



CURRICULUM VITAE

Dr. Christoph Peter

PhD
Senior Consultant, GxPAssure



Recognised Areas of Expertise:

- Over 15 years' experience spanning the full pharmaceutical lifecycle, from early-stage clinical development to large-scale commercial manufacturing.
- Proven track record in preparing facilities for regulatory inspections and guiding organisations through complex compliance, quality system implementation, and inspection readiness initiatives.
- Hosted 30+ regulatory inspections and 40+ client CMO audits, demonstrating strong leadership in audit preparation and execution.
- Extensive auditing background, having led or co-led 70+ audits across contract manufacturers, contract laboratories, and suppliers of critical raw materials for ATMP and RNA-based vaccine programmes.
- Completed 30+ internal self-inspections covering all aspects of ATMP and RNA-based vaccine manufacturing and testing.
- Experienced collaborator with a broad network of industry stakeholders, including academic start-ups, university research groups, and major global pharmaceutical companies.
- Contributor to 10+ due diligence assessments, supporting strategic decision-making across diverse development and manufacturing environments.

Current Employment:

- Independent Consultant working on behalf of GxPAssure Limited
- Partner of Peter Auditing GbR



Career History:

- **July 2024 – Present: Peter Auditing GbR (Heidelberg, Germany) – Partner**

Peter Auditing offers the following services to their customers:

- Qualification, requalification, and for cause audits of CMOs, suppliers, and service providers
 - Preparation for audits and inspections by performing gap assessments and mock inspections
 - Supporting due diligences by evaluating Quality aspects of potential partners
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- **October 2022 – May 2024: BioNTech SE (Mainz, Germany) – Vice President Global Systems Quality**
 - Performed international audits of internal and external CMOs, suppliers, and service providers
 - Performed international Quality due diligences for the acquisition of new products
 - Established a global Quality systems organization
 - Established a global eQMS
 - Quality representative for the management board
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- **October 2019 – September 2022: BioNTech SE (Mainz, Germany) — Vice President Quality**
 - Performed international audits of internal and external CMOs, suppliers, and service providers
 - Performed international Quality due diligences for the acquisition of new facilities
 - Key point of contact for regulatory authorities during the commercialization and distribution of the Covid19 vaccine Comirnaty
 - Developed the Quality organization from an early clinical to a commercial stage
 - Final Quality responsibility for the Covid-19 vaccine Comirnaty.
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- **June 2018 – September 2022: BioNTech SE (Mainz, Germany) - Qualified Person for ATMPs according to §15 (3a) AMG**
 - Certification of patient individualized cancer vaccine batches for international early phase clinical trials
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- **November 2016 – September 2019: BioNTech SE (Mainz, Germany) — Head of Quality**
 - Performed international audits of internal and external CMOs, suppliers, and service providers
 - Performed self-inspections for all Quality relevant areas



- Performed national Quality due diligences for the acquisition of new facilities
 - Hosted inspections by local and national authorities for obtaining and maintaining the manufacturing license for patient individualized cancer vaccines
 - Hosted sponsor audits
 - Developed the Quality system and the organization to fit the needs for aseptic manufacturing of products for clinical trials
- **January 2013 – October 2016: apceth GmbH & Co. KG (Munich, Germany) - Head of Quality Management**
 - Performed international audits for internal and external CMOs, suppliers, and service providers
 - Performed self-inspections for all Quality relevant areas
 - Hosted inspections by local and national authorities for obtaining and maintaining the manufacturing licenses for gene and cell therapy products
 - Hosted customer audits
 - Developed the Quality system to fit CDMO activities in the cell and gene therapy field
- **September 2011 – October 2016: apceth GmbH & Co. KG (Munich, Germany) - Qualified Person for ATMPs according to §15 (3a) AMG**
 - Certification of internal and customer products for early phase clinical trials
- **September 2008 – December 2012: apceth GmbH & Co. KG (Munich, Germany) - Head of Manufacturing**
 - Performed international audits for internal and external CMOs, suppliers, and service providers
 - Represented the manufacturing department in inspection by local and national authorities for obtaining and maintaining the manufacturing licenses for gene and cell therapy products
 - Established a team, the facility, and processes to manufacture genetically modified stem cells for early clinical trials

Education:

- 2005 – 2008: Postdoctoral Fellow - Stanford University (Stanford, CA, USA)
- 2004 – 2005: Postdoctoral Fellow - Max-Planck-Institute for Medical Research (Heidelberg, Germany)
- 1999 – 2003: Doctoral Thesis - Max-Planck-Institute for Medical Research (Heidelberg, Germany)
- 1993 – 1999: Biology Studies (Major Molecular Biology - Ruprecht-Karls University (Heidelberg, Germany)

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