

# VIKTORIA KAMANN-KRONGARDT, M.D.; MBA CURRICULUM VITAE



## Summary

I am an employee and contractor (interim Management). I bring extensive experience in Quality and Quality Assurance in pharma operations in external and internal manufacturing.

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

My career history includes more than fourteen years of global activities (Solid understanding 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.

White Belt, Green Belt in the Lean Six Sigma Management. I have experience as a Qualified Person / Responsible Person / FvP (IMP, DP, DS, Medical Devices, biotechnology industry,) I am a Qualified Person PV / pharmacovigilance.

### I bring with one

- Proven effective leadership of cross-functional teams in an agile working environment, and delivering cross-disciplinary processes
- Good understanding of disease area and customer-centric strategy planning, medical evidence planning (in particular clinical development and real-world data approaches), global regulatory and patient access environmental good knowledge of medical terminology and the clinical development process
- Demonstrated prioritization and planning skills, working in self-managed teams and with OKRs or outcome-based planning method



## Work experience

### CLINIPACE 2022 – present

Qualified Person FvP / Responsible Person

### ALPEN PHARMA AG GROUP 2022 – present (SWITZERLAND, GERMANY, RUSSIA, UKRAINE, GLOBAL)

Fachverantwortliche Person FvP / Qualified Person  
Swissmedic Bewilligung: Nr.512066-102665770

### BIOVIS LIFE SCIENCES AG 2021 – present

Contractor-Fachverantwortliche Person (FvP) / Qualified Person /  
Swissmedic Bewilligung Nr.512088-102657570 – part time



## Personal Information

### Address

Hinterdorf 22a  
CH-4424 Arboldswil

### Mobile

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### Email

viktoria\_krongardt@hotmail.de

### Nationality

German

### Date of birth

March 24, 1975



LinkedIn

viktoria-kamann-krongardt-386a0a68

## Other skills and abilities

### Language proficiency

German

English

Swiss German

Russian

French

### Driver's license

Group B

### **CANNOPHARMA GMBH GERMANY 2019 – 2022**

Contractor part-time, BtM-Beauftragte, Verantwortliche Person nach GDP according to §2 AMWHV and §52a AMG and §6 BtMG

### **ROMMELAG CMO, WERK MAROPACK AG 2020 – 2022**

Contractor Senior Quality Assurance Specialist (Lead Auditor, Service Provider, Training) – part time

### **QS-QK-SERVICE KRONGARDT GMBH, SWITZERLAND 2008 – present**

CEO / Consulting FvP, QP, Coaching

**Firmennummer** CHE-242.028.910 / **UID-Nummer:** CHE-115.989.321 MWST Handelsregisteramt des Kantons Base-Landschaft, PF 448, 4144 Arlesheim

### **F. HOFFMANN - LA. ROCHE 2018 – present**

Contractor Senior Quality Assurance Manager IMP Quality Operation  
Deputy of Qualified Person (Responsible Person), QRM Business Manager

**Responsibilities:** 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

### **COMPANY LEXAMED AG AND COMPANY CANNOPHARMA 2018**

Contractor Qualified Person Medical Device and Medical Products - part time

#### **Responsibilities:**

GDP / Logistic, Operational Supply team

API / Batch Record IMP/ QMS-Dokumentation-Release

Management Review (KPI)

Projects QA (CSV/ Continuous Manufacturing, Laboratory)-Release

Responsible Person for import, export and foreign trade pursuant to section 2, Art. 9-10 and section 3, Art.13-14 of the Medicinal Products Licensing Ordinance (Arzneimittel-Bewilligungsverordnung AMBV; Classified Compilation of Federal Legislation SR 812.212.1).

Manage inspections by Regulatory Agencies, e.g. Swiss Medic, FDA

- Review of QMS documentation (Complaints, Deviations, Change Control, CAPA)
- Pharmacovigilance Individual Case Study Report for Third Party

### **VIFOR PHARMA 2017 – 2018**

Contractor Head of Quality Assurance Group / Deputy of Qualified Person

**Responsibilities:** Ensure the application of the GMP and GDP directives, Deviation, Change Control, Audits, OOS, OOT, OOE, Batch record review, Preparation and participation in internal and external inspections / audits, IT Manufacturing / Scientific Data Management System, KPI / PQR / Quality Management Review, Quality System (LIMS, ERP, STARLIMS)

### **TILLOTTS PHARMA, SWITZERLAND [www.tillotts.com](http://www.tillotts.com) 2015 – 2017**

Employee Head of Quality Unit / Deputy of Qualified Person and FVP

**Responsibilities:** IMP Batch release, Technical, administrative and personal management of the Quality Control Laboratory

## PHARMA CONSULTING-QS-QK-SERVICE BERLIN - OSNABRÜCK, GERMANY 2005 - 2018

[www.qs-qk-service.de](http://www.qs-qk-service.de)

Director Quality Control and Quality Assurance / Interim Management

**Clients:** University of Berlin, Hospital Charité, University of Hamburg, Hospital Eppendorf, Bayer Pharma, BioGenex, Dr. Kade (Transfer Konstanz-Berlin) Jan 2018 - March 2018

**Other Clients:**

**01 / 2014 - 05 / 2014**     **AESICA PHARMACEUTICALS LTD, MONHEIM, GERMANY, ENGLAND, USA**  
CMO Manager, Contractor, Interim Management

### Skills and Experience

- Quality Assurance / Audit / Control
- PQR / APR / GDP / GMP / KPI
- QC / QM / QA / Manufacturing / Supply Chain

**01 / 2011 - 12 / 2013**     **BAXTER INTERNATIONAL INC., HALLE/WESTFALEN, GERMANY, USA**  
Microbiologist Subject Matter Expert, Validation and Deviation Management Expert, Contractor, Interim Management

### Skills and Experience

- RABS and cRABS
- Isolator technology
- Cleaning validation
- Packaging
- Bioindicators Management / QM / QS / QC
- Media Fill
- Reports / EM / CAPA / Deviations
- Risk Assessment
- Validation / Qualification / (PQ) / IQ / Reports
- Validation methods
- Equipment qualification
- STARLIMS / LIMS
- Change Control / QA / PQR
- Binominal Statistic
- Environmental Monitoring / Trend EM
- Audit
- Cleaning / Hygiene / Disinfection

**01 / 2010 - 12 / 2011**     **DCS INNOVATIVE DIAGNOSTIK SYSTEM HAMBURG-BERLIN, USA**  
Sales Representative / Research Scientist / Formulation of Medical Devices, Contractor

### Skills and Experience

- Supply Chain Medical Devices
- Design, Risk and Product Validation of Medical Devices
- Distribution and Consulting and of Molecular Diagnostic Product
- Immunohistochemistry
- Clinical Investigation Evaluation of Medical Devices
- Quality Control Medical Devices
- Chemotherapy
- Consulting Labor
- Molecular Diagnostic Products.
- Cancer Prognosis and Consulting

**08 / 2010 - 01 / 2011**     **BIOTRONIK BERLIN AREA, GERMANY**  
Quality Management / Quality Control Consultant, Contractor, Interim Management

### Skills and Experience

- Design, Risk and Product Validation of Medical Devices

**01 / 2009 - 01 / 2010**     **EMSLAND-ALLER AQUA GMBH, GOLSSSEN, GERMANY**  
Quality Assurance Manager / Quality Assurance Consultant, Contractor, Interim Management

**02 / 2008 – RIEMSER PHARMA GMBH, GREIFSWALD AREA, GERMANY**  
**01 / 2009** Research Scientist / Manufacturing / Quality Control / Authorization, Contractor

#### **Skills and Experience**

- Organization Manufacturing Vaccine, Serum (human and animal vaccines viral and bacterial human vaccine)
- Analysis and Testing
- Organization Quality Control
- Biotechnology

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

**Responsibilities:** Organization: Quality Control, Microbiology, Management, OOS/CAPA, Deviation, Qualification and Validation

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

**Responsibilities:** Clinical microbiology, Microbiological Laboratory, Manufacturing human and animal vaccines



## **Education**

**2011 – 2014 YORK-NSB-DBA, UK, ENGLAND (UK), [www.nsf-dba.com](http://www.nsf-dba.com)**  
Qualified Person Pharma / Responsible Person (FvP)

**2002 – 2005 UNIVERSITY OLDENBURG, GERMANY**  
Management and Communication, Business, MBA

**1992 – 1998 SIBERIAN MEDICAL UNIVERSITY, RUSSLAND, TOMSK, [WWW.SSMU.RU](http://WWW.SSMU.RU)**  
Faculty of Medical and Biological, Field: Biochemistry + Medicine



## **Certificates and Courses**

**LERNWERKSTATT OLTEN**  
Mentor /Business and Organisation Coach

**PERSPECTIVA BASEL-SCHWEIZ UNIVERSITÄT**  
Systemic Structural Constellations and Coaching  
Development of organisation

**YORK-NSF-DBA-UK, UNIVERSITY OF STRATHCLYDE [www.nsf-dba.com](http://www.nsf-dba.com)**  
Trainer and Training as a Qualified Person

**BASEL UNIVERSITY SWITZERLAND - PERSPECTIVA INSTITUT**  
Mediation Conflict Management

**VIKTORIA KAMANN-  
KRONGARDT, M.D.; MBA  
ZEUGNISSE**