Bernard Delacruz

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15 years of writing experience in Biotech, Medical Devices & IVDs

SUMMARY:

- 15+ years of writing experience for biotech, medical devices, and in vitro diagnostics.
- Fostered good rapport with other teams (Regulatory Affairs, Legal, Marketing, Quality, R&D, and others) to break through roadblocks, solve problems, and reach consensus.
- Driven review cycles to deliver high-quality documents on time while adapting to shifting priorities.
- Working familiarity with labeling requirements (21 CFR 801) and quality regulations and standards (FDA 21 CFR 820; ISO 13485).

WRITING / EDITING EXPERIENCE:

- Written/edited package inserts and Instructions For Use (IFU) 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:

- Electronic Quality Management Software (EQMS): MasterControl, Veeva, Documentum, TeamCenter Enterprise, Grand Avenue Software.
- XML-based content management systems: AuthorIt, Vasont.
- 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:

Technical Writer Consultant (Part-time contractor) **Whiterabbit.AI—Santa Clara, CA** **Nov 2023 to Present**

- Supported the writing and editing of a user manual for a Software as Medical Device (SaMD) to analyze mammograms.

Technical Writing Consultant (Full-time contractor) **Halozyme—San Diego, CA** **Sep 2023 to Present**

- Supported the writing, editing, and transfer of SOPs from Antares Pharma to Halozyme.
- Managed reviews and approvals in MasterControl and Veeva software per QSR (21 CFR 820) and ISO 13485.

Freelance Writer/Editor **BJD Tech Writing LLC—San Diego, CA** **Jun 2023 to Present**

- Principal, BJD Tech Writing LLC. Providing scientific and technical writing and editing services to biotech, medical devices, and in vitro diagnostic companies. www.bjdtechwriting.com

Senior Technical Writer **LumiraDx—Solana Beach, CA** **Mar 2022 to Dec 2022**
(Full-time contractor}

- Participated as technical writing SME to facilitate 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 QSR (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. Maintained document templates.

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

- Edited regulated labeling (package inserts and IFUs) for Procleix blood testing kits.
- Edited hardware and software user manuals for Procleix Panther instrument for laboratory technicians.
- Participated in efforts to integrate, revise, and make obsolete documents from Hologic acquisition.
- Collaborated with other teams as a technical writing SME. Conducted document reviews with stakeholders and drove review cycles to meet deadlines. Proactively managed multiple projects to meet shifting priorities.
- Used FrameMaker software 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 R&D, 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 QSR (21 CFR 820) and ISO 13485.
- Managed user manuals and technical literature in an XML-based content management system (AuthorIt).

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

- Edited regulated labeling (package inserts and IFUs) and patient-facing user manuals for insulin pumps, continuous glucose monitoring systems, and consumables.
- Collaborated cross-functionally with other teams. Facilitated document reviews. Participated in phase reviews.
- Managed user manuals in an XML-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%.

Web Content Specialist **Life Technologies—Carlsbad, CA** **2010 to 2011**

- Developed style guide for online catalog and trained 100+ product managers.
- Led "Top 500" project to rewrite 500+ catalog entries to improve click-through and increase sales.

Freelance Writer/Editor **2009 to 2016**

- Wrote feature articles for the American Medical Writers Association (AMWA) Pacific/Southwest newsletter.
- Presented talk on medical device labeling for AMWA Pacific/Southwest Chapter.
- Copy edited 10+ textbooks (University Readers/Cognella).

Medical Writer **City of Hope Medical Center—Duarte, CA** **2006 to 2008**

- Provided scientific, data analysis, and writing support to clinicians. Prepared journal manuscripts and poster abstracts.
- Prepared slide decks for continuing medical education lectures, scientific meetings, and patient groups in topics of diabetes and endocrinology. Performed scientific literature searches and compiled up-to-date research.
- Copy edited 2 medical textbooks per AMA and publisher's style guide. Coordinated with 20+ authors on 60+ chapters. Wrote an introductory chapter for one textbook.
- Wrote reports, letters to philanthropic donors, web content, and press releases.

Postdoctoral Researcher **Keck Graduate Institute—Claremont, CA** **2000 to 2006**

- Studied gene regulation in response to metabolic changes in the yeast Pichia pastoris.
- Bridged system biology and computational groups to analyze genome sequences and RNA expression data.
- Copy edited protocols manual (Pichia Protocols, 2nd Edition, Springer).

EDUCATION:

- Ph.D., Biology, University of California, San Diego
- B.A., Biology, University of California, Santa Cruz

ADDITIONAL COURSEWORK:

- Certificate, Regulatory Affairs for Medical Devices (UCSD Extension, in progress)
- Technical Communications 101 (Society of Technical Communication)
- Technical Copyediting (UCSD Extension)
- Intermediate Medical Writing - Medical Devices (RAPS)
- Introductory Medical Writing (RAPS)