

CURRICULUM VITAE

Personal data

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Education

11/2013	Certificate Workshop and Meeting Moderator (IHK)
08/2013	Certificate QM-Auditor (IHK), Munich
07/2012	Certificate NLP Master Coach, mindsystems, Munich
07/2011	Certificate NLP Master, mindsystems, Munich
06/2010	Certificate "Internal Auditor", DGQ, Frankfurt/M.
03/2009	Certificate NLP Learning Coach, mindsystems, Munich
03/1992	PHD in Biology, MPI of Psychiatry /Biochemistry/ LMU, Munich
10/1988	Diploma in Biology, TUM, Munich
07/1981	High school graduation, Munich

Expertise summary

8.0 years	Quality Management / GCP-Auditing
2.5 years	Regulatory Affairs / quality assurance
1.5 years	Product management
2.5 years	Project management / clinical monitoring
3.0 years	Molecular biology
7.0 years	Personal coaching and communication trainings

Position

03/2013 - current	GCP-Auditor, QM-Auditor, QA-Consultant, Trainer, Coach, Moderator, <i>AuditDialogConcept, Munich, Germany</i>
12/2009 - 02/2013	Director Quality Assurance <i>FGK Clinical Research GmbH, Munich, Germany</i>
07/2008 - 11/2009	Quality Assurance Manager <i>FGK Clinical Research GmbH, Munich, Germany</i>
02/2005 – 09/2007	Regulatory Affairs / Quality Assurance Associate <i>Nycomed Pharma GmbH, Unterschleißheim, Germany</i>
04/1996 – 01/2005	Maternity Leave / Team leader in welfare area
10/1994 – 03/1996	Product Manager <i>Nycomed Arzneimittel GmbH, Ismaning, Germany</i>
03/1993 – 09/1994	Clinical Monitor <i>Nycomed Arzneimittel GmbH, Ismaning, Germany</i>
04/1992 – 09/1992	Clinical Research Associate <i>L.A.B. GmbH & Co., Munich, Germany</i>

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Executive summary in QA

- GCP- Auditing (as lead auditor): system-audits, clinical trial audits (on-sites, TMFs), process-audits, internal audits, internal process checks, subcontractor-audits, mock-inspection, IIT - sponsor-audits, clinical study report audit
- Advice and guidance in quality issues and prioritization of any necessary measures
- Development, implementation and supervision of CAPA-tracking
- Supervision of internal audits/process checks
- Escalation of non-compliances to company management
- Preparation for and accompanying during inspections by Health Authorities and second-party audits
- Final quality review of study documentation
- Advice, guidance and development of SOPs, forms and checklists
- Support of Management Board in initiation of activities for continuous improvement of quality and compliance
- Yearly Quality Plan as part of Management Review
- Concept and implementation of specific job-related training programs
- Training/orientation of newly hired Quality Managers; GCP/SOP-training program of affiliates
- QA-support and supervision of affiliates

Additional experience

- Coaching using NLP-coaching and systemic coaching tools
- Change management
- Conflict management
- Graves-Value-System tools for change management and conflict management
- Moderation of workshops, meetings and projects
- Team development and leadership
- Trainings of communication skills and self-management for auditors and CRAs
- GCP-training for investigators
- Co-Monitoring and supervision
- Visualization tools and creative methods
- Monitoring of clinical trials and project management
- Regulatory affairs
- Product management

Membership

DGGF- Deutsche Gesellschaft für Gute Forschungspraxis e. V.
DGPharMed – Deutsche Gesellschaft für Pharmazeutische Medizin e.V.
NLpaed – Verband für neurolinguistische Verfahren in Bildung und Erziehung e.V.

Knowledge of languages

German	native speaker
English	fluent

Training (on demand)

An overview of trainings has been listed separately and will be updated on a regular basis.

Date: 25.05.2016

Signature: not signed