



CURRICULUM VITAE

VIKTORIA KAMANN-KRONGARDT M.D.; MBA

PERSONAL INFORMATION

Address

Hofmattring 24
CH-4417 Ziefen

Mobile

+41 76 690 33 63

Email

viktoria_krongardt@hotmail.de

Nationality

German/Switzerland

Date of birth

March 24, 1975

LinkedIn

viktoria-kamann-krongardt-386a0a68
www.qs-qk-service.com

Certifications Owner

Helvetic Medical GmbH -2024
<https://www.helvetic-medical.ch>

QS-QK-SERVICE KRONGARDT GMBH, SWITZERLAND

Responsible Person, CEO/QP, Services
www.qs-qk-service.com
Firmennummer: CHE-242.028.910
UID-Nummer: CHE-115.989.321 MWST

OTHER SKILLS AND ABILITIES

Language proficiency

German, English, Swiss German, Russian

Driver's licence

Group B

SUMMARY

I am an employee and contractor (interim Management). I bring extensive experience in Quality and Quality Assurance (Responsible Person/ Qualified Person) in pharma operations in external and internal manufacturing. GDP, distribution, warehousing and transportation experience, Ability to collaborate and partner well at all levels, globally, regionally & cross-functionally.

Good Knowledge of Swiss healthcare legislation, GXP regulations and industry standards, Ability to make decisions on GxP /pharmaceutical activities to ensure regulatory compliance of trading licenses and local regulatory requirements, Key interactions with global and regional stakeholders including Supply Chain, Legal, Tax, Quality. Strong partnerships and collaborations to ensure clear definition of requirements and compliance with the respective trading licenses. Key interactions with numerous stakeholders in Quality (Regional Quality, External Supply Quality). A strong understanding of industry and business, applicable legislation and regulatory compliance requirements. White Belt, Green Belt in the Lean Six Sigma Management.

A unique blend of expertise, encompassing patient safety in both the pharma and medical device (Pharma and Dia divisions), clinical development, quality, and regulatory affairs. I have had the privilege of working in both Local and Global roles, which has further enriched my enterprise thinking and understanding of the industry and patients' needs.

My career history includes more than fourteen years of global activities

(Solid und of Oral Solid Dosage, Recombinant and Sterile products manufacturing, Medical Devices, Vaccines (packaging, testing, warehousing processes and validation), solid background in people leadership and development groups of 110 people is built on a collaborative and end powering approach.

As a mediator and group leader of Quality Operation, I have demonstrable ability in the implementation of a Lead operation system in a global network with respect to international business and cultural differences and development business strategy (open, dialogue, empathy).

My leadership skills have enabled me to successfully lead businesses and teams, while my entrepreneurial experience and mindset have allowed me to build commercial skills for impact and drive benefits to patients faster.





WORK EXPERIENCE

Alpen Pharma GmanwerinabH 2020 – Present part time Contractor

Responsible Person

Fachverantwortliche Person FvP

Qualified Person Swissmedic Bewilligung: Nr.512066-102721806

F. HOFFMANN - LA. ROCHE 2018 – 2024 Contractor

Senior Quality Assurance Manager IMP Quality Operation Deputy of

Qualified Person (Responsible Person), QRM Business Manager

Quality Assurance and Quality Control IMP Quality Operations, Technics and IMP Service Provider Qualification, Participation and execution of external Audits in the context of service provider and supplier qualification as an auditor, Supply chain, CLOs, Lead Auditor / Lead Investigation; CSV / IT QA-Assurance

Covidien AG 2022 – 2024 Contractor

Responsible Person

Fachverantwortliche Person FvP / Qualified Person / Director of Quality

Swissmedic Bewilligung: Nr.511264-102682025

Movianto GmbH 2022 – 2024 Contractor

Responsible Person

Fachverantwortliche Person FvP

Qualified Person Swissmedic Bewilligung: Nr.512514-102676778

MUNDIPHARMA MEDICAL COMPANY/ MUNDIPHARMA LABORATORIUM GMBH 2021 – 2024 Contractor

Responsible Person

Fachverantwortliche Person FvP

Qualified Person Swissmedic Bewilligung: Nr.511400-102679523

Regeneron AG 2023 – 2024 Contractor

Responsible person / Quality Oversight global

R-pharma AG 2020 – 2023 Contractor

Senior Qualified Person Person

(biological / Cell / antibody products / CMOs – Quality Oversight)

Fachverantwortliche Person FvP / Qualified Person / Director of Quality

R-pharma international AG 2022 – 2024 Contractor

Director Quality Oversight - (CMOs – Quality Oversight)

Lexamed AG / Cannopharma AG 2018 – 2023 Contractor

Contractor Qualified Person Medical Device and Medical Products

Biovis Life AG 2021 – 2023 Contractor

Fachverantwortliche Person (FvP) / Qualified Person / QPPV

Swissmedic Bewilligung Nr.512088-102657570



Rommelag CMO AG 2020 – 2022 Contractor
Senior Quality Assurance Specialist (Lead Auditor, Service Provider, Training)

Vifor Pharma AG 2017 – 2018 Contractor
Head of Quality Assurance Group / Deputy of Qualified Person

TILLOTTS PHARMA, SWITZERLAND AG 2015 – 2017 Employee
Head of Quality Unit / Deputy of Qualified Person and Responsible Person

AESICA PHARMACEUTICALS LTD 2013 – 2014 Contractor
CMO Manager / QA-Manager

BAXTER INTERNATIONAL INC 2011 – 2013 Contractor
Technical Expert (Validation / Qualification), Manufacturing / Laboratory

DCS INNOVATIVE DIAGNOSTIK SYSTEM GMBH 2010 – 2013 Contractor
Sales Representative of Medical Devices

BIOTRONIK BERLIN AREA, GERMANY AG 2009 – 2010 Contractor
Technical Expert / Expert of Quality Management

EMSLAND-ALLER AQUA GMBH 2009 – 2010 Contractor
Senior Quality Assurance Manager

RIEMSER PHARMA GMBH, GREIFSWALD AREA, GERMANY 2008 – 2009 Contractor
Quality Assurance Manager / Expert for biological Manufacturing and Quality control

QS-QK-Service Krongardt GmbH 2004 – 2008
CEO / Consulting

BELA PHARM, VECHTA, GERMANY 1999 – 2004 Employee
Quality Assurance Manager / Quality Control Expert

CENTER FOR STATE HYGIENE AND PHARMA, RUSSLAND 1999 – 2000 Employee
Doctor Biochemistry + Microbiologist





EDUCATION

UNIVERSITY, Tübingen, Baden-Württemberg, GERMANY

[https://uni-tuebingen.de/pharmaceutical faculty](https://uni-tuebingen.de/pharmaceutical%20faculty), Qualified Person Pharma / Responsible Person

UNIVERSITY, St. Gallen, SWITZERLAND

Business Coach, Consulting Coach

UNIVERSITY, Basel, SWITZERLAND

Management

YORK-NSB-DBA, UK

www.nsf-dba.com

Qualified Person Pharma / Responsible Person (FvP)

UNIVERSITY OLDENBURG, GERMANY

Management and Communication, Business, MBA

SIBERIAN MEDICAL UNIVERSITY, RUSSLAND, TOMSK, WWW.SSMU.RU

Faculty of Medical and Biological, Field: Biochemistry + Medicine



CERTIFICATES AND COURSES

PERSPECTIVA BASEL-SCHWEIZ UNIVERSITÄT

Systemic Structural Constellations and Coaching

Development of organization

YORK-NSF-DBA-UK, UNIVERSITY OF STRATHCLYDE www.nsf-dba.com

Trainer and Training as a Qualified Person

ASEL UNIVERSITY SWITZERLAND - PERSPECTIVA INSTITUT

Mediation Conflict Management



CERTIFICATION

- QRM Management
- Quality Oversight
- IMP Expert
- ECA - Computerised System Validation Master Class
- ECA Certified Quality Assurance Manager
- Expert of AI -artificial Intelligence
- Training - AI (Artificial Intelligence) in a GxP Environment
- ECA - Training Quality Oversight
- ECA - Training - Complaint Handling and Recall Management,
- QPPV Training
- Deviation and CAPA
- Lead Investigator
- Lead Auditor
- Responsible Person GDP
- Technical QA
- Validation and Qualification Training
- Continuous Manufacturing
- Calibration
- Responsible Person for Medical Devices
- DATA Integrity Expert
- GMP Expert
- GDP Expert
- QP Training
- Validation analytical method
- CSV Expert
- Expert of Aseptically Manufacturing
- Biotechnology

