

## Curriculum Vitae



### Dr. Astrid Sanders

Managing Director / Manager / Lead

**KEY WORDS:**

Project Management, PMO, Computer System Validation, QMS, CSV, QA, GMP, Annex 11, CFR 21 Part 11, SOX, PMI, PMO, ITIL®, GAMP®, SOP, communication, Track & Trace

**HER CURRENT REFERENCES:**

Siemens. Novartis. Sanofi. Bayer.

**CV SUMMARY:**

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' 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.



## Professional Working Experience

04/2013      Company: Sanders & Associates GmbH  
– now        Position: Managing Director / Manager / Lead

### Key focus of activities

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

03/2009      Company: Tatkraft – Dr. Astrid Sanders  
– now        Position: Independent Consultant

### Key focus of activities

- 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

04/2008 –      Sabbatical  
2/2009

7/2005 –      Company: sanofi-aventis  
03/2008      Position: Deputy Director IT Processes, Communication and Quality Management  
**Global responsibility / Managing executive / Member of global IT Management Board**

### Key focus of activities

- 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

Key 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 and best practice related audit program
- Approved SOX, GMP compliance by external auditors

11/2004 – Company: sanofi-aventis  
06/2005 Position: Manager - Strategy, Portfolio and Quality Management

**Global responsibility / Managing executive / Member of global IT Management Board**

Key focus of activities

- 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

Key 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 – Company: Aventis  
11/2004 Position: Manager - Quality and Compliance / GxP Validation Leader

**Global Management position**

Key focus of activities

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

Key Achievements

- 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 – Company: KPMG Consulting AG (today: bearingpoint)  
07/2001 Position: first consultant / soon senior consultant

**Global Business Process Redesign and SAP R/3 Implementation**

Summary of activities: 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

## Training and Background

### Training Summary

- Validation of computerized systems – requirements for the pharmaceutical Industry CFR 21 part 11
- Electronic Data and signature – requirements for the pharmaceutical Industry CFR Part 11
- Change Management in the realm of IT projects / Change Management
- Study in industrial psychology and economics
- Validation of computerized systems by the use of a common, standardized IT methodology
- International Consulting Skill Training
- Advanced 21 CFR Part 11 Training (electronic data and signature)
- Information Technology Risk Management PMI
- Managing Information Technology Projects PMI

### 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