
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, supplier evaluation and selection, project monitoring at the supplier's site, Factory Acceptance Testing (FAT), transportation, installation, commissioning and Site Acceptance Testing (SAT)
- Qualification of equipment and facilities / Validation of processes 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 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, particularly for dialysis and blood-oxygenation, but also for water purification and biotechnical applications (hollow fiber based bioreactors and harvesting filters)
- Systems for the production, storage and distribution of purified water and WFI
- Packaging processes (primary and secondary packaging), particularly for sterile packaging according to DIN ISO 11607-1 and -2
- Workplace and process design using cardboard engineering

completed & ongoing freelance projects

- 2024 **Region Nuremberg, manufacturer of medical disposables**
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: manufacturer of blood-oxygenators:**
Projekt management for the relocation of production facilities
- 2023 **Dresden: vaccine manufacturer:**
Project management for updating regulatory requirements in the pharmaceutical production field (GMP Annex 1), initial set up of CCS, project management in the design and implementation of new cleanroom garments as well in the renovation of cleanroom airlocks
- 2020 - 23 **Lake Constance region and Manchester (UK) area: 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 for single-use items according to DIN ISO 11607-1 and -2
- 2020 **Lausitz region: private ambulatory care service:**
Business consulting for optimizing the existing quality management system to meet new legal requirements
- 2019 - 20 **Region Dresden and Heilbronn: manufacturer of blood-oxygenators:**
Consulting and project management for market entry into the USA, particularly process developments and validations
- 2019 **Region Munich: manufacturer of medical devices:**
Participation and consulting in a project for equipment qualification for production and testing facilities
- 2018 **Region Frankfurt/Main: manufacturer of pharmaceutical equipment:**
Execution of Installation qualification of a biopharmaceutical facility for production of insulin

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 type 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 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)

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, basic 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

Döring, S., Oetken, M., Gasch, T., Leffler, U.-S., Oehlmann, J. und Markert, B. (1999): Schwermetalle in Sedimenten der Neiße - Konzentrationen und Wirkungen auf Benthosorganismen. In: Oehlmann, J. und Markert, B. (Hrsg.): Ökotoxikologie / Ökosystemare Ansätze und Methoden. ECOMED Verlagsgesellschaft Landsberg, S. 294 - 300.

Döring, S., Korhammer, S., Oetken, M. und Markert, B. (2000): Analysis of phytochelatins in plant matrices by pre-column derivatization, HPLC and fluorescence detection. Fresenius J. Anal. Chem. Vol. 366, No. 3, Feb. 2000, S. 316-318.

Döring, S., Schulze, S. und Werner, P. (1999): Elimination of chlororganic compounds by adsorption and simultaneous microbiological degradation on activated carbon. In: Schriftenreihe biologische Abwasserreinigung, No. 12: Behandlung von Abwässern mit halogenorganischen Verbindungen. TU-Berlin, S. 187-196.

Döring, S. und Storz, P. (2001): Zusatzqualifikationen für Chemieberufe. In: Berufsbildung. Zeitschrift für Theorie und Praxis in Betrieb und Schule, 55.Jg.(2001), Heft 68, S. 15-18.

Storz, P., Düwel, F. und Döring, S. (Hrsg.) (2001): Berufswissenschaftliche Forschung zur Verbundausbildung für Hochtechnologieberufe. Bd. 19 der Buchreihe Arbeit - Bildung - Beruf, ISBN 3935929-05-6.

Uhlig, S., Döring, S. und Rothmaler, D. (2002): Auswertung des Ringversuchs „Vergleichbarkeit von Chlorophyll-a-Bestimmungen“ im Rahmen des Bund-Länder-Messprogramms Nord- und Ostsee. Erstellt im Auftrag des Bundesministeriums für Umwelt, Naturschutz und Reaktorsicherheit, FKZ 360 07 020.

Kayser, G., Münster, A. und Döring, S. (2004): Enzymatic conversion of soluble oligo- and polysaccharides in hollow fiber membrane reactors. Posterbeitrag auf dem trilateralen Workshop "Science at Euroregion Neisse", 25.-26.11.2004 in Zittau.

Döring, S., Richter, J., Dressler, S., Sacharjat, M., Bergner, K., Marx, U. und Klaus, U. (2005): Addressing unmet high density cell culture needs with a novel disposable miniaturized bioreactor technology. Posterbeitrag auf der „Bioperspectives 2005“, 10.-12.5.2005 in Wiesbaden.

Klaus, U., Döring, S., Richter, J., Dressler, S., Sacharjat, M., Bergner, K., Giese, C. und Marx, U. (2005): A novel miniaturized bioreactor for predictive immunogenicity testing of drugs. Posterbeitrag anlässlich des "5th World Congress on Alternatives & Animal Use in the Life Sciences", 21.-25.8.2005 in Berlin

Klaus, U., Döring, S., Richter, J., Dressler, S., Sacharjat, M., Bergner, K., Ammer, R., Giese, C. und Marx, U. (2006): Predicting immunogenicity of drugs in tissue culture systems. Posterbeitrag bei der 24. Jahrestagung der Biotechnologen der Dechema, 26.-28.9.2006 in Wiesbaden

Meyer, L., Kroll, S., Beutel, S., Glöckler, J., Döring, S., Klaus, U. und Scheper, T. (2006): Processing of a hollow fiber micro-bioreactor for applications in cultivation and downstreaming. Posterbeitrag bei der 24. Jahrestagung der Biotechnologen der Dechema, 26.-28.9.2006 in Wiesbaden

Klaus, U., Döring, S., Richter, J., Dressler, S., Sacharjat, M., Demmler, C., Bergner, K., Ammer, R., Giese, C., Marx, U. (2007): Introduction of an automated disposable tissue culture system for prediction of drug immunogenicity. Posterbeitrag zur 20. Jahrestagung ESACT, 17.-20.06.2007 in Dresden