Curriculum Vitae

Personal information

Amani Al-Sarraf

Work experience

1. Employer: LEO Pharma
   - Start date: 052021
   - End date: 042022
   - Position: SENIOR FORMULATION SCIENTIST FOR MANUFACTURING SCIENCE, BIOLOGICS
   - Activities: Process and formulation senior scientist for newly marketed antibody based formulation. I was responsible for authoring M3 documents for submission to new markets in close collaboration with regulatory affairs. In addition, I offered support to the contract manufacturers for implementation of improvements and provide product impact assessment for manufacturing process exceptions.
   - Country: Denmark
2. Employer: LEO Pharma
   - Start date: 082020
   - End date: 032021
   - Position: R&D SENIOR FORMULATION SCIENTIST FOR CMC BIOLOGICS
   - Activities: In this role, I have given process and formulation expert support to obtain marketing authorization in US and EU for the newly developed antibody based product. Worked on documentation for drug product commercial manufacturing process validation, process control strategy and transport validation. After submission I was heavily involved in answering several rounds of authority questions.
   - Country: Denmark
3. Employer: LEO Pharma
   - Start date: 122016
   - End date: 082020
   - Position: R&D SENIOR FORMULATION SCIENTIST FOR PHARMACEUTICAL PRODUCT SUPPORT
   - Activities: Process and formulation expert for a variety of formulations both topicals and injectables. I have offered scientific support on row materials, formulation, process related issues, and maintained CMC documentation for marketed products. I have also worked on several technology transfers projects and functioned as lead for root cause investigations for out of specification events. I have also functioned as manager for a product portfolio support group managing and prioritising improvement projects including decision making and change management.
   - Country: Denmark
4. Employer: BIOGEN
   - Start date: 042013
   - End date: 122016
   - Position: LARGE SCALE MANUFACTURING COMPLIANCE SPECIALIST
   - Activities: Authoring and revising Master Production Records and procedures for DS purification processes. Integration of automation in the manufacturing process and development of partial electronic batch records. Exception handling and documentation in addition to administering and executing process changes and technology transfers according to cGMP.
   - Country: Denmark
5. Employer: BIOGEN
   - Start date: 012012
   - End date: 042013
   - Position: CLINICAL SUPPLY CHAIN QUALITY SPECIALIST, INTERNATIONAL CLINICAL DISPOSITION
   - Activities: Quality assurance support to clinical operations in Europe and rest of world, handling of exceptions occurring at the clinical sites, review of batch records of clinical finished goods, review and approval of transfer documents and batch transactions. Handling of transport temperature excursions by interpretating and extrapolating limited stability data. Administration of eRIMS and update of Marketing Authorization Applications. Process optimization, procedure update and staff training were also performed continuously.
   - Country: Denmark

Education and training

1. Subject: FACULTY OF PHARMACEUTICAL SCIENCES, UNIVERSITY OF COPENHAGEN
   - Start date: 092003
   - End date: 102011
   - Qualification: Cand.pharm, pharmacist
   - Organisation: Master thesis in the area of protein formulations. Thesis title: Human Serum Albumin as a Model for Probing the Influence from Solution Properties on Protein Adsorption onto Solid Surfaces.
   - Country: Denmark

Additional information

Publications

Projects

Memberships

Other Relevant Information

Courses 2020 Environmental health and safety (arbejdsmiljø uddannelse) 2019 Validation and Process Control for Electron Beam Sterilization, Risø High Dose Reference Laboratory DTU Nutech, Technical University of Denmark 2018 International Symposium on Mixing in Industrial Processes IX, ISMIP9, Birmingham University 2018 Training in Drug Device Combination Products (DDCP), LEO PHARMA 2018 Godkendelse af lægemidler – Regulatoriske tips og tricks, Pharmakon 2017 Quality by Design and quality risk assessments, LEO PHARMA 2017 Out of specification investigation, industrifarmaceutforening (IFF) 2017 Developing Specifications for Drug Substances and Drug Products 2015 Change Management, Biogen 2015 Cultural Communication, Biogen 2014 MS_ Basic Therapeutic Overview, Biogen 2014 Change Control, Biogen 2013 Train the Trainee, Biogen 2012 Handling Deviations, CAPA´s and Planned Exceptions. Biogen 2012 Advanced user of Electronic Documentation Systems, Authoring and Reviewing GXP Controlled Documents. Biogen 2012 Writing and Performing Investigations. Biogen 2012 Master of Business Administration (Mini MBA10 ECTS), Competer 2011 Market Analysis, Katapult 2009 Lean and Innovation, Katapult