



**Beate R. Schmidt**, MSc, MDRA, RAC, biologist by training (MSc from Heidelberg University, Germany), is an accomplished regulatory professional with 20+ years of in-depth experience in the development and licensing of innovative medicinal products, in Europe and North America (USA, Canada).

Since 2012, Beate works as a freelance regulatory consultant and collaborates with DDR (Drug Development and Regulation - [www.ddrmedic.com](http://www.ddrmedic.com)). Her therapeutic area experience includes oncology/hematology, rheumatology, autoimmune disorders, immunological/transplant indications, blood products.

Beate held various leading positions in the international biotechnology and pharmaceutical industry including Associate Director, Regulatory Affairs at Aspreva Pharmaceuticals Corp. and Director, Regulatory Affairs at Micromet AG. In these roles she gained extensive experience with all regulatory aspects of early and late-stage preclinical and clinical development of novel and biotechnology-derived drugs for rare, chronic or life-threatening indications.

In 2009 she joined the European Medicines Agency (EMA) as a Scientific Administrator in the Safety and Efficacy of Medicines sector. As a Product Team Leader she was responsible for the coordination of all types of regulatory procedures for a broad range of leading-edge and follow-on products.

From 2013-2017, she served as the RAPS European Liaison and has contributed in the past to the RAPS Online University as a Biologics Senior Faculty Member. She is also a faculty member of the IFAPP-King's College professional certification program "Medical Affairs in Medicines Development".

Beate's academic training includes a Master's degree in Drug Regulatory Affairs (MDRA) from the University of Bonn as well as the Regulatory Affairs Professionals Societies' (RAPS) Regulatory Affairs Certification (RAC) for the EU and US, respectively. In 2014, she completed a Master's degree in Health Economics, Policy & Management at the London School of Economics (LSE). She obtained a certificate Market Access Manager from the European Business School (EBS, Oestrich-Winkel, 2016) and did an internship in 2012 at the German Federal Joint Committee (Gemeinsamer Bundesausschuß, G-BA).