

Manisha Swargam

Regulatory Compliance & Strategic Consulting Professional

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💡 PROFESSIONAL SUMMARY

Results-driven **Regulatory Compliance Specialist** with **9+ years of expertise** in food, beverages, and dietary supplement compliance across **Health Canada, CFIA, and USFDA regulations**. Proven track record in **accelerating regulatory approvals, optimizing compliance strategies, and reducing risk exposure** for multinational brands. Adept at **regulatory intelligence, pre-market approval, product labelling, and quality assurance**. Passionate about streamlining regulatory pathways and enhancing cross-functional collaboration for seamless market entry.

💎 CORE COMPETENCIES

- ✓ **Regulatory Compliance:** Health Canada, CFIA, USFDA, HACCP, GMP
 - ✓ **Pre-Market Approval:** Product registration, dossier preparation, licensing
 - ✓ **Labelling & Claims Review:** Ingredient declarations, allergen labeling, compliance audits
 - ✓ **Regulatory Strategy & Consulting:** Roadmaps, risk mitigation, global expansion
 - ✓ **Quality Assurance & Audits:** HACCP audits, GMP compliance, supplier approvals
 - ✓ **Regulatory Intelligence & Research:** Compliance databases, impact assessments
 - ✓ **Software & Tools:** InDesign (Label Design), Regulatory Databases, Compliance Tools
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📁 PROFESSIONAL EXPERIENCE



Food Regulatory Affairs Specialist

📍 *Dovetale Collections, Ottawa, Canada* | 📅 *March 2024 – Present*

- **Led regulatory compliance efforts** as the **primary liaison with CFIA**, ensuring **100% approval rate** for imported food products and reducing regulatory approval times by **30%**.
- Partnered with **15+ manufacturers** to develop **100+ compliant product labels**, cutting approval turnaround time by **40%** and ensuring full **CFIA compliance**.
- Automated **NFT generation** for **200+ labels per quarter**, improving labeling accuracy by **99.9%** and reducing compliance errors by **50%**.
- **Spearheaded HACCP audits**, improving compliance scores by **20%** and reducing non-conformance issues by **35%**, exceeding industry benchmarks.
- Streamlined **new product onboarding**, enabling **30+ product launches per year** and cutting supplier approval time by **25%**.



- Managed **50+ regulatory certifications**, ensuring **100% audit readiness** and reducing documentation errors by **60%**.
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Assistant Manager – Food & Dietary Supplements (CoE)

 *Freyr Regulatory Solutions Hyderabad, India* |  *December 2016 – September 2023*

- Designed and executed **regulatory compliance roadmaps** for **50+ food and dietary supplement products**, achieving a **98% first-pass approval rate** (industry avg: **90%**).
 - Led **cross-functional teams** (product, marketing, legal), reducing compliance review turnaround time by **35%** and accelerating product launch cycles.
 - Conducted **ingredient and claims validation** for **100+ SKUs**, ensuring **100% compliance** with **CFIA and USFDA** regulations while mitigating legal risks.
 - Advised **20+ global clients** on regulatory strategies, guiding **50+ successful product launches** across North America.
 - Delivered **30+ training sessions**, upskilling **50+ employees** in **regulatory compliance**, boosting efficiency by **20%**.
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Analyst – Regulatory Intelligence

 *Cognizant Technology Solutions Hyderabad, India* |  *September 2013 – November 2016*



- Researched and maintained a **global regulatory intelligence database** covering **20+ markets**, enhancing data accuracy by **30%** for strategic decision-making.
 - Acted as **SME (Subject Matter Expert)**, resolving **100+ client queries** on **labeling, registration, and advertising compliance**, reducing compliance errors by **25%**.
 - Developed **regulatory reports** for global markets, increasing compliance strategy efficiency by **40%** and improving risk assessment accuracy.
 - Created **10+ regulatory webinars and thought leadership articles**, increasing industry engagement and brand authority by **20%**.
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EDUCATION

 **Master of Pharmacy (Pharmaceutics)** – Osmania University, 2014

 **Bachelor of Pharmacy** – Kakatiya University, 2011


CERTIFICATIONS

-  **HACCP Manager Certificate Course**
-  **Nutrition Labelling Online Certificate** (Certificate #35533) – *Public Health Agency of Canada (PHAC)*



TECHNICAL SKILLS

- ✓ **Label Design & Development:** Adobe InDesign, Compliance Software
- ✓ **Regulatory Database Management:** FDA, CFIA, Health Canada Databases
- ✓ **Quality & Compliance Tools:** HACCP, GMP, Risk Analysis

PUBLICATIONS & RESEARCH

 **Dissertation:** *Enhancement of Solubility and Bioavailability of Hydrochlorothiazide Using Solid Dispersion Technique*

ADDITIONAL INFORMATION

-  **National Achievement:** Secured a **national rank of 3022** in **GATE (GPAT-2011)**.
 -  **Industry Engagement:** Participated in **multiple workshops & seminars** on **drug development & regulatory affairs**, enhancing industry expertise.
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