Curriculum Vitae

Dr. Klaus Graumann

Home address:
Rotholz 387c
A-6220 Buch (Austria)

Born: April 25,1967 in Schärding / Austria

Married, two children (Gabriel (9 yrs), Greta (3 yrs))

At a glance

- PhD in Biotechnology with over 19 years of experience in the biopharmaceutical industry
- Involved in the development of commercial Novartis biopharmaceuticals including biosimilars (Sandoz)
- Experience with process development and manufacturing of a broad range of product formats from peptides, recombinant proteins / mAbs to virus-like particles (New Biological Entities and Biosimilars) of the Novartis / Sandoz pipeline
- Led the Technical Project Management team from 2010 to 2014 (CMC part, biosimilars mainly)
- Vast line function management experience with team size up to over 200 FTEs
- Experience with technical Due Diligences processes, CMO site selection / facility fit exercises and manufacturing process transfer execution (NVS network, CMOs)
- Experienced in managing in a matrix environment and across organizational boundaries
- Profound understanding of CMC development strategy, DS and DP manufacturing processes, compliance and regulatory topics
- Well established and connected in the biotech community

Professional Career, Responsibilities

Since July 2018:
CEO (designated) of Phoenestra GmbH

- Start-up in the field of induced pluripotent stem cells (iPSC)
- Seed financing and operational start-up planning
- Business development

Since August 2018:
Biotech Consultant (registered)

- Consultant in the area of drug substance for biopharmaceuticals (Techn Development and Manufacturing)
- Manufacturing Process Transfers
- CMC Document review

May 2016 – June 2018

Global Head Drug Substance Development (Late-Phase), Novartis Biologics Develoment and Manufacturing (BTDM)

- Late-phase development for the Novartis Biologics pipeline
- Management and global coordination of three DS development sites
- Budget planning and reporting

June 2014 – April 2016

Head Strategy & Operations Global Technical Development, Sandoz Biopharmaceuticals)

- Creation and lead of a Functional Network for CMB, USP, DSP and Statistics
- Process Development Strategy / Quality by Design (focus on biosimilars)
- Manufacturing Process Transfer Management (Drug Substance)
- Technology Strategy and Coordination of a "New Technology" Network
- Strategic Projects

July 2010 to June 2014

Head Global Technical Development Operations (Global Technical Development, Sandoz Biopharmaceuticals)

- Leading a group of Technical Project Leaders, Resource and Tech Transfer Managers (DS), located on different Novartis / Sandoz sites
- Biosimilar pipeline, NBE pipeline (DS part only)
- Technology evaluation and development, global initiatives, support of Due Diligences

October 2009 – June 2010

Head Global Technical Development Operations (Biopharmaceutical Operations (BPO), Sandoz Biopharmaceuticals)

- Deputy and support of the Head of Global Technical Development, BPO
- Managing TD groups in US, CH, SLO, DE and AT
- Interface Management with other Novartis Divisions
- Technology development, global initiatives, support of Due Diligences

April 2009 – October 2009

Head Global Technical Development a.i. (Biopharmaceutical Operations, Novartis Pharma / Sandoz Biopharmaceuticals)

- Technical Development and clinical manufacturing for innovative biopharmaceuticals and the Biosimilars pipeline
- Functional manager of Technical Development (Sandoz) and Manufacturing Science & Technology (Novartis Pharma) groups worldwide
- Interface management with Novartis Biologics and Sandoz Biopharmaceuticals
- Technology development, Global initiatives, support of Due Diligences

May 2005 – March 2009

Head Microbial Development (Biopharmaceutical Operations, Sandoz Site Kundl / Austria)

- Center of Excellence for recombinant microbial biotechnology for the Novartis group (60 associates)
- Process development and optimization at lab / pilot scale, tech transfers to manufacturing sites, process validation support
- GMP manufacturing of Drug Substance up to 1000 L scale (DSP only)
- Interface management (Novartis group and Third Party customers)
- Support of registration file submissions and audits
- Development of Platform technologies, Technology evaluations, support of Due Diligences

June 2003 – April 2005

Group Head Downstream Process Development (Sandoz, Site Kundl / Austria)

- Coordination of Downstream process development, tech transfers and process optimization

- Technical project management, coordination of resources for three development labs, budgeting
- Support of registration file submissions
- Development of platform technologies, development plans

February 2001 – May 2003
Lab Head Downstream Process Development (Biochemie, now Sandoz, Site Kundl/Austria)

- Downstream process development and optimization
- Tech transfers (internal)
- Technical project management (Subteam member)

October 1999 – January 2001
Team Leader Manufacturing (Boehringer Ingelheim Austria, Vienna)

- Implementation of Downstream processes at production scale
- Clinical trial material production
- Process validation support

May 1999 – July 1999
Consultant (LifeSensors Inc., Malvern PA, USA)

- Setup of protein purification for research purposes
- Assay development

Academic Training

March 1994 - March 1999
PhD in Biotechnology from the University of Life Sciences and Renewable Resources, Vienna, Austria

March 1994 – August 1994
Visiting Scientist (SmithKline Beecham now Glaxo SmithKline (GSK), Conshohoken PA, USA)
"Mutants of hER-α: cloning and testing in a yeast reporter assay system"

January -March 1994
Research associate at the Institute for Applied Microbiology, Vienna

April 1993 – November 1993
Military Service

March 1986 – March 1993
Master in Food- and Biotechnology at the University of Life Science and Renewable Resources, Vienna, Austria

1977 – 1985
Gymnasium (Schaerding, Austria)

1973 – 1977
Elementary school (Schaerding, Austria)

Publications, Presentations and Conference Organization

Numerous oral and poster presentations at conferences, symposia
Co-organizer of a Novartis-internal biotech conference series (BioPro)
Member of several scientific conference committees: Recovery of biological products XV, ESBES, ECAB, HIC/RPC, RPP conference series

A Jungbauer and **K Graumann**: Biopharmaceuticals: discovery, development and manufacturing. *Biotechnol J. 2012 Dec;7(12):1422-3*

Mandenius CF, **Graumann K,** Schultz TW, Premstaller A, Olsson IM, Petiot E, Clemens C, Welin M.: Quality-by-design for biotechnology-related pharmaceuticals. *Biotechnol J. 2009 May;4(5):600-9.*

Graumann K. and Premstaller A.: Manufacturing of recombinant therapeutic proteins in microbial systems. *Biotechnol. J.,* 2006 Feb;1(2):164-86. Review.

Graumann K. and Ebenbichler A.-A.: Development and scale-up of preparative HIC for the purification of a recombinant therapeutic protein. Chem. Eng. Technol., 2005, 28 (11) pp. 1398-1407

Schuster M., Wasserbauer E., Ortner C., **Graumann K.,** Jungbauer A., Hammerschmid F., Werner G.: Short cut of protein purification by integration of cell-disrupture and affinity extraction. *Bioseparation*, 2000;9(2):59-67.

Graumann K. and Jungbauer A.: Agonistic and synergistic activity of tamoxifen in a yeast model system. *Biochem. Pharmacol.* 2000 Jan 15;59(2):177-85.

Graumann K. and Jungbauer A.: Quantitative assessment of complex formation of nuclear-receptor accessory proteins. *Biochem. J.,* 2000 Feb 1;345 Pt 3:627-36.

Feng W., **Graumann K**., Hahn R., Jungbauer A.: Affinity chromatography of human estrogen receptor-alpha expressed in *Saccharomyces cerevisiae*. Combination of heparin- and 17beta-estradiol-affinity chromatography. *J. Chromatogr. A.,* 1999 Aug 6;852(1):161-73.

Breithofer A., **Graumann K**., Scicchitano M.S., Karathanasis S.K., Butt T.R., Jungbauer

A.: Regulation of human estrogen receptor by phytoestrogens in yeast and human cells. *J. Steroid Biochem. Mol. Biol.,* 1998 Dec;67(5-6):421-9.

Graumann K., Breithofer A., Jungbauer A.: Monitoring of estrogen mimics by a recombinant yeast assay: synergy between natural and synthetic compounds? *Sci. Total Environ.,* 1999 Jan 12;225(1-2):69-79.

Graumann K., Wittliff J.L., Raffelsberger W., Miles L., Jungbauer A., Butt T.R.: Structural and functional analysis of N-terminal point mutants of the human estrogen receptor. *J. Steroid Biochem. Mol. Biol*., 1996 Mar;57(5-6):293-300.

Koller G., **Graumann K**., Kramer W., Sara M., Jungbauer A.: Laboratory-scale production and purification of recombinant HIV-1 reverse transcriptase. *J. Chromatogr. B Biomed. Appl.,* 1995 Feb 3;664(1):107-18.

Memberships

Member of the Editorial Board of “Biotechnology Journal”
European Society of Biochemical Engineering Sciences (ESBES), Member of the Scientific Committee for the ESBES conference series
ÖGMBT (Austrian Society for Genetics and Molecular Biotechnology)
DECHEMA (German Chemical Society)
American Chemical Society (ACS)

Other interests

Family
Outdoor activities
Cultural activities
Travelling