eurofins | BioPharma Product Testing

QUALITY ASSURANCE AND REGULATORY SERVICES

Eurofins BioPharma Product Testing Toronto, Inc. formerly Experchem Laboratories, Inc. provides Regulatory Affairs, Quality Control/Quality Assurance and Compliance (GCP, GLP, GMP) consulting services for pharmaceuticals (Drugs), natural health products (NHPs), medical devices (MDs) and cosmetics.

Our professional consulting team has in-depth knowledge of Health Canada, U.S. Food and Drug Administration (FDA), and European Medicines Agency (EMA) regulations to assist you with your quality and regulatory projects.

Pharmaceuticals for sale in Canada must be labelled, registered, and sold in compliance with Health Canada requirements. We use our knowledge to help our clients comply with all legislative requirements to establish a well-designed and correctly implemented pharmaceutical quality system (also known as a Quality Management System) that incorporates good manufacturing practices (GMP) and quality risk management.

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CANADA

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Quality Assurance Services

- GMP 3rd Party Audit services and gap analyses
- Development and Implementation of GMP Compliant Quality Systems
- QAP for ongoing Quality Control and Quality Assurance needs
- Prepare Technical Quality and Pharmacovigilance Agreements
- Prepare and maintain Standard Operating Procedures (SOPs)
- Host or assist with Regulatory (Compliance) Health Canada Inspections from Start to Close-out
- Preparation of Finished Product Specifications
- Design and implement Stability Studies program
- Deviation and CAPA management
- Master Production Documentation review, approval and maintenance
- Generate and/or Review Annual Product Quality Reviews (APQR)
- Customized GMP Training Services (new staff or annual training programs)
- Product Recalls - Health hazard evaluation and recall classification
- Complaint Handling and Management
- Pharmacovigilance and Post-Market Surveillance

Regulatory Consulting Services

Eurofins Biopharma Product Testing supports manufacturers, packagers, labelers, suppliers, distributors, importers, warehouses and prospective licence holders.

- Establishment Licence Applications and Amendments for Drugs (DEL), Medical Devices (MDEL) and Natural Health Products (NHP Site License)
- Regulatory assessment and classification of products based on ingredients and label claims.
- Product Licence Applications, Amendments and Notifications
    - o Pharmaceutical Drug Products (DIN)
    - o Natural Health Products (NPN, DIN-HM)
    - o Medical Devices (MDL)
- Label reviews of Drugs, Food, Medical Devices and Natural Health Products for compliance to Health Canada requirements
- Product Label Development including Drug Facts Table to help maximize claims and expedite product approvals
- Cosmetic product consulting (label & ingredient reviews, cosmetic notification)
- Good Pharmacovigilance Practices (GVP) services (PSURs, PBRERs)