



JEFFREY MARTIN

SENIOR CONSULTANT STERILIZATION/QUALITY SYSTEMS

Quality subject matter expert with national and international industry recognition serving for over twenty years in device and pharmaceutical industry in terminal sterilization, Quality Systems and operations.

SKILLS PROFILE

- Leader and mentor for validation personnel in performance of sterilization and microbiology efforts across a diverse pharmaceutical and medical device industries. Supporting terminal sterilization and aseptic processing validation.
- Active participation in the following AAMI working groups for the development and review of US standards for validation, control and routine monitoring.
 - AAMI/ST/WG 01, **Industrial EO sterilization WG – Co-Chair and US expert to ISO / TC198**
 - 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 and 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 – member and US expert to ISO/ TC 198 WG 14**
 - AAMI/ST/WG 63, Sterilization residuals WG - 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

Director Corporate Quality Technology

8/30/2004 — 2016

Alcon a Novartis company, Fort Worth Texas

- Subject matter expert reporting to the Head of Pharmaceutical Quality
- Member and contributor to the Novartis Sterility Assurance Expert Network, Medical Device Expert Network, and Microbiology Expert Network. Member of Novartis Key Opinion Leaders.
- Responsible for sterilization practices for all Alcon divisions (Surgical, Pharmaceutical, Vision Care)
- Maintain best practice and requirements for sterilization, aseptic processing, clean rooms, controlled environments and cleaning validations.
- Actively deal with validation strategies for EO, Radiation, Moist Heat, Dry Heat, SIP, Bulk, and media fill process simulations across Alcon franchises. Provide guidance



for other Novartis divisions in troubleshooting processes.

- Mentor and develop site competencies.

Sterility Assurance, Sterilization Science and Environmental Services - Manager **Oct. 1997 — 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.
 - o Operational, financial, and environmental compliance for EES - Manage eight direct reports in technical operations, and a group of 25 +. Interfaces with manufacturing, R&D, franchise development, and business development.

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

SQS Consulting, El Paso Texas

- Consulting in the following areas: Quality systems, sterilization process validation, product, packaging, process validation, 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.

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

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

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

ARGON MEDICAL a Bristol Myers Company; Athens, Texas

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



EDUCATION AND TRAINING

Co-author of the sterilization chapter of Biomaterials Science 3rd edition Elsevier Academic Press.

- Current** **PDA, ISPE, AAMI corporate representative, ASTM**
- 2008** **Alcon General Management Development (GMD) trained.**
- 2000 -** **Green Belt Six Sigma and LEAN Certified. J&J Management**
2004 **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.**