

Dr Bernhard Unterlinner

Apotheker

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Focus Areas

- Interim Management / Restructuring
- Qualified Person (QP) / Vice President (VP) Activities
- Quality Assurance / Quality Management
- Manufacture of Biopharmaceuticals / Chemical and Herbal Medicines
- Inspection Management / Audits
- Obtaining Authorizations / Certificates (Manufacturing, Wholesale)
- Project Management
- Operational Support

Experience

- 2019 – **Interim Manager and Consultant**
- Founder of Pharma & Biotech Consulting – Dr. B. Unterlinner
- 2017 – 2019 **Head of Quality and Third-Party Management, Klinge Pharma, Holzkirchen**
- Establishing of Quality Management, Manufacturing, and Pharmacovigilance Systems for a newly founded pharmaceutical company
- 2016 – 2016 **Head of Global Quality Unit: Biopharmaceutical Processes, Novartis AG**
- Further development and harmonizing of biotechnological processes
- Integration of quality systems for biopharmaceuticals
- 2011 – 2015 **Director of Operations, Fresenius-Kabi, Neufahrn/Munich**
- Deputy Site Manager, QP
- Head of Aseptic Manufacturing, Quality Assurance, and Quality Control
- 2008 – 2010 **Head of Quality Assurance, Catalent, Schorndorf**
- QP and Project Lead for Site Expansion and FDA Approval
- Qualification, Validation, Training, Audits, Documentation, Contracts, PQR
- 2002 – 2008 **Head of Quality and CMC Documentation, Fujisawa, Munich**
- QP for sterile and non-sterile solid, semi-solid, and liquid dosage forms
- Preparation and maintenance of CTD Modules 2 & 3 for international approvals
- 1999 – 2002 **Head of Quality Assurance, Hoffmann-La Roche AG, Basel**
- Responsible Person (CH) and QP
- QM for aseptic manufacturing of a blockbuster antibiotic