Jeffrey Martin

777 Windemere Way | Keller, Texas 76248 | Cell: 817-455-2217

Consultant and Subject Matter Expert with over twenty-five years of experience in medical device and pharmaceutical processing, Sterility Assurance, terminal sterilization, Quality Systems and operations.

SKILLS PROFILE

- Leader and Mentor for validation of sterilization and microbiology efforts across a diverse medical device and pharmaceutical industry. Expertise in medical device terminal sterilization and pharmaceutical aseptic processing validation requirements.
- Regulatory body recognition as industry expert.
- Active participation in the following AAMI and ISO working groups for the development and review of US and international standards.
    - AAMI/ST/WG 01, **Industrial EO sterilization WG – US expert to ISO / TC198 and former Co-chair of AAMI WG1**
    - AAMI/ST/WG 02, Radiation sterilization WG - member
    - AAMI/ST/WG 03, **Industrial moist heat sterilization WG – US expert to ISO/ TC 198 WG3**
    - AAMI/ST/WG 09, **Aseptic processing WG - US expert to ISO/ TC 198 WG9**
    - AAMI/ST/WG 12, Instructions for reusable device reprocessing - member
    - AAMI/ST/WG 42, **Dry heat sterilization WG – US expert to ISO/ TC 198 WG 14**
    - AAMI/BE/WG 11, Allowable limits for Leachable substances WG11 member
    - AAMI/ST/WG 93, Cleaning of reusable medical devices - member
    - AAMI/ST/WG 96, Compatibility of materials subject to sterilization – member and prior Co-chair for development and revision of the AAMI TIR 17 - 2008

EMPLOYMENT HISTORY

President and Principal Consultant — 6/3/2016 — Current

Sterilization and Quality Systems Consulting LLC

- Independent and contract-based consulting to medical device and pharmaceutical companies in meeting regulatory requirements and mitigating regulatory and internal audit observations and issues.
  Recent Projects:
    - Aseptic Processing validation, SIP validation, risk assessment for environmental monitoring, mitigation and corrective actions of environmental and personnel practices for FDA warning letter
    - USP Monograph product requirements and testing
    - Container Closure Integrity Testing Validation, Disinfectant Efficacy Validation, Swab Sampling Recovery Validation
    - Combination product ethylene oxide sterilization validation, stability and 2X sterilization.
    - OTC drug manufacturer CGMP assessment in preparation for FDA audit, environmental controls, process validation, mixing and cleaning validation, inspection and test method validation
    - Dose Audit Failure investigation and risk assessment for medical devices
    - Ethylene oxide process and equipment validation, Process Equivalence, Parametric Release,
    - Moist Heat process assessment, Steam Air Mixture, and water cascade sterilizers - IQ/OQ and PQ of Microbiological & Physical Qualification, BI determination, BI / Bioburden Approach
    - R&D EO sterilizer requirements specifications, purchase, installation, process development for and validation for clinical trials
    - BSL- 3 safety assessment - facilities, personnel practices, process safety and security
    - Medical Device Ethylene Oxide process residual limits and reduction
    - Packaging equipment IO/OQ/PQ, test selection, sample size, process window determination
    - Medical Device Product and packaging shelf-life studies
    - EO Process re-qualification BI Failure investigation and root cause analysis

Director Corporate Quality Technology — 8/30/2004 — 6/03/2016

Alcon a Novartis company, Fort Worth Texas

- Sterilization subject matter expert reporting to the Head of Pharmaceutical Quality

Responsible for sterility assurance and validation practices for all Alcon business units (Surgical, Pharmaceutical, Vision Care) for 23 manufacturing sites facilities world-wide, maintain best practice and requirements for sterilization both internally and contract-based operations, aseptic processing, clean rooms, controlled environments and cleaning validations

- Recognized corporate leader and consulting member of the following - Novartis Sterility Assurance Expert Network, Medical Device Expert Network, and Microbiology Expert Network. Member of Novartis Key Opinion Leaders on external standards and regulations.
- Mentor and leader for development of site competencies in sterilization validations, sterilization facilities development, process validations, facility validations and environmental control.

Sterility Assurance, Sterilization Science and Environmental Services - Manager **Oct. 1997 — August 2004**

JJMI - El Paso, Texas; Arlington, Texas; Ethicon Endo Surgery (EES) – Cincinnati, Ohio; Albuquerque, NM

- Served in multiple locations as Departmental Manager for Sterility Assurance, Sterilization Science, Facilities Engineering, and Environmental Engineering.
- Responsible for the sterilization of internal and contract manufactured products worldwide.
    - Operational, financial, and environmental compliance for EES gamma irradiators - Manage eight direct reports in technical validation operations, and a group of 25+associates. Interfaces with manufacturing, R&D, franchise development, and business development.

Consultant - Self Employed **Oct. 1996 - Oct. 1997**

SQS Consulting, El Paso Texas

- Consulting in the following areas: Quality systems, EO sterilization process validation, product, packaging, statistical process control, calibration, materials management, process mapping and process development to meet US GMP / Quality System, ISO, and TGA requirements and guidelines.
- Clients; 3M, J&J, Fresenius, Alpha Medical.

General Manager Technical Services **July 1994 - Sept. 1996**
RCM Converters Inc., El Paso, Texas

- Departmental responsibilities for Quality, and Materials Management, Production Planning, Engineering, and Product Development. Led company efforts in developing systems for ISO 9001 certification, MRP system procurement and implementation, facilities and clean rooms. RCM Converters Inc. was a 3M incubator business.

Corporate Director QA/RA, Quality Assurance Manager, Operations Manager **Aug. 1991 - July 1994**

ISOMEDIX INC., Whippany NJ.; Spartanburg, SC.; El Paso, Texas;

- Responsible for EO and gamma irradiation validations and sterilizer operations for a large number of customers.

Supervisor QA Microbiology/Sterilization **Feb. 1989 - Aug.1991**

ARGON MEDICAL a Bristol Myers Company; Athens, Texas

- Responsible for internal EO sterilizer validations and operations, microbiology and chemistry labs.

Previous positions - Medical Sales Representative, Pathology Laboratory Supervisor, Medical Technologist/ Clinical Microbiologist **May 1979 - Feb. 1989**

EDUCATION AND TRAINING

Current	**PDA, AAMI Corporate Member, ASTM, ISPE**
Publication	Co-author of the sterilization chapter of Biomaterials Science 3rd edition Elsevier Academic Press
2008	**Alcon General Management Development (GMD) trained.**
2000 - 2004	**Green Belt Six Sigma and LEAN Certified. J&J Management Fundamentals. Process Mapping trained.**
June 1995	**Completed ISO training requirements as RAB certified Lead Auditor**.
1982-1985	**UNIVERSITY OF TEXAS AT TYLER,** Tyler, Texas. Completed 32 hours of undergraduate business courses and 16 hours of graduate courses towards MBA.
1977-1979	**SOUTHWEST TEXAS STATE UNIVERSITY,** San Marcos, Texas. Bachelor of Science in Medical Technology. Completed clinical internship at Scott and White Hospital in Temple, Texas. Board

registered and certified Medical Technologist by American Society of Clinical Pathologists, MT(ASCP).

1975-1976 **UNIVERSITY OF TEXAS AT EL PASO,** El Paso, Texas.

1973-1975 **TEXAS TECH UNIVERSITY,** Lubbock, Texas.