Dr. Andreas Eberle

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WORK EXPERIENCE

08.2023 **FREELANCE – PHARMACEUTICAL CONSULTANT**
(Interims Management and Solution for Pharmaceutical Industry)

- among others, Temporal Engagement at CO.DON GmbH for Global Projects

07.2017 - 08.2023 **CO.DON GMBH (CO.DON AG) – LEIPZIG/TELTOW, GERMANY**
(120 EMPLOYEES, TURNOVER: 7 MM €)

04. 2023 – 08.2023 **Global Consultant**

- Support of ReLive Biotechnologies Ltd. in the production expansion at the Shanghai site, and management roadshows

11. 2019 – 03.2023 **Vice President, Side Head Leipzig**

- Commissioning Leipzig facility
- Responsible for 50 Employees, 5 direct reports (Section Managers: Manufacturing, QA, QC, SCM, Engineering)
- Responsible for commercial manufacturing ATMP (personalized medicine) at the full GMP facility
- Developing CMO-Business
- Production within isolators and clean rooms

07.2017 – 10.2019 **Vice President, Head of Global Manufacturing (Teltow facility)**

- Responsible for 58 Employees, 5 direct reports (Section Managers)
- Responsible for commercial manufacturing ATMP (personalized medicine) at the full GMP facility (production schedule, maintenance, investments, KPI reporting)
- Production within isolators and clean rooms
- in 2018 and 2019 leading the start-up of the Leipzig facility, scale-up and triple capacity

07.2012 - 06.2017 **IDT BIOLOGIKA GMBH – DESSAU, GERMANY**
(1,600 EMPLOYEES, TURNOVER: 200 MM €)
(CMO-Business/Animal Health)

09.2016 – 06.2017 **Senior Director, Technical Operations Drug Product**

- (from September 2016 on) Acceptance of Position and responsibility of the whole filling facilities
- Responsible for 350 Employees, 6 direct reports (Section Managers: Manufacturing, SCM, Qualification, Engineering)
- Responsible for commercial manufacturing at the full GMP facility incl. compounding, aseptic filling, and visual inspection (production schedule, maintenance, investments, KPI reporting)
- 9 filling lines for ampoules, vials and syringes, lyophilized and liquid products, Cleanrooms and Isolators
- approximately 50 inspections p.a. (customers and authorities (US, Europe, ROW)
- Cooperation with Drug substance department, Packaging department, Logistics, Engineering QA/QC department, Supply chain, Development department, Sales & Marketing, Finance, HR, Works Council

07.2012 – 08.2016 **Director Bulk Sterile Manufacturing**

- Responsible for 240 Employees, 8 direct reports (Production Managers, Engineering, Qualification/Validation)
- Responsible for commercial manufacturing at the full GMP facility incl. compounding, aseptic filling, and visual inspection (production schedule, maintenance, investments, KPI reporting)
- 6 filling lines for ampoules, vials and syringes, lyophilized and liquid products, Clean room technology
- approximately 34-40 inspections p.a. (customers and authorities (US, Europe, ROW)

05.2008 – 06.2012 **MERCKLE GMBH (RATIOPHARM GROUP) – ULM, GERMANY**
(2,800 EMPLOYEES, TURNOVER: 1.9 BN €)

Head of biopharmaceutical Manufacturing (Associate Director)

- Responsible for 18 employees
- Responsible for the full GMP routine production incl. compounding, aseptic filling, visual inspection and secondary packaging of sterile products filled in pre-filled syringes
- building up a visual inspection group

02.2005 – 04.2008 **CILAG AG (JOHNSON & JOHNSON) – SCHAFFHAUSEN, SWITZERLAND**
(1,300 EMPLOYEES, TURNOVER 360 MM CHF**)**

02.2008 – 04.2008 **Principal Scientist**

- Transfer of syringe manufacturing knowledge and skills to a fill-finish pilot plant team

02.2005 - 01.2008 **Head of Eprex Group (Associate Director)**

- 5 direct reports
- Technical support of the respective products at the Cilag AG and at the CMO with regard to process- and product technology, validation, change control and deviation management
- Process optimization using 6 sigma tools (Green belt theoretical education)

10.1999 – 01.2005 **AVENTIS BEHRING GMBH (CSL BEHRING) – MARBURG, GERMANY**
(5,600 EMPLOYEES, TURNOVER 1.1 BN €)

08.2002 – 01.2005 **Head of production compliance (Senior Manager)**

- 8 direct reports
- GMP support of Filling department (sterile filling in ampoules, vials and syringes, lyophilized and liquid products) and packaging department (support of deviation and change management, process optimization)
- Representative of the department during inspections (FDA, EU, Japan), organization and execution of inspections, development of follow-up plans

10.1999 - 07.2002 **Head of Qualification (Senior Manager)**

- 6 direct reports
- Responsible for Qualification VMP, DQ, IQ, OQ, PQ, RQ (Re-Qualification) and CQ (Change-Qualification)
- Planning and execution of Equipment-Qualification, incl. lyophilizers, autoclaves, hot air ovens and tunnels, pasteurizers, production vessels etc.
- Planning and execution of Utility Qualification, incl. HVAC, compressed air, WFI, clean steam

12.1997 – 09.1999 **LIFE SCIENCES MEISSNER & WURST GMBH – STUTTGART, GERMANY**
(200 EMPLOYEES, TURNOVER 3 MM €)

01.1999 – 09.1999 **Lead validation engineer (Manager)**

- Leading Validation/Qualification projects as a consultant (incl. VMP, DQ, IQ, OQ, PQ, RQ (Re-Qual.) and CQ (Change-Qual.)
- Working on different projects (design of turn-key facilities) at several companies within the pharmaceutical industry

12.1997 - 12.1998 **Validation Engineer (Manager)**

- Development and Execution of Validation/Qualification Studies (DQ, IQ, OQ, PQ, RQ (Re-Qual.) and CQ (Change-Qual.)

EDUCATION

04.1994 – 09.1996 **TECHNICAL UNIVERSITY BERLIN**
Dissertation (Dr.-Ing.)
- Safety fermentation using micro encapsulated systems

10.1987 – 03.1993 **TECHNICAL UNIVERSITY BERLIN**
University studies (Biotechnology - Bioengineering)

QUALIFICATIONS

Languages	German (first language), English (fluently), French (basics)
Computer Skills	SAP, Family/ERP, MS-Office, MS-Project, Visio, MiniTab