GXP Assure
Supporting GxP Compliance Worldwide

CURRICULUM VITAE

Dr. André Rieks

Doctor of Science (Dr. rer. nat.)
Senior Consultant

Recognised Areas of Expertise:

Senior Executive Consultant with more than 25 years of leadership experience in global biopharmaceutical and life sciences organizations. Extensive track record building and transforming quality organizations, implementing enterprise GxP compliant systems, and leading complex international manufacturing and development programs. Recognized for driving operational excellence, regulatory compliance, and large-scale quality transformation initiatives across Europe, the United States, and Asia.

Deep expertise across global quality governance, clinical operations QA, CMO management, and technology transfer from development through commercial manufacturing.

- Global Quality Leadership with span of control of 10+ direct and 80+ indirect reports
- Enterprise Quality Systems (QMS/eQMS) & cGxP Compliance (EU, FDA, SFDA, MHRA)
- Quality Remediation & Inspection Readiness
- Quality Assurance & Operations
- Good Distribution Practice Management
- Operational Excellence & Change Management
- Technology Transfer
- CMO & Strategic Partner Management
- Global Program & Cross-Functional Leadership

Notable Career Contributions

- Established and led Global Clinical Operations QA at BioNTech SE, ensuring compliant manufacturing and supply of investigational medicinal products across global clinical programs.
- Implemented enterprise GxP Quality Management Systems across multiple organizations, including global electronic QMS platforms and corporate governance frameworks.

- Played a leadership role in quality operations supporting the global launch of the COVID-19 vaccine Comirnaty®.
- Led EU-GMP compliant technology transfer and manufacturing implementation across Chinese CMO networks for biopharmaceutical production.
- Successfully delivered quality remediation programs, regulatory compliance initiatives, and organizational restructuring across global pharmaceutical companies.
- Managed complex technology transfer and manufacturing scale up projects across Europe and Asia, improving operational efficiency and regulatory readiness.
- Bilingual German and English speaker

Current Employment:

- Independent Consultant working on behalf of GxPAssure Limited

Career History:

- **2025 – 2026: Elanco Animal Health Inc., Cuxhaven, Germany – Site Head of Quality**

  Ensuring vaccine products manufactured in compliance with Annex 1 and cGMP requirements. Responsible for bridging strategic quality planning with operational execution to guarantee timely product release.

  - Restructured Quality Organization and implemented lean operational excellence
  - Guided establishment and execution of local quality remediation program

- **2024 - 2025: BioNTech SE, Cambridge, USA / Mainz, Germany - Head of Global Systems**

  Responsible for establishing a corporate global GxP Quality Management System to harmonize quality operations across the BioNTech network from preclinical development to commercial manufacturing.

  - Developed a global GxP framework supporting quality governance across international operations
  - Standardized quality processes across the global manufacturing and development network

- **2021 - 2024: BioNTech SE, Cambridge, USA - Lead Global Clinical Operations QA**

  Established and led the Global Clinical Operations Quality Assurance organization responsible for quality oversight of investigational product manufacturing and supply.

  - Built and implemented the global Clinical Operations QA function
  - Ensured GxP compliant manufacturing and supply across global clinical development programs

- **2021: BioNTech SE, Shanghai, China - Lead Operations Asia**

  Operational and quality liaison for the COVID-19 vaccine program in China, Hong Kong, Macau, and Taiwan.

  - Oversaw quality operations within joint and **corporate steering committees**
  - Guided technology transfer and manufacturing scale up with Chinese CMO partners

- **2020 – 2021: BioNTech SE, Mainz, Germany - Lead Operational QA / Product Quality Complaints**

  Established the corporate Product Quality Complaint management system supporting the global launch of Comirnaty®.

  - Build and implemented the global complaint management framework and processes
  - Ensured compliant handling of product quality complaints during global commercialization

- **2020: Santen Pharmaceutical Co., Ltd, Geneva, Switzerland - Project Management Coach**

  Supported technology transfer programs for sterile products through project leadership coaching.

  - Implemented structured project monitoring and budgeting procedures
  - Strengthened risk management and cross functional communication processes

- **2019 – 2020: Gedeon Richter Pharma GmbH, Cologne / Eschborn, Germany - Head of Quality Assurance & Responsible Person (AMG §52a)**
  Led quality assurance operations and quality system improvements during a corporate remediation program.

- Implemented a new GDP compliant quality management system across German subsidiaries
- Strengthened regulatory compliance and operational quality standards

- **2019: Ayoxxa Biosystems GmbH, Cologne, Germany - Chief Quality Officer / Head of Production**

  Responsible for implementing companywide quality systems and optimizing production operations.

  - Implemented Total Quality Management framework and training program
  - Introduced lean manufacturing guidelines and supply chain improvements

- **2018: GSK Vaccines GmbH, Marburg, Germany - Quality Consultant, Deviation Management**

  Led investigations for deviations in vaccine manufacturing following FDA inspection findings.

  - Successfully closed multiple critical deviation investigations and CAPA programs

- **2018: MSD Burgwedel Biotech GmbH, Burgwedel, Germany - QA & Technology Transfer Consultant**

  Supported technology transfer for Ebola vaccine production and implemented harmonized quality processes.

  - Established streamlined issue management processes for human and animal vaccine programs

  Provided senior quality and operational consulting across leading pharmaceutical and biotechnology companies in Europe and Asia. Responsibilities included technology transfer, EU-GMP certification, manufacturing scale-up, supply chain development, and commercialization of pharmaceutical products.

- **2017 – 2023: Kemiex AG - Head of Quality Assurance & Responsible Person**

- **2017 – 2018: Boehringer Ingelheim GmbH & Co. KG - Consultant Global Quality Agreements**

- **2017: Zelhealth GmbH - Responsible Person for Narcotics §3 BtMG**

- **2016: Roche Diagnostics GmbH - Quality Management Systems Consultant**
- **2016: MSD Animal Health - Senior Technology Transfer Manager**
- **2015: Dynavax Europe GmbH – Head of QA**
- **2015 – 2016: Pharmsol GmbH - Chief Quality Officer & Responsible Person**
- **2013 – 2014: ACA Müller ADAG Pharma AG - Chief Quality Officer**
- **2011 – 2014: Zhejiang Apeloa Kangyu Biopharma Ltd. - Senior Technology Transfer Manager**
- **2009 – 2011: Datong Tongxing Pharmaceutical - Chief Technology Officer**
- **2009 – 2018: BMP AG - Qualified Person AMG §14**
- **2006 – 2008: Biotex GmbH - Chief Scientific Officer**

Education:

- Doctor of Science (Dr. rer. nat.) - Technical University of Hamburg
  "Stereospecificity and chiral recognition of enzymes optimized by genetic and process engineering"
- Diploma in Chemistry (Dipl. Chem.) - University of Hamburg
  "Genetic engineering of Penicillinamidase for the resolution of racemic amino acids"