



## CURRICULUM VITAE

# Sylvia Peter

Dr. rer. nat.  
Senior Consultant



### Recognised Areas of Expertise:

- Accomplished pharmaceutical professional with over 15 years' experience spanning early-stage clinical development through to full commercial readiness. Proven ability to support cross-functional teams, streamline operations, and contribute to the successful progression of therapies across the development lifecycle
- > 25 international vendor/supplier audits:
  - Full service CROs
  - Data management/statistics CROs
  - Clinical laboratories
  - Clinical imaging vendors
  - Pharmacovigilance CROs
  - IRT providers
  - Drug supply vendors
  - Clinical pharmacology CROs
- > 14 Investigator site audits (on-site and remote):
  - EU, US, GB, AUS
  - Phase I/II/IV, medical device trials (ISO 14155)
  - Indications: Oncology, Dermatology, Allergology, Pulmonology
- > 25 system audits (e.g. self-inspections of departments and processes):
  - Clinical Operations
  - (e)TMF
  - Data Management & Statistics
  - Pharmacovigilance
  - Training Systems
  - Archiving
  - Information Technology
  - Human Resources
  - Company Affiliates



- > 15 document audits:
  - Clinical Trial Protocol
  - Informed Consent Form
  - Clinical Study Report
  - Investigator Brochure

### **Current Employment:**

- Independent Consultant working on behalf of GxPAssure Limited
- Partner at Peter Auditing GbR (Heidelberg, Germany)

### **Career History:**

- **July 2024 – Present: Peter Auditing GbR (Heidelberg, Germany) - Partner**
  - Peter Auditing offers the following services to their customers:
    - Conducting GCP contract audits for vendor qualification, requalification and project audits, investigator site audits, document and system audits, sponsor self-inspections, Quality Consulting Services (SOP writing, Gap analyses)
- **March 2022 – April 2024: Affimed GmbH (Mannheim, Germany) - Head of Clinical QA**
  - Planning and execution of Affimed's clinical audit strategy
  - Perform internal audits, vendor qualifications, investigator site audits
  - Assessment and implementation of regulatory requirements to Affimed's QM system
  - Provision of GCP trainings
  - Hosting GCP self-inspections
  - Writing, revising and managing SOPs
  - Maintenance and improvement of Affimed's QM system (auditing, CAPA, vendor qualification, training system)
  - Leading the GCP quality management team
  - GCP QA support for clinical operations, medical affairs, safety, drug supply, regulatory affairs, clinical pharmacology, pharmacovigilance departments and cross-functional program teams
- **September 2018 – February 2022: Affimed GmbH (Mannheim, Germany) - GCP Quality Manager**
  - Perform internal audits, vendor qualifications, investigator site audits
  - Writing, revising and managing SOPs
  - Provision of GCP trainings
  - Hosting GCP self-inspections

- Maintenance and improvement of Affimed's QM system (auditing, CAPA, vendor qualification, training system)
  - Managing and improving Affimed's Training Management System (paper & electronic)
  - Support of Computer Systems Validation activities (e.g. eTMF)
  - GCP QA support for clinical operations, medical affairs, safety, drug supply, regulatory affairs, clinical pharmacology, pharmacovigilance departments and cross-functional program teams
- **April 2017 – August 2018: Navitas Life Sciences, formerly Ecron Acunova (Frankfurt am Main, Germany) – Quality Assurance Manager GCP**
    - Internal auditing, partner & vendor qualifications
    - Writing, revising and managing SOPs
    - Assessment of KPIs
    - Consultation of operational teams in compliance questions
    - Review and approval of forms/templates for clinical trials
    - Deviation/CAPA Management
    - Supporting inspections from local authorities
    - Supporting customer qualifications
- **October 2016 – March 2017: MEDA Pharma GmbH & Co. KG acquired by Mylan (Bad Homburg, Germany) – Quality Manager GCP/GLP**
    - Developing, performing and managing the GCP auditing program as Lead GCP Auditor (internal processes, document audits, CROs, clinical trial sites) including CAPA follow-up
    - Review of operational plans and CRF for NIS and PASS studies
    - Writing, revising and managing SOPs for Corporate Clinical Affairs
    - Hosted customer audits
    - Monitoring compliance with all regulatory requirements
- **June 2014 – August 2016: apceth GmbH & Co. KG (Munich, Germany) – Regulatory & GCP Compliance Manager**
    - Quality Assurance Tasks:
      - Developing, performing and managing the GCP auditing program as Lead Auditor (auditing CROs, investigator sites, clinical laboratories, drug supply vendors) including CAPA follow-up
      - Writing, revising and managing SOPs for Clinical Development
      - Perform Quality reviews of essential documents and TMF
      - Ensuring that regulatory, documentation and recordkeeping requirements are adhered to internally and externally at partner CRO
      - Assisting in the development of GCP trainings of personnel in functional areas involved in the execution of clinical trials



- Supporting inspections from local authorities and customer audits
- Regulatory Tasks:
  - Planning and coordinating regulatory procedures (e.g. CTA, ODD, Scientific Advice) including preparation and updating regulatory documentation
  - Supporting Senior Management in the development of the regulatory strategy
  - Participation at scientific advice meetings (PEI) and oral hearing (COMP/EMA)
  - Responsible for TPP (target product profile) for lead product
  - Identification of training and educational needs regarding compliance
- **December 2012 – October 2013: Maternity Leave**
- **January 2011 – November 2012: apceth GmbH & Co. KG (Munich, Germany) – Clinical Trial Manager**
  - Quality Assurance Tasks:
    - Developing and writing of SOPs (clinical operations; interface between GCP and TPG (Transplantation law) regarding all processes of bone marrow donation)
    - Leading of GMP/GCP compliance meetings
    - Team Training
  - Clinical Operations Tasks:
    - Trial project management (Phases I/II, indications: COPD; solid tumors)
    - Leading of clinical trial team
    - CRO selection and oversight
    - Vendor oversight
    - Coordination of DSMB meetings, preparation and supply of relevant materials
    - Preparation and submission of CTA and amendments to the German competent authority (Paul-Ehrlich Institute) and German local Ethics committee
    - Writing and submission of annual DSUR
- **March 2010 – December 2010: Maternity Leave**
- **September 2009 – February 2010: apceth GmbH & Co. KG (Munich, Germany) – Head of Quality Management**
  - Coordination of the self-inspection program
  - Leading of the quality management team
  - Responsible for operational Quality Management and establishing a GMP-compliant QM system at apceth in close collaboration with internal departments and external consultants
  - Planning and coordination of GMP trainings
  - Writing, coordination and oversight of all relevant SOPs

- Preparation of annual plans (training plan, self-inspection plan, auditing plan)
- Responsible for oversight/qualification of external vendors and laboratories
- Handling of Deviations and CAPA
- Supporting inspections from local authorities

**December 2008 – February 2010: apceth GmbH & Co. KG (Munich, Germany) – Preclinical Research Scientist**

- Supervising construction and equipping of preclinical laboratory
- Oversight of pre-clinical vendors
- Establishing of methods in apceth's laboratories
- Training and supervising technicians

**Education:**

- April 2005 – September 2008: Stanford University (Stanford, CA, USA)
  - Postdoctoral Fellow
- June 2001 – December 2004: Ruprecht-Karls University, Department of Virology (Heidelberg, Germany)
  - Doctoral Thesis
- October 1996 – May 2001: Ruprecht-Karls University (Heidelberg, Germany)
  - Biology Studies (Major Molecular Biology)