Marlen Dalkowski
Quality Management Consultant with validAID
Brueder-Grimm-Str. 26a

35039 Marburg

phone: +49 177 33 47 951
eMail: marlen.dalkowski@validAID.de

Curriculum vitae

Career Profile

Highly motivated, analytically thinking Quality Management Consultant with 10+ years experience in the Pharmaceutical- / Life-Science and Medical Device Industry and proven expertise in Quality Management, Life Science Process- and Project Management and EU GMP regulations.

Personal

Date of Birth	13.12.1981
Place of Birth	Schwerin
Personal Status	married

Education

2018	**Certificate Quality Management Consultant, Quality Manager, internal Quality Auditor** TQCert GmbH, Kassel **Certificate Life Science Process- and Project Management** HGA Hessische Gesundheitsakademie, Hanau **GMP Certificate** HGA Hessische Gesundheitsakademie, Hanau
2009	**Diploma Degree in Politics and Economics** Philipps-University Marburg, Germany
2001	**Abitur** Humboldt Gymnasium, Gifhorn

Marlen Dalkowski

Quality Management Consultant with validAID
Brueder-Grimm-Str. 26a

35039 Marburg

phone: +49 177 33 47 951
eMail: marlen.dalkowski@validAID.de

Professional Experience

2018 - today	**Quality Management Consultant** validAID, Marburg - Ensuring Quality by counseling regulatory compliance - Focus on: Data Integrity | CSV | Quality Management | Project Management - Laws and Guidelines: DIN EN ISO 9000: 2015 | DIN EN ISO 9001:2015 | DIN EN ISO 9004:2009 | DIN EN ISO 19011: 2011 | GAMP 5 | EudraLex Annex 11 | 21 CFR Part 11 / 210 / 211 | AMWHV | Q8 | Q9 | Q10 | EudraLex Chapter 4 Documentation - Verification activities: IQ | OQ | PQ | SAT
2015 – 2017 **and** **2013 – 2014**	**GMP / CSV Consultant** Ingenieurbüro Röhrig GmbH Switzerland - Maintenance of the CSV documentation - Execution of CSV activities - Preparation and execution of Risk Assessments (FMEA) - Vendor Evaluation - Managing and evaluating TrackWise data - Manage and track audit / inspection findings - Document Management responsible - Training Management responsible - 1st & 2nd level user support for condor-User
2006 - 2013	**Project Coordinator** Ingenieurbüro Röhrig Marburg, Germany - Project Coordination in the MARS Project (building of a new facility at Marburg / Görzhausen) - Facility Management - Maintain qualification documentation - Risk Analysis and Installation Qualification - Creating as-built specifications - Creating SOPs - Maintain, coordinate, plan and create hold time studies for product-touching media in the Atlas Systems Atlas (DMS) and TrackWise (QMS)

Extra-Professional Training / Committee Work

- QMB, QM, iQA	TQCert GmbH, Kassel
- LSPPM	HGA Hessische Gesundheitsakademie Hessen, Hanau
- GMP	HGA Hessische Gesundheitsakademie Hessen, Hanau
- English	Cambridge ESOL Level I Certificate am Passmore College Marburg
- SAP	SAPTM ERP Basics (SAP01-SAP Overview) Release SAP 6.0 EhP4 at Date up education GmbH

Marlen Dalkowski

Quality Management Consultant with validAID
Brueder-Grimm-Str. 26a

35039 Marburg

phone: +49 177 33 47 951
eMail: marlen.dalkowski@validAID.de

Projects

2019	**Quality Management Consultant** CSL Behring GmbH, Marburg Data Integrity: **A**nalytical **S**ervices **Q**uality (QC CSL Behring Marburg) Remediation Plan - Expand / Update ASQ SOPs regarding Qualification (IQ, OQ, PQ) - Implementation of Data Lifecycle Process in ASQ including data creation, data processing and data storage concepts: temporary or long term archiving, data deletion concepts - Implementation of Periodic Reviews for ASQ Systems
2015 – 2017 **and** **2013 – 2014**	**GMP / CSV Consultant** Hoffmann La Roche AG, Basel, Switzerland - Maintenance of the CSV documentation - Execution of CSV activities - Preparation and execution of Risk Assessments (FMEA) - Vendor Evaluation - Managing and evaluating data in TrackWise - Manage and track audit / inspection findings - Create and manage documents in the Document Management System (condor) - 1st & 2nd level user support for condor-User - Managing data for Training System (PharmSchul) - Manage documents in Microsoft TouchPoint
2009 - 2010	**Project Coordination** Siegfried Ltd. (Zofingen, Schweiz) - Maintain qualification documentation - Creating and performing Risk Analysis and Installation Qualification for the Requalification of synthesis plant for drug production - Performing the Risk Analysis and reporting its results, - Installation Qualification and Operational Qualification for the initial qualification of the plant for halogenation - Create as-built specifications - Creating SOPs
2006 – 2009 **and** **2010 – 2013**	**Project Coordination** Novartis Vaccines & Diagnostics GmbH & Co. KG (Marburg) - Project Management Assistance in the MARS Project (building of a new facility at Marburg / Görzhausen) - Documentation of space management in Facility Management System - Maintain, coordinate, plan and create hold time studies for product-touching media in the Atlas Systems Atlas (DMS) and TrackWise (QMS)

Marlen Dalkowski
Quality Management Consultant with validAID
Brueder-Grimm-Str. 26a

35039 Marburg

phone: +49 177 33 47 951
eMail: marlen.dalkowski@validAID.de

Language Skills

German (mother tongue)
English (fluent)