

# Curriculum Vitae

## Dr. Müller, Andreas

Telemannweg 21  
07743 Jena

Landline: +49-3641440493  
Mobile: +49-1633045723  
Email Private: [anmueller22@gmail.com](mailto:anmueller22@gmail.com)  
Email Business: [info@mpqc.de](mailto:info@mpqc.de)  
Homepage: [www.mpqc.de](http://www.mpqc.de)  
Date of birth: 1962/02/22  
Place of birth: Bad Frankenhausen  
Marital status: divorced, 3 children



### Profile:

- 19 years' experience in analysis of organic and bioorganic species
  - Two years experience in molecular biology and cell culture
  - Wide interdisciplinary specialized knowledge regarding medicine and chemistry
  - Experienced in management by motivation and leadership
  - Quick comprehension, optimised and cost-conscious application for routine analysis
  - A long experience in leadership of project management
  - High soft skills and integrity
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### **Relevant professional experience:**

01/2014 – today      *Consultant in Quality Control & Quality Assurance*  
Creation, Testing and Approval of manufacturing and analytical procedures  
Creation, Testing and Approval of deviations and change control procedures  
Creation, Testing and Approval of standard operation procedures (SOP)  
Collaboration in relevant manufacturing questions  
Collaboration in audits and self-inspections; presentation of relevant points from QA and QC in these questions  
FDA Remediation and Readiness Support  
Coordination of investigations regarding deviations and resulted measures of approved change control procedures  
Follow up of deviations documents, change control documents and CAPAs  
Providing of the internal work flow and to contract givers regarding changes and deviations  
Organization and management of meetings regarding quality relevant topics  
Experience in the GMP related testing of incoming pharmaceutical goods and raw materials (APIs)  
Experience with biopharmaceutical raw materials and ingredients  
Experience with the releasing of raw materials and ingredients for a pharmaceutical production (APIs)  
Experience in the handling of deviations, OOS (Out of Specification) and OOT (Out of Trending) results and of authorities requests  
Preparing of recommendations for the conception, implementation and the continuous improvement of systems/processes of the QMS (Quality

Management System), e. g. for handling with deviations and changes in a GMP regulated environment or escalation of potentially significant quality events

Conception, creation and performance of a comprehensive in-house training

Providing of training standards for the employee

Quality assessment of OOT results

Periodical creation of trend reports

Leading, motivating and developing of employees according to leadership principles of the company

03/2012 – 01/2014

IDT Biologika GmbH

CAPA Manager for the interface Compliance – Quality Control and Manufacturing

Dealing with deviations and OOS under compliance aspects in the area of Quality Control and in Manufacturing

CAPA Management

Consultant in the framework of trainings and qualification

Trainer in workshops for Root Cause Analysis and CAPA

Project management in SAP-Projects

Excel Sheet Validation

Review of batch records, deviation reports, chromatograms, batch reports and other quality records

Quality Risk Assessment

Audit tracking

FDA Remediation and Readiness

Change Control

APQR

Document Management

2012/01 – 2012/02

Meets a new challenge

2007/10 – 2011/12

Bayer Weimar GmbH und Co. KG

Compliance Management

Overall responsibility for the Product Quality Review on the site

Change Management,

CAPA Management,

Deviations,

Self-inspections and Audits,

FDA Remediation and Readiness

Supplier Management,

Document Management,

Archiving

Qualification and Validation, VMP

Consultant in the framework of trainings and qualification

2006/09 – 2007/09

Berlin-Chemie AG

Head of the LC/HPTLC Release Lab

Responsibility: Release analytics for raw materials and API's, bulk ware, drug products und stability testing of the whole spectrum of drug products

of the Berlin-Chemie AG  
Method development  
Release testing of APIs, raw materials, stability samples, dyestuffs,  
Release analytics relating to GMP standards  
Technical and disciplinary responsibility for up to 10 technicians  
Transfer of analytical methods,  
Qualification of equipment in the LC/HPTLC Lab,  
Validation of analytical procedures  
Preparation of SOP's,  
Revision of test procedures

- 1993/05 – 2006/08 Department of Internal Medicine Jena, Division of Rheumatology, Osteology and Nephrology:  
Head of a special clinical lab  
Responsibility: Development of new analytical methods for the  
Determination of markers for routine-, order- or research analytics  
Routine analytics  
Setup of a new molecular biological lab with cell culture  
Cooperation with clinical and industrial national and international partners  
Technical and disciplinary responsibility for up to 5 technicians  
Apprenticeship of doctoral students and technicians and schooling in line with practical work  
Management of projects  
Setup of a MS Access based patient's data base
- 1992/11 – 1993/04 Head of a project "Modification of steroids and biological testing"
- 1992/09 – 1992/10 Meets a new challenge
- 1988/09 – 1992/08 Friedrich – Schiller – University Jena / Thuringia, Department for Organic and Macromolecular Chemistry  
Scientific assistant, dissertation  
Management of laboratory courses and lectures
- 1980/05 – 1980/09 Job in a factory in my home town Sondershausen

### **Scientific Qualifications:**

Since 1992 Participation in professional trainings organized by different suppliers (Agilent, Axel Semrau, Promocell) and by the German Chemical Society on the following fields:  
HPLC  
Gas Chromatography  
Gas Chromatography – Mass Spectrometry  
Mass Spectrometry  
Thin Layer Chromatography  
Cell culture, troubleshooting cell culture and cell based assays  
Statistics with SPSS

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### **Spectrum of methods:**

HPLC with UV-, Fluorescence- und electro-chemical detection  
Handling of full automated auto sampler as a roboter in the sampling preparation  
Liquid - Chromatography for preparative purposes and protein separations

Thin-Layer-Chromatography with analysis  
IR - Spectroscopy  
NMR - Spectroscopy  
Gaschromatographie  
Mass - Spectroscopy (LC-MS, GC-MS)  
Cell culture  
RT - PCR und PCR  
Cell based Assays  
Elektrophoresis  
ELISA

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### **EDV-Knowledge:**

Microsoft: Windows, MS Word, MS Excel und MS Access, MS Powerpoint – very good knowledge  
Agilent: Chemstation – very good knowledge  
Merck: HSM 2000 – very good knowledge  
EZ-Chrome-Elite  
Sun: Staroffice 8.0 – very good knowledge  
SAP  
SPSS  
Endnote  
Photoshop  
Network Inter- und Intranet  
Data bases  
EDV - based measurement and – handling of data

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### **Language skills:**

English, Russian, basic skills French

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### **Apprenticeship:**

1993/04	Promotion „Investigations for regio selectivity of selected nucleophils compared to oxosteroids – a contribution for the difficulty of protecting groups Magna Cum Laude
1983/10 – 1988/08	Friedrich-Schiller-University Jena / Thuringia Study: Synthesis chemistry Specialisation: Organic Chemistry Degree: Diplom – Chemiker, Grade 1.3 Subject of the work: „Investigations for the reaction of 17-Keto-steroids with Nitroalkane-derivates“
1980 - 1983	Military service in the navy
1976 – 1980	EOS Sondershausen Thüringen, higher education entrance qualification
1968 – 1976	POS Sondershausen Thüringen

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**Outside one's job:**

Since 2000

Hobby

Digital Photographie and Imaging

Jena, 2019-04-10

A handwritten signature in black ink, appearing to read 'W. Huber', followed by a long horizontal flourish.