GXP Assure
Supporting GxP Compliance Worldwide

CURRICULUM VITAE

Michael Paar

Senior Consultant, GxPAssure

Recognised Areas of Expertise:

- Pharmacist with overall 17 years of experience in the pharmaceutical industry.
- Working at a manufacturer and sponsor of clinical trials (Phase I – III) for DNA based medicines and gene therapy medicinal products as Head of Quality Control, Director Quality Control, Director QA and Operations and Qualified Person.
- Different consulting projects in the areas of GMP, GDP and GCP and acting as Qualified Person EU for clients.
- Profound knowledge of the GMP/GDP/GCP regulated environment and requirements as well as links between the GMP, GDP and GCP areas.
- Qualified Person according § 15 (1) (medicinal products) and (3a) (gene therapy medicinal products) German Medicinal Products Act
- Responsible Person Narcotics (German Narcotic Drugs Act)
- Project and Personnel Management
- Corporate reorganization
- Complete set-up, implementation and maintenance of GMP (APIs and medicinal products), GDP and GCP systems as well as inspection preparation (inspection readiness)
- Extensive knowledge of the laws and provisions for medicinal products, investigational medicinal products and APIs (AMG, AMWHV, CFR) and guidelines (GMP, ICH, FDA) as well as regulations in the GCP area.
- Area of expertise: Investigational Medicinal Products (IMPs), Advanced Therapy Medicinal Products, Medicinals Products and Active Pharmaceutical Ingredients inclusive the relevant regulations (EU GMP Guide Part I including Annexes like Annex 1, Annex 13, Annex 16; EU GMP Guide Part II; EU GMP Guide Part IV)
- Strong experience in audits, inspections and due diligence processes
- Languages: German (mother tongue), English (fluent in written and spoken)

Current Employment:

- Aug 2024 to Date
- Senior Consultant, GxPAssure Ltd.
- Owner & Director of Paar Pharma Consulting
- Independent GMP & GDP Quality consultant providing a range of services
- Supported multiple companies in improving quality & compliance across a wide range of areas including:
    - Proactive consultation & continuous improvement
    - Inspection Readiness
    - Remediation following regulatory action
    - Third Party auditing & supply chain management

Career History:

- **Feb 2015 – Present: Independent Quality Consultant**
    - Qualified Person according § 15 (1) (medicinal products) and (3a) (gene therapy medicinal products) German Drug Law
    - Trainings and auditing services
    - GMP/GDP consulting and services for API and (investigational) medicinal product manufacturers, laboratories and wholesalers

- **Mar 2016 – Feb 2019: Director QA and Operations / Qualified Person, Mologen AG**
    - Maintenance and further extension of the quality assurance/management system of the company (mainly GMP and GCP area)
    - Member of the management committee (group of employees responsible for corporate management during absence of executive board)
    - Project and Personnel management
    - Release of all quality relevant documents
    - Review of job descriptions and organigrams
    - Communication with competent authorities (first contact)
    - Inspections (first contact)
    - Organization and conduct of internal and external audits
    - Reporting to executive board (partly supervisory board)
    - Supervision of corrective and preventive actions
    - Planning and conduct of trainings
    - Release and monitoring of audit and training plans
    - Advice for QA tasks of all departments
    - First contact for all regulatory questions regarding manufacturing and control of APIs and medicinal products
    - Coordination of quality planning and support/improvement of quality awareness

- Release of APIs (microbiological origin, cell-based and DNA-based products)
- Release of IMPs / INDs (gene therapy medicinal products; medicinal products) – qualified person according § 15 (1) and (3a) German Drug Law
- Batch Record Review for batch certification
- Risk management
- Assessment of deviations and changes
- Handling of complaints and recalls of products
- Handling of OOx-results
- Project work (research and development)

- **Jan 2010 – Feb 2016: Director Quality Control / Qualified Person, Mologen AG**
  - Director of the quality control departments at two manufacturing sites
  - Release of APIs (microbiological origin, cell-based and DNA-based products)
  - Release of IMPs (gene therapy medicinal products; medicinal products) – qualified person according § 15 (1) and (3a) German Drug Law
  - Batch Record Review for batch certification
  - Member of the quality assurance
  - First contact for all regulatory questions regarding manufacturing and control of APIs and medicinal products
  - Risk management
  - Assessment of deviations and changes
  - Monitoring of the effectiveness of CAPA
  - Handling of complaints and recalls of products
  - Monitoring and collaboration on all qualifications and validations
  - Release of GMP-relevant documentation (Specifications, SOPs, etc.)
  - Preparation of Investigational Medicinal Product Dossiers and IND applications (CMC)
  - Handling of OOx-results
  - Stability studies
  - Audits of suppliers and contract manufacturers / laboratories
  - Evaluation and qualification of suppliers
  - Communication with competent authorities (first contact)
  - Project work (research and development)
  - Control of hygiene monitoring (clean rooms for the aseptic manufacturing)
  - Project and Personnel management
  - Reporting of the GMP-status of the manufacturing sites to the executive board (partly supervisory board)
  - Responsible for the inspection readiness of both sites
  - Training of employees

- **May 2009 – Dec 2009: Qualified Person and Head of Quality Control**

- **May 2007 – Apr 2009: Head of Quality Control**

Education:

- **Degree in Pharmacy (Freie Universität Berlin) July 2007**
- Jan 2021 „Experiences with remote audits and virtual inspections“ at GXP Engaged Auditing Services GmbH, Germany (virtual)
- May 2020 „7th annual conference Qualified Person“ at ChemAcademy, Germany (virtual)
- May 2019 „6th annual conference Qualified Person“ at ChemAcademy, Köln, Germany
- 2016 - 2019 Regular self-training and review of legislation as responsible person for the internal training of employees on changes in
- the GMP laws, regulations and guidelines, Company in Berlin, Germany
- Dec 2016 “ICH GCP” at Whitehall Training, web-based
- Mar 2016 “Continued and on-going process verification” at ChemAcademy, Berlin, Germany
- Oct 2013 “GMP meets GCP” at European Compliance Academy, Basel, Switzerland
- Dec 2011 “Rapid Microbiological Methods Conference” at European Compliance Academy, Berlin, Germany
- Nov 2011 “Quality aspects for manufacturing of ATMPs” at BBLife, Berlin, Germany
- Nov 2010 “Vergleichbarkeit von Produkten während der Arzneimittel- und Wirkstoffentwicklung” at BBLife, Berlin, Germany
- Mar 2010 “Verantwortungsverbund im Arzneimittel-Recht: QP, Leitung der Herstellung sowie Qualitätskontrolle” at PTS Training Service, Darmstadt, Germany
- Mar 2009 “Interner Auditor Life Sciences” at BBLife, Berlin, Germany
- Feb 2009 “Qualified Person Education Course” at QP Association, Amsterdam, Netherlands
- Jan 2009 “Projektmanagement Basiswissen” at Haufe Akademie, Berlin, Germany
- Dec 2008 “GMP-Hygiene Basis-Schulung” at Concept Heidelberg, Berlin, Germany
- Sep 2008 “Expert for APIs” at PTS Training Service, Niederkassel, Germany
- Jun 2007 “AMWHV” at PTS Training Service, Duesseldorf, Germany