Dr. Andreas Ockenfels
Dipl.-Chem.
Pharma Consulting

Stolze-Schrey-Str.2
46539 Dinslaken
Phone +49.(0)2064.77 59 202
Fax +49.(0)2064.77 59 203
Mobil +49.(0)176.30 507 942

ockenfels@phar-ao.com
www.phar-ao.com

Profile

PhD in Chemistry, more than 15 years international experience in the pharmaceutical industry, several years in managerial position at service organizations for control especially of biopharmaceutical products.

Sound know how in implementation, reorganization and harmonization of quality systems under GLP and GMP in the areas quality control and manufacturing. Profound knowledge in quality control, performance of trainings and audits of European authorities or US-FDA.

I offer consulting and support in the following areas:

- Quality management, with implementation, reorganization or optimization of quality management systems especially under GLP and GMP
- Quality control, preparation or review of validation-, testing- or qualification documents
- Interim management: Quality Management and Quality Control
- Training in quality management and quality control
- Changes, deviations (CAPA), complaints, out of specification (OOS): Support for implementation of changes, processing of deviations and CAPA, complaints and OOS
- Audits: Performance of internal or external audits under GLP, GMP, ISO 9001 and 13485
- Support for qualification of equipment and validation computer based systems and Excel sheets
- Preparation, moderation of risk analysis
- Support for qualification of suppliers
- Preparation and review of quality agreements
- Project management
- Coaching

I offer the following knowledge and competencies:

- Quality management and quality control: from quality control of pharmaceutical, in particular biopharmaceutical products for international clients with managerial responsibility,
- Project organization: by implementation, reorganization or integration of quality systems, internally and externally, in the area of quality control and manufacturing,
- scientific and technical background: process oriented approach, solving of complex and cross linked problems,
- communication, including facilitation and presentation: sophisticated communicative skills as well as an outgoing and confident personality,
- Training: practice related, demand oriented, didactically structured, methodically sound,
- Flexible, with accurate, structured and interdisciplinary way of working, hands on mentality,
- proven ability to work under pressure, highly motivated,
- client oriented, highly competent negotiation skills in German and English, with intercultural competency,
- offering an independent as well as solution oriented approach.

I would appreciate to support you with my knowledge and competencies.

PROJECT HISTORY

since January 2015	Implementation of GLP in existing GMP system incl. successful inspection of authority, small-size biopharmaceutical company, Bielefeld, Germany
January - December 2014	Interim positions, e.g. Head of Quality Assurance, Head of Process Quality, evaluation and optimization of quality processes, deviation, change and CAPA management, process and quality data evaluation, subsidiary of a mid-size US based biopharmaceutical company, near Duesseldorf, Germany
March 2013	FDA inspection according 21CFR 210 and 211, mid-size bio-pharmaceutical company, near Kiel, Germany
February 2013	FDA inspection according 21CFR 110 and 111, mid-size pharmaceutical company, near Nuremberg, Germany
since January 2013	Lectures for students of Biotechnological Instrumentation Engineering, University of Applied Science, Bielefeld, Germany
December 2012 - December 2013	Interim Manager Quality Management Systems, establishment and optimization of processes and systems especially in the quality control unit, root cause analyses in production, mid-size subsidiary of a global company in the area of medical devices and pharmaceuticals, near Osnabrueck, Germany
since June 2012	Interim Head of Quality Assurance and Quality Control, small-size biopharmaceutical company, Bielefeld, Germany
May 2012	FDA inspection according 21CFR 210 and 211, mid-size pharmaceutical company, near Nuremberg, Germany
February - October 2012	Self-inspections and supplier qualification, mid-size subsidiary of global pharmaceutical company, Munich, Germany
November 2011 - November 2012	FDA remediation program, deviation and CAPA management, mid-size subsidiary of global pharmaceutical company, near Salzburg, Austria
October 2011	Support in preparation of technical and marketing material, small size manufacturer of sensors, Dusseldorf, Germany

CV

Date of birth	February 1969

EMPLOYMENT HISTORY

since Oct 2011	Independent Consultant
Oct 2008 - Oct 2011	Director Quality Management, Charles River Pharmaceutical Services GmbH, Erkrath, Germany; Services: External quality control under GLP and GMP especially of biopharmaceutical starting materials, intermediates, active pharmaceutical ingredients and final products - Managed the quality assurance department (Quality Control GMP) - Harmonized the quality system with the global quality system, maintained and improved the quality system of the site - Having been responsible for inspections by international clients and authorities (e.g. US FDA) as well qualification of subcontractors for their compliance
Nov 2002 - Sep 2008	Director Quality Management, NewLab BioQuality AG, Erkrath, Germany; Service: External quality control under GLP and GMP especially of biopharmaceutical starting materials, intermediates, active pharmaceutical ingredients and final products - Managed the GMP quality unit at the site in Erkrath and between 2005 and 2008 also of the GLP quality unit at the site in Cologne - Maintained and improved the quality system according to national and international GMP laws and regulations and client requirements - Having been responsible for projects for implementation, reorganization and harmonisation of quality management systems in manufacturing and quality control at different sites - Having been responsible for inspections by international clients and authorities (e.g. US FDA) as well qualification of subcontractors for their compliance - Supported in designing validations of bioanalytical methods
Mar 2001 - Oct 2002	Quality Assurance Manager, NewLab BioQuality AG, Erkrath Reviewed and released of quality related documents: protocols, Standard Operating Procedures, reports, Certificates of Analysis, change- and deviation control-documentation, qualifications, performed internal and external inspections, conducted audits by clients and authorities.
Jan 1996 - Dec 2000	Chemist (part time) Landers-Kreislaufwirtschaft, Wesel/Rhine
Jan 1991 - Sep 1992	Mechanic and Salesperson, TS-Automobile, Sinzig/Rhine, repaired and sold cars
Sep 1985 - Jun1988	Apprenticeship as an Laboratory Assistant, Institut for Organic Chemistry and Biochemistry of the University Bonn

EDUCATION

Apr 1998 - Jan 2001	Dissertation works, Max-Planck-Institut for Radiation Chemistry, Mülheim/Ruhr; PhD, Gerhard-Mercator University Duisburg, supported by a research grant of Friedrich-Ebert foundation, Bonn
Dec 1997	Award for diploma thesis by rectorat of the Gerhard-Mercator University and the University Society Duisburg
Oct 1991 - Aug 1997	Study of chemistry, Gerhard-Mercator University Duisburg, Diploma thesis at Max-Planck-Institut for Radiation Chemistry, Dipl.-Chem.
Dec 1990	General qualification for university entrance, Kaiserslautern
Aug 1988 - Jun 1989	Advanced technical college entrance qualification, Gewerbliche Bildungsanstalten der Stadt Bonn

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