CAPABILITIES AND EXPERIENCE
CINDY VAN DUKER

WORK EXPERIENCE

Landrich Group (2021 – Present)
- Responsible for providing regulatory IDE/IVD expertise and advise to medical device and IVD clients including preparing, reviewing, and submitting IDE applications including follow- up reporting

Regulatory Consultant (2019 – Present)
- Responsible for providing regulatory expertise and advise to medical device and IVD clients

Associate Director, Regulatory Affairs: Illumina, Inc. (2016 – 2019)
- Developed global regulatory strategies for next generation sequencing IVD assay, software, and instrument development teams
- Supported next generation sequencing instrument registrations for China, S. Korea, and Japan
- Participated in FDA pre-submission meeting for companion diagnostic assay and meetings with Japan PMDA

Director, Regulatory Affairs, Myraqa, Inc. (2010 – 2016)
- Responsible for providing expertise and advise to medical device and IVD clients regarding regulatory compliance and strategic planning.
- Submitted PMAs, IDEs and pre-submissions to FDA
- Participated in FDA pre-submission meetings and advisory committee meetings

Manager, Regulatory Affairs, Volcano Corporation (2006 – 2009)
- Developed strategies for Class II and Class III cardiovascular medical device submissions
- Participated in Pre-IDE meetings
- Responsible for 510(k) submissions, CE marking, coordinated Shonin submissions
- Assessed engineering, manufacturing, and quality changes for regulatory requirements

Program/Project Manager, Intel Corporation, Digital Health Group (2006)
- Developed and implemented a Quality System for regulatory planning and clinical trials for a new medical device division
- Developed strategy for CE marking medical devices in Europe

Manager, Regulatory Affairs, Dade Behring, Inc. (1998 – 2006)
- Managed 510(k) submissions to FDA for IVD product line
- Participated in preparation of PMA submissions to FDA and CE marking of European product line
- Lead team to re-register product lines in Japan
- Represented RA, QA, and Operations on R&D Project Teams

Regulatory Affairs Specialist/Technical Project Manager, Biomune Systems, Inc. (1995 – 1997)
- Updated CMC section of IND
- Prepared clinical/statistical reports and study protocols for Phase I and II studies
- Developed procedures for validation of in vitro assays
- Coordinated clinical studies

Regulatory Affairs Supervisor, HGM Medical Laser Systems, Inc. (1993 – 1994)
- Filed MDRs, Initial/model change reports, annual reports and recall effectiveness reports
- Created documentation including DMRs, DHRs, complaint records, operator's manuals, and service manuals

EXPERIENCE HIGHLIGHTS

Focused, quality-driven associate director with 25+ years of regulatory experience within diverse manufacturing environments. Highly skilled at regulatory submissions and strong knowledge of guidance under ISO 13485 and FDA's Quality System Regulations (QSR). Experience with EUAs, Pre-Submissions, IDEs, PMAs, 510(k)s, CE Design Dossiers, Technical Files, Canadian Licenses, ROW registrations and China and Japan Submissions.

EDUCATION & ACCREDIATION

- Master of Science, Biomedical Engineering – California State University, 1995
- Bachelor of Science, Electrical and Electronic Engineering - California State University, 1992
- Bachelor of Science, Biochemistry – University of California Davis, 1989