	Curriculum Vitae **Dr. Joachim Schoch-Bösken**	

Personal Data

Name **Dr. Joachim Schoch-Bösken**

Title Validation Consultant

Contact

jsb-validierung
Zwischen den Bächen 9
D – 79618 Rheinfelden

Tel: +49 7623 79 49 82
Mobile: +49 176 42 60 85 72

E-Mail: jsb-val@online.de
Internet: http://www.jsb-validierung.de
http://www.jsb-validation.com

Education

- Examine in Biology, Social Sciences, Educational Sciences
- Doctorate in Ecology (with Pharmacology and Toxicology)

Technical Background

- IT-Experiences (since 1983)
- IT Project Manager (since 1989)
- Document Management and Archiving (since 1990)
- Validation of Computerized Systems (since 1996)
- Project Management Methodologies (since 1999)
- Perform Trainings for IT-Validation (since 2002)

Focus

Computerized Systems Validation (CSV) of IT systems in Life Sciences companies:

- Validation consulting (Validation Strategy, Coaching, Audits)
- Validation co-working (templates, draft documents, Risk Assessments, reviews)
- Validation work packages (writing of all validation documents until sign-off, performance of testing etc.)
- System and supplier audits for IT systems under GxP
- Build up or reviews of SOPs and templates for CSV
- Trainings (1/2 - 4 days) for IT validation and project management
- Methods: GAMP, PMI

Job experiences at University

1983 – 1988	University of Münster (Germany), Build up of PC-Databases for data management, simple statistical calculations and literature databases
1987 – 1988	University of Münster (Germany), Information Retrieval in Online-Databases

Job experiences in the Pharmaceutical Industry

1988 – 1991	Responsible for coordination of technical and scientific IT systems
1989 – 1990	Selection of LIMS (Laboratory Information and Management System)
1989 – 1991	Selection, implementation, and system administration of a HP-UX based system for packaging development
1991 – 1993	Assistant of the Head of R&D; built-up of R&D controlling unit; responsibility for Information Retrieval, Document Management and Archiving (4-6 people)
1994 – 1998	Department head (“Information and Documentation”) with responsibility for 6 to 10 people (Archive, Library, Information Retrieval, DMS, Internet)
1993 – 1998	Development and support of a SCO-UNIX-based document archiving system in Drug Regulatory Affairs, Clinical Research and Pharmaceutical Development
1995 – 1997	Concept and implementation work for the Internet presentation of a pharmaceutical company, In-house-trainings for Internet usage
1997 – 1998	Selection, design, development, implementation, and validation according GMP of a Windows-based DMS for a Quality Assurance unit

Job experiences in the Agrochemical Industry

2002 – 2005	Project management for an international document management system used for Regulatory Affairs and Production

Projects performed as Consultant in a Consultancy Company

1999	Project manager for 2 teams (CH and US) in a validated migration and archiving project in GCP area
1999 – 2001	Project Management, coaching and support in a DMS-project for improving the complete R&D process up to submissions. Implementation of electronic signatures and electronic submissions. Work in the project team, validation consulting and hands-on work during the rollout with training and support in 3 locations.
2011	Data Migration from file system and Excel metadata into a DMS
2001 – 2002	Validation of an Enterprise Resource Planning’ (ERP) system for goods and finance flow in the GMP environment of a pharmaceutical manufacturing site
2001 – 2002	Validation Audit followed by validation support in a department of clinical data (CDMS) and biometry for the biostatistical procedures and systems
2001	Validation of an archive system (GLP, GCP)
2015	Consulting for the validation of a Chromatography Data System
2015	Consulting for the approach in Excel validation
2015	Validation of a clinical database in the Cloud (with vendor audit)
2015	Retrospective validation of a release system in a pharmaceutical company
2015-2016	Einführung eines eDMS in einer pharmazeutischen Firma
2016	Workshop zum Vorgehen bei der Validierung eines ERP-Systems
2016	Audit der IT-Infrastruktur eines Herstellers von APIs

Projects performed as independent Consultant

2002	Audit of a pharmaceutical production system (GMP) regarding compliance with Validation (CSV) and 21 CFR Part 11.
2003 – 2005	Build up of a SOP system for IT projects and system operations in a pharmaceutical ‚Contract Research Organization' (CRO). Further validation coaching during the project for implementation of a clinical database management system (GCP)
2004 – 2005	Implementation of a new Drug Safety System (Replacement of 2 existing systems) with data migration and new technical infrastructure – consultancy and validation work for compliance with CSV and 21 CFR Part 11 (GCP)
2005	Validation of a „Coding-Tool" (MedDRA) for clinical databases
2005	Validation of a clinical database for a producer of medical devices
2005 – 2006	Consultancy and validation work on different systems in a human pharmacology station - compliance with CSV and 21 CFR Part 11 (GCP)
2005 – 2006	Consultancy for the validation of an ERP system for warehouse and distribution management of pharmaceutical products (GMP-GDP)
2005 – 2006	Consultancy and validation work on an ERP system for production planning and management for a producer of medical devices
2005 – 2006	Validation of a new Document Management System (DMS) for management and distribution of SOPs for a Chemical Production Plant (GMP)
2006	Validation of In-vitro-Diagnosis Software for a Medical Devices company. Qualification of infrastructure (Network and server)
2006	Consultancy for generation and updates of SOPs of clinical data used in a Biostatistical department (GCP)
2006	Project-QM during the integration of a new interface (system change) of a Drug Safety Systems (GCP)
2006	Audit and workshop for the revalidation strategy of an ERP system (GMP)
2006	Risk Analysis and Compliance Management of different systems in pharmaceutical production and delivery of goods (GMP)
2006 – 2007	Validation of a Post Marketing Surveillance database with worldwide access through the internet (GCP)
2006 – 2009	Validation of a Lab. Information and Mgmt System (LIMS) implementation (GLP)
2007	Project Quality Manager for two related IT-Projects regarding Metadata and preparation for electronic Protocols under GCP
2007	Training and Coaching in an implementation project for a worldwide IT-QS
2007	Preparation and implementation of a Quality Management System (QMS) for a software service company (development, configuration and support)
2007-2008	Validation of a new release of an existing Drug Safety System (GCP)
2007-2008	Pre-Selection of DMS and eCTD followed by a DMS selection and implementation for SOP Management, CAPA (GMP), R&D and Regulatory Affairs (GLP, GCP)
2007-2008	Centralization of IT Infrastructure with virtualizing (VMware) of all GxP environments
2007-2008	Project Quality Manager for preparation of a „Data Conversion Factory" for clinical data (GCP) in different submission-relevant formats
2007-2008	Validation of a clean room monitoring system for a producer of medical devices
2007-2008	Consultancy for a software company (Enterprise Content Mgmt - ECM) regarding implementation of a QMS and support for first projects in the Life Sciences area
2007-2010	Project Quality Manager for development and implementation of new releases of an international used database system for the regulatory status of products worldwide
2008	Audit of a Software producer (DMS)
2008	Validation of an Internet-based new Drug Safety System (GCP) for international use together with an existing system in HQ

2008	Selection of a Document Management System (DMS) under GxP to be used for SOP Mgmt, CAPA, Deviations, R&D, and submission preparation
2008	Audit of a software producer (DMS for Life Science)
2008-2009	Validation of an eCTD system
2008-2009	Validation consulting and PM support for s Distribution company (GDP) regarding the implementation of an automatic Warehouse Management System (incl. Supplier Audit)
2008-2009	Validation of IT Infrastructure with virtualization, Citrix farm and the implementation of an electronic archive under GxP with mirroring of data on two locations
2008-2009	Harmonization of SOPs and Templates for CSV within an international pharmaceutical company
2008-2009	Writing of new SOP System and Validation of medical device systems
2009	Audit at a chemical company producing excipients for pharmaceutical industry
2009	Retrospective Validation of a LIMS and a DMS in a Central Laboratory (GLP)
2009	Validation of a functional enhancement of a custom developed Pharmacovigilance system (GCP)
2009-2010	Validation of a major update with integration of new business processes for a Pharmacovigilance system (GCP)
2009-2010	Strategy, coaching and support for the qualification of an IT-Infrastructure in a multinational company
2009-2011	Validation and Testing of a LIMS in two locations (GLP)
2009-2012	Validation of a Document Management System (DMS) under GxP for SOP Mgmt, CAPA, Deviations, R&D, and submission preparation in international locations. Further updates for Global Labeling and OTC products.
2009-2012	Planning and implementation of a DMS for Contract Management and SOP Management in QA (GCP)
2009-2012	Audit and validation consulting for a Warehouse Management System at a Distribution company (GDP). Support of system enhancements with new interfaces and a revalidation.
2010	Workshop for market access under GxP for a producer of an eLearning system
2010	Support for the preparation of an FDA Audit
2010	Retrospective Validation of a LIMS in an Analytical Laboratory (GLP)
2010-2011	Further development and harmonization of an ERP system on two sites
2011	Implementation of a few changes in a warehouse management system (GMP)
2011	Retrospective Validation of an EDC system in a CRO (GCP)
2011	Revalidation of an ERP system for a manufacturer (GMP)
2011-2012	Concept of clinical data archiving and implementation of quality controlled process for long-term preservation of GCP relevant data
2011-2012	Implementation and validation of a Learning Management System (LMS) running at the supplier as ‚Software as a Service' (SaaS) under GxP
2012	System Selection of a Document Management System as replacement for an existing DMS under GxP
2011-2013	System selection and subsequent validation for the implementation of a regulatory tracking system (GxP)
2011-2013	Prospective Validation and PM support for a LIMS in an QC Lab (GMP)
2011-2013	Update of SOPs and Templates for the IT-Validation (GxP)
2012-2013	Update of a DMS for QA, R&D and Global Labelling (GMP, GCP)
2013	Further development of a Learning Management System (LMS as SaaS) and rollout for other departments (GxP)

2013	Update and validation of a submission management system (GxP)
2013	Qualification of a new server environment (GxP)
2013	Qualification of a SQL server update
2012-2014	Implementation of a Middleware and a ‚Warehouse Management System' (WMS) as replacement for a systems running from a third party (GMP) and additional application for a Warehouse Management system
2013-2014	Interface between an eDMS and a LMS for initiating training when a documents to be trained is updated.
2013-2014	Introduction of the validation of Excel sheets
2012-2015	Implementation of an ERP system in a logistic company with an Interface to an existing Warehouse Management Systems
2012-2015	Introduction of an existing eDMS in different locations and organizational units
2013-2015	Implementation of a tracking tools in an Audit Management area of a Quality Assurance unit
2014-2015	Support of a logistic company for the revalidation of IT systems
2015	Support of a software company by introducing their product in the regulated environment under GxP
2015	Selection of a eDMS in a pharmaceutical company
2015	Split of an ERP system during the founding of a new company from an existing one
2014-2016	Update of an existing LIMS and consolidation of today two separated systems

Trainings performed

Since 2002	In-house trainings for Validation (CSV) in different companies, especially for initial training of team members in validation projects
2004-2008	Regular trainings managed by a training agency with a 4-days-training "Certified IT-Project Manager under GxP") performed 2-4 times per year
2005-2008	Regular trainings managed by a training agency with a 4-days-training ("Certified GLP-Manager") performed 2-3 times per year (Part CSV – 2 days)
2005-2013	Regular in-house trainings for a pharmaceutical company offered for IT staff regarding CSV and 21 CFR Part 11 Since 2007 the source is harmonized with a new project methodology
Since 2007	Regular trainings managed by a training agency with a 2-days-training of "Validation of IT Systems under GLP".
Since 2010	Market overview of LIMS, moderation of LIMS supplier within a LIMS forum
2014	Training of validation within a medical devices company
2015	Training of validation under GLP within a company for crop protection