

Profile

Melanie Geiger

Consultant

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EDUCATION

- 2002-2006 ✓ Diploma in Business Information Systems (E-Commerce)
(University of Cooperative Education Heidenheim, Germany)
- 2002-2006 ✓ Bachelor's Degree of Arts with Honour (Open University London,
England)
- 2005 ✓ ADA (Training Qualifying Examination) (IHK Ost-Württemberg,
Germany))
- 1992-2002 ✓ A-Levels (Peutinger Gymnasium Ellwangen, Germany)

PROFESSIONAL TRAININGS

- 2008 ✓ Quality System Manager (until July 2009); (SAQ Qaulicon)
- 2008 ✓ GAMP 5: Implementation by the means of a Real Life Project
(Concept Heidelberg)
Certificate:: Computer Validation Expert
- 2008 ✓ Corrective & Preventive Action (CAPA) Training (internal)
- 2008 ✓ Audit Behaviour (internal)
- 2008 ✓ Validation of IT Systems (Concept Heidelberg)
- 2007 ✓ GMP- /FDA requirements for IT Systems and Data security
(Concept Heidelberg)
- 2007 ✓ CSV Basics (internal)
- 2005 ✓ Master thesis „Extract useful information from Customer
Complaints for building and implementing a knowledge base“
- 2005 ✓ Seminar paper „using complaints management for customer
loyalty“.
- 2005 ✓ SAP R/3 Basics (external)

- 2003 ✓ Java Basic (external)
- 2003 ✓ Microsoft Access (external)
- 2002 ✓ Lotus Notes (external)
- 2002 ✓ Microsoft Power Point (external)
- 2002 ✓ Microsoft Excel (external)
- 2002 ✓ Microsoft Word (external)

LANGUAGES

- ✓ German (mother tongue)
- ✓ English (very good knowledge; written and oral)
- ✓ French (simple knowledge)

CORE SKILLS

- ✓ IT-Project management
- ✓ Validation within a GxP environment
- ✓ Laws & standards: 21 CFR Part 11 & 820, EMEA Annex 11, GAMP, EG-GMP-handbook, APV-Guideline
- ✓ ITIL Fundamentals (Service Support, Service Delivery)
- ✓ Quality management
- ✓ Knowledge management

BUSINESS EXPERIENCE

- Project-
Management** ✓ Project lead and project organisation of IT projects
- Project- und
Process-
Management** ✓ Writing Standard Operating Procedures (SOPs) and Technical Instructions (TOPs) for IT processes.
- Compliance
Management** ✓ System testing (IQ/OQ) and IT-infrastructure-qualification.
- Training** ✓ Creating Instruction material
✓ Conducting SAP BW basic training courses

METHODS AND TOOLS

- Project-Management**
 - ✓ Critical Path Planning
 - ✓ GAMP 4
 - ✓ GAMP 5
 - ✓ Risk analysis
 - ✓ Traceability
- Compliance Management**
 - ✓ FDA/EMEA, GxP (Life Science) regulations
 - ✓ ISO 9000
 - ✓ Risk analysis and –management: GAMP, FMEA, HACCP, Ishikawa diagram
- System-development**
 - ✓ V-Model (CSV)
 - ✓ Testing: Strategy, Schedule and Execution
 - ✓ Traceability Matrix
- Process modelling**
 - ✓ Flow Charts
- SW Tools**
 - ✓ Microsoft Office incl. Access, Visio, MS Project
 - ✓ MindManager

INDUSTRIES

- ✓ Life Science, Health, Multimedia

PROJECT EXPERIENCE

Subject Area		Project description/ Responsibility
Year / Duration	2009 / ongoing	Conduction of SAP R/3 basic training courses for a Swiss pharmaceutical company.
Service	Training	
My role	Trainer	
Subject Area		Project description/ Responsibility
Year / Duration	2009 / 7 months	Conduction of Compliance Assessments for applications for a Swiss pharmaceutical company.
Service	Compliance Management	
My role	Project collaborator	
Subject Area		Project description/ Responsibility
Year / Duration	2008 / 1 month	Development and conduction of CSV Workshops for a Swiss pharmaceutical company.
Service	System Validation	
My role	Trainer	
Subject Area		Project description/ Responsibility

Year / Duration	2008 / 3 months	Preparation of GAMP 5 trainings (internal project).
Service	Training	
My role	Project collaborator	

Subject Area		Project description/ Responsibility
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Year / Duration	2008 / 3 months	Working on the proof of concept phase for a LIMS implementation project a German pharmaceutical company.
Service	System Validation	
My role	Project collaborator	

Subject Area		Project description/ Responsibility
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Year / Duration	2008 / 1 month	Create procedure for ongoing periodic reviews of GxP relevant systems for a Swiss medical engineering company.
Service	System Validation	
My role	Project collaborator	

Subject Area		Project description/ Responsibility
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Year / Duration	2008 / 1 month	Create Validation Plan and User Requirement Specification for the Validation of an Excel Spreadsheet for a Swiss medical engineering company.
Service	System Validation	
My role	Project collaborator	

Subject Area		Project description/ Responsibility
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Year / Duration	2008 / 2 months	Development and conduction of SAP BW basic training courses for a Swiss pharmaceutical company.
Service	Training	
My role	Trainer	

Subject Area		Project description/ Responsibility
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Year / Duration	2007 / 1 month	Create IT Security Policy for a Swiss pharmaceutical company.
Service	System Validation	
My role	Project collaborator	

Subject Area		Project description/ Responsibility
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Year / Duration	2007 / 1 month	Preparation and execution of a risk analysis for a Labelling System for a Swiss medical engineering company.
Service	System Validation	
My role	Project collaborator	

Subject Area		Project description/ Responsibility
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Year / Duration	2007 / 4 months	Preparation and execution of OQ and PQ tests for a PK/PD system as well as updating relevant system documentation (SOPs) for a German pharmaceutical company.
Service	System Validation	
My role	Project collaborator	
Subject Area		Project description/ Responsibility
Year / Duration	2006 / 1 month	Writing Standard Operating Procedures (SOPs) and Technical Instructions (TOPs) for IT-Processes for a Swiss pharmaceutical company.
Service	System Validation	
My role	Project collaborator	
Subject Area		Project description/ Responsibility
Year / Duration	2006 / 1 month	Preparation and execution of a risk analysis for a records-management-system for a medium-sized Swiss pharmaceutical company.
Service	System Validation	
My role	Project collaborator	
Subject Area		Project description/ Responsibility
Year / Duration	2006 / 3 months	Reorganization of the IT Policy and IT Standards for a world leading multimedia based company in America.
Service	IT Management	
My role	Project collaborator	
Subject Area		Project description/ Responsibility
Year / Duration	2006 / 3 months	Implementing a knowledge base with customer complaint information for a leading provider of medical and hygiene products in Germany.
Service	Knowledge Management	
My role	Project leader	
Subject Area		Project description/ Responsibility
Year / Duration	2003 / 2 months	Conception of a data base for scheduling trainees within the different departments automatically for a leading provider of medical and hygiene products in Germany.
Service	Project Management	
My role	Project leader	