Curriculum vitae

Bettina Rankl,
Nee: Ebi
Dipl.Ing. Biotechnology

Senior Expert Scientific & Regulatory Affairs

i.DRAS GmbH
International Drug Regulatory Affairs Services
Munich, Germany
www.i-dras.com

E-mail: bettina.rankl@i-dras.com

Place & Date of Birth	25.May 1975, Munich
Nationality	German
Academic Education	University: October 1994 – May 1999 University of Applied Sciences Weihenstephan, Freising Degree: Dipl. Ing (Graduate Engineer) Biotechnology
Post Graduate Positions and Professional Experience	Since October 2008: Senior Expert Scientific & Regulatory Affairs, i.DRAS GmbH, Germany March 2004 – July 2005 & April 2006 – October 2008: Manager Regulatory Affairs, GPC Biotech AG, Germany March 2003 – February 2004: Senior Associate Regulatory Affairs & Drug Safety, GPC Biotech AG, Germany May 1999 – February 2003: Research Associate & Senior Research Associate Cell Biology – GPC Biotech AG, Germany November 1998 – April 1999: Thesis, Department of Quality Control Biology, Rentschler Biotechnologie GmbH & Co. KG, Germany

	September 1997 – February 1998: Internship, Inflammatory Disease Unit, Roche Bioscience, USA March 1996 – August 1998: Student Assistant Department of Cell Biology and Quality Control, Baxter Deutschland GmbH, Germany
Expertise/Consulting	▪ Authoring of regulatory documents ▪ Filing strategy EU (National, MRP, DCP, Centralised, Abridged applications) ▪ Compilation and filing of marketing authorisation applications ▪ Response to agency questions ▪ Detailed and professional support with presubmission meetings and Scientific Advice meetings ▪ Regulatory Compliance ▪ Change Management & Variations ▪ Coordination of national and international marketing authorisation projects ▪ General regulatory & scientific project management
Professional Education	Participation in several seminars and trainings on the following topics : ▪ Clinical Trial Applications ▪ Marketing Authorisation Procedures in the EU and USA ▪ Medical Writing ▪ Development Biologicals ▪ (e)CTD ▪ Pharmacovigilance
Professional Service	Member of DGRA