Bernard Delacruz
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OVERVIEW:

- 15 years of technical writing experience in biotech, medical device, and in vitro diagnostics. Extensive experience with Instructions for Use, user manuals, package inserts.
- Certificate in Regulatory Affairs for Medical Devices from UCSD Extension. Working familiarity with medical device regulations (FDA 21 CFR 801; MDD/MDR; IVDD/IVDR), and quality systems standards (21 CFR 820; ISO 13485).
- Strong written and oral communication skills and extensive experience with cross-functional collaboration with Regulatory Affairs, Quality, Marketing R&D, User Experience, and other teams.
- Driven review cycles to deliver high-quality documents on time while adapting to shifting priorities.

WRITING / EDITING EXPERIENCE:

- Written/edited user manuals, package inserts, and Instructions For Use (IFUs) for medical devices and in vitro diagnostics.
- Written/edited internal documents (SOPs, work instructions, V&V reports, batch records, etc.)
- Written/edited technical marketing copy (web catalog, sales brochure, microsite).

COMPUTER / TECHNICAL EXPERIENCE:

- XML-based content management systems: AuthorIt, Vasont.
- Electronic Quality Management Software: MasterControl, Veeva, Documentum, TeamCenter Enterprise, Grand Avenue Software.
- Microsoft Office suite: Word, PowerPoint, Excel, Teams, SharePoint, Visio.
- Adobe Acrobat Pro software.
- Adobe Creative Suite and other graphics software (Photoshop, Illustrator, InDesign, SnagIt).

RECENT POSITIONS:

Senior Technical Writer (Contractor) **Halozyme—San Diego, CA** **Sep 2023 to Present**

- Supported harmonization and transfer of SOPs and work instructions from Antares Pharma to Halozyme.
- Managed reviews and approvals in MasterControl and Veeva quality management software per 21 CFR 820 and ISO 13485.
- Provided technical writing support to Quality teams.

Senior Technical Writer (Contractor) **LumiraDx—Solana Beach, CA** **Mar 2022 to Dec 2022**

- Facilitated development and submission for IVD products. Supported submission of two SARS-CoV-2 assay kits for CE IVDD certification in three months.
- Reviewed and released 50+ documents in Grand Avenue Software per 21 CFR 820 and ISO 13485 in three months.
- Created and updated SOPs, work instructions, V&V reports, and batch records for transfer from R&D to Manufacturing and Regulatory Affairs teams. Updated design input/output documents and DHF.

Technical Writer **Grifols—San Diego, CA** **Mar 2019 to Mar 2022**

- Edited regulated labeling (package inserts and IFUs) for Procleix blood nucleic acid testing (NAT) kits.
- Edited hardware and software user manuals for Procleix Panther high-throughput screening instrument for laboratory technicians.

- Participated in efforts to integrate, revise, and make obsolete documents from acquired Hologic NAT group.
- Conducted document reviews with stakeholders and drove review cycles to meet deadlines. Proactively managed multiple projects to meet shifting priorities.
- Participated in quality reviews and CAPAs.
- Used FrameMaker to manage IFUs and user manuals.
- Released documents in Documentum software per QSR (21 CFR 820) and ISO 13485.

Technical Writer II **Abbott—Sylmar, CA** **2016 to 2019**

- Edited regulated labeling (package inserts and IFUs) for cardiac rhythm management devices and pacing leads per revised standards (ISO, IEC) and regulations (MDD/MDR, AIMDD).
- Collaborated cross-functionally with other teams, including Regulatory Affairs, Legal, Quality, and Systems Engineering, to maintain quality and meet goals.
- Drove review cycles to achieve deadlines. Proactively managed multiple projects to meet shifting priorities.
- Released documents through TeamCenter Enterprise per 21 CFR 820 and ISO 13485.
- Managed user manuals and technical literature in an XML/DITA-based content management system (AuthorIt).

Technical Writer II **Medtronic Diabetes—Northridge, CA** **2013 to 2016**

- Edited regulated labeling (package inserts and IFUs), user manuals, quick start guides, and software guides for insulin pumps, continuous glucose monitoring systems, and consumable diabetes devices.
- Collaborated cross-functionally with other teams. Facilitated document reviews. Participated in design reviews. Participated in user experience testing of consumables.
- Managed user manuals in an XML/DITA-based content management system (Vasont).
- Maintained department style guide in coordination with Medtronic's international style guide team.
- Trained in GDP, GMP, HIPAA/data privacy, quality systems, and FDA/EMA labeling requirements.

Technical Marketing Coordinator **Bachem—Torrance, CA** **2011 to 2013**

- As sole writer/editor, produced monthly email newsletter distributed to 20000+ customers.
- Wrote feature articles on academic and industry peptide researchers. Compiled news items on peptide technology. Wrote articles about Bachem peptide products and custom peptide synthesis services.
- Created a marketing brochure and a mini-site for Melusine Venom Libraries. Increased visitors by 200%.

EDUCATION:

- Certificate, Regulatory Affairs for Medical Devices, UCSD Extension
- Ph.D., Biology, University of California, San Diego
- B.A., Biology, University of California, Santa Cruz

RELEVANT COURSEWORK:

- Quality Management Systems for Medical Devices (UCSD Extension)
- Design Control for Medical Devices (UCSD Extension)
- Regulatory Submissions for Medical Devices (UCSD Extension)
- Post Market Topics for Medical Devices (UCSD Extension)
- Technical Copyediting (UCSD Extension)
- Technical Communications 101 (Society of Technical Communication)
- Intermediate Medical Writing - Medical Devices (RAPS)
- Introductory Medical Writing (RAPS)