DEBRA M. LEIBOLD, MD, PHD

Blue Bell, PA 19422 | debraleibold@gmail.com | 215-815-0142 | linkedin.com/in/debraleiboldmdphd

GLOBAL LABELING STRATEGIST: CLINICAL, REGULATORY, RISK, SAFETY

US, EU, Japan (FDA, PMDA, EMA) Regulatory Compliance – Consensus-Driven CCDS, USPI, SmPC Documentation

ETHICAL FULL LIFECYCLE LABEL DEVELOPMENT THAT NEVER CUTS CORNERS

- **UPenn-Educated MD/PhD brings decision-makers to the table to negotiate resolution**, leading to the creation and maintenance of clear and compliant product labels that educate HCPs and patients.
- **Labeling strategy and leadership that brings product labeling and groundbreaking products to market**, supporting first-of-its-kind vaccines, rare disease treatments and global filings that expand the underserved's access to lifesaving medications.
- **History of success guiding labeling, risk management and product safety** for diverse therapeutics that prevent and treat diseases amongst the leading cause of death worldwide for pharmaceutical giants Merck, Shire, AstraZeneca and J&J.

GLOBAL LABELING EXPERIENCE

Consultant **2015-2023**
YourEncore & Opus Regulatory, Inc.
Global Labeling Strategist/Project Management for J&J, Shire and AstraZeneca

Recruited by these providers of drug development and commercialization advisory services to lead labeling projects and provide interim leadership at AstraZeneca, Johnson & Johnson and Shire Pharmaceuticals.

Clinical Leader Consultant – J&J

- Drove resolution of labeling inconsistencies between in-country (EU, US, ROW, Japan) and HQ/company core data sheets (CCDS). Guided Committee that made recommendations and executed corrective plans based on review of database and literature.
- Partnered with CRO to author worldwide clinical summaries used to correct in-country labeling and that supported changes to CCDS then communicated globally – resulting in filings that increased access to life-changing anti-infective, internal medicine and oncologic treatments.

Sr Labeling Contractor/Specialist – Regulatory Drug Project Development – AstraZeneca

- Developed, updated and rectified inconsistent SOPs, guidelines and Toolbox documents used to create and maintain US and EU Prescribing, Core Product & Marketing Information (CPI and MPI).

Global Regulatory Affairs Labeling Consultant – Shire Pharmaceuticals

- In Interim role during wind-down of Chesterbrook, PA locale, harnessed conflict resolution talents to achieve consensus throughout development, revision and maintenance of product labeling used to treat rare diseases.
- Participated in full lifecycle labeling discussions and drafted labeling text, rationales and responses to agency comments.
- Developed CCDS, US, EU and Japanese patient and healthcare labeling and content for revisions filing, new guideline compliance and updates based on new clinical data.

Merck & Co. **2002–2011**
Sr. Medical Director, Clinical Risk Management & Safety Surveillance (2010–2011)

Pivoted following corporate restructure as sole physician on team focused on Clinical and Product Safety. Co-chaired Risk Management Safety team.

- Performed competitor product reviews and safety surveillance used to review critical adverse experiences, author/co-author and update product safety reports, risk management plans and responses to agency inquiries.

PRODUCTS: M-M-R II, Liquid Pedvax, PedvaxHIb, Haemophilus b Conjugate, Noxafil, Cancidas, Various Investigational Drug Candidates

Sr. Director/Labeling Physician, Worldwide Product Labeling (2002–2010)
Recruited, trained and led 15-member writing team who transformed complex medical directives into clear, direct and life-saving labeling published in Company Data Sheets (CCDS) and Core Patient Information (CPI) collateral for patients and healthcare professionals in the US, EU and worldwide subsidiaries.

Labeling Leadership

- Championed proactive consensus-building and conflict resolution across Research, Statistics, Joint Venture Leadership, Legal and Marketing laser-focused on the bottom line: "What do the doctor and patient need to know?" in support of label development for applications, revision filings, local label maintenance, agency response, etc.

- Shepherded labeling through management review as Chair of Worldwide Product Circular Review/Approval Committees. Tackled >25 products concurrently from Target Product Labeling through Phase II, Phase III, and Post Market, and in Adverse Experience Reports.

- Remained abreast of global regulatory requirements throughout creation and review of labels for vaccines and products to treat everything from hypertension to infectious diseases.

Labeling Process Improvement

- Established process that identified and addressed medical concerns and secured FDA approval for first-of-its-kind HPV vaccine Gardasil – paving the way for future groundbreaking medications and complex joint ventures.

- Instituted framework that shaved months off of product timelines – and ensured labeling never cut corners during pressure-packed journey to gain FDA approval and be first to market.

- Spearheaded development of tracking system that monitored subsidiary implementation of label safety updates that complied with HQ-created company data sheets. Represented Worldwide Product Labeling during agency audits.

PRODUCTS: Gardasil, RotaTeq, ProQuad, M-M-R II, Varivax, Vaqta, Pneumovax, Recombivax, Isentress, Crixivan, Invanz, Stromectol, Emend, Arcoxia, Cozaar, Hyzaar, Renitec, Co-Renitec, Prinivil, Prinzide, Aggrastat. Cosopt, Trusopt, Timoptic, OTCs.

Additional Experience

Expert Witness (2023 – 2025)

Product Labeling, Prescribing Information, Efficacy Information, Safety Information, Label Development, Label Updates, Labeling Guidance

Director, Worldwide Editing & Labeling | **MERCK & CO.** (1993–2002)

Supported development of labeling for multiple products in Phase II, Phase III, and post-market. Scientifically edited clinical documents for accuracy, data support, consistency within and across documents, 100% support of product labeling, and compliance to external and company guidelines. Shepherded clinical documents through review to achieve hard-earned consensus. Emerged as a US, EU and global regulatory labeling landscape (i.e., CCDS, USPI, SmPC) expert well-versed in labeling for diverse therapeutic areas.

Associate Director, Professional Communications – Human Health Division | MERCK & CO. (1990–1993)

Harnessed MD/PhD acumen as a de facto Marketing watchdog, performing medical reviews of field sales training and marketing collateral, and preparing database to respond to questions from healthcare professionals.

Licenses & Certifications

Medical Physician & Surgeon | State of Pennsylvania

Board Certified | American Board of Internal Medicine

Industry Affiliations

American Medical Association
Pennsylvania & Montgomery County Medical Societies

Professional Development

Tufts University Center for Study of Drug Development | *Clinical Pharmacology, Drug Development & Regulation*

Drug Information Association | *Global Perspectives on Medical Technical Writing & Document Preparation for the Pharma Industry & Regulatory Agencies*

Merck & Co. | *Public Speaking, Management and Leadership*

Pri-Med | Pennsylvania Medical Society | Thomas Jefferson University
CMEs related to Medical Safety, Risk Management and Internal Medicine, including GI, Neurology, Cardiovascular, Pulmonary, Oncology.

Education

University of Pennsylvania | MD & PhD, Medicine & Molecular Biology
Swarthmore College | BA, Biology w/Chemistry Concentration
NIH National Cancer Institute | Biotech Fellowship