



GxP-CC Data Integrity Services



Data Integrity Workshops



Framework Assessments



DI Spot Checks



Process and System Assessments



GEMBA Walks and Audits



Inspection Preparation



Europaallee 33
Kaiserslautern 67657
Germany



info@gxp-cc.com





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
laboratory 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**



Dr. Thaleia Papadopoulou, Consultant
Data Integrity in **GCP**
and **manufacturing**





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

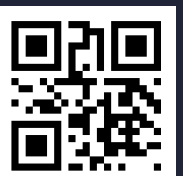
CUSTOMIZE

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





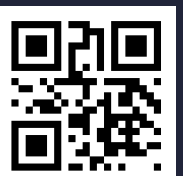
DI Spot Checks

- 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





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 continuously 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)

