

Profile

Volker Roeder

Senior Manager

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EDUCATION

- 1987 ✓ Gymnasium (Abitur) (secondary school, 'A' levels)
- 1993 ✓ Engineering diploma (university of applied science); Subject: Engineering Physics
- 1996 ✓ Software developer, Software Engineering

PROFESSIONAL TRAINING

- 1998 ✓ Clean rooms and insulators, Swiss Association of Clean Room Technology, Zurich
- 1999 ✓ Extension works and technical installations at pharmaceutical production sites, APV
- 1999 ✓ Qualification of HVAC systems & cleanrooms; PTS
- 2000 ✓ Professional presenting and moderating; Roland Albert
- 2000 ✓ Cleaning and cleaning validation; PTS
- 2000 ✓ Auditing experts - GMP Auditor; PTS
- 2000 ✓ More impact through better personal and relationship management; Stöger & Partner
- 2000 ✓ GMP basic training; Concept Heidelberg
- 2000 / 2001 ✓ Quality control experts; PTS
- 2002 ✓ Pharmaceutical water; PTS
- 2002 ✓ Presentation technics- basic training; Neuland & Partner
- 2003 ✓ Pharmaceutical project management; PTS

- 2003 ✓ 9th GMP Conference (participant) PTS
- 2005 ✓ GMP Conference (participant) PTS
- 2005 ✓ 11th VDI Symposium "Clean room technology from the concept to the qualified operation - today and in future"; VDI
- 2006 ✓ PAS-X user group meeting; Werum
- 2006 ✓ ISPE-D-A-CH Congresses EBR, PAT
- 2006 ✓ 1st German pharmaceutical production conference; Concept Heidelberg
- 2007 ✓ GMP and technology congress; PTS
- 2008 ✓ GAMP 5; ISPE-GAMP-D-A-CH
- 2008 ✓ GMP-Compliant Design and Construction of Pharmaceutical equipment ; PTS
- 2009 ✓ License to Lead - Time management & personal organizational skills
- 2009 ✓ Maintenance in the pharmaceutical industry (speaker & participant); Marcus Evans
- 2009 ✓ GMP and technology congress; PTS
- 2009 ✓ License to Lead - Conflict management
- 2010 ✓ Quality and process management for pharmaceutical and life sciences
- 2010 ✓ License to Lead - Mastering negotiations - the art of reaching agreements and getting what you want
- 2010 ✓ GAMP 5; ISPE-GAMP-D-A-CH
- 2010 ✓ GMP Conference; Testo
- 2010 ✓ Validation master class; Concept Heidelberg

SPECIAL ACTIVITIES

- 2004 - 2010 ✓ Speaker at the seminar "Validation of computerized systems in the pharmaceutical industry"; VDI - Knowledge forum, 2 - 3 seminars per year
- since 2005 ✓ Speaker on "Validation of computerized systems; GAMP and ERES" at various internal meetings and conferences
- since 2005 ✓ Providing in-house trainings, GxP audits including GAP analysis and recommendations on Quality Management requirements.

- 2006 - 2007 ✓ Collaboration on preparation and revision of VDI guidelines for clean room technology (VDI-2083)
- since 2006 ✓ Member of ISPE, (currently non-active), member of DACH-COP: PAT

LANGUAGES

- ✓ German (mother tongue)
- ✓ English (very good oral and written knowledge)
- ✓ Italian (basic written knowledge)
- ✓ Latin (basic knowledge)

INTERNAL ROLE

- ✓ Service Manager Quality & Risk Compliance

CORE EXPERTISE

- ✓ GxP - Quality, risk and compliance management
- ✓ Management, coordination and operational execution of qualification & validation projects;
- ✓ Change control and CAPA processes as part of the life cycle
- ✓ Project management
- ✓ Document-Management-Systems
- ✓ Risk management
- ✓ GxP audits of clients, partners and suppliers
- ✓ Setting up GxP-QM systems
- ✓ Setting up CSV systems
- ✓ Developing and managing GxP-compliant transfer strategies (R&D → scale-up → commercial production)
- ✓ GxP-compliant, operation and maintenance of computerized systems
- ✓ Commissioning and qualification of GxP production sites and laboratories, including equipment
- ✓ Hygienic concepts of/for GxP production sites

- ✓ Validation of cleaning and production processes
- ✓ Validation of analytical methods
- ✓ Preparation and execution of master plans (Qualification & Validation) and SOPs
- ✓ Annual reports (Annual Product Review; Product Quality Review)
- ✓ Site Master Files

RELEVANT PROFESSIONAL EXPERIENCE

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|------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Program and Project Management | <ul style="list-style-type: none">✓ Leading internal and external co-workers as “Scientific Manager”✓ (Co-) Project leadership on various national and international projects |
| Process Management & Organizational Development | <ul style="list-style-type: none">✓ Strategy development and operational implementation in the context of internal and external technology transfers (national & international)✓ Setting up a GMP-compliant Quality Management System✓ Implementing training and advanced training programs✓ Preparing and implementing validation strategies |
| Performance Measurement | <ul style="list-style-type: none">✓ Monitoring, assessments and mitigations for project management (time & budget) |
| Compliance Management | <ul style="list-style-type: none">✓ Responsible Scientific Manager for GxP & QMS issues✓ (Co-) accountable representative to national & international official inspectors and & partners in GxP issues |

METHODS AND TOOLS

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|------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Project Management | <ul style="list-style-type: none">✓ MS Project✓ Company-specific PM Tools |
| Process Management & Organizational Development | <ul style="list-style-type: none">✓ CAPA & other methods of continual improvement processes✓ FMEA & FMECA; Ishikawa / Fishbone✓ Mind Mapping✓ Modeling business processes MS Visio✓ Designing & moderating workshops✓ Organizational change management |
| Compliance Management | <ul style="list-style-type: none">✓ Quality & GxP: FDA, EMEA, ICH, PIC/S, ISPE, ZLG; SwissMedic (IKS), AMWHV, AMG✓ Risk : ICH Q9, ISO 14971, FMEA / FMECA; HACCP |

- ✓ CSV: GAMP4 / GAMP5; DIN EN 62304
 - ✓ Compliance rules: SOx,
 - ✓ Technology: Machinery Directive, International standards and , norms (ISO, EN, DIN, SN)
- System Development**
- ✓ Analytical and creative techniques: Workshops, Brainstorming, Mind Mapping
 - ✓ Procedural models: V-Model (CSV)
 - ✓ Company-specific LC Tools
 - ✓ Testing: Strategies, Planning and Implementation, Traceability Matrix

INDUSTRIES

- ✓ Pharmaceutical
- ✓ Chemical
- ✓ Medicine products technology
- ✓ Mechanical Engineering & Construction
- ✓ Software suppliers

PROJECT EXPERIENCE

Subject area	Technology transfer	Project description/ responsibilities
Year/ duration	2008 - 2011	Responsible for quality management incl. conceptual and operational development, coordination & implementation of the qualification strategy as part of the commissioning, setting up, qualification scale-up and transfer of a new pharmaceutical technology from research and development scale to production scale (internal and external contract manufacturer (USA))
Service	QRC	
Client	Pharmaceutical company (<= 5,000 employees) Germany / USA	
My role	(Co-) Project leader	
Subject area	Production technology	Project description/ responsibilities
Year/ duration	2005/10 - 2008/03	Responsible for quality management and operational qualification during construction, commissioning and qualification of a new research building, incl. inspection by the notified body and appropriate apparatus (TGA & machine technology)
Service	QRC	
Client	Pharmaceutical company (<= 5,000 employees) Germany	
My role	(Co-) Project leader	

Subject area	Monitoring	Project description/ responsibilities
Year/ duration	2010 - 2011	Project-planning and implementation incl. validation of a network-based computerized system for recording and monitoring defined environmental conditions (T, P, H)
Service	QRC / CSV	
Client	Pharmaceutical company (<= 5,000 employees) Germany	
My role	Project leader	
Subject area	CSV	Project description/ responsibilities
Year/ duration	2003 - 2005	Ongoing quality management and operational system validation (CSV) with a medical device supplier of refractive ophthalmological systems
Service	QRC / CSV	
Client	Global corporation (>= 10,000 employees) Germany / USA	
My role	Project leader CSV / SQA	
Subject area	QRC	Project description/ responsibilities
Year/ duration	2004/3 - 2004/09	Transfer and revalidation of a manufacturing site, delivering critical key components for medical products (refractive ophthalmological systems)
Service	QRC / CSV	
Client	Global corporation (>= 10,000 employees) Germany / USA	
My role	Consultancy & coaching	
Subject area	QRC	Project description/ responsibilities
Year/ duration	2002 - 2005	Planning and carrying out various GxP audits with GAP analysis of existing conditions, including preparing sets of recommendations (mock audits)
Service	Mock Audit	
Client	Div. pharmaceutical company (<= 10,000 employees) Germany / Europe	
My role	Auditor	

Subject area	QRC	Project description / responsibilities
Year / duration	2003 - 2004	Carrying out risk analyses and operational qualification throughout design and construction of a laboratory for high-potency substances
Service	Qualification	
Client	Global corporation (c. 100,000 employees) Germany / USA	
My role	Project leadership Qualification	
Subject area	QRC	Project description / responsibilities
Year / duration	2002 - 2004	Ongoing project quality management and operational qualification in construction and relocation of a research building
Service	Qualification	
Client	Pharmaceutical company (<= 5,000 employees) Germany	
My role	Project leadership Qualification	
Subject area	QRC	Project description / responsibilities
Year / duration	2001 - 2003	Creation and Implementation of a quality management system (GMP & GDP) for a hospital pharmacy (logistics, manufacture, quality control), including preparing SOPs, Site Master Files, carrying out employee training and working with the official inspections for granting the distribution (wholesale) license and manufacturing license for sterile and non-sterile products. Medical products and specialist items.
Service	Compliance	
Client	Hospital pharmacy (c. 50 employees) Switzerland	
My role	Project management / Operational implementation	
Subject area	QRC / CSV	Project description / responsibilities
Year / duration	2002	Speaker in internal training courses in computer system validation at international pharmaceutical sites
Service	Training	
Client	Global corporation (> 100,000 employees) Switzerland / Europe	
My role	Trainer / Speaker	

Subject area	CSV	Project description / responsibilities
Year / duration	1999 - 2003	Ongoing quality management on various projects in computer system validation at international pharmaceutical sites
Service	Validation	
Client	Global corporation (> 100,000 employees) Switzerland / Europe	
My role	Project Quality Manager	
Subject area	QRC	Project description / responsibilities
Year / duration	1999 - 2001	Ongoing project quality management and operational qualification during construction of a sterile test laboratory, including working with inspection authorities (FDA)
Service	Qualification	
Client	Global corporation (> 100,000 employees) Germany	
My role	Project Quality Manager / Operational implementation / Supplier selection	
Subject area	QRC	Project description / responsibilities
Year / duration	1998 - 1999	Planning and operational project implementation of cleaning validations in the sterile production and central dispensing at a pharmaceutical site
Service	Validation	
Client	Global corporation (> 100,000 employees) Switzerland	
My role	Operational implementation	