THE
REGULATORY & COMPLIANCE
LEADERS™

Madhur Jadawala

Lead Consultant

Contact Information

T: (905) 363-1182 x 230

TF: 1 (877) 877-5152 x 230

F: (905) 542-7981

E: mjadawala@qualityandcompliance.com

2550 Argentia Rd., ◆ Suite 119, ◆ Mississauga ON ◆ L5N 5R1

Madhur is an experienced regulatory consultant, who has worked in an industrial Good Manufacturing Practices (GMP) setting and has proven technical writing, communication, and project management skills. He has worked with a wide range of health products including drugs, natural health products (NHPs), and cosmetics.

Skills & Highlights, Big Project

Quality Control (QCO)

- Co-hosted Health Canada GMP, GVP Audits
- Released finished products into Canadian market for sale after ensuring all the Canadian GMP requirements are met, including appropriate manufacture, tests, labelling, expiry dates, transportation, etc.
- Prepared and reviewed Annual Product Quality Reviews, Master Production Documents (MPD), Drug Master Files (DMF), Batch Records, Test Methods, Change Control documents, Method and Process Validation, Quality Assurance Reports (QAR)
- Wrote, edited, and updated Standard Operating Procedures (SOPs) ensuring regulatory requirements are met
- Reviewed manufacturer's Certificate of Analysis (CoA) and Certificate of Manufacturing (CoM) against the Canadian Finished Product Specifications (FPS), extract data from the temperature data loggers and review acceptability/compliance
- Helped in preparation of audits and inspections by Health Canada and US FDA

- Served as a Regulatory Consultant to clients for importing and selling their products in Canadian market; helped them meet the Quality and GMP requirements for drugs/NHPs in Canada
- Prepared and reviewed FPS for NPN/DIN applications, technical reports such as Warehouse Temperature Mapping Protocols, Stability Protocols
- Managed the domestic/foreign Adverse Drug/Event Reaction Report (ADR/AER) reporting to Marketed Health Products Directorate (MHPD) of Health Canada for various clients, and other pharmacovigilance activities
- Maintained samples in the warehouse with proper labelling (i.e., Retain, Quarantine, Destruction) so as to make them traceable and accessible when required

Regulatory

- Prepared, coordinated, and supervised Health Canada regulatory submissions for Drugs (DIN), Natural Health Products (NHPs - NPN), Cosmetic, Sunscreens, over-the-counter products (OTCs), etc. and maintained compliance of products and establishment/site licences
- Filed Natural Health Product Directorate (NHPD) Product Licence Applications (PLAs) and Amendments (PLCs) in Electronic (ePLA) format
- Maintained an active knowledge of the status of pending approvals and shepherd registrations through the approval process
- Researched and reviewed Food and NHP labels, claims, and nutrition fact panel
- Compiled Drug Establishment Licence (DEL), Site Licence (SL) applications and amendments, Category IV and Labeling Standard Drug Identification Number (DIN) submissions
- Responded to clarifications (Clarifax/IRN) from Health Canada within specified time frames

Validation

- Developed stability protocols (RT, Accelerated, Intermediate) for drugs, NHP including all test parameters to validate shelf-life
- Reviewed Method validation protocols/Reports against ICH requirements

Technical Writing

- Wrote, edited, and updated GMP SOPs ensuring regulatory requirements are met

Education

- Post-Graduate Certificate, Regulatory Affairs (Honours), Humber Institute of Technology and Advanced Learning, Toronto, Ontario

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- Bachelor of Science in Pharmacy (Honors), Gujarat Technological University, Gujarat, India
- Graduated with first class distinction (3.82 GPA as per WES Canada evaluation)
- Diploma, Biotechnology Technician – Industrial Microbiology, Centennial College, Scarborough, Ontario

Professional Development/Career-Development

- Design and Interpretation of Clinical Trials – Course, John Hopkins University, Coursera.org

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