Dr. Matthias Brunner, Drug Regulatory Affairs Consultant

Worked for more than 15 years in several companies in drug regulatory consulting, the pharmaceutical industry and the German Federal Institute for Drugs and Medical Devices (BfArM) with an in-depth focus on pharmaceutical quality and Module 3 for new Marketing Authorisation Applications (MAA, NDA), Clinical Trial Applications, Variations/Changes and medicinal product development.

Engagements as expert lecturer at training courses for Regulatory CMC topics.

Initiated and drafted a pharmacopeial text for Germany and EU on Microbiological Requirements for Unpreserved Dosage Forms in Multi-Dose Containers, in cooperation with pharmaceutical companies, primary container manufacturers, microbiological laboratories, authority members and independent experts.

Worked in 'Life Sciences' research on DNS and peptide sequencing and detection, and fundamental research on 'Bio-chips'.

Studied Chemistry at the University of Heidelberg and the University of Bristol (UK) and Toxicology at the University of Leipzig.

Consultancy Portfolio

- CMC regulatory strategies and support for medicinal products in MAA and developmental projects
- Writing and updating of Module 3/Module 2.3 (CMC) documents for MAA/NDA, variations/changes and for clinical trial applications
- Module 3/2.3 preparation in CTD/eCTD format; creation of EU 'Baseline Dossier'
- Assessment, review and gap analyses of Module 3/Module 2.3 documents
- CMC management and change management for active substances (drug substances) and medicinal products (drug products)
- Regulatory compliance
- Responding to deficiency letters of EU and international authorities
- Technical assessment for MA procedures and legal cases
- Microbiological aspects and testing strategies for unpreserved dosage forms in multi-dose containers
- Special expertise in quality aspects of nasal, ophthalmic and auricular products
- Assessment on application of current laws and regulations

D-69123 Heidelberg • Hans-Bunte-Str. 8
Tel.: 0(049)6221 / 79 650 78
Info@DRA-Consultant.eu
http://www.DRA-Consultant.eu

May 2019