Wambach Consulting

Service spectrum

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Interim Management

and

Project Management

in companies of the

Life Sciences industry

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Quality is as individual as life itself. Because it affects the entire lifecycle of a product or service, quality should be a holistic endeavour within an organization.

This is exactly my approach for your company.

Image source: wallpaperaccess.com

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➢ Industry experience

Marketing authorization holders - contract manufacturers - service providers
Small and medium-sized companies and groups

Companies for
- Pharmaceuticals
- Biologics / Biotechnology products
- Medical devices
- Food
- Feed
- Seeds

Service companies like
- Laboratories
- Logistics (transport & storage)

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Pharma: all pharmaceutical dosage forms – solids, semi-solids, liquids, injectables …
Medical devices: of all classes and
Combination products (MDR compliance)

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➢ Main competences

Leadership - organisation - management - personnel management - mindset strengthening

- Corporate management (CEO); operations experience; interim director / Head of Quality - locally and globally - incl. strategy, budget, staff responsibility
- Quality strategy setup - locally and globally
- eQMS and eDMS planning, setup, contract negotiation
- Digitalisation, Transformation, Change-Management and use of AI
- KPIs and trending
- Validation of analytical methods and software (eQMS) incl. Transfers (AMT / TT)
- Auditing – incl. audit programm development, auditor training

International standards, laws and regulations

- GMP, GDP, GLP inclusive their Annexes; partly GCP
- AMG, AMWHV, MDR
- 21 CFR parts 11, 210, 211, 820
- ICH Q regulations, PIQS GMP guideline, PDA and WHO Technical Reports
- ISO 9001, 13485, 14644, 17025, 19011, 22000
- GAMP5, HACCP, HSE / SGU, CCS in aseptic manufacturing

* (e) = electronic

Wambach Consulting – my Services

➢ Interim Management / Project Management / Audits

- Interim management of global and local quality units
- Interim management of departments like
  - Quality Units (QU)
  - Quality Assurance (QA / QS)
  - Quality Control (QC)
- Management of local and cross-site projects (national/international)
  - conception, planning
  - realization (hands-on)
  - management
- Audits
  - Lead Auditor for GMP, GDP, GLP, ISO9001, ISO17025
  - Internal Auditor for ISO13485, ISO22000, HACCP,
- Trainings
  - Quality management including QA/QS and QC (GxP and ISO)
  - Auditor education based on ISO19011
  - HSE in laboratories

Image source: wallpaperaccess.com

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➢ Proven successful project completion

- Setup of a routine hygiene monitoring system in biopharmaceutical manufacturing - BioPharma
- Development of a corporate quality strategy for a group of companies – Pharma *
- Quality Management Systems (QMS): Planning, Design, Implementation, Improvement, Centralization - Pharma, private and official Laboratories, Regulatory Authority
- eQMS software system - vendor selection, project planning, development of an eDMS, implementation of various quality modules, staff training and development of interfaces to RIM, LIMS, ERP software - Pharma
- Cross-departmental and cross-site process development for recall management – Pharma
- Inspection preparations FDA, EAEU, ANVISA and local authorities - Pharma and Laboratories
- Auditing and gap analyses of complex, integrated QMS – Pharma
- Restructuring of a quality unit including onboarding of new employees – Pharma
- Conception of a bacterial endotoxin stability study, roll-out to all of the client's sites and products as well as presentation of the results as part of an FDA inspection – BioPharma
- Qualification of laboratory equipment and cleanroom equipment incl. media – MedTech, BioTech
- Validation, Transfer and introduction of analytical methods, e.g. bacterial endotoxin tests (BET) – MedTech, BioPharma
- Compliance checks of combination products according to MDR, ISO13485 and GMP – Pharma
- Nitrosamine risk assessments - concept development and implementation – Pharma
- Development of training systems for auditors based on ISO19011 – Pharma

* branch, where project was conducted

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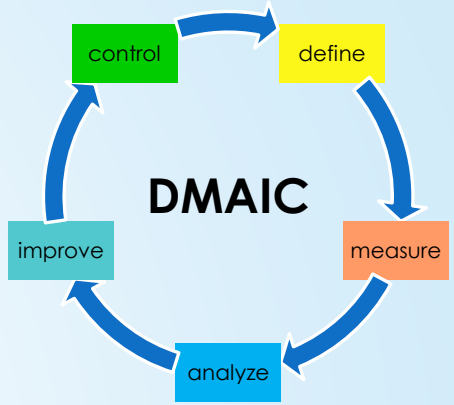
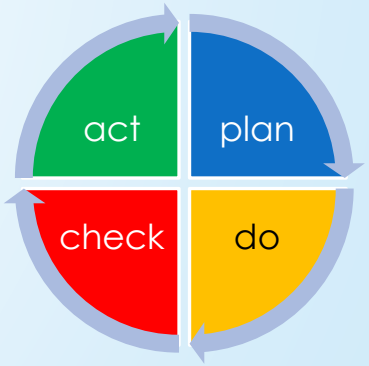
- Previous Interim Manager roles

  CEO (service laboratory for food & pharma testing)
  Director Global Quality (Pharma)
  Head of Global Quality Unit (Pharma)
  Head of Quality Unit (Pharma)



Responsibilities

- Strategy - local and global; development, implementation, management
- Budget - annual planning, reviews during the year
- Personnel - reorganization, motivation, onboarding, dismissal
- Quality management reviews - monthly; preparation, reporting
- KPI - definition, evaluation, trending, review, reporting
- M & A - review of quality-relevant figures and data, statements
- Key initiatives - planning, management, reporting
- Authorities - contact person, management of inspections
- Contracts - QTA and procurement; creation, review, negotiation, approval
- (e)QMS / (e)DMS – design, implementation, validation, improvement
- Risk Management – design, implementation, managing
- QMS documentation - creation, review, approval
- Change management - review, approval, rejection
- Non-conformities and CAPA – evaluation, review, trending, approval, rejection



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➢ Audit, Self-Inspection & Inspection history 2020 - 2025

Status: 23/07/2025

AUDITS HISTORY FILE by Dr. Christoph Wambach

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Year	Audited site	City	Country	Audit scope	Standard	Client
Jun 25	A & M Stabtest	Bergheim	Germany	Bioanalytical Testing, Extractable and Leachable studies	GMP	Qualifyze
Dez 24	Recipharm	Wasserburg	Germany	SI: QC and packaging materials receipt	GMP	Recipharm (RWA)
Dez 24	Recipharm	Wasserburg	Germany	SI: validation and media fill	GMP	Recipharm (RWA)
Nov 24	INOVYN Deutschland	Rheinberg	Germany	petrochemical and oil products for Pharma packaging	ISO 9001	Qualifyze
Oct 24	OMPG	Rudolstadt	Germany	Pharma laboratory services	GMP, ISO17025	Qualifyze
Feb 24	Wörwag Pharma LLE	Budapest	Hungary	GVP-inspection by Hungarian authority - Q-support	GVP, GMP	Wörwag Pharma HQ
Feb 24	Wörwag Pharma HQ QU	Böblingen	Germany	GMP-inspection by local authority	GMP	Wörwag Pharma HQ
Oct 23	Bioassay Laboratory	Heidelberg	Germany	Bioassay Pharma testing - qualification audit	GMP, AMG, AMWHV	Qualifyze
Aug 23	Mauermann Arzneimittel	Pöcking	Germany	Pharma manufacturing and laboratory; solida	GMP, GLP	Wörwag Pharma HQ
Feb 23	Wörwag Pharma Operation	Lodz	Poland	Pharma manufacturing and laboratory; solida	GMP, GLP	Wörwag Pharma HQ
Dec 22	Cargill	Sas van Gent	Netherlands	Pharma excipient manufacturing and logistic	ISO9001, GDP	SQA / Big-Pharma client
Oct 22	DR. KADE Pharm. Fabrik	Berlin	Germany	Eurasian / Russian-GMP	GMP	DR. KADE Pharm. Fabrik
Sep 22	DR. KADE Pharm. Fabrik	Berlin	Germany	SI / internal audit: QC laboratories	GMP, ISO17025	DR. KADE Pharm. Fabrik
Jul 22	DR. KADE Pharm. Fabrik	Berlin	Germany	SI / internal audit: medical device handling	ISO13485	DR. KADE Pharm. Fabrik
Jun 22	DR. KADE Pharm. Fabrik	Berlin	Germany	SI / internal audit: supply-chain management	GDP	DR. KADE Pharm. Fabrik
Jun 21	Verbio	Bitterfeld	Germany	Excipient manufacturing	IPEC, ISO9001	Eurofins Pharma Services
Mar 21	IQVIA	Reading (remote)	UK	ALCOA, PIC/S, GMP, FDA 21 CFR 11, GAMP5		DR. KADE Pharm. Fabrik
Dez 20	Wessling Laboratories	Münster	Germany	qualification audit on behalv of a Pharma client	GLP, GMP	Eurofins Pharma Services
Nov 20	Takeda (remote)	Oranienburg	Germany	semi-solid pharmaceutical, food suppl.	GMP	DR. KADE Pharm. Fabrik
Okt 20	Sanochemia (remote)	Neufeld	Austria	API-manufacturer	GMP, ICH-Q7	SQA / Big-Pharma client
Okt 20	DFE Pharma	Nörten-Hardenberg	Germany	Excipient manufacturing	GMP, IPEC, ISO9001	SQA / Big-Pharma client
Sep 20	Esparma Logistic, site 2	Osterweddingen	Germany	storage & shipment of DP, pakaging mat.,	GDP	DR. KADE Pharm. Fabrik
Jul 20	Esparma Logistic, site 1	Irxleben	Germany	storage & shipment of DP, pakaging mat.,	GDP	DR. KADE Pharm. Fabrik
Apr 20	Schott AG	Mainz	Germany	glas vial, glas tubes manuf. &testing	GMP, GLP, IPEC	SQA / Big-Pharma client
Jan 20	Variopack GmbH	Nidda-Harb	Germany	semi-solid pharmaceutical, food suppl.	GMP, GDP	DR. KADE Pharm. Fabrik
Dez 19	Krewel-Meuselbach	Berg.-Gladbach	Germany	granules & solid pharmaceuticals	GMP	DR. KADE Pharm. Fabrik

There were further more audits conducted and authority inspection participations before 2020.
Details can be forwarded on request.

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I take responsibility

- **Interim Management**
  in the event of vacancies, restructuring or reorganization of their quality units.

- **Project Management**
  Proper planning, professional and agile management as well as timely and successful completion of your projects.

- **Compliance**
  Ensuring the best possible compliance of your quality managementsystem with all applicable laws, standards and regulations.

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I advise and/or support you

- Coaching and Training

  Activities to increase employee motivation

  Development and implementation of quality-related employee training programmes

- Audits

  Conducting audits as a certified lead auditor for GMP and ISO standards worldwide at
  - Excipient and Active Pharmaceutical Ingredient (API) manufacturers and traders,
  - Traders and manufacturers of intermediate and finished pharmaceutical products / Contract Manufacturing Organizations (CMO)
  - Logistic and Laboratory service companies

  in Pharma, BioPharma and Biotech companies.

- Inspections

  Preparing your company for national and international inspections and customer audits and accompanying such inspections in a leading role.

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Mode of operation

Commitment, respect, appreciation as well as ethical and moral leadership characterize my actions.

Professional, solution- and strategy-oriented action with a view to the entire company and the goal of always ensuring the highest possible quality of results, is what drives me.

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I look forward to your enquiry for

- Interim Management
- Project Management
- Compliance projects
- Transformation projects
- Digitalization projects
- Integrated Management Systems
- Auditing and Gap-analysis
- Inspection preparation
- Staff trainings

with focus on Quality

- Pharma
- BioPharma
- BioTech
- MedTech
- Food
- Quality-Management-Systems
- Covering the entire product lifecycle from material supply to distribution and all processes

Comprehensive Quality Services because Quality should be a holistic endeavour within your organization.

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