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Dr. Klaus von Jan

Summary:

Dr. von Jan has a broad background in diverse areas primarily covering the Life Sciences and BioPharma industries both in Europe and in the United States. Dr. von Jan has extensive expertise in Quality Assurance and also brings solid experience and knowledge that includes Regulatory and GMP processes and procedures. Dr. von Jan frequently participates in regulatory and industry audits, and has acted as primary liaison with several international authorities during the course of numerous manufacturing inspections. In addition, Dr. von Jan has acted as a consultant on the design and implementation of various QA systems in accordance with ISO9001 standards, and he has consulted on many GMP. GLP, Quality and Process Improvements in the Biotechnology, Hospital, Chemical, Food Service and Computer Software industries. Since 2002 Dr. von Jan has focused and concentrated his efforts with an emphasis on establishing and executing global enterprise-wide quality standards and processes including his work as the primary business lead for the deployment of a global electronic document management system and controlled document change processes at Chiron Corporation.

Experience

2006 - current

CRS: Independent Consultant working within the pharmaceutical industry:

- GMP/GLP - Consulting for pharmaceutical companies; see reference list

Founding Compliance Systems GmbH: Development, distribution and implementation of TrueCompliant, a software tool to manage GMP requirements in pharmaceutical environment. Homepage: www.compliancesystems.de

1996–2005 Chiron Corporation Marburg, Germany

Director Quality Assurance Bulk Manufacuring; Germany

- Business lead for the design, development and implementation of global electronic deviation management system for BioPharma, Blood Testing and Vaccines business operations (2005).
- Business lead for the design, development and implementation of global

electronic document management system for BioPharma, Blood Testing and Vaccines business operations (2003). Developed a leading edge global change control framework for all controlled documents within Chiron and facilitated major design workshops and events.

- Responsible for all quality related issues in the company; chief-liaison for international authorities including coordination and preparation of U.S. more than 20 FDA-inspections.
- Project leader and management representative for the implementation of an Environmental Management System according ISO 14001 and EMAS.
- Director Quality Assurance: Management responsibilities for operations and budget of 60 FTEs in the Vaccines QA group; responsible for performance evaluations and salary recommendations.
- Responsible for various harmonization projects including efficiency improvements programs quality improvements, change control procedures, validation programs, and deviation management at Chiron; mainly between multiple Chiron sites and operations in Europe.
- Responsible for management of Change Control procedures according to the cGMP guidelines.
- Responsible for development and deployment of validation procedures for Chiron Behring, HMR Marburg und InfraSerV Marburg; including the implementation of qualification and validation procedures.
- Responsible for performing internal and external GMP inspections.
- Stewardship of the cGMP status of key Chiron products (RabAvert and DT) concentrate for further manufacturing.
- Primary liaison for QA Training of local personnel.

1988–1996 Millipore BioSyntech GmbH Hamburg, Germany

Head of QC and QA

- Since 1988: Lead member and manager in start-up of Quality Control department; including the development of analytical methods for nucleotides and amino acid derivatives. Further responsibilities for management of seven staff and technicians, and responsibility for the evaluation, purchase and installation of the department's analytical equipment.
- Since 1993: Manager of the new Quality Assurance department; responsible for the implementation of a QA-system according to the ISO 9000 standard; and responsible for the successful certification by DQS (Deutsche Gesellschaft zur Zertifizierung von Managementsystemen).

1987–1988 University of Stuttgart Stuttgart, Germany

Scientific Research

- Research on Synthesis of modified TRH-analogues
- Further responsibilities: Teaching apprentices and students in organic chemistry.

1993 - 2006

Additional Experience

- Instructor at Pharma Training Service (PTS) - Since 2002: Relevant

courses: „Experte für Audits“; „Planung und Implementierung von Elektronischen Dokumentenmanagementsystemen“; „Pharmagerechte Dokumentation“

- Auditor for the Guideline 93/42 EWG concerning medicinal products in the area of medicinal disposables; microbiology and hygienic; sterilization with Ethylenoxide, steam and radiation; clean room technology and packaging technology - Since 1998
- Environmental Management Auditor for the DQS - Since 1996
- Completed more than 100 audits for the DQS in chemistry, pharmaceutical industry, waste treatment, engine industry and services. - Since 1994
- Consulting work for several companies concerning the implementation of QA-Systems according ISO 9000ff and GMP - Since 1994
- Lead Auditor for the DQS for ISO 9001 and EfbV - Since 1993

Education

- 1984 - 1987: PhD thesis on evaluation of the structure and synthesis of modified oligonucleotides; mark „very good“.
- 1983 - 1984: Diploma in Organic Chemistry; thesis on Solid Phase Synthesis of DNA-biomolecules; mark „very good”
- 1977 - 1983: Studying Chemistry in Stuttgart at the Technical University, diploma degree mark „Good“.

Industry Training

- Nov. 1998: Leadership Part II, St. Gallener Business School
- Oct. 1998: Leadership Part I, St. Gallener Business School
- Sept. 1998: Basics in Finance and Controlling, Future
- Nov. 1996: Quality Control Laboratory cGMP Compliance and Auditing, Technomic
- Nov. 1995: TQM, FMEA
- Feb. 1995: Auditor for Environmental Management Systems by DGQ
- Oct. 1993: Leading people Part II, Mercury Academie
- June 1993: Leading people Part I, Mercury Academie
- March 1993: Auditor by DGQ
- Dec. 1992: Quality Ingenieur by DGQ

Industry Publications

- **Planning and Implementation of an Electronic Document Management System within a Pharmaceutical Company**; Jürgen Höfer a, Thomas Geyer a, Katharina Arnold-Gross a und Dr. Klaus von Jan, ESCS Software-Entwicklungs GmbH a, Gorxheimertal, und Chiron Behring GmbH & Co. b, Marburg; December 2002
- **Preparation of Blood Stem Cell Concentrates under Clean Room Conditions A with Background Conditions B, Part 2**; Markus Ritter a, Reinier Mutters b, Nimrod Schwella a, Joerg Beyer a, Thomas Wündisch a, Herbert Rüdiger b, Dr. Klaus von Jan c und Andreas Neubauer a; Klinik für Hämatologie, Onkologie und Immunologie, Zentrum für Innere

Medizin, Philipps-Universität a, Marburg, Institut für medizinische Mikrobiologie und Krankenhaushygiene, Philipps-Universität b, Marburg, und Chiron Behring GmbH & Co .c, Marburg; August 2001

- **Preparation of Blood Stem Cell Concentrates under Clean Room Conditions A with Background Conditions B, Part 1**; Markus Ritter a, Reinier Mutters b, Nimrod Schwella a, Joerg Beyer a, Thomas Wündisch a, Herbert Rüdiger b, Dr. Klaus von Jan c und Andreas Neubauer a; Klinik für Hämatologie, Onkologie und Immunologie, Zentrum für Innere Medizin, Philipps-Universität a, Marburg, Institut für medizinische Mikrobiologie und Krankenhaushygiene, Philipps-Universität b, Marburg, und Chiron Behring GmbH & Co .c, Marburg; June 2001

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