perspective of data integrity

In addition, there will be a **Discussion Forum** at the end of day 1 where all delegates will have the opportunity to ask specific questions to benefit from the speakers' experiences in this field.

Target Audience

The conference is intended for the technical and managerial personnel who deal with data integrity issues including analytical development and quality control analytical laboratories in pharmaceutical companies, contract research and manufacturing organisations. QA personnel responsible for quality oversight of data integrity work will also find the conference invaluable.

Moderator

Dr Bob McDowall, R D McDowall Ltd, Bromley, Kent, UK

Programme

Introduction – Laboratory Data Integrity: Where Are We Now? ⏩ *Dr Bob McDowall*

- Overview of data integrity since October 2016 conference
- Warning letter update
- Regulatory guidance update
- GAMP Guide on Records and Data Integrity

Regulatory Requirements and Expectations ⏩ *Dr Franz Schönfeld*

- Legal requirements, European and international guidelines and guidance documents
- Case study: data integrity in the quality control lab and how it relates to the continuous improvement process
- Inspection findings

Mitigating Data Integrity Risks in Pharmaceutical Manufacturing ⏩ *Travis Frick*

- What is "data integrity"?
- What is "metadata"?
- What primary data integrity risks are associated with data systems (paper, electronic, and hybrid)? How can these risks be mitigated?
- How can manipulation of electronic records be detected?
- What are the requirements of/best practices for validating a computer system/ electronic records?
- What are the most important things for companies to do or recognize regarding manufacturing data integrity?

Programme

Metrics for Laboratory Data Integrity ⏩ *Dr Bob McDowall*
- What are metrics?
- Metrics will change throughout a data integrity programme: assessment and remediation phases
- Suggested metrics for routine chemical analysis

Case Study: Data Integrity from Research to Manufacturing: Balancing Analytical Science and Regulatory Compliance ⏩ *Dr Markus Dathe*
- Patient safety, freedom of research and speed to market: the dilemma of development
- DI in the development lifecycle – phase appropriate requirements
- Is it just regulations or common sense?
- The TITO principle and how to avoid it
- Benefits of data integrity measures
- Data ownership as a key prerequisite for DI compliance

Instruments with Integrated Software and Data Integrity ⏩ *Dr Markus Dathe*
- The new USP <1058> and the Lab Instrument classes
- The class B and Data Integrity
- The hubris of hybrids – paper complicates everything!
- Criticality: how critical is critical?

Scope and Detail of a Second Person Review ⏩ *Dr Bob McDowall*
- US and EU regulatory requirements for second person review
- Responsibilities and SOP for the review
- Key requirement for the review: objective evidence
- Paper record review
- Hybrid system review problems
- Electronic system set up – is the software up to the job?
- Assays where second person review can be problematic

Using Data Flow Mapping to Identify Data Integrity Concerns ⏩ *Travis Frick*
- What is 'Data Flow Mapping'?
- How to execute 'Data Flow Mapping'?
- The benefits of 'Data Flow Mapping'
- Examples of 'Data Flow Mapping' detecting data integrity concerns

Data Integrity: An Instrument Suppliers Perspective ⏩ *Gunnar Danielson*
- The extent to which all data are complete, consistent and accurate throughout the data lifecycle" – the lifecycle starts at the beginning – at the source of the data
- It's about the controls throughout the whole process
- Common misconceptions of benchtop instruments
- Start with correct data – finish well

Data Integrity Audits – An Analytical Perspective ⏩ *Dr Siegfried Schmitt*
- What to expect when preparing an audit for data integrity
- The analytical laboratory - from the clinical setting to the certified laboratory (50 shades of grey?)
- How to plan the audit (access to site, systems and records; length of audit, location of audit, etc.)
- Performing the audit (access to staff, access to systems and records - let the hunt begin!)
- From black holes to compliant records - where to draw the line?
- The audit report - explaining the unexplainable, the difficult and the obvious

Review of the GAMP Guide: Records and Data Integrity ⏩ *Dr Bob McDowall*
- Overview of the new guide
- Review and Discussion of key sections of the Guide:
  - Data governance framework
  - Data life cycle
  - Risk management
  - Management, development and operation appendices

Lab Data Integrity Conference, 18-19 October 2017, Barcelona, Spain

Programme

Laboratory Control Systems: how to prevent Data Integrity violations ⏩ *Danilo Neri*

- Strongly enforced Data Integrity Requirements in the latest 3 years by almost every Regulated Agency in the latest guidances issued by MHRA, WHO, FDA and recently by PIC/S.
- Particularly importance in the laboratory environment where data created within the analytical processes are relied upon to ensure the Product Quality
- Requirement to implement every control measure oriented to prevent Data Integrity violation either through automatic functionalities and interim manual procedures
- Need to routinely monitor the effectiveness of these measures in pharmaceutical companies

Post-Conference Workshop **Audit Trail Review for Laboratory Systems**, 20 October 2017

Programme

Why Is An Audit Trail and Its Review Important?

- Part 11 and Annex 11 / Chapter 4 requirements for audit trail
- Regulatory requirements for audit trail review
- Guidance documents for audit trail review
- Do I really need an audit trail?

What is in a Name?

- What do we look for in an application for auditing?
- Pros and cons for event logs and audit logs?
- Audit trail(s) ?
- Part 11 compliant system - does this help data integrity?

Workshop 1: Which Audit Trail to Review?

Attendees will be presented with an overview of the audit trails within an application and the content of each log. Which audit trails should be reviewed and when in the context of the work performed by the laboratory data system?

What are GMP-Relevant Data?

- Annex 11 requires that audit trails monitor GMP-relevant data – what are GMP-relevant data?
- Critical data?

Workshop 2: Identifying GMP Relevant Data

Attendees will be presented with a list of records to identify if they are GMP records and how critical they are to help focus the second person review of audit trail data.

Review of Audit Trail Entries

- What are we looking for in an audit trail review?
- Process versus system: avoiding missing data integrity issues
- Regulatory requirement is “frequent review” of audit trails
- What do we need to validate and what to check?
- Suspected data integrity violation - What do we need to do?

Workshop 3: Reviewing Audit Trail Entries

Attendees will be provided with the output of an audit trail to review and see if any potential issues are identified for further investigation.

Controls to Aid Second Person Review of Audit Trails

- Procedural controls for data review
- Technical considerations for audit trail review e.g.
  - Identifying data that has been changed or modified – how the system can help
  - Documenting the audit trail review has occurred
- Review by exception – how technical controls can help
- Have you specified and validated these functions?

Speakers:

Dr Bob McDowal, R D McDowall Ltd., Bromley, Kent, UK
Dr Markus Dathe, F. Hoffmann-La Roche AG, Basel, Switzerland

Speakers

Gunnar Danielson, Mettler Toledo GmbH, Switzerland
From computerized systems Gunnar has, for the past 7 years, focused specifically on laboratory workflow optimization and regulation compliance. At Mettler Toledo he leads a global group advocating for data integrity and workflow solutions. With the increased focus on benchtop instruments (source data), computerized systems and data integrity in the lab, he is involved in an increasing number of trainings, white papers, and seminars

Dr Markus Dathe, F. Hoffmann-La Roche AG, Basel, Switzerland
Analytical and Process Chemist, more than 20 years of practical experience in laboratory, quality and informatics functions. Markus held several positions in life sciences and pharma operations of Novartis since 1997, joined Siegfried in 2006 and is GMP coordinator in the chemical development and supply of Hoffmann-La Roche in Basel since 2011. He had been successfully leading the global projects like CDS, LIMS QMS.

Travis Frick, Head of Data Integrity and Analytics, GlaxoSmithKline Vaccines, Belgium
Travis has attended Lehigh University where he earned a bachelor's degree in Industrial Engineering and a master's degree in Management Science. He has gained operational manufacturing and Quality operations experience at both GSK and Novartis over his career. During his career Travis has worked very closely with data management and controls to deliver Data Integrity at varying levels of the organization. Travis brings international experience as well as first-hand experience to deliver data integrity remediation in a Global environment. He is currently leading the GSK Vaccines Data Integrity and Analytics activities based out of Wavre, Belgium.

Dr Bob McDowall, R D McDowall Ltd., UK
Analytical chemist with over 40 years' experience including 15 years working in the pharmaceutical industry; Bob has been a consultant for over 20 years. He has been involved with the validation of computerised systems for over 30 years and has recently published the second edition of Validation of Chromatography Data Systems. Bob is 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. He was a contributor to the GAMP Good Practice Guide for Validation of Laboratory Systems, second edition and is a core industry member of the GAMP Data Integrity SIG. He is an SME for input and review of the new GAMP Guide on Records and data Integrity.

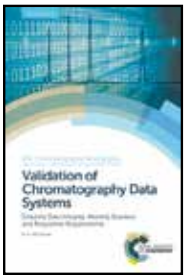
Dr Danilo Neri, PQE, Italy
In over 20 years of experience, Danilo has managed the validation process for the Computerised System used in the Life Science environment (e.g. ERP, MES, LIMS, EDMS, eCRF) focusing on Data Integrity requirements and he has supported the implementation of Quality Systems for the IT governance. As PDA-certified Auditor of Computer Products Suppliers, Danilo has executed many audits to Computer Products Suppliers. In the last years, he has presented a number of lectures related to Data Integrity in international congresses.

Dr Siegfried Schmitt, PAREXEL International, UK
Siegfried Schmitt has been working in industry and in consulting roles since 1989 and has performed well over a hundred audits around the globe. In his role as Principal Consultant with PAREXEL he supports clients in all matters of quality and compliance. He is the editor of the book "Assuring Data Integrity for Life Sciences", which has been published in English and in Chinese.

Dr Franz Schönfeld, GMP Inspector, Government of Upper Franconia, Germany
Franz Schönfeld is a pharmacist by profession. After his graduation, he worked at a hospital in Nuremberg and at a retailer in Bayreuth. In 2003 he joined the local GMP inspectorate in Ansbach before he was allocated to Munich and Bayreuth. He was formerly deputy head of the national experts group for radiopharmaceuticals and is now head of the national expert group for APIs and excipients.

Social Event

In the evening of the first conference day, 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.



Literature
Participants of this Conference can purchase the 2nd Edition of Dr Bob McDowall's book "Validation of Chromatography Data Systems" (Royal Society of Chemistry) with a discount of 20%! You will receive the order form for this book at the conference.

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

Dates
Lab Data Integrity Conference
Wednesday, 18 October 2017,
09.00 h - 18.00 h
(Registration and coffee 08.30 h - 09.00 h)
Thursday, 19 October 2017,
08.30 h - 16.00 h

Post Conference Workshop
Audit Trail Review for Laboratory Systems
Friday, 20 October 2017,
09.00 h - 16.00 h
(Registration and coffee 08.30 h - 09.00 h)

Venue
Barceló Sants
Placa dels Paisos Catalans, s/n
Estació de Sants
08014 Barcelona, Spain
Phone +34 93 503 53 00
Fax +34 93 490 60 45
email sants@barcelo.com

Fees (per delegate plus VAT)
Lab Data Integrity Conference
ECA Members € 1,690
APIC Members € 1,790
Non-ECA Members € 1,890
EU GMP Inspectorates € 945
The conference fee is payable in advance after receipt of invoice and includes conference documentation (USB stick, no print-outs), dinner on the first day, lunch on both days and all refreshments.
VAT is reclaimable.

Post-Conference Workshop Audit Trail Review for Laboratory Systems
ECA Members € 790
APIC Members € 840
Non-ECA Members € 890
EU GMP Inspectorates € 445.-
The conference fee is payable in advance after receipt of invoice and includes conference documentation (print-outs), lunch and all refreshments. VAT is reclaimable.

Lab Data Integrity Conference & Post-Conference Workshop Audit Trail Review
ECA Members € 2,290
APIC Members € 2,390
Non-ECA Members € 2,490
EU GMP Inspectorates € 1,245.-

Accommodation
CONCEPT has reserved a limited number of rooms in the conference Hotel. You will receive a room reservation form when you have registered for the course. Reservation should be made directly with the hotel. Early reservation is recommended.

Registration
Via 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
ECA has entrusted Concept Heidelberg with the organisation of this event.

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

For questions regarding content:
Dr Günter Brendelberger
(Operations Director) at
+49-62 21/84 44 40,
brendelberger@concept-heidelberg.de

For questions regarding reservation, hotel, organisation etc.:
Ms Susanne Ludwig
(Organisation Manager) at
+49 (0) 62 21 / 84 44 44,
ludwig@concept-heidelberg.de

Important Information!
The presentations of the Lab Data Integrity Conference will be available for download and print-out approx. one week before the conference. You will also receive a USB memo stick when you register in Barcelona.
Note: there will be no print-outs available during the conference.

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

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P.O. Box 10 17 64
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69007 Heidelberg
Germany

Registration form (please complete in full)

+49 6221 84 44 34

☐ **Lab Data Integrity Conference,**
18-19 October 2017, Barcelona, Spain
☐ **Post-Conference Workshop "Audit Trail Review for Laboratory Systems",**
20 October 2017, Barcelona, Spain

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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 HEIDELBERGwill 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)! (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.

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