Alexandra Maier
Biologist (M.Sc.) and Senior Project Management Professional

Curriculum Vitae

Professional Experience

Since 08/17 — Director Finance & Contracts, Clinical Trial Centre Cologne (CTCC)

Key responsibilities

- Strategic leadership and oversight for CTCC
- Overall CTCC budget responsibility
- Contract management
- Initiate and drive process improvement
- Line management of managers

01/17-05/17 — Senior Project Director, PRA HealthSciences GmbH, Mannheim

Key responsibilities

- Global cross-functional leadership and study oversight of complex oncology studies
- Key Client contact, internal and external stakeholder management
- Piloting of new Project Management Systems

08/12-12/16 — Assoc. Dir. GCPM at UCB Biosciences GmbH, Monheim

Key responsibilities

- Line management and mentoring of up to 18 direct reports (PMs, Assoc. PMs, CTAs and Admins)
- Evaluation and development of direct reports, including implementation of corrective/ disciplinary actions
- Development of training materials, presenter and trainer
- Insourcing of contract staff & Service Provider Management
- Participation in and leadership of process improvement initiatives
- Global budget & resource planning responsibility for UCB's clinical research department

06/10-07/12 — Project Director, PMP at COVANCE CAPS GmbH, München

Key responsibilities

- Global cross-functional supervision and leadership of a global phase III oncology study (1100 patients, 300 sites in 28 countries)
- Full budget responsibility (> 40M EUR), change order negotiation
- Key contact for Client, internal and external Stakeholders
- Support proposal development & bid defence participation
- Presenter & trainer at internal and external meetings

09/05-05/10 — (Senior) Project Manager at COVANCE CAPS GmbH, München

Key responsibilities

- Operational planning and execution of global phase I- III trials according to ICH/ GCP, SOPs and local regulations (>800 patients, ≥160 sites in up to 40 countries worldwide)
- Global and regional leadership of international study teams
- Audit preparation, follow up and CAPA implementation
- Line Manager for CRAs & Associate Project Managers
- Budget forecast/ review/ control; Earned Value Analysis (EVA)
- Support proposal development & bid defence participation

- Development and execution of project specific documents, plans and guidelines

07/04-08/05 Senior CRA at COVANCE CAPS GmbH, München

Key Responsibilities

- LTC/ lead CRA for Germany for an international Phase III trial (coordination of 3 CRAs, 14 sites with 174 pts)
- Local Ethics and Competent Authority submissions
- Site selection, initiation, coordination and monitoring of local sites for several international phase II and III studies
- Trip report review

04/04-06/04 CRA at PAION GmbH, Aachen

Key Responsibilities

- Coordination of an international phase II trial (102 patients, 44 sites, 12 countries)
- Co-monitoring visits/ pre-audit visits at US sites
- CRO surveillance/ control
- Internal Trial Master File audit

10/02-03/04 CRA at ORTHO BIOTECH Div. of JANSSEN-CILAG GmbH, Neuss

Key Responsibilities

- LTC for a national phase III study (612 patients, 103 sites)
- Ethics and Competent Authority submissions
- Protocol/ Amendment/ ICF/ CRF development
- CRA training, chair project review meetings
- Trip report review

08/99-09/02 Field Based Monitor (FBM) at ORTHO BIOTECH Div. of JANSSEN-CILAG GmbH, Neuss

- Conduct site selection, initiation, monitoring and close out visits for national phase IIIb, IV trials and NIS
- Support the set up of an IIT monitoring system
- Project specific communication with marketing and sales department

04/99- 07/99 Start of a Ph.D. project at "Zentrum für Molekulare Medizin der Universität Köln"
with focus on immunology

10/98- 03/99 Biologist at „Biofrontera Pharmaceuticals GmbH", Leverkusen
with focus on differential display

07/97- 09/98 Experimental dissertation at "Max-Dellbrück-Laboratorium in der MPG", Köln;
Subject: "Analysis of transcription in human cells by means of a counter selective marker"

08/91- 11/92 Associate researcher at "Luitpold Pharma", München, with focus on microbiological quality control

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University

11/92- 07/97	Study of biology at "Friedrich-Alexander-Universität", Erlangen; Major subject: molecular genetics Graduation: Master of Science, M.Sc. (Diplom Biologin)

Vocational Training

08/89-08/91	Vocational College "Berufsfachschule für Chemie und Pharmazie Dr. v. Morgenstern", Braunschweig Graduation: Associate Researcher (Biologisch technische Assistentin, BTA)

Scholar Education

07/76-06/89	Lessing-Gymnasium, Braunschweig General college certificate (Abitur)

Further Activities/ Certification

Since 06/17	Advanced training as Quality Management Responsible (QMB)
04/16	Manager as a Coach training
02/16-12/16	Leadership of eConsent pilot
05/15-12/16	Active TransCelerate eConsent workstream member
04/13-03/14	Accelerate Leadership Training
11/12-12/16	Leadership of Informed Consent Initiative at UCB Biosciences
09/12	Change Management Training for Line Managers
12/11-07/12	Part of quality improvement initiative at Covance/ RBM
05/10	Project Management Professional PMP (PMI)
02/10	Certified Project Manager (CPM), PMLG
08/08	Development of training matrixes and scoring systems for CRAs
04/07	Project Management certification course (Covance internal)
03/07-01/08	Part of Six Sigma initiative for quicker identification of pending CRF pages
11/99	Sales training at JANSSEN-CILAG GmbH
08/99-03/04	Participation in several work groups

Cologne, October 2017