



Bernhard Antes

HEAD OF QA

GMP/GDP LEAD AUDITOR

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

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 Meini Gasse

Sep 1987 - Jun 1991



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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), Docu Bridge (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