

Olivia Bennett

Regulatory Affairs Specialist | FDA Submissions, Labeling & Compliance

San Diego, CA | (858) 555-0114 | olivia.bennett@email.com | linkedin.com/in/oliviabennett-regulatory

FDA 510(k)

IND / NDA

ISO 13485

21 CFR 820

EU MDR

Labeling

SUMMARY

Regulatory Affairs Specialist with 3.5 years of experience in the medical device and pharmaceutical industries. Prepared and supported 12 FDA submissions, achieved a 100% on-time submission record, and helped secure 6 clearances and approvals. Skilled in 510(k) and IND support, labeling, post-market compliance, and cross-functional regulatory strategy.

SKILLS

Regulatory Submissions: FDA 510(k), IND/NDA Support, Technical Documentation, Labeling Review, Regulatory Intelligence, Change Control, Annual Reports

Quality & Standards: 21 CFR Parts 11, 50, 56, 210/211, 820, ISO 13485, ISO 14971, EU MDR (Basics), Complaint & MDR Reporting, CAPA

Tools: Veeva Vault RIM, MasterControl, eCTD Publishing, SharePoint, Excel, Smartsheet

EXPERIENCE

Regulatory Affairs Specialist

Jun 2023 – Present

Pacific MedTech Innovations — San Diego, CA

- Prepare and support FDA 510(k) and technical file submissions for Class II devices, with a 100% on-time submission record.
- Contributed to 6 FDA clearances and approvals by coordinating responses to agency questions within required timelines.
- Review labeling, IFUs, and promotional materials for 40+ products to ensure compliance with 21 CFR and ISO standards.
- Manage change control assessments for 90+ design and process changes; determine regulatory impact and filing needs.
- Track global regulations and brief R&D, Quality, and Marketing on requirement changes.

Regulatory Affairs Associate

Jul 2022 – May 2023

BioNova Pharmaceuticals — San Diego, CA

- Compiled eCTD sections for IND amendments and annual reports.
- Maintained regulatory databases and submission trackers in Veeva Vault RIM.
- Supported 2 FDA inspection readiness audits with zero critical observations.

HIGHLIGHTS

Regulatory Excellence Award 2024; RAPS member; contributed to the company's first EU MDR gap assessment.

EDUCATION

Bachelor of Science in Biochemistry

University of California, San Diego — La Jolla, CA
2022 | GPA 3.6

Certificate in Regulatory Affairs

UC San Diego Extension — San Diego, CA
2023

CERTIFICATIONS

- Regulatory Affairs Certification (RAC) — RAPS, in progress
- ISO 13485 Internal Auditor Training
- GCP Certification (CITI)