



## RENATE MAIER

GxP Consultant

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[www.brqualityconsulting.com](http://www.brqualityconsulting.com)

Renate is a passionate quality operations and contamination control expert with broad scientific background in chemistry and biochemistry.

### PROFESSIONAL SKILLS

- GMP, GDP
- Contamination Control
- Environmental Monitoring
- Commissioning & Qualification
- Batch Record Review & Release

### TECHNICAL SKILLS

- TrackWise QMS
- MODA, LIMS
- KNEAT Gx
- OpenText Documentum
- Proteomics – MaxQuant, Perseus, Mascot, Skyline, Phyton
- Adobe Illustrator, Photoshop
- Microsoft Applications

### LANGUAGE SKILLS

- German ■■■■
- Hungarian ■■■■
- English ■■■■
- French ■

### COURSES & TRAININGS

- Good Scientific Practice
- Project Management
- Advanced Biostatistics

### EXPERIENCE

02/2022 – 05/2024

*Permanent Employment*

#### **Senior QA Specialist, Contamination Prevention & Control, Environmental Monitoring**

*Lonza AG, Visp, Switzerland*

- Review and approval of facility qualification related documentation, including OQ and PQ plans and reports
- Facilitate and author contamination control risk analysis, including assessments for definition of environmental and clean utilities monitoring frequencies
- Maintenance and further development of quality systems, including authoring of SOPs in the area of process, facility, clean utilities, quality control and gowning
- Conducting gap-assessments and defining remediation actions to ensure regulatory compliance
- Act as expert in customer audits and regulatory inspections, presenting aspects related to contamination control, environmental and clean utilities monitoring
- Compiling environmental monitoring batch release reports
- Review and approval of deviations, change requests and CAPAs
- Provide advise and coach internal stakeholders on hygiene related topics and GMP requirements
- Establish and maintain pest control program including review and approval of regular pest control reports

11/2017 – 01/2022

*Permanent Employment*

#### **Research Assistant / Doctoral Student**

*University Freiburg, Faculty of Biology II, Germany*

Project: "Role of Pex14p and Pex25p in peroxisome biology and biogenesis"

- Doctoral student at RTG2202: "Transport across and into membranes" (Research Training Group DFG)
- Working with yeast cultures under S1 conditions
- Recombinant protein purification using affinity chromatography
- SDS-PAGE and quantitative western blot analyses
- Phosphorylation, complex and interaction analyzes using mass spectroscopy, including analysis of mass spectroscopy data
- Personal supervisor for an assistant researcher and general supervision of Bachelor and Master students

09/2015 – 11/2015

*Permanent Employment*

**Internship Research Assistant**

*University Freiburg, Faculty for Chemistry and Pharmacy, Germany*

Project: "Overproduction of Complex I variants and crystallization of NuoEF<sub>His</sub> C182G<sup>F</sup>"

- Working with bacterial cultures under S1 conditions
- Recombinant protein purification using affinity chromatography
- Crystallography

**EDUCATION**

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11/2017

**Master of Science, Biochemistry and Biophysics**

*University Freiburg, Faculty for Chemistry and Pharmacy, Germany*

Master thesis in Functional Proteomics and Biochemistry:  
 "Study of the functional role of Pex5p phosphorylation for peroxisome biology"

09/2015

**Bachelor of Science, Chemistry**

*University Freiburg, Faculty for Chemistry and Pharmacy, Germany*

Bachelor thesis in Molecular Bioenergetics:  
 "Structural and functional characterization of the NADH:ubiquinone oxidoreductase subcomplex NuoEF<sub>His</sub> from Aquifex aeolicus"

05/2011

**General University Entrance Qualification**

*Gynnasium am Deutenberg Villingen-Schwenningen, Germany*