

Dr. Andreas Eberle

Alte Strasse 6
04229 Leipzig
Germany

Phone +49 151 722 370 19
Andreas.Eberle@ef-con.eu
www.ef-con.eu



PERFORMANCE SUMMARY

Key Processes

- CAPA
- Deviation
- Change Control
- Batch Record Review
- Personnel Management (up to 350 employees)
- Hands-on writing/reviewing of GMP-Documents
- Head of Production / Leitung der Herstellung (§§ 12, 13 AMWHV)

Technology

- Clean Room
- Aseptic Filling
- RABS, Isolator
- HVAC, WFI, Clean Steam, Compressed Air
- Autoclave, Lyophilizer
- Planning, Commissioning, Maintenance
- Sterilization

Products

- Vials
- Ampoules
- Prefilled Syringes
- Cartridges
- Autoinjector
- Pen
- Safety Devices
- Medical Devices

Liquid, Freeze-Dried Powder

Authorities / Guidelines

- local German authorities LAVG Brandenburg, Regierungspräsidium Tübingen, Landesdirektion Sachsen (LDS)
- Paul Ehrlich Institute (PEI)
- USA (FDA)
- Korea (Korean FDA)
- Brasil (ANVISA), Mexico (SALUD)
- Turkey (TITCK)
- European Medicines Agency (EMA), Schweiz (Swissmedic)
- GMP, AMWHV, ATMP
- ICH Q8, Q9, Q10

Special Processes

- Installation Qualification (IQ)
- Operational Qualification (OQ)
- Performance Qualification (PQ)
- Validation Master Plan (VMP)
- Site Master Plan (SMP)
- Batch Record (BR)
- Risk Analysis (RA)
- GAP-Analysis
- Process Validation (PV)
- Executing of Qualification activities regarding IQ, OQ, PQ

SUMMARY OF PROJECT EXPERIENCE FREELANCE

Recipharm – Wasserburger Arzneimittelwerk GmbH, Wasserburg, GERMANY

- Coordination of preparations for the GMP-acceptance inspection of a filling line by the local authorities

Recipharm – Wasserburger Arzneimittelwerk GmbH, Wasserburg, GERMANY

- Support Head of Operations department, reorganization of validation (APS concept, re-validation)

Recipharm – Wasserburger Arzneimittelwerk GmbH, Wasserburg, GERMANY

- Consultant QA Qualification, Upgrade-Project Annex 1, support, Support with commissioning of a isolator-based small filling line

Haupt Pharma Wülfig GmbH (Aenova Group), Hannover Region, GERMANY

- Head of production (Leitung der Herstellung gemäß §12 AMWHV), Closing of sterile area (final APS, final Qualification of Equipment and Utilities)

BellaSeno GmbH, Leipzig, GERMANY

- Consultancy for different GMP-Projects, e.g. Cleanroom for 3D-print, CSV

SUMMARY OF PROJECT EXPERIENCE DURING EMPLOYMENT

ReLive Biotechnologies Ltd., Shanghai, CHINA

- Support for the establishment and expansion of production at the Shanghai site
- Support management in roadshows as part of investor relations work

CO.DON GmbH, Leipzig, GERMANY

- Planning and implementation of the Leipzig production site; 3 isolators, 16 docking stations, 144 incubators, HVAC, WFI, pure gases (compressed air, CO2-System)
- Concept development and establishment of contract manufacturing

IDT Biologika GmbH, Dessau, GERMANY

- Project responsibility for the installation of a new visual inspection area (manual and automatic optical inspection)
- Upgrade of an aseptic filling line (bulk production, filling line, pre- and post-processing)

TEVA ratiopharm (Merckle GmbH), Blaubeuren/Ulm, GERMANY

- Modernization of an aseptic filling line for bulk syringes with associated packaging line and visual inspection (Blaubeuren/Ulm, Germany)

TEVA ratiopharm (Merckle GmbH), Kfar Saba, ISRAEL

- Subproject management: Troubleshooting of an aseptic filling system for nested ready-to-use syringes

TEVA ratiopharm (Merckle GmbH), Mexico City, MEXICO

- Subproject management: Troubleshooting/GMP upgrade for the processing of nested ready-to-use syringes (Mexico City, Mexico)

Johnson & Johnson, Schaffhausen, SWITZERLAND

- Subproject management: New filling line for nested ready-to-use syringes, including E-beam
- Subproject management: Development of a new auto-injector ("passive syringe") and co-inventor of the design and introduction of a new attachable needle unit for syringes ("Needle assembly for a prefilled syringe system," International Patent No. PCT/IB2006/002792, US No. 12/064,252) (2009)

Aventis Behring GmbH, Vienna, AUSTRIA

- Project management for qualification within the GMP upgrade of the Vienna Floridsdorf production facility (bulk manufacturing, aseptic filling, freeze-drying, supply systems)

Technical University of Berlin, Berlin, GERMANY

- Project on process development and optimization of "safety fermentation with microencapsulated systems"
- (Patent: "Microcapsules" DE 197 56 499.2 (1997))