

Dr. Andreas Eberle

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WORK EXPERIENCE

since **09.2023**

FREELANCE – PHARMACEUTICAL CONSULTANT

(Interims Management and Solution for Pharmaceutical Industry)

- For a complete list of projects please refer to www.ef-con.eu

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, Site 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
