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PROFESSIONAL EXPERIENCE AND ACCOMPLISHMENTS

Quidel Corporation. San Diego, CA **01/2020-present**
Manufacturer of IVD's and point of care tests. **Dir. Regulatory Affairs**
Responsible for a staff of 5 covering domestic and international regulatory affairs, product approvals and licensing for the FDA and rest of the world. Analyze complaints and vigilance activities. Manage and lead the IVDR transition.

Sotera Wireless Inc. San Diego, CA **05/2018 – 01/2020**
Developer of the ViSi mobile patient monitoring system. **Sr. Dir. Quality and Regulatory Affairs**
Lead a team of 10 covering quality and regulatory activities. Maintain EU and global registrations. Formal management representative and host of FDA and other inspections. R&D liaison.
Accomplishments:
(i) Rescued and redirected a 510(k) to successful clearance
(ii) Initiate and maintain a cradle-to-grave, company-wide quality metrics program

BD, formerly CareFusion, Inc., San Diego, CA **03/2010 – 03/2018**
Manufacturer of medical devices and drug products. **Director Regulatory Affairs**
Responsible for the worldwide FDA, quality system and compliance auditing of 48 manufacturing, repair, and distribution facilities. Managed the company's standards program. Experience with confidential and ethics investigations. Managed the budget and supervised 3 audit managers and 2 QA/IT systems validation managers. Company SME on risk management, UDI, software, auditing and compliance. Experience with due diligence and M&A activities.
Accomplishments:
(i) Established a risk-based global audit system that incorporated FDA and global compliance metrics,
(ii) Established a company-wide access system for standards including semi-annual regulatory updates,
(iii) Led the corporate transition for both ISO 14971:2012 and ISO 13485:2016,
(iv) Provided global regulatory updates to all employees on a monthly basis,
(v) Filed three 510(k) submissions based on rush requests from sites,
(vi) Coordinated a global cost-saving response to the FDA's regulation for symbols on medical device labeling, and,
(vii) Provided quarterly comments to the Board and executives on compliance, audits, and global regulatory developments.

Addition Technology, Inc., Des Plaines, IL **03/2007-03/2010**
Manufacturer of corneal implants. **Director Regulatory Affairs and Quality Assurance**
Responsible for two facilities, the quality system, regulatory affairs, and product quality for US/FDA Class III corneal implants that are sold globally. Maintained PMA and HDE submissions in the USA. Managed audits by FDA, the EU and other countries. Carried out internal and vendor audits and managed the supplier management system. Wrote and maintained EU Technical Files. Served as the IRB contact for clinical trials. Formal management representative.
Accomplishments: Obtained domestic and international product approvals.

Siemens Molecular Imaging, Hoffman Estates, IL **03/2003 – 03/2007**
Manufacturer of SPECT and SPECT/CT systems. **Senior Manager, Global Regulatory Affairs**
Responsible for global product submissions for combined SPECT and CT systems and supporting software programs. Supervised a staff of three. Served as the regulatory affairs contact for five global research facilities.
Accomplishments:
(i) Obtained worldwide approvals for both imaging systems and diagnostic, stand-alone software packages for combined imaging modalities,

(ii) Obtained FDA clearance for the first combined SPECT / CT system.

Abbott Laboratories, Abbott Park, IL **02/1992 - 03/2003**
Manufacturer of medical devices, drugs, diagnostics, and infant formula.
Director, Corporate Quality Assurance (1992-1997)
Reported to a corporate officer. Chief company liaison with FDA and policy-making bodies, industry associations, and standards organizations. Served as the independent reviewer for corporate audits and compliance-based program activities. Chaired the worldwide engineering standards committee governing building codes for offices, laboratories and the use of architectural materials to comply with domestic and international requirements. Managed up to 11 direct reports.
Accomplishments:
(i) Managed the corporate succession planning process,
(ii) Developed position papers for use at the board level covering quality and regulatory issues,
(iii) Carried out company-wide training initiatives.

Director, Corporate Regulatory Affairs (1997-2003)
Managed medical device submissions, complaints and recalls for hospital-based intravenous and analgesia systems.
Accomplishments:
(i) Submitted eight 510(k)'s,
(ii) Organized responses to FDA for three untitled letters,
(iii) Organized and managed four worldwide recalls.

APPOINTMENTS:

- FDA. Member - Medical Device Dispute Resolution Panel. 2009-2012.
- Volunteer. UCSD, IRB / Institutional Review Board. 2015 – 2019.
- Elected to the RAPS Board of Directors. January 2020 – December 2022.
- Editorial Advisory Board. Medical Device and Diagnostic Industry Magazine. 2005 – 2017.
- GMDN Agency, industry representative. 2014 – 2018.
- Participation on International Committees: (a) ISO 14971. (b) ISO 13485. (c) ISO TC 209 - Cleanrooms.
- Volunteer. Past president and officer: San Diego Regulatory Affairs Network. 2010 – 2018.

ADDITIONAL:

1) Compliance and Auditing:
Coordinated FDA and global quality system auditing, compliance and scheduling on an annual basis. Revamped the strategy, scheduling, priorities, and methods for a global auditing program using risk-based principles. Managed responses to Notified Bodies and FDA Warning Letters. Took place at: BD, CareFusion and Abbott.

2) External Relations:
Formal corporate liaison to FDA and other agencies. Primary contact with patient safety groups, standards organizations and industry associations both in the USA and in other countries. Submitted more than 200 formal comments to FDA. Took place at Abbott.

3) Consensus and Cost Savings:
Developed a public-facing web page that communicated FDA's medical device symbol requirements saving $3 million USD, 2017. Took place at BD.

EDUCATION:
BS, Biology and Political Science, University of Wisconsin at LaCrosse
Certificate in Executive Management, UCLA (a one-year program)

CERTIFICATIONS:
ASQ: CQE, CQA, CSQE, CPGP
RAPS: Regulatory Affairs (RAC), RAPS Fellow – 2018, Board of Directors
ISACA: CISA, Certified Information Systems Auditor (cyber security)

Note: Earlier positions in manufacturing quality control and quality engineering for parenteral drugs and software-based medical devices.