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GxP-CC Data Integrity Services

Data Integrity Workshops

Framework Assessments

DI Spot Checks

Process and System Assessments
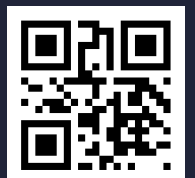
GEMBA Walks and Audits

Inspection Preparation

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Dr. Ulrich Köllisch, Partner
Lead several industry Data Integrity
campaigns, **trainer** for industry and
regulatory authorities, auditor and speaker
PDA **IG Leader**

Sarah Wittmar, Senior Consultant
Data Integrity system and process
assessments in **manufacturing** and
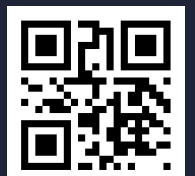**labroratory** environments

GxP-CC Data Integrity Team

Dr. Tanja Küssau, Consultant
Data Integrity in
pre-commercial (**R&D**)
environment

James Francum, CEO
Certified Data Integrity
auditor, **speaker** and **trainer**

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Data Integrity in **GCP**
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Data Integrity Workshop

- Customize your Data Integrity Workshop: Your case studies, our content and experience
  - Data Flow Mapping
  - DI Risk Assessment
  - Data Governance Principles
  - Audit Trails and AT Reviews
  - Access Control and Segregation of Duties
  - Data Retention
  - DI and the Human Factor: Quality Culture
  - Next steps: From Data Integrity to Quality Intelligence

CUSTOMIZE
Your Content,
Your Case Studies!

Framework Assessments

- You are not sure if your Data Integrity and Data Governance framework meets the current regulations?
- We can help to check your framework against current **regulations** and **best** industry **practice**
  - Data Integrity SOPs
  - Data Review Strategy
  - Access Control, Data Retention and Audit Trail procedures
  - Connection with process validation, CSV and Equipment Qualification framework
- Our templates and our project experience ensure an effective and high quality assessment
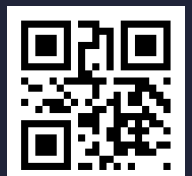
DI Spot Checks

- You want to use an example process to see where you stand and learn how to conduct an assessment? Here we go!
  - Interviews and document review
  - Review of existing DI Risk Assessments for your example process
  - Gap assessment report traced to current regulations
  - Proposed remediation actions categorized by criticality

Process and System Assessments

- Do you need support with your Data Integrity program by implementing process and system assessments?
- We are a experienced team to support your Data Integrity program with hands-on assessments
  - DI Assessment reports including Gaps and proposed remediation actions
  - Collaboration with all relevant stakeholders
  - Process management and reporting
  - Oversight Report: "DI Maturity Level"
- We can provide a network of experts

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GEMBA Walks and Audits

- You want to learn where you are standing with an audit?
  - We have specialized DI auditing experience (on-site or remote) and hold the most relevant certificates
  - We know the latest inspection trends and are dedicated to show you the potentials for improvement
- Ever wondered how you could foster quality culture and bring business and leadership (or quality unit) closer together?
  - GEMBA walks are an excellent tool to continously improve your QMS
  - We always provide a lessons learned closing session

Inspection Preparation

- What are latest inspection trends?
- Which are the must-haves and what are no-gos?
  - Mock Audits to detect blind spots
  - Document preparation and consulting
- Fundamentals on Auditing
- Regulatory overview from the inspector's perspective (e.g., FDA, PIC/S)