Curriculum Vitae

Personal information

Marianne Schmidt

Work experience

1. Employer: Danish Medicinal Agency
   - Start date: 032019
   - End date:
   - Position: Non_clinical assessor
   - Activities: Assessments of all areas of toxicology, pharmacokinetics and pharmacology (including safety) of medicines according to current ICH guidelines. Member of the NS OEG and participant in NITWG, drafting guidance on nitrosamines as well as evaluations of in silico data, in vitro and in vivo mutagenicity data and carcinogenicity data. Involved in ATMP assessments and New Alternative Methodology (NAM) assessments. Assessor on SAW procedures and participant in ITF BM.
   - Country: Denmark
2. Employer: Ferring Pharmaceuticals
   - Start date: 082018
   - End date: 022019
   - Position: Global Regulatory Affairs Manager
   - Activities: Responsible for regulatory submissions, approvals and compliance, preparing and carrying out regulatory strategies for world wide market expansions and renewals of medicinal products Preparing the CMC part of the product dossier, module 2.3 QOS and module 3 documents for MMAs/NDAs and answering authority questions Coordination of input from stakeholders, reviewing documents and ensuring consistency and compliance with regulatory CMC guidelines (ICH guidelines for module 3) Performing regulatory impact assessment of CMC changes for established products to ensure that the adequate documentation is generated to support the change
   - Country: Denmark
3. Employer: Danish Environmental Agency
   - Start date: 052010
   - End date: 072018
   - Position: Toxicologist
   - Activities: Non_clinical assessor, undertaking toxicological and pharmacokinetic evaluations of chemicals assessing ADME properties and a broad range of toxicological endpoints in in vitro and in vivo studies in accordance with OECD guidelines as well as assessment of the relevance of effects in toxicological studies for the human health. Establishing No Observed Effect Levels, Safety Factors and Acceptable Exposure Levels of chemicals as well as performing risk assessments for the exposure of humans. Regulator managing the assessment and approval of biocidal active substances and products for the European and Danish national market according to current legislation and guidelines, i.e. via the Mutual Recognition Procedure and the Central Procedure. Quality assessor, undertaking assessment of a range of physical_chemical properties, substance identity and impurities as well as analytical method validation. Several years of experience as the Danish delegate of the Coordination Group under the European Commision and the Toxicological Expert Group in ECHA, discussing and reaching agreement on referrals in relation to the Mutual Recognition Procedure for Biocidal products and developing guidance. International experience from EU meetings, both presenting and discussing toxicological issues, developing guidance and negotiating the terms of use.
   - Country: Denmark

Education and training

1. Subject: University of Copenhagen, Pharma School
   - Start date: 092004
   - End date: 112009
   - Qualification: Cand. Pharm.
   - Organisation: Master's thesis in in vitro cell toxicology
   - Country: Denmark

Additional information

Publications

Projects

Memberships

Other Relevant Information