Curriculum Vitae

Dr. Christoph Wambach

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Core Competencies

- **PhD in chemistry and certified ISO and GxP Lead Auditor**
- **> 25 years experiences QMS development (ISO, GMP, WHO) and people management**
- **>9 years of experience in international pharmaceutical GMP (EU GMP, WHO GMP, PIC/S, 21CFR, GLP, GDP);**
- **>3 years of specialized experience in vaccine and biological product manufacturing**
- **Certified lead Auditor for GMP, GDP, GLP, 21CFR, IPEC, ISO9001, ISO17025**
- **Biologics / (bio)pharmaceutical dosage forms including sterile manufacturing**
- **Contamination Control Strategy (CCS) & Routine Hygiene Monitoring setup**
- **Quality Risk Management (QRM), root cause analysis, Audit & SI programs**
- **Digital eQMS implementation (TrackWise, Veeva Vault, Amplexor, IQVIA SmartSolve)**
- **Well experienced in digitalization (LIMS, eQMS)**

Professional profile

I'm an internationally experienced (interim) manager and project manager with a strong track record in pharmaceutical quality management including all relevant processes like deviation, CAPA, Change, complaint, recall and audit management. As a senior quality expert in the Life Sciences sector with profound experience as CEO and Interim Manager as Director and Head-of, I own extensive expertise in all field of Quality. I have successfully led numerous international initiatives involving the design, implementation, and optimization of pharmaceutical Quality Management Systems (QMS) of Pharma, BioPharma and Biologics companies (MAH, CMO). My in-depth knowledge includes aseptic manufacturing CCS and monitoring systems aligned with relevant standards e.g. EU GMP, CFR, WHO GMP. I am adept at identifying quality gaps, resolving compliance issues, and driving continuous improvement in complex manufacturing operations. I have a proven track record of leading various international projects and key-initiatives to a successful conclusion with team, milestone and budget responsibility. As a certified lead auditor, I have conducted a wide range of ISO and GxP audits in life science companies and authorities worldwide covering any dosage form. I thrive in multicultural and interdisciplinary environments, with a leadership style that emphasizes cross-functional collaboration, strategic thinking, and a strong quality culture.

Career summary

05-2025 – 08-2025 **Senior GMP consultant** at **Richter Biologics** in Bovenau, Germany; successful setup of a routine hygiene-monitoring concept with connection to LIMS & eQMS
→ **Focus:** routine hygiene monitoring concept, digitalization

11-2025 – 04-2025 **QA Compliance & Aseptic manufacturing support** at **Recipharm** in **Wasserburg,** Germany; streamlining Quality processes; QMS & CCS improvement;
→ **Focus:** eQMS integration, deviation, CAPA, Change Control, EU GMP, FDA

12.2022 – 07-2024 **Interim Director Global Quality Unit** at **Wörwag Pharma** in Böblingen, Germany; staff: 1500; turnover: 331 Mio € in 2024; 5 direct reports covering 37 employees at HQ +75 in 2 manufact. sites & legal entities worldwide; budget responsib. >5 Mio €;
→ Successful implementation of a global Quality strategy
→ successful integration of a second manufacturing unit including digitalization, eQMS
→ successful M&A support (Q due diligence);

02.2020 - ongoing **Senior Lead Auditor** on behalf of three (US, French & German) certification bodies; conducting GMP, GDP, GLP and ISO (9001, 13484, 17025) audits at CMOs, API, Excipient, vaccine manufacturers, labs, logistic and packaging sites in Europe.

10.2019 – 10.2022 **Senior Quality Consultant & Project Leader & Lead Auditor** at **DR. KADE, Berlin**; staff: 170; turnover: 117 Mio € in 2021; main project leads:
→ authority accepted Nitrosamine & cross-contamination Risk Assessments;
→ design, planning and successful introduction cloud-based eQMS & RIM softwares
→ reorganization of Audit & self-inspection Management;

05.–10.2019 **Senior Project Lead** and consultant at **TETEC AG**, Reutlingen, Germany; staff: 130; turnover: 10,8 Mio € in 2022; successful clean-room GMP equipment qualification including media support, RABS & isolator systems; hygiene risk management and contamination control system (CCS) design and introduction;
→ Biologics, aseptic manufacturing, hygiene risk management

04.2019 **Bioexam AG, Luzern Switzerland**; staff: 14; revenue: unkown; FDA inspection readiness audit and QMS gap-analysis; CAPA-plan;
→ client passed FDA inspection successfully

11.2017 – 01.2019 **Interim Head of Quality** at **Wörwag Pharma** in Böblingen, Germany; staff: >1000; turnover: 270 Mio € in 2021; lead up to 21 employees with 3 direct reports and budget responsibility of approx.. 2.2 Mio €; strategy & KPI setting; lead auditor at CMO for injectables (aseptic manufacturing); contact person for local and international health authorities; PQRs; leading analytical & manufacturing Tech-Transfers & global recalls; responsible for QMR & KPI reporting
→ stopped fluctuation; successful design & setup a Global-SOP system
→ successful reorganization of the Q-department incl. onboarding new staff;

01.2016 – 10.2017 **Leading an international Project** at **Boehringer Ingelheim,** BioPharma site Biberach; staff: 50k, turnover: 18 Bio EUR in 2017; lead a cross-site (US, China, EU), inter-divisional project on all BioPharma products (injectables, vaccines) with a budget of 6.5 Mio €; FDA accepted strategic concept and the scientific study design; agile Project Management;
→ full acceptance of the developed study-design and result evaluation by FDA

08.2015 – 03.2016 **Project Lead & Quality consultant** at **Maquet** (Getinge Gr.), Hechingen Germany staff: 6300, turnover: 1,7 Bio EUR in 2017; Qualification of lab devices after GMP;
→ successful introduction of a new sampling methods of medical **class III-devices**
→ FDA accepted implementation of a mobile Bacterial Endotoxin Test system

04. – 08.2015 **Quality Consultant & Auditor & Trainer;** Quality Management, QA, QC, QS; expert for food, seed and pharma testing; set-up & improvement of QMS

01.2014 – 03.2015 **Interim CEO & Quality Head** at **GeneCon International GmbH; Baesweiler, Germany; biotechnological testing;** staff: 9**,** turnover 2014: unkown
Financial, organizational & scientific responsibility;
→ recapitalization of a bankrupt company with 145 international customers;
→ revenue increase of 9% within 7 month;

2012 - 2014 **QMS Expert, Trainer, Auditor at Saudi Arabian Food and Drug Authority (SFDA),**

Saudi Arabia (GIZ project); staff: approx.. 1200 in 2014; design and setup of a centralized QMS; improved HSE tasks; setup a SFDA-Quality-headquarters; conducted auditor-, QMS - and Lab.-Expert trainings; lead auditor at various SFDA labs (ISO17025, GLP, laboratory safety); setup a Real-Time PCR laboratory

2008 – 2011 **QMS Consultant & Auditor for UNIDO development project in Bangladesh;** audits at 5 governmental laboratories of BAEC, BARI, BCSIR, FIQC (2 labs); designed and supervised the setup of a new laboratory for BAEC; setup of QMS under ISO17025 requirements; conducted QMS trainings for laboratory experts

06.1999 - 2013 **Founder, CEO, Head of Quality & Auditor** at **Euregio Analytic BioChem GmbH; Germany,** a food, feed, seed, pharma (API) and biotech testing & QM consultancy services; staff: up to 26; turnover: 820k in 2012**;**
CEO: budget, HR & scientific responsibility; test method development for API, pharma & biotech product analysis; international representation & acquisition; subcontractor for pharma and biotech; set up a subsidiary in Austria; worldwide consultancies; enabled a yearly revenue increase of 8 - 14% with at least more than 220 active international customers; LIMS design and setup; development of QMS after ISO 9001 & ISO 17025; implementation QC and validation processes;
Project Manager: initialized and lead int. R&D projects; one by US customers order

02.-05.1999 **GET GmbH;** consultant services for chemical industry and governmental authorities

07.98 – 01.99 **Gödecke AG / Parke Davis GmbH; Pharma Industry;** Medical Representative

Education and qualifications

03.2024	Alphatopics GMP-CMC webinar
08.2020	PDA webinar "Remote Audits: New Challenges and Opportunities"
11.2019	Combination products in Pharma; training at Concept Heidelberg
03.2019	Lead GMP Auditor; trained by Concept Heidelberg
05. + 06.2017	certified "cGMP Compliance Manager"; trained by Concept Heidelberg
02.2017	"FDA and cGMP authority inspections"; trained by Concept Heidelberg
11.2016	participation on PharmaLab congress; Bacterial Endotoxin workshop
2011	**"**Internal auditor" ISO22000, IFS, BRC; trained by Bureau Veritas, Germany
1998 - 1999	**"**Quality & HSE auditor" ISO9001 / SCC; TÜV Rheinland, Germany
1984 - 1998	PhD chemistry; University of Bonn; dissertation in coop. with Bayer AG, Germany

Personal skills

- Manager C & D level experienced
- Solid, semi-solid, liquid incl. aspetic products
- Lead auditor GxP, ISO9001, 13485 and 17025
- Successful project management
- Proven people management & development
- digitalization projects eQMS, aseptic sampling
- Agile Project Management (Kanban) knowledge
- flexible and readiness on international travels and relocation
- creatively & analytical in thinking
- decision-maker and business developer
- strong strategic and business acumen
- budgeting and organizational skills
- successful team building experience

Other details

Date of birth	15th September 1964
Marital status	married, two children
Languages	German (native), English (fluent), Spanish (basic)
IT Skills	MS Office, LabVantageLIMS, Veeva Vault, Amplexor eQMS/RIM, TrackWise eQMS, IQVIA eQMS SmartSolve and RIMSmart (key-user); SAP S/4 HANA, SAP-Succes Factors training management
Driving License	full/clean