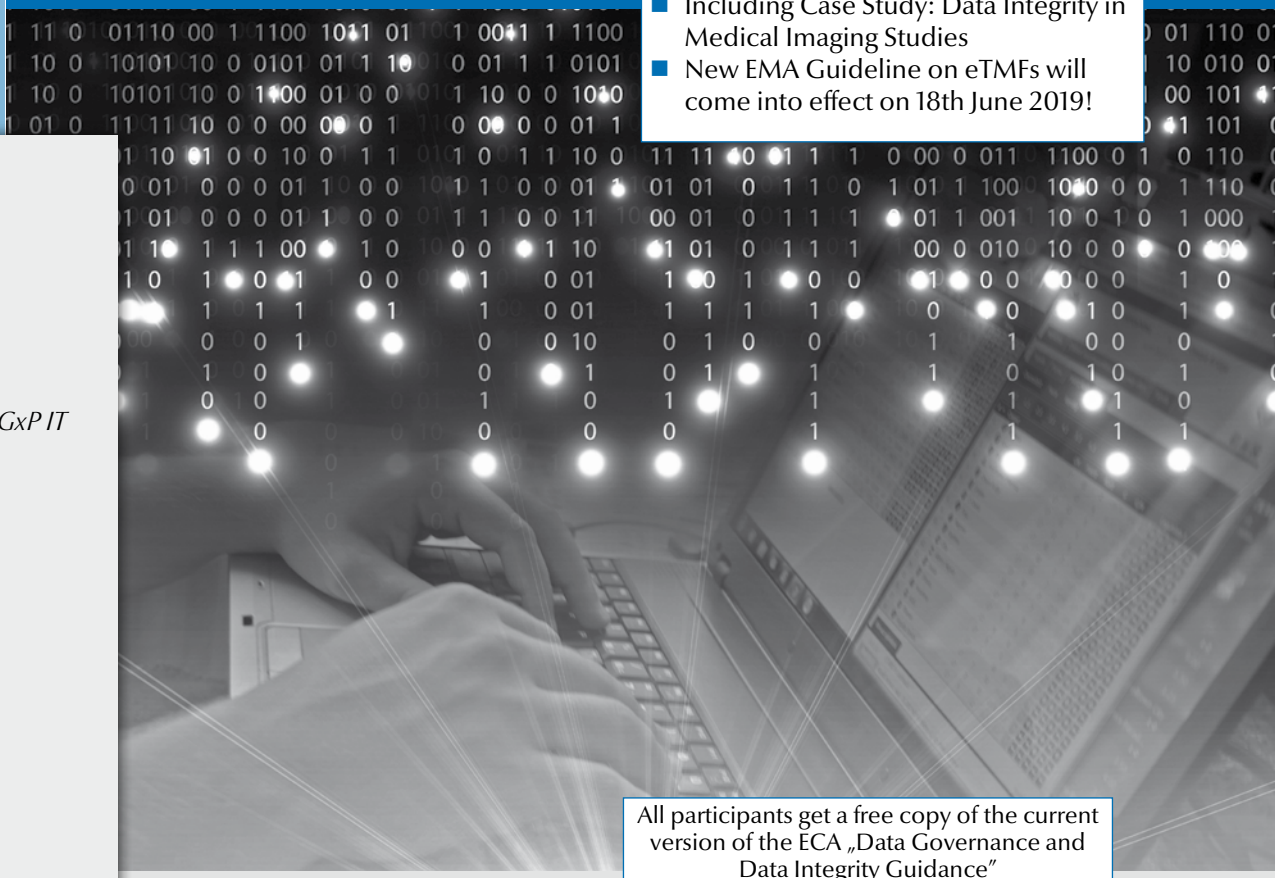
20 YEARS ECA Academy Your GMP/GDP Information Source

D.I.C.T - Data Integrity in Clinical Trials

How to secure global GMP- **and** GCP-compliant data governance

- Including Case Study: Data Integrity in Medical Imaging Studies
- New EMA Guideline on eTMFs will come into effect on 18th June 2019!



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

SPEAKERS:

Ib Alstrup
Medicines Inspector, GxP IT

Frank Henrichmann
Parexel

Dr Marina Mangold
Esculape

Dr Wolfgang Schumacher
Chair of ECA IT Compliance Group, formerly with Roche

17-18 September 2019 , Copenhagen, Denmark

HIGHLIGHTS:

- eTMF, eCRF & Electronic informed consent
- Responsibilities of Investigator, Sponsor and Monitor & Inspection findings
- Electronic Document Management and Change Control Systems to Ensure Data Integrity
- Randomization & Trial Supply Management
- European Data Protection Regulation 2018 - Impacting Clinical Trials!?
- Workshop on typical situations with Data Integrity Impact

This education course is recognised for the ECA GMP Certification Programme „Certified Pharmaceutical Development Manager". Please find details at www.gmp-certification.eu

D.I.C.T - Data Integrity in Clinical Trials

17-18 September 2019 , Copenhagen, Denmark

Objectives

During this Course you will get to know the **principles of Data Integrity (DI)** in the light of **GCP** requirements. You will learn

- How to manage hybrid systems with their forms and templates, e.g. (electronic) informed consent, (e)CRF
- How to maintain data integrity for physical, hybrid and full electronic records
- How to establish a GCP compliant and pragmatic change control process
- How poor practices and falsification can be detected in the daily business
- How to train staff in Good Documentation Practice and Data Integrity
- How multilingual documents can be managed and controlled
- How to avoid typical data integrity failures
- How to prepare for a Health Regulatory Inspection

Speakers from Industry and Authority will show **what you need to consider** to establish and maintain a GCP/GMP compliant data governance system.

Background

The inspection in the context of clinical trials may cover **good manufacturing practices** (GMP) as regards the manufacturing of the **investigational medicinal products** (IMP) or **good clinical practice** (GCP) for the conduct of clinical trials.

Two corresponding documents are dealing with these inspections:

- **Implementing Regulation (EU) 2017/556 of 24 March 2017 on arrangements for GCP Inspections:** This Regulation lays down detailed arrangements for **GCP inspections** procedures and requirements regarding training and qualifications of **GCP inspectors**. The sponsor of a clinical trial and the investigator are to ensure that the clinical trial is conducted in accordance with the principles of **GCP**. Compliance with the GCP principles, including with standards relating to **data integrity**, is to be verified by means of inspections. **Inspectors** shall have the ability to make professional judgments in relation to the compliance with applicable legislation and guidelines and shall be able to assess **data integrity.**
- **Commission Delegated Regulation (EU) 2017/1569 of 23 May 2017 on arrangements for GMP-Inspections** (as regards IMPs): Ensures conformity with GMP for IMPs and makes provisions on inspections. Regular inspections should be carried out as referred to **Regulation (EU) No 536/2014 (CTR)** and third country manufacturers should be inspected at least if there is a suspicion that the IMPs are not manufactured by applying quality standards at least equivalent to those applicable in the EU. **Inspections may be unannounced** and Inspectors shall be empowered to examine any documents relating to the object of inspection, **make copies of records or printed documents and print electronic records.**

In clinical trials, usually large amount of data is collected and this data is more and more electronically recorded and processed. The check of the integrity of data is mandatory and is usually performed by the clinical monitor who, in the past, preferentially reviewed only the documentation, but not the history of data entries. Particular emphasis should be put on the **hybrid systems**, where data are manually transferred from paper to the electronic application, i.e. from the case record forms (CRFs), a process which is very error prone. If electronic systems (**eCRFs**) are used for the data entry by the medical doctors involved in the clinical study, the clinical monitor may need to review the correctness of the electronic data, i.e. if data was modified or "cleaned" after the first entry.

Furthermore, the European Medicines Agency (EMA) recently published their new **guideline on Content, Management and Archiving of the (e)TMF** which will come into effect on 18th June 2019. According to the guideline areas to consider during quality checks and review include the following:

- Validation of the eTMF, with formal procedures in place to manage this process,
- **Audit trail review,**
- Routine QA measures, e.g. system audits of eTMF-management processes (sponsor),
- Ensure the eTMF is readily available and directly accessible to the competent authority, e.g. for inspection purposes (sponsor).

In addition, sponsors contract out an increasing number of tasks in clinical trials. During inspections of commercial as well as academic trials, an increasing amount of deviations from GCP standards have been identified by the inspectors in view of sub-standard contractual arrangements and related procedures. Special consideration should be given on training and quality systems. Experience suggests that vendors accepting tasks on electronic systems are frequently knowledgeable on IT systems and sometimes on data protection legislation, but not necessarily on GCP requirements, quality systems, etc.

The challenges with these tasks are frequently underestimated. The risk-based approach concepts of the new ICH E6 (R2) GCP Guideline, which is valid in the EU as of June 14, 2017, are also applicable for data integrity. Additionally, the revised ICH E6 Guideline contains detailed requirements regarding validation of computer based systems used in clinical trials.

Therefore it is necessary to know the risks regarding data integrity and computerized systems in GCP area and to establish risk management measures to implement reasonable and efficient GCP/GMP compliant global data governance systems.

Target Audience

- Employees involved in designing, conducting, evaluating, and documenting of clinical trials including clinical monitors, nurses and doctors.
- Validation manager, QA manager, project manager, data manager, and statisticians.
- Pharmaceutical companies, sponsors, contractors (for example CROs, analytical labs) and vendors for electronic systems (including hosting partner).
- Inspectors responsible for performing GCP/GMP inspections and needing to understand and assess data integrity.

Programme

Data Integrity Principles and their Impact on Clinical Trials
- Critical Data in the clinical area
- Standards, regulations and guidelines – What is relevant for clinical data?
- How to set-up a Data Integrity program – Pragmatic approach
- Roles and Responsibilities

Responsibilities of Investigator, Sponsor and Monitor
- Responsibilities of Investigator, Sponsor and Monitor regarding DI:
  - according to current legislation
  - according to the CTR
- Inspection findings

Electronic Document Management and Change Control Systems to Ensure Data Integrity
- Requirements for source documents (e.g. medical records) & identification lists
- Transfer to eRecords & eDocuments
- How to establish a compliant and pragmatic change control process

Trial Master File - (e)TMF
- Requirements for TMFs
- eTMFs & eTMF systems
- Transfer to eTMF

Randomization & Trial Supply Management
- GCP or GMP....what Regulations are really applicable?
- Why is this area so critical? – a high level risk assessment considering Randomization, Labeling, Packaging, Blinding
- What are the critical data and how can we safeguard them?

Records – Life Cycle and Data Integrity Issues
- How to make systems compliant to meet regulatory expectations?
- Pragmatic approaches for legacy systems
- Tasks of the IT department

Vendors and Contractors of electronic systems and clinical data management: considerations and pitfalls
- Training and quality systems, GCP Standards to be followed
- Status of contracts, distribution of tasks
- Audits and inspections
- Compliance with the protocol
- Information about agreed output

Electronic informed consent and eCRF: Hybrid Systems and Review
- Second person review for critical areas
- Do we need to review Audit Trails?
- Data Integrity compliant practice

GMP / GCP compliant document management
- Criteria for Data Integrity
- ALCOA rules
- eDMS systems and electronic signatures – essential elements

Case Study: Data Integrity in Medical Imaging Studies
A step-by-step analysis of a Data Integrity Issue focusing on
- Technical and Procedural Controls
- Risk Assessment & Management for Data Integrity
- Potential Impacts and Consequences

Can we avoid this in the future?

European Data Protection Regulation 2018 - Impacting Clinical Trials!?
- Rights of the Data Subject
- Tasks for the Data Controller and Data Processor
- IT data security requirements

Workshop
Participants will analyse typical situations with Data Integrity impact and discuss solutions.

Speakers

Ib Alstrup

Danish Medicines Agency | Medicines Control & Inspection | Medicines Inspector, GxP IT

Since 2017, Ib Alstrup is working as GxP IT Medicines Inspector at the Danish Medicines Agency. Prior before moving to the authority, he worked for Novo Nordisk in Copenhagen in the role of a Principal Specialist and Lead Auditor for GLP and GCP Audits. In this role he was responsible for interpreting and communicating new regulatory requirements, advising and supporting implementation of related quality assuring activities and training colleagues in Computer Systems Validation (CSV) and IT Security. Furthermore, he planned and conducted internal audits and supplier audits of Clinical (GCP) and Pre-Clinical (GLP) Contract Research Organizations (CROs) with focus on CSV and IT Security.

Frank Henrichmann

Parexel | Sr. Director Safety Services QM | Process Optimization & Continuous Improvement

Frank is heading the Safety Services Quality Management Group (SSQM) after working for 11 years within the Technology Quality Management (TQM) organization, following 20 years working for a Pharma Company. His current position includes leading a global team of Quality Experts within PAREXEL's Process Optimization and Continuous Improvement group that focuses in Pharmacovigilance operations. Frank also participates in industry groups like ISPE GAMP.

Dr Marina Mangold

Esculape | Clinical Research Professional

Dr Marina Mangold, studied molecular microbiology, and has 7 years CRO experience in the areas of Project Management and Data Management. She worked for an international CRO as Head of eClinical Solutions before she decided in 2016 to work as a consultant (Clinical Research Professional) for Data Management, Validation of eClinical Systems and Medical Writing.

Dr Wolfgang Schumacher

Chair of ECA IT Compliance Group, formerly with Roche

Dr Schumacher studied chemistry and pharmacy. After entering Asta Medica, he headed different positions. From 2001 to 2016 he was Head of the department of Quality Computer Systems at F. Hoffmann-La Roche, Basle. He is a member of the ECA Advisory Board.

Easy Registration

Reservation Form:
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69007 Heidelberg
Germany

Reservation Form:
+ 49 6221 84 44 34

e-mail:
info@concept-heidelberg.de

Internet:
www.gmp-compliance.org

Date

Tuesday, 17 September 2019, 9:00 to 17:45
(Registration and coffee 8:30 to 9:00)
Wednesday, 18 September 2019, 8:30 to 15:00

Venue

Radisson Blu Scandinavia Hotel
Amager Boulevard 70
2300 Copenhagen S, Denmark
Phone +45 3396 50 00
Fax +45 3396 55 00
Scandinavia.meetings.events@radissonblu.com

Fees (per delegate plus VAT)

ECA Members € 1,590
APIC Members € 1,690
Non-ECA Members € 1,790
EU GMP Inspectorates € 895

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/POG when you have registered for the course. 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.

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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For questions regarding content please contact:
Dr Andrea Kühn-Hebecker (Operations Director) at +49-62 21/84 44 35, or per e-mail at kuehn@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc. please contact:
Ms Isabell Neureuther (Organisation Manager) at +49-62 21/84 44 49, or per e-mail at neureuther@concept-heidelberg.de.

Social Event

In the evening of the first course 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.

GMP/GDP Certification Programme

This seminar is recognised within the GMP Certification Programme. By attending selected seminars, the participant can acquire an additional certificate. We offer the following modules:
ECA Certified Validation Manager
ECA Certified QA Manager
ECA Certified API Production Manager
ECA Certified Quality Control Manager
ECA Certified Technical Operations Manager
ECA Certified Computer Validation Manager
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ECA Certified Microbiological Laboratory Manager
ECA Certified Sterile Production Manager
ECA Certified Biotech Manager
ECA Certified Pharmaceutical Development Manager
ECA Certified GMP Auditor
ECA Certified GDP Compliance Manager
ECA Certified Packaging Manager
ECA Certified Data Integrity Manager

On the internet at www.gmp-compliance.org you will find a text explaining which seminars are recognised for which certificates. Or you send an e-mail to info@gmp-compliance.org or a fax to +49-6221- 84 44 64 with the request for information about the GMP Certification Programme. We will then send you our brochure on the topic

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☐ Mr ☐ Ms

Title, first name, surname

Company Department

Important: Please indicate your company's VAT ID Number **P.O. Number (if applicable)**

Street/P.O. Box

City Zip Code Country

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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 %
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Terms of payment: Payable without deductions within 10 days after receipt of invoice.
German law shall apply. Court of jurisdiction is Heidelberg.

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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.