



## **PROFILE**

Pharmacist passionate about GMP Quality, with 25 years of broad experience in the pharmaceutical industry: in QA, QC and manufacturing of human medicines, APIs, veterinary medicines, clinical samples, aseptic filling of biotechnologically produced active ingredients, including contract manufacturing organizations

## **FAVORITE PROJECTS**

Consulting / Training on Quality Culture mindset including the Passion4Quality approach

Consulting / Training / hands-on support in any Quality System (Complaints, Deviations, Changes, CAPAs, Quality Risk Management, Quality Management Reviews, Self-Inspections, Trainings, Warehousing, Transport etc.)

FDA / authority inspection readiness or remediation programs

Audit support / lead of authority or customer inspections

Performing supplier audits at API sites or other contractors

QC (Sampling, Incoming good controls, OOS procedures, Transfer & validation of analytical methods etc.)

Cleaning validation

Qualified Person (QP) tasks according to AMG § 15 (1) 1

Supplier qualifications, Quality agreements, CMO management

## WORK EXPERIENCE

08/2024-	FREELANCE SENIOR QUALITY CONSULTANT
	Consulting on cleaning validation concepts for various customers (new API production/ new solid manufacturing site)
	FREELANCE SENIOR QUALITY CONSULTANT
	From lab to launch: development of Quality Mindset / Lean QMS for a clinical stage biopharmaceutical platform company.
04/2024-07/2024	HEAD OF QUALITY, ENTOURAGE PHARMA CONSULTING AG, MÜNCHEN
	Supporting pharma quality teams with customer-specific tailored solutions with measurable results through providing a hybrid consulting model in a combination of strategy- and hands-on-consulting.
05/2023-04/2024	BUSINESS COACHING
03/2023-08/2023	FREELANCE SENIOR QUALITY CONSULTANT
	Development of a cleaning validation concept for the processing of highly potent substances
09/2022-12/2022	INTERIM SITE QUALITY HEAD, SWISSFILLON / TEN23 HEALTH
	Heading QA and QC with focus on the preparation and conduction of the Swissmedic authority inspection.
03/2022-06/2022	INTERIM SITE QUALITY HEAD, STADA
	Heading QA and QC with focus on the implementation of a new quality culture at a biotechnological API site. Program Lead of the FDA readiness project.
11/2020-02/2022	FREELANCE SENIOR QUALITY CONSULTANT, BIONTECH
	Establishment of a Complaint Management System for the Covid-19 vaccine Comirnaty®. Monitoring / risk assessment in close contact with the state authorities. Continuous process optimization with further sterile Fill & Finish partners.
04/2020-07/2021	FREELANCE SENIOR QUALITY CONSULTANT
	Leading webinars, in-house trainings on "GMP in warehouse/logistics" topics
	QC transfer to a contract lab & set up of the future new process & definition of responsibilities for external analytics
12/2019-HEUTE	FREELANCE AUDITOR
	Conducting audits at European API manufacturers & at German pharmacies having aseptic filling production
02/2018-11/2019	FREELANCE SENIOR QUALITY CONSULTANT(Aseptic filling)
	Setup of the quality management system in a new production site to obtain the manufacturing license, with the following focus:
	- QM process design / setup of SOP system
	- Support of all authority and customer inspections, Performing external audits
	- Quality Lead in the project to harmonize the QM systems with the parent company

	- Supplier qualification for suppliers, contract laboratories, service providers, QM system for incoming goods & storage & transport
01/2017-11/2017	SENIOR QUALITY MANAGER, SANOFI GMBH, FRANKFURT  The job was transferred to Sanofi Deutschland GmbH as part of the business transfer (Boehringer Ingelheim's CHC business swapped for Sanofi's Animal Health business). The field of activity remained unchanged.
06/1997-12/2016	BOEHRINGER INGELHEIM GMBH & CO KG (=BI)
05/2014-12/2016	SENIOR QUALITY MANAGER – EXT. MANUFACTURING, BI  Quality lead within interdisciplinary project teams for new products until market launch. Focus: auditing / qualification of contract manufacturers, negotiation of quality agreements, release of process validation batches.
10/2011-03/2012	MATERNITY LEAVE 3. CHILD
06/2011-04/2014	HEAD OF LABORATORY, API PRODUCTION, BI  Head of Competence Center CLEANING VALIDATION & PROCESS MONITORING: Leadership of approx. 25 employees in a 3-shift laboratory.  Establishment of the cleaning concepts for API production sites, execution of cleaning validations, development / validation of analytical methods & execution of process monitoring analyzes
09/2010-05/2011	QUALIFIED PERSON, ANIMAL HEALTH, BI QP according §15 AMG: Release of veterinary medicines (manufactured in USA and Mexico, imported into the EU)
02/2010-08/2010	PROJECT MANAGER PHARMA PRODUCTION, BI Optimization of pharma manufacturing / packaging processes according LEAN principles, accompanied by Mc Kinsey
11/2007-01/2010	PROJECT LEAD FDA (PAI)-READINESS, BI Lead of the preparation of an FDA Inspection (PAI) as part of the NDA of a blockbuster product. Project management for all departments involved. Accompanying several FDA and MOCK inspections. Improve employee's presentation skills.
02/2007-10/2007	PARENTAL LEAVE 2. CHILD
02/2006-01/2007	QUALITY MANAGER VALIDATION & QUALIFICATION, BI Concept development and approval of validation documents (cleaning and process validations)
02/2005-01/2006	PARENTAL LEAVE 1. CHILD
10/2001-01/2005	HEAD OF LABORATORY, QUALITY CONTROL SOLIDA, BI Leadership of approx. 25 employees. Batch release of finished medicinal products as "Kontrollleiter" / AMG (German law). Responsibility for release analytics, method development, validation, transfers, stability studies, submission documentation.
2000-2003	HEAD OF LAB CLEANING VALIDATION, BI Establishment of a laboratory specialized in CV analysis, approx. 10 employees CV process development & creation of the Global Company Corporate Guideline, incl. worldwide training for all BI production sites PAI preparation & responsibility in FDA inspections
1999-2001	JUNIOR EXPERT, TEAM PROCESS AND TECHNOLOGY, BI

	Support for the transfer of NCEs from development to routine production, including preparation of submission documents.
06/1997-1999	JUNIOR EXPERT, CTS MANUFACTURING, BI

## **EDUCATION**

11/1991-05/1997	PHARMACIST, UNIVERSITY DEGREE, Johannes-Gutenberg-Universität, Mainz
11/1996-04/1997	TRAINEESHIP IN A PHARMACY, Einhorn-Apotheke, München
05/1996-10/1996	TRAINEESHIP IN PHARMA INDUSTRY, Boehringer Ingelheim GmbH & CoKG
1989-1991	PHARMACEUTICAL TECHNICAL ASSISTANT (PTA), Ludwig Fresenius, Frankfurt
1980-1989	ABITUR, GERMAN HIGHSCHOOL DEGREE, Rabanus-Maurus-Gymnasium, Mainz