



PROFILE

Quality Manager with over 25 years of experience in the pharmaceutical industry. Strong command of the English language. Excellent management and leadership skills. Used to work with cross-functional, global teams. CS- Validation and Digitalization expert. Proponent of an open communication and feedback culture. Used to handle fast changing goals/tasks and react in a solution-oriented manner. Well-organized with the demand of completing tasks according to given timelines.

SKILLS

- GxP compliant Q Systems / eQMS
- ISO9001/17025/27001
- Computerized System Validation
- Data Integrity/Digitalization
- Internal and External Audits
- Staff and User Training
- Process Improvement
- Leadership

Bernhard Antes

HEAD OF QA
GMP/GDP LEAD AUDITOR

WORK EXPERIENCE

Head QA Systems Austria/Lead Auditor *Valneva Austria GmbH | 2012 - present*

Managing the QA Systems team with 7 direct reports, System Owner for the Global eQMS, Managing global projects with stakeholders from all Valneva sites, Acting as GMP/GDP Lead Auditor for external and internal audits, CS Validation expert

Founding Shareholder, Research Associate *f-star GmbH | 2006 - 2012*

Development of therapeutic antibodies/antibody fragments, Protein Purification (AEKTA platform), Cell Culture, FACS based assays, Cell sorting, Biacore, ELISA, SDS-PAGE, IEF-PAGE, Western Blot, Mass Spectrometry, Small-scale QM system

Research Associate / QC Team Lead *igeneon AG | 2001 - 2006*

Immunotherapy of cancer, Team Lead QC, Purification (AEKTA platform), Cell Culture, FACS based assays, Cell sorting, Biacore, ELISA, SDS-PAGE, IEF-PAGE, Western Blot

EDUCATIONAL HISTORY

Federal Training and Research Institute for Industrial Chemistry, HTL Rosensteingasse *Biochemistry, Biotechnology and Genetic Engineering | Sep 1995 - Jun 2000*

Secondary School BRG16 *Sep 1991 - Jun 1995*

Primary School VS Julius Meinl Gasse *Sep 1987 - Jun 1991*

PUBLICATIONS

Journal of Biotechnology, 2011

"Integrin binding human antibody constant domains-Probing the C-terminal structural loops for grafting the RGD motif"

Protein Engineering, Design & Selection, 2010

"Introducing antigen-binding sites in structural loops of immunoglobulin constant domains: Fc fragments with engineered HER2/neu-binding sites and antibody properties"

J Pharm Biomed Anal., 2010

"Qualification of a microfluidics-based electrophoretic method for impurity testing of monoclonal antibodies"

J Chromatogr B Analyt Technol Biomed Life Sci., 2007

"Analysis of lysine clipping of a humanized Lewis-Y specific IgG antibody (IGN311) and its relation to Fc-mediated effector function"

PRESENTATIONS

2011 Biacore and MicroCal User Meeting, Milano (Italy)

"mAb2™ - A new generation of bispecific therapeutic antibodies"

2009 Biacore and MicroCal User Meeting, Heidelberg (Germany)

"The use of Biacore as a versatile tool in the development of modular antibodies"

INTERNSHIPS

Civilian Service

Otto Wagner Hospital | 2000 - 2001

Supporting the Bacteriology and Histology Laboratory

QC Operator

Baxter AG | Jul to Sep 2000

Supporting the QC laboratory for plasma products

COURSES AND TRAINING

- Self and Time Management (B. Schneider)
- Conflict Management (M. Werkusch-Klahn)
- Leadership Development Module 1 (Mediatum)
- Leadership Coaching (S. Bichl)
- Cloud Computing im GxP Umfeld (Concept Heidelberg)
- GMP/GDP Anforderungen an Lager und Transport (Concept Heidelberg)
- IT für Nicht ITler (Concept Heidelberg)
- Computervalidierungsbeauftragter (Concept Heidelberg)
- Lead Auditor (Concept Heidelberg)
- GMP Auditor (Concept Heidelberg)
- Six Sigma Yellow Belt (Six Sigma Austria)
- Certified QS-/GMP officer for the pharma industry (Concept Heidelberg)

TOOLS

SmartSolve (eQMS), Trackwise (eQMS), DocuBridge (eQMS), Microsoft Ax (ERP), Labware LIMS, Metacompliance (e-learning), PowerBI, Sharepoint, MS Office, Nintex Orchestration Tool, Workable (Recruiting), Work Compass (Performance Mgmt), ValidSign (e-signature), DocuSign (e-signature), Chromeleon (HPLC), Unicorn (Chromatography), Adobe InDesign, Teams

PERSONAL INTERESTS

Leather Craft, Acrylic painting, Finnish Lapphunds, Archery, Fitness, Travelling, Music



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