

Manisha Swargam

Regulatory Affairs Specialist | Food and dietary supplement regulatory Compliance (Canada, EU, US) | Certified Food Safety HACCP Manager | Nutrition Labeling Specialist

Ottawa, Ontario, Canada

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Summary

Regulatory Affairs Specialist with 10+ years of expertise ensuring regulatory compliance, and market access across Canada, US, EU for wide range of food categories and also dietary supplements. Proven success leading multi-country regulatory strategies, streamlining submissions, achieving 100% compliance in CFIA inspections, and accelerating time-to-market. Certified in Food Safety (HACCP) and Nutrition Labeling, with strong cross-functional collaboration skills, risk management expertise, and a passion for bringing safe, innovative products to consumers.

Core Competencies

- ✓ Regulatory Strategy & Compliance (CFIA, Health Canada, FDA, EFSA)
 - ✓ Product compliance & Labeling Approval
 - ✓ Risk Assessment & Regulatory Intelligence
 - ✓ Document Management
 - ✓ Supplier & Stakeholder Management
 - ✓ CFIA food regulations
 - ✓ Training, Team Leadership & Mentorship
 - ✓ Food Safety (HACCP), Nutrition Labeling certifications
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Professional Experience

Dovetale Collections, Ottawa, ON

Food Regulatory Affairs Specialist

Mar 2024 – Present

- Led end-to-end QA, RA and safety audits across 1000+ SKUs, applying CFIA standards, improving audit readiness.
- Verified imported product labels and collaborated with 80+ suppliers.
- Created CFIA-compliant ingredient, and nutritional panels, ensuring accuracy for CFIA regulations.
- Act as the primary liaison between our company and regulatory agencies, including the Canadian Food Inspection Agency.
- Proofread and approve final label copy of all new products launched by the company. Maintain updated spreadsheets and databases of packaging artwork files, finished product list, spec sheets, and suppliers to ease the audit process.
- Managed and maintained Canada Packer's product registrations and SKUs across international markets, ensuring accurate and timely submissions.
- Developed and applied expert knowledge of labeling regulations for both Canadian (CFIA) and international markets to support compliant product launches and updates.
- Ensured end-to-end regulatory compliance for both existing SKUs and new product innovations across packaging, labeling, and claim validation.
- Provided regulatory subject matter expertise to cross-functional teams, supporting ideation, claims review, and packaging execution.
- Reviewed and approved label changes from a regulatory standpoint and provided backup for ECR (Engineering Change Request) processes.
- Participated in cross-functional project teams across ideation, development, claim validation, and final packaging graphics approval.
- Partnered with packaging suppliers to implement components that meet company quality and efficiency standards, offering technical support during rollout.
- Maintained and managed supplier data, ensuring traceability requirements.
- Supported continuous improvement efforts in regulatory workflows, packaging compliance, and cross-departmental coordination.
- Supported R&D teams in the development and launch of new products, ensuring compliance with regulatory requirements. Organize and manage R&D and

manufacturing specific documentation such as technical regulatory specifications, HACCP, Safety Audit reports, allergen management policy.

- Ensured all records and product information were audit-ready, contributing to a culture of continuous compliance.
 - Acted as support function for Operations in maintaining food safety, authenticity, legality, and quality.
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Freyr Regulatory Solutions

Assistant Manager – Food & Dietary Supplements

Dec 2016 – Sep 2023

- Develop and implement strategies to ensure compliance with local, state, and federal safety regulations.
- Providing regulatory road map to clients to build strategy for multiple product categories like Food, Dietary Supplements, FSDUs, FSMPs, Prebiotic Food, Probiotic Food, Nutraceuticals, Plant extracts or Botanical supplements
- Ability to work on Canada Food and Drug Regulation (FDR), Safe Foods for Canadians Act and Regulations and Natural Health Products Regulation (NHPR)
- Worked on submission of Product License Application (PLA) for Canada.
- Performing a complete label review and identifying the changes to make it compliant to the target market.
- Preparing and review of product labels including product name, ingredient statement, allergen declaration, description, kosher, nutrition facts panel and claims as applicable.
- Ensure compliance to Regulatory Requirements (CFIA, USDA, FDA), food safety programs (HACCP), Good manufacturing practices (GMP), and finished product specifications
- Maintaining the track of the projects, trackers, presentation of revenue to the management and trained the subordinates of the team.
- Collaborate cross-functionally with product development, marketing, and legal teams to ensure regulatory compliance throughout the product lifecycle.

- Worked with product development team to support product claim(s) and active ingredient(s) quantification.
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Cognizant Technological Solutions

Regulatory Intelligence Analyst

Sep 2013 – Oct 2016

- Tracked and analyzed regulatory developments (FDA, EMA, MHRA, PMDA, Health Canada, ANVISA), delivering impact assessments for product strategies.
 - Built and maintained a regulatory intelligence database supporting submission planning and lifecycle management.
 - Delivered intelligence reports summarizing key regulatory trends and competitor activities, influencing strategic decisions.
 - Developed automated reporting templates, reducing reporting time by 30% and improving accuracy.
 - Research and analysis of clinical data related to bio-pharmaceutical companies.
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Education

Master's Degree, Pharmaceutical Sciences (A+)

Osmania University, 2012–2014

National level 3022 rank in Masters Entrance Exam

Bachelor's Degree, Pharmacy (Distinction)

Kakatiya University, 2007–2011

Certifications

- **Certified Food Safety HACCP Manager (CFSHM)**, Canadian Food Safety Group, Feb 2024, ID: HACCP02745
 - **Nutrition Labeling Specialist**, Public Health Agency of Canada
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Technical Skills

- SharePoint, PowerPoint, Excel, Google Sheets, Adobe, Databases
- Highly organised and exceptional in documentation management
- Great level of attention to detail