



Your RA & QA Team

Comprehensive Regulatory and Quality Strategies

Drugs • Natural Health Products • Medical Devices • Cosmetics • Food
Regulatory Affairs Submissions • Project Management • Quality Assurance & GMP

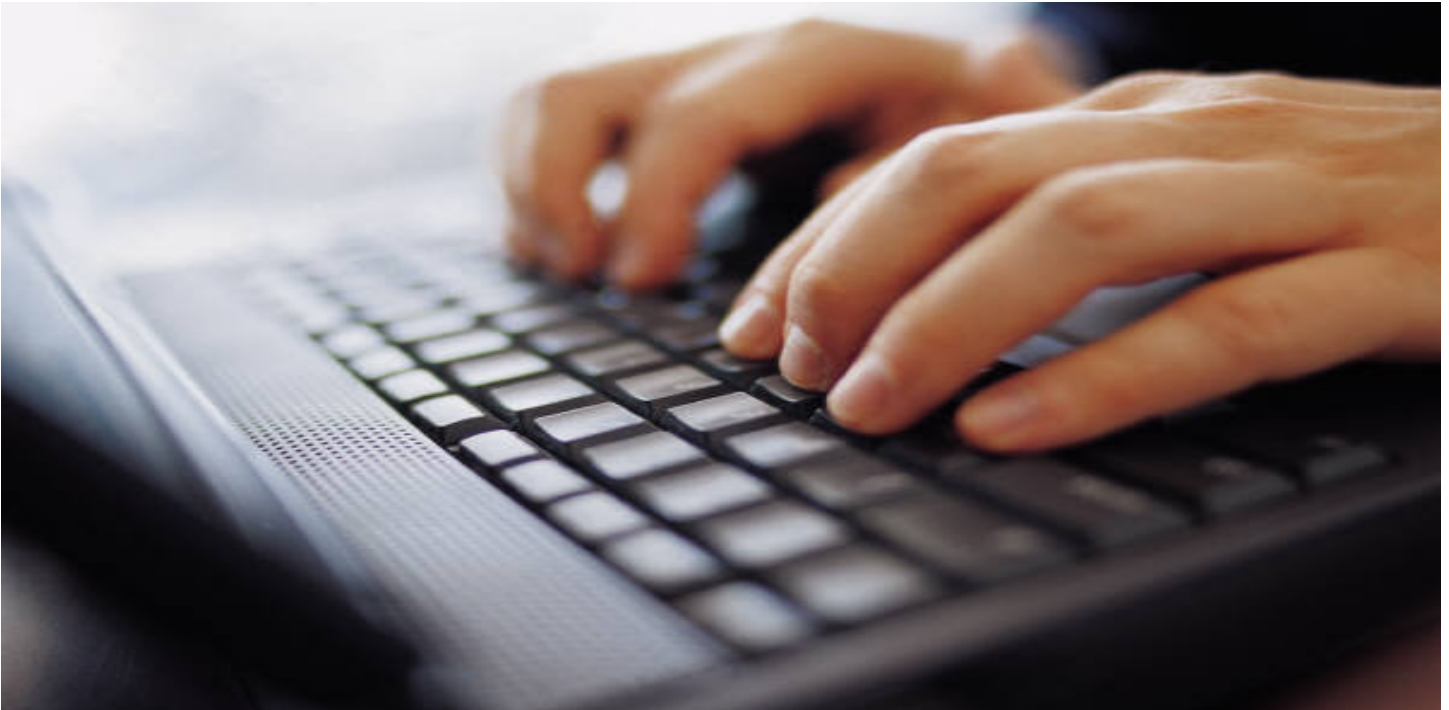


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OUR COMPANY



We provide our clients with superior benefits:

- Comprehensive regulatory and quality strategies to ensure product launches, re-launches and rebranding are successful with “first-time right” objectives
- Expert opinion, extensive experience and knowledge
- Full business perspectives and “out-of-the-box” thinking
- Secure cloud file sharing for document exchange
- Expedited response timelines and cost savings
- Competitive fees and project-based costing

OUR EXPERTISE

We “LEAP over regulatory and quality hurdles” because:

- We know Health Canada’s requirements and anticipate possible questions
- We develop regulatory strategies and pathways to improve submission approval rates, reduce costs, and decrease timelines
- We have a proven track record for optimal submissions
- We have successfully negotiated with regulators and agencies
- We have over 26 years of combined industry experience
- We learn our clients’ business needs and objectives



Leverage • **E**fficient • **A**ttention • **P**rofessional

OUR SERVICES

Drugs • Natural Health Products • Medical Devices • Cosmetics • Food



Regulatory Affairs



Quality Assurance



Project Management



Import / Export
Activities

Collaborating with our organization allows you access to:

- A Canadian expert that interfaces and files product submissions with health authorities
- A Canadian review of product labelling, formulations, and promotional materials for regulatory compliance
- An authorized Quality representative to release regulated products in Canada
- Developing regulatory and product launch plans to ensure all deliverables are met and on budget
- Obtaining FDA and Health Canada establishment licensing and registrations

COMPREHENSIVE RA & QA STRATEGIES

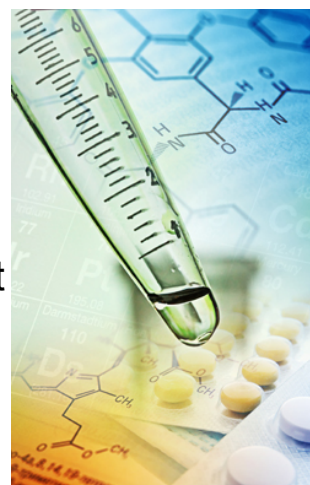
REGULATORY AFFAIRS

Business Reviews
Clinical Trial Applications
Cosmetic Notifications
Drug Submissions (Rx and OTC)
Medical Device Applications (Class 2 to 4)
Natural Health Product Licence Applications (PLAs)
Export Certificates for Canadian Manufacturers
Ingredient and Formulation Review
Product Review and Feasibility
Consumer Product Support



QUALITY ASSURANCE

Audit Preparation, Representation and Follow-up
Site License Support - Natural Health Products (NHP)
Drug Establishment Licensing Support
Medical Device Establishment Licensing Support
ISO 13485 Registrar Selection, Implementation & Support
Electrical Safety Considerations
Ongoing Product Support (Drug / NHP release)
Recalls and Complaint Management
SOP Preparation and Implementation



IMPORT / EXPORT

Drugs • Natural Health Products • Medical Devices • Cosmetics • Consumer Products



**Complete business
solutions and process
optimization for product
imports and exports**

Supporting your import / export activities in these areas:

- Export certificates for Canadian manufacturers
- Embassy document legalizations / authentications
- Transportation carrier selection and temperature monitoring studies
- Transportation of Dangerous Goods (TDG) and Material Safety Data Sheets (MSDS) review
- Conducting audits and document reviews for the acceptability of foreign and domestic manufacturing sites
- Obtaining FDA and Health Canada Establishment licencing and registrations
- Supporting Canadian and global product submissions to authorities
- Label and promotional material reviews for compliance
- Test laboratory selection and set-up



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