Curriculum Vitae

Dr. Astrid Sanders

Program Manager

Certified Validation Lead

Project Manager

Quality Manager

Coach

Communication - Change Management

21 years' experience in global Life Science Industry / IT / CSV

Dr. Astrid Sanders

Managing Director / Manager / Lead

Dr. Sanders has been working in life science industry since 1999. Starting as senior consultant at KPMG (today: Bearing Point), she moved forward into the industry soon. 2001 she became global Quality Manager at Aventis, later sanofi-aventis/Sanofi.

As Deputy Director 'IT Processes, Communication and Quality' at Sanofi she was a member of the global IT Management Board leading a team based at various locations in US, UK, France and Germany. Together with her team she ensured regulatory compliance, efficient working processes and internal communication of IT projects and operations globally.

2009 Dr. Sanders started her own business ‚TatKraft' and in 2013 the Sanders & Associates GmbH.

HER CORE COMPETENCIES:
Quality. Regulatory Compliance. Project Management. Communication. Organizational Change Management.

HER REFERENCES:
Siemens. Novartis. Sanofi. Bayer.

Sanders & Associates GmbH
Moltkestraße 13
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Professional Working Experience

04/2013 – now

Company: Sanders & Associates GmbH

Position: Managing Director – Project Lead – Validation Lead - Managing Consultant
Supporting clients with expertise in:

- Computerized System Validation
- Risk Management
- GxP compliant IT System Operation
- IT Project and Program Management and Controlling
- Quality Management System (GMP / ISO / Process and Plant Safety)
- Change Management / organizational changes
- Business / IT Processes optimization
- Communication / Coaching
- Track & Trace (Implementation / Operation of IT Systems to address serialization / aggregation requirements)

Achievements / Projects:

- Project management / validation Track & Trace
- Support and leadership of global IT Projects
- Re-Validation of global ERP Systems
- Validation of global Laboratory Information Solution
- Development / implementation / continuous improvement of global IT Quality Management Systems (ISO, GMP, ITIL).
- Development / implementation / continuous improvement of global Quality Management Systems for Process and Plant Safety

03/2009 – now

Company: Tatkraft – Dr. Astrid Sanders

Position: independent consultant
Supporting clients with expertise in:

- Project Leadership and Management
- Computerized System Validation
- Quality Management
- Compliance /QA Auditor
- QA Interim Management
- Business/IT Processes optimization
- Communication / Coaching
- Change management and organizational changes
- Quality Management System and Manuals

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04/2008 – 02/2009 Sabbatical

07/2005 – 03/2008

Company: sanofi-aventis

Position: Director IT Processes, Communication and Quality Management
Global responsibility / Managing executive / Member of global IT Management Board
Responsibilities:

- Company standards (cGMP, SOX etc.)
- Quality and Compliance Management (cGMP / SOX / ISO / ITIL)
- Internal audit und follow-up / Management of external audit activities
- Project Supervision (Methodology, Risk Management, Change Management, Quality Management)
- Internal communication, team building, conflict management
- Program and Project Management
- Internal business process design
- Member of the global management board
- Team management – 10 team members based in Bordeaux, Paris, Frankfurt, Kansas City, London

Achievements

- Successful (in-time/in-quality/in-budget) global harmonization of working processes in the context of post-merger and implementation of a supporting IT system
- Development and implementation of a common GMP compliant Quality Management System
- Project supervision/coaching for more than 200 IT projects in 2007
- Development and execution of GMP compliance training
- Established efficient internal communication and collaboration
- Successful implementation of GMP audit program
- Approved SOX, GMP compliance by external auditors

11/2004 – 06/2005

Company sanofi-aventis

Position: Manager - Strategy, Portfolio and Quality Management
Global responsibility / Member of global IT Management Board
Responsibilities

- Quality Management System (ISO 9000:2000 / 9001:2000 / GMP/ ITIL)
- IT strategy und project portfolio management
- Post-merger Communication
- Contractor's Management
- Team management - 6 team members located in London, Frankfurt, Bordeaux, Kansas City

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Achievements

- Established efficient global team, their training and qualification
- Development of the global IT strategy and implementation as basis of portfolio management
- Established Quality Management System (ISO, GMP, ITIL)
- Efficient communication in the context of the post-merger situation

08/2001 – 11/2004

Company: Aventis

Position: Manager - Quality and Compliance / GxP Validation Leader

Global Management position

Responsibilities:

- Quality Management and Project Methodology
- Training
- Project supervision – Project Methodology, Risk and Change Management
- Team Management - 2 team members located in Frankfurt

Achievements (among others)

- Transfer of an global expert team into an global department
- Training of appr. 350 individuals
- Implementation of an standardized way of delivering projects
- Implementation of a global Change Management Process

04/1999 – 07/2001

Company: KPMG Consulting AG (today: BearingPoint)

Position: first consultant / soon senior consultant

Global Business Process Redesign and SAP R/3 Implementation

Responsibilities

- Change Agent in the context of the global SAP implementation
- Training of end users
- On-boarding events and project marketing
- Content Management Website and project communication
- Prior engagements as Quality Specialist, SAP specialist for SAP/R3 QM and EH&S

Training and Background

Training Summary

- Data Integrity and Good Documentation Practice – Green Mountain Quality Assurance
- Advanced 21 CFR Part 11 Training (electronic data and signature) - Concept Heidelberg
- Validation of computerized Systems – requirements for the pharmaceutical Industry CFR 21 part 11- Concept Heidelberg

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- Electronic Data and signature – requirements for the pharmaceutical Industry CFR Part 11 - Concept Heidelberg
- Validation of computerized Systems using a common, standardized IT methodology - Concept Heidelberg
- Information Technology Risk Management - PMI
- Managing Information Technology Projects - PMI
- Change Management in the realm of IT projects / Change Management - KPMG
- International Consulting Skill Training / Workshop – KPMG

University and PhD

- PhD Study (Institut für Chemo- und Biosensorik- ICB, Münster)
- Graduation: Dr. rer. nat. (English: PhD), 'magna cum laude'

- Study of Chemistry (Westfälische Wilhelms Universität – WWU, Münster)
- Graduation: Diplom Chemiker (English: Diploma chemistry), 'sehr gut (English: very good)'

Language

German: mother tongue – English: business fluent – French: Basics

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