digital chameleon

Dr. Diana LÄMPE

SENIOR MANAGER QUALITY & COMPLIANCE

PROFESSIONAL SKILLS

- Quality & Risk Management
- Computer System Validation (CSV) according to GAMP5
- Audit Preparation/Regulatory Compliance within Pharmaceuticals (EMA,FDA,PIC/S,ISO)
- Project Management (Agile & Traditional)
- GxP,GMP
- SOP Creation/Review

RELATED SKILLS

- Development Management knowledge
- Project Management skills
- Marketing Biotech experience
- Interactive Response Technology (IRT)
- Clinical Coordination
- Clinical Studies
- FDA CFR Part 11, 211, 212, 820, EU GMP –Annex 11, ISO 13485, ISO 14971, ISO 27001, ISO 9001, MHRA, EMA, PDA, WHO, FDA Guidelines re: Data Integrity, GxP (GCP, GDP, GMP, GLP)

LANGUAGES

ENGLISH: Business fluent
GERMAN: Native
FRENCH: Intermediate proficiency
SPANISH: Intermediate proficiency

CONTACT PERSON

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ABOUT

Bioscientist with 20 years international experience in the life science industry. Passionate Project Manager and Quality Professional with broad overseeing understanding and in-depth hands-on experience in many aspects of this GxP-regulated industry. Attentive patient listener dedicated to overcoming emerging challenges with a clearly structured and positive approach to problem solving.

WORK EXPERIENCE

- Project Leader, Clinical Supply, Product Management and Quality Management expert within the Pharmaceutical industry (Novartis PharmaAG, Cell Concepts GmbH)
- Bio-Scientist by training with 20 years of work experience within the life science industry in various positions
- Broad overseeing understanding and in-depth hands-on experiences in many aspects of this GxP-regulated industry
- Specialized in the management of cross-functional change projects with strong focus on business processes, systems, interfaces and compliance
- Designed, launched and operated an integrated clinical supply system landscape with two standardized IVRS/IRT systems, an operational data-store, an IMP release platform, SAP and a real-time communication backbone under GxP
- Provided mentoring and guidanceas a business QA in Development Quality in compliance aspects, reviewed and approved CSV lifecycle documents, and managed deviations and CAPAs for assigned projects and computerized systems.
- Designed business concept, launched and operated a validated integrated system landscape with a workflow-based automated real-time messaging between 6 external and internal GxP-regulated applications of the clinical drug supply landscape.
- Computer validation of multiple GxP-regulated systems and bi-directional interfaces with inter-functional risk-based testing end-to-end.

EDUCATION & TRAINING

- CSV Manager (Zertifizierte Computervalidierungs-Beauftragte), Concept Heidelberg/GER- (2020)
- Several cGMP, cGDP and QA GxP courses, Novartis Group - (2004 - 2019)
- GMP Complaint and Deviation Investigation Certification, Novartis Group - (2018)
- IR Management Development programme, IIR Management Development London/GBR - (2007)
- Development Manager program, Mercer Delta Faculty/USA - (2004 –2005)
- Several project management courses, George Washington University/USA - (2003 –2004)
- Doctoral thesis in anaerobic microbiology, University Freiburg/GER - (1996 –1999)
- Master thesis (Diplom) in microbiology/biotechnology, University Freiburg/GER - (1995 –1996)
- Graduate study in Biology, University Freiburg/GER- (1991 –1995)

CLIENTS

Karl Storz, Tuttlingen/DE ▪ Novartis PharmaAG, Basel /CH ▪ Cell Concepts GmbH, Umkirch /DE