

Aruna Ashok Kherde

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PROFESSIONAL EXPERIENCE

Senior Engineer, Tata Elexi

08/2022 – Present

- Assists the Regulatory Affairs Manager for ensuring compliance with the requirements set by the EU Medical Device Regulation and other regulatory bodies for medical devices registration across different geographies.
- Product Registration Support- APAC, LATAM, EMEA, Canada, China, Russia.
- Prepare and review the documentation required for Change submission, Notification, Re- registration of Medical devices
- Provide guidance to team in the preparation of documents for change submission, notification, re-registration packages of Medical Devices for regulatory agencies submission.
- Understands existing technical files / design dossiers/Technical documentation summary by reviewing documentation available for compliance to CE mark of EU and prepare the Country specific STEDs.
- Performs a Regulatory watch to identify and respond to new or revised regulatory requirements as per the Input by Geo Ras
- Tracks the status of applications under regulatory review and provides updates to the Core Regulatory team.
- Maintains logs of communication and outcomes with regulators and other relevant internal or external stakeholders.
- Collects, organizes, and maintains files on local, regional, and global regulatory intelligence and other related information.
- Research requirements (local, national, international) and options for regulatory submissions, approval pathways and compliance activities.
- Maintains information systems (electronic and paper) for regulatory information and reports.
- Oversee and ensure maintenance of regulatory licenses renewals in a timely manner.
- Clearly conveys information to peers, supervisors, and other stakeholders.
- Supports the development of internal RA systems and procedures.
- Maintains SOPs related to RA activity and suggests update of the QMS.
- Participated in Regulatory assessment of Engineering/ Design change execution.

Executive, Agio Pharmaceutical, Pune

06/2017 – 07/2018

- Preparation of Dossier as per CTD and ACTD format for ASEAN, European Countries, GULF Countries and others as per country specific guidelines.
- Preparation of Technical documents required for dossier preparation like Finished Product Specification including Standard Testing Procedure, Certificate of Analysis (COA), Stability Report, Dissolution Report and Annual Product Quality Record (APQR).
- Preparation and Formulation of Tablets, Capsules on Pilot scale batch for Sample preparation for Dossier Submission.

Trainee, Zim Laboratories Ltd, Nagpur

09/2015 – 10/2016

- Preparation of Dossier as per CTD and ACTD format for ASEAN, European Countries, GULF Countries and others as per country specific guidelines.
- Preparation of Technical documents required for dossier preparation like Finished Product Specification including Standard Testing Procedure, Certificate of Analysis (COA), Stability Report, Dissolution Report and Annual Product Quality Record (APQR).
- Preparation and Formulation of Tablets, Capsules on Pilot scale batch for Sample preparation for Dossier Submission.

EDUCATION

M. Pharm (Pharmaceutics), RTM, Nagpur University, Nagpur

06/2015

CGPA: 8.5/10 Coursework: Modern Pharmaceutical Analytical Techniques, Novel drug delivery systems, Pharmaceutical Formulation Development, Intellectual Property Rights

B. Pharm RTM, Nagpur University, Nagpur

05/2013

Percentage: 66.76% Coursework: Pharmaceutics, Pharmaceutical Analysis, Biochemistry, Engineering Drawing, Medicinal Chemistry, Industrial Management and Pharmaceutical Marketing, Forensic Pharmacy

D. Pharm MSBTE, Mumbai

05/2010

Percentage: 76.70% Coursework: Pharmaceutics, Pharmacology, Pharmacognosy, Hospital and Clinical Pharmacy, Pharmaceutical Chemistry, Pharmaceutical Jurisprudence

TECHNICAL SKILLS

- Medical Device Regulations, EUMDR Regulation, USFDA
- Regulatory Documentation, ISO 13485
- Risk Management ISO 14971
- Good Manufacturing Practice (GMP)
- Regulatory Compliance
- Labelling Art Work, Draft label generation

ACADEMIC PROJECT

"Fast Dissolving Film: A Novel and Innovative Drug Delivery System"

- Fast-dissolving films are stamp-size polymeric films that have the capacity to dissolve in the oral cavity and allow the active moiety to reach the systemic circulation via oral mucosal membranes. The potential advantage of this dosage form is the ease of handling, good stability, and portability in nature. This chapter describes mucosal membrane, barrier properties, physiological aspects of drug absorption via oral cavity, method of manufacturing of films, and marketed formulations.

Certifications & Licenses

**Registered Pharmacist of
"State Pharmacy Council"
Maharashtra (Registration No.
115519).**

Customer Satisfaction Award
Received Customer Satisfaction
Award from Tata Elxsi