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 (CTA, IMPD, IND), Variations/Changes and medicinal product development.

Had been engaged as expert lecturer at training courses on Regulatory CMC topics like Module 3 writing.

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 labelling, 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 regarding pharmaceutical quality aspects of medicinal products for MAA/NDA, clinical trial applications (CTA/IMPD/IND) and developmental projects
- Writing and updating of chemical-pharmaceutical documentation (Module 3/2.3) and further regulatory CMC documents for all regulatory purposes
- Writing and updating of Active Substance Master File (ASMF) / Drug Master File (DMF)
- Module 3/2.3 preparation in CTD/eCTD format, in required granularity for eCTD submission; Creation of EU 'Baseline Dossier'
- Assessment, review and gap analyses of Module 3/2.3 documents, creation of deficiency lists
- Regulatory CMC Management and Regulatory Change Management for active substances / drug substances and medicinal products / drug products
- Assessment of regulatory compliance
- Responding to deficiency letters of competent authorities
- Consolidation of dossiers (e.g. from fragments, past variations); Transformation/re-formatting of legacy chemical-pharmaceutical documentation
- Microbiological aspects and testing strategies for unpreserved dosage forms in multi-dose containers
- Special expertise in quality aspects of nasal, ophthalmic and auricular products; tablets, capsules and sterile parenterals

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