

# [First Last Name]

[City, State/Country] | [email@example.com] | [+1 (555) 555-5555] | [LinkedIn URL]

## PROFESSIONAL SUMMARY

Detail-oriented **Regulatory Affairs Specialist** with [X] years of experience supporting global submissions, lifecycle management, and compliance for [pharmaceutical/medical device/biotech] products. Proven track record coordinating **regulatory submissions** (e.g., [IND], [NDA], [510(k)], [CE Mark]), maintaining compliant product documentation, and partnering cross-functionally with R&D, Quality, and Clinical teams. Adept at interpreting evolving **FDA, EMA, and ICH** requirements and translating them into clear, actionable guidance for internal stakeholders.

## PROFESSIONAL EXPERIENCE

### [Regulatory Affairs Specialist] | [ABC Biopharma Inc.]

[Month Year] – Present | [City, State/Country]

- Prepared, reviewed, and coordinated submission of [IND amendments, annual reports, and clinical trial applications], ensuring adherence to **FDA, ICH, and local regulatory** requirements and reducing agency information requests by [X]%.
- Maintained and updated **regulatory dossiers and product labeling** in [eCTD] format using tools such as [EXTEDO/DocuBridge/Insight Publisher], supporting on-time approval of [X] new indications and [Y] labeling updates.
- Collaborated with cross-functional teams (R&D, Quality, Clinical, Pharmacovigilance) to assess regulatory impact of **CMC changes, safety signals, and process improvements**, providing clear guidance that shortened internal review cycles by [X] days.

### [Regulatory Affairs Associate] | [Global MedTech Solutions]

[Month Year] – [Month Year] | [City, State/Country]

- Supported preparation and compilation of **510(k) submissions, technical files, and design dossiers** for Class II/III medical devices, contributing to [X] successful clearances within targeted timelines.
- Conducted regulatory intelligence and gap assessments against **FDA, EU MDR, ISO 13485, and ISO 14971** requirements, summarizing key changes and risks in concise briefing documents for senior management.
- Maintained **registration databases, product listings, and UDI records** using [Veeva Vault/TrackWise/SharePoint], improving data accuracy and enabling rapid retrieval of documentation during audits and inspections.

## EDUCATION

### [B.Sc. in Regulatory Affairs / Pharmaceutical Sciences / Life Sciences] | [University Name]

[Month Year] – [Month Year] | [City, State/Country]

- Relevant coursework: [Regulatory Affairs for Drugs & Biologics], [Clinical Research & GCP], [Quality Systems & Risk Management], [Pharmaceutical Law].

### [Regulatory Affairs Certification (e.g., RAC – Drugs/Devices)] | [Regulatory Affairs Professional Society or Institution]

[Month Year] – [Month Year] | [Online/City, State/Country]

- Completed specialized training in [global regulatory strategies, submission planning, and lifecycle management].

## SKILLS

- Regulatory Expertise:** [FDA IND/NDA], [ANDA], [510(k)], [EU MDR/IVDR], [ICH guidelines], [GxP], [ISO 13485], [ISO 14971].
- Documentation & Submissions:** [eCTD publishing], [regulatory dossiers], [CMC documentation], [labeling and artwork review], [SOP development].
- Tools & Systems:** [Veeva Vault], [MasterControl], [TrackWise], [Documentum], [Microsoft Office (Word, Excel, PowerPoint)], [SharePoint].
- Regulatory Intelligence:** [monitoring guidance updates], [competitive analysis], [risk assessment], [impact analysis] for global markets.
- Cross-Functional Collaboration:** Partnering with [R&D], [Quality Assurance], [Clinical Operations], [Pharmacovigilance], and [Manufacturing] to align on regulatory strategy.
- Communication & Writing:** [clear technical writing], [summary reports], [responses to health authority queries], [presentation of regulatory strategies] to stakeholders.
- Soft Skills:** [attention to detail], [time management], [problem-solving], [stakeholder management], [adaptability in fast-changing regulatory environments].

## SELECTED PROJECTS

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### [Global Labeling Harmonization Initiative] | [ABC Biopharma Inc.]

[Month Year] – [Month Year]

- Led regulatory workstream to **standardize product labeling** across [X] markets, reviewing SmPC/PI, IFU, and packaging components to align with updated safety and efficacy data.
- Coordinated with local affiliates and medical writers to implement label changes, reducing country-specific discrepancies by [X]% and supporting consistent global branding.

### [510(k) Submission Readiness for Class II Device] | [Global MedTech Solutions]

[Month Year] – [Month Year]

- Compiled and quality-checked **substantial equivalence, performance testing, and risk management** sections, ensuring documentation met FDA expectations and internal quality standards.
- Developed a standardized checklist and templates for future submissions, decreasing preparation time for subsequent 510(k)s by [X]%.