J.M. "Jake" O'Donnell

InSilva Consulting, SP
www.insilvacon.com

About InSilva Consulting: Expert quality management system consultancy specializing in FDA regulatory compliance for medical device manufacturers, contract manufacturers and suppliers. Extensive experience with QMS assessments, FDA 483 and warning letter responses, real-time inspection support, QMS remediation projects, and consent decrees.

Professional Experience

February 2021 – Present: **Principal Consultant and Sole Proprietor – InSilva Consulting, SP**. New launch consultancy providing services including mock FDA audits (routine, for-cause, and PMA inspections), development of FDA 483 and Warning Letter response communications, QMS remediation program development, and expert guidance on specific compliance issues relating to CAPA, design controls, purchasing controls, complaint handling, vigilance reporting, production and process controls including process validation, and site transfers.

February 2016 – February 2021: **Sr. FDA Compliance Principal – Regulatory & Quality Solutions LLC** (now RQM+). Served as R&Q's lead expert on FDA compliance of client Quality Management Systems. Services provided include mock FDA inspections including identification of regulatory risks and expert guidance on managing identified risks, development and/or review of FDA 483 and Warning Letter responses, design and execution of responsive remediation programs, supplier audits, and acquisition due diligence audits. Clients served ranged from global multinationals to small emerging firms across a wide range of device niches (respiratory therapy, critical care monitoring, diagnostic imaging, orthopedic implants, interventional cardiology, automated injection systems, catheters, IVDs, blood-wetted disposables, physical therapy, opthalmic, dental, SAMD, etc.)

Highlights: Served as third-party expert consultant in assessing and reporting compliance of a large global device manufacturer under terms of a DOJ/FDA consent decree. Average Net Promoter Score above 9 of 10 for individually executed projects over a 5 year period.

June 1994 – January 2016: **Consumer Safety Officer – Medical Devices (FDA Investigator), U. S. Food & Drug Administration**. Performed approximately 400 FDA inspections as lead investigator, including routine, for cause and PMA inspections of medical device manufacturers and contract sterilizers. Based at Pittsburgh Resident Post throughout this period.

Highlights: Spent two years (2014-2015) assigned to FDA's dedicated medical device team for international inspections conducting high priority international inspections across Asia, Europe, North and South America, and the middle East. Routinely received assignments for the then Philadelphia District's highest visibility device inspections. Routinely developed and presented training for both new hire device investigators and industry.

July 1983 – May 1994: **Aerospace Engineer – Naval Air Warfare Center.** Civilian employee of Naval Air Warfare Center providing full-spectrum engineering support to the Naval Air Systems command. Duties included component level technology development, system test and evaluation, and fleet support (sustaining engineering) relating to mechanical power drive and rotor support systems in propulsion systems of naval aviation fixed and rotary wing platforms.

Highlights: Recipient of multiple Sustained Superior Performance and Meritorious Service awards.

Education

BS Mechanical Engineering – The Pennsylvania State University, University Park, PA; May 1983.

Certifications:

ISO 13485:2016 Lead Auditor (TPECS) – Certificate # 8926092-189995 (BSI NA)
- MD: Medical Devices Quality Management Systems; ISO 13485:2016
- AU: Management Systems Auditing; ISO 19011:2018
- TL: Leading Management System Audit Teams; ISO 19011:2018

Contact Details:

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References available upon request.