doering-pqm

Dipl.-Ing. Stefan Döring
Project Management and Consulting for the Pharmaceutical and Medical Device Industry

personal information

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Nationality: German

Birthday: 25/07/1970

Language skills: German (native language)
English (fluent)
Polish (intermediate proficiency)

my services offered include

- Evaluation of existing production processes and deriving conclusions regarding compliance with standards, as well as opportunities for process optimization and enhancing process security and stability
- Accompanying procurement processes, including the creation and alignment of specifications and requirements documents (URS), supplier evaluation and selection, project monitoring at the supplier's site, Factory Acceptance Testing (FAT), transportation, installation, commissioning and Site Acceptance Testing (SAT)
- Initial, Re- and Decommissioning Qualifications / Validations including peripherals
- Temporary Quality project management (data analysis, change management, CAPA)
- Change management in the regulatory environment of existing Quality Systems
- Technology research, evaluation, development and implementation
- Design transfer from development status to serial production
- Product and process risk analyses including peripherals (particularly FMEA)
- Facilitation of workshops on Quality Management and risk assessment / elimination
- Research, evaluation, and implementation of second sources (alternative suppliers)
- Regulatory and technical supplier qualification
- Patent research and evaluation, support for patent applications
- Audit preparation and follow-up, conducting preventive mock audits, in-house or at suppliers/customers site

advanced knowledges

- Fabrication and processing of hollow fiber membranes and modules
- Systems for production, storage and distribution of purified water and WFI
- Packaging equipment qualification and product/processes validation, particularly for sterile packaging systems according to DIN ISO 11607
- Relocations of production facilities
- Initial, Re- and Decommissioning Qualifications / Validations
- Workplace and process design using cardboard engineering

completed & ongoing freelance projects

2025 **Region Bad Homburg, Germany, manufacturer of medical components:**
Selection and establishment of a modified packaging material for a triple sterile packaging system, product- and process validations; qualification of a robotic system for automated packaging in combination with an automated camera control system for sterile packaging (IQ/OQ/PQ).

2024 **Region Nuremberg, Germany, manufacturer of medical disposables:**
Qualification of new forming tool for Blisters, Validation of sterile packaging processes under updated legal framework conditions and knowledge transfer to a new production site abroad.

2023 - 24 **Region Dresden and Heilbronn, Germany, manufacturer of medical disposables:**
Project management for the relocation of production facilities incl. Q/V at both sites.

2023 **Dresden, Germany, vaccine manufacturer:**
Project management for updating regulatory requirements in the pharmaceutical production field (GMP Annex 1 update), initial set up of CCS, project management in the design and implementation of new cleanroom garments as well in the renovation of cleanroom airlocks following updated framework and technical conditions.

2020 - 23 **Lake Constance Region, Germany and Switzerland, Manchester Region (UK), manufacturer of medical devices:**
Project management and consulting on consolidation processes for sterile packaging due to the implementation of the Medical Device Regulation (MDR), development of a soft blister packaging for single-use medical devices, project management in the relocation of medical device production, validation of a sterile packaging pouch system for single-use items according to DIN ISO 11607-1 and -2.

completed & ongoing freelance projects

2020 **Lausitz Region, Germany, private ambulatory care service:**
Business consulting for optimizing the existing quality management system to meet new legal requirements.

2019 - 20 **Region Dresden and Heilbronn, Germany, manufacturer of medical disposables:**
Consulting and project management for market entry into the USA, particularly process developments and initial qualifications / validations.

2019 **Munich, Germany, manufacturer of medical devices:**
Participation and consulting in a project for equipment qualification for production and testing facilities.

2018 **Frankfurt Region, Germany, manufacturer of pharmaceutical equipment:**
Execution of Installation qualification of a biopharmaceutical facility.

previous professional development

2014 - 2018 **BBraun Avitum Saxonia GmbH,**
Dpt. Of Global Process Engineering

Senior Project Manager for engineering and procurement projects with the following areas of focus:

Construction of a production facility for hollow fibre dialysers, comprehensive and sustainable project management in process development, engineering, and procurement projects. Procurement and implementation of new production equipment and technologies. Technical support for quality management processes (change control, CAPA, design control). Design change. Monitoring of global patent activities. Execution of equipment qualification and process validation. Close collaboration with developers, marketing, suppliers, and regulatory authorities during development and design transfer to production. Primary and secondary packaging development.

2008 - 2014 **BBraun Avitum Saxonia GmbH,**
Dpt. of Research and Development

Development Engineer, Scientific Researcher
with the following areas of focus:

Project management in research and development projects. Participation in product and process development. Development of test equipment and methods for membrane characterization. Design Transfer of a new generation of hollow fibre membrane to production.

2007 - 2008 **Pharmatec GmbH**

Project Manager
with the following areas of focus:

Project management for the creation of large scale customized production facilities in the Life Sciences sector. Preparation of proposals and specifications. Project execution until Site Acceptance Testing (SAT), including on site qualification.

2003 - 2007 **Saxonia BioTec GmbH**

Product Manager - Hollow Fiber Bioreactors
with the following areas of focus:

Comprehensive product management for disposable hollow fiber devices. Monitoring of production processes. Development of customized products. Product and process development for hollow fiber bioreactors and transition to production. Administrative tasks. Close collaboration with customers, research institutes and suppliers.

2002 - 2003 **Quodata GmbH**

Development Engineer

with the following area of focus:
Project assignment; development of an automated ELISA method for detecting hormone-like substances in trace concentrations in water.

2000 - 2002 **University of Technology Dresden, Chair of Chemical Engineering**

Scientific Researcher

with the following areas of focus:
Scientific analysis of product and process chains. Analysis of qualification requirements in high technologies.

1999 - 2000 **University of Technology Dresden,**
Chair of Waste Management and Contaminated Sites treatment

Scholarship holder

with the following area of focus:
Investigations on the microbiological remediation potential of contaminated aquifers.

education

1997 **Imperial College of Science, Technology and Medicine, London**

Internship semester at the Department of Geology

Investigations on heavy metal contamination of river sediments with special consideration of analytical uncertainties

1995 - 1999 **International Graduate School Zittau, Chair of Environmental Engineering and Analytics**

Degree program: Environmental Engineering (Advanced Studies)

Diploma thesis: Investigations on the induction of phytochelatins in the water moss Fontinalis antipyretica under the influence of heavy metals and its utilization as a biomarker for heavy metal-contaminated aquatic systems.

1992 - 1995 **University of Technology Dresden**
Undergraduate studies in Geography and Physics

Continuing education (selection)

2024	MS project Update
2023	Biosaxony eV: Agile Project Management in the Life Sciences
2021	PAConsult GmbH: Validation of Packaging Processes
2021	TÜV Süd: Update DIN EN ISO 11607:2020
2020	RKW Sachsen GmbH: Classical Project Management
2020	Biosaxony eV: Access Paths to the Healthcare Market, Options, and Criteria
2020	EXCO GmbH: Quality and Risk Management in Medical Devices
2019	Valicare GmbH: Advanced GMP Training
2019	TÜV Süd Akademie: ISO 13485: 2016 – What is new?
2019	Vocational Academy (BA) Bautzen: Lecture on Quality Management in the field of Medical Engineering
2019	TÜV Süd Academy: Supplier Management in the Medical Device Industry
2016	TÜV Süd Academy: Management Systems for Medical Device Manufacturers according to ISO 13485 and implementation of DIN EN ISO 9001
2016	BBraun Project Management Office: Profix II, project simulation
2016	Medical Packaging Days, Schaffhausen (Schweiz)
2015	BBraun Project Management Office, basisc in Profix Project Management

2015 Association for the Advancement of Medical Instrumentation (AAMI):

Quality System Requirements and Industrial Practice

2015 Institute for Packaging Technology of VVL (e.V.):

Transport Packaging: Optimization through Transport Suitability Testing

2015 TÜV Süd Academy:

Requirements for the Validation of Sterile Packaging Processes and Packaging Design for Medical Devices

2014 Association for the Advancement of Medical Instrumentation (AAMI):

Design Control Requirements and Industrial Practice

2014 Regular Services GbR:

Risk Management according to EN ISO 14971 for the Medical Device Industry

2014 Dr. Herterich & Consultants:

Training and Workshop on Qualification & Validation

2013 Regular Services GbR:

Corrective and Preventive Actions (CAPA), Seminar und Workshop

patents

WO 2008/055652, Supply system for cell culture module

EP 3 202 435 A1, Filter Module Packaging Unit

EP 3 202 434 A1, Filter Module Packaging Unit

EP 3 202 672 A1, Med. Sterile Packaging Unit

EP 3 511 707 A1, Device and Method for Determining the Absorption Capacity of an iron based Oxygen Absorber