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

35039 Marburg

phone: +49 178 592 8788
eMail: melanie.feldmann@validAID.de

Curriculum vitae

Career Profile

Enthusiastic Biophysicist with advanced knowledge in high resolution fluorescence microscopy. Well-organized and structured work attitude combined with a curious mind to constantly learn something new and leave a footprint in medical device industry. Fluent in German and English.

Personal

Date of Birth	28.04.1991
Place of Birth	Bad Kreuznach
Personal Status	Unmarried

Education

2015	**Master of Science in Biophysics** Goethe University, Frankfurt am Main, Germany
2012	**Bachelor of Science in Biophysics** Goethe University, Frankfurt am Main, Germany
2009	**Abitur** Hohe Landesschule, Hanau

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Professional Experience

2018 - today	**Quality-Management Consultant (Pharma & Medical Devices)** validAID, Marburg - Ensuring quality / Data Integrity by counseling on regulatory compliance with a focus on: - Medical Device Regulation – Computer System Validation (CSV) - Laws and Guidelines: MDR 2017/745 – MDD 93/42/EEC – MPG ISO 13485:2016 QMS – ISO 14971:2012 Risk Management GAMP 5 – 21 CFR Part 11 / 210 / 211 – ICH Q8, Q9, Q10 (PQS) EudraLex Annex 11 – EudraLex Chapter 4 - Project Management - Programming in Python
2016 - 2018	**Flight Attendant** Lufthansa AG, Frankfurt am Main - Willingness to travel worldwide to broaden intercultural expertise - Staying calm in difficult situations and resolving conflicts with customers
2015 - 2016	**Part-time worker in retail** Gries Deco Company, Frankfurt am Main - Providing individual advise for customers - Responsible for closing the cash accounts - Performing initial training of new colleagues
2014 - 2015	**Research Assistant** German Cancer Research Center, Heidelberg - Optimization of optical systems (STED microscope) regarding compactness and efficiency - Research and selection of suitable optical components (mirror, filter) - Development and construction of opto-mechanical components (Autodesk Inventor) and their technical documentation - Programming stepper motors as a filter system (Labview) - Master Thesis written in LaTeX
2010 - 2014	**Supervisor of a practical course** Goethe University, Frankfurt am Main, Germany - Responsible for optical experiments of the practical course “Physics for Physician” - Instructing students and correcting reports - Improving instructions for better understanding

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Extra-Professional Training & Committee Work

2019	**Specialist for Quality Management according to ISO 13485:2016** **(TÜV SÜD Training, Part I)** - Foundation Course for Quality Management - Requirements for Management Systems - Structure and scope of the ISO 13485:2016
2018	**Manager Regulatory Affairs for Medical Devices** **(Internal Training)** - Law Foundation Course - ISO 13485:2016 – Quality Management Systems - Clinical Evaluation - Technical Documentation (MDR 2017/745) - ISO 14791:2012 – Risk Management - Data Integrity (WHO, EMA, FDA, MHRA, PIC/s)
2018 - today	**GAMP DACH Special Interest Group (SIG) for Audit Trail Review**
2019 - today	**GAMP DACH Special Interest Group (SIG) for Medical Devices**

Projects

2019 - today	**Computer System Validation Consultant (CSV) – Medical Devices** MAQUET CP (Getinge Group), Rastatt Follow-up Project for CSV according to GAMP 5 - Creating a System / Process Documentation - Manuals / Instructions

2019 - today	**Computer System Validation Consultant (CSV) – Medical Devices**
	MAQUET CP (Getinge Group), Rastatt
	
	Project Assistance for CSV Project according to GAMP 5
	- Establishing processes in compliance with Data Integrity requirements
	- Creating the Validation Documents
	  - Initial Assessment
	  - URS with Part 11 Requirements
	  - Validation Plan
	  - Risk Analysis / FMEA
	  - Design Qualification
	  - Installation Qualification (Q system)
	  - Performance Qualification
	  - Installation Qualification (P system)
	  - Validation Report

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2018 - 2019	**Junior Computer System Validation Consultant (CSV) – Pharma** CSL Behring, Marburg CSV assistance for the Virtual Line Controller (VLC) Project - Analyzing the business process - Creating the Validation Plan - Preparation and Documentation of Validation Tests - Risk Analysis - Checking for Compliance with 21 CFR Part 11

Language Skills

German (mother tongue)
English (fluent)
French (basic)