Donna Gallagher

Medical Device Biocompatibility, Cleaning and Sterility Subject Matter Expert

Malvern, PA - Email me on Indeed: indeed.com/r/Donna-Gallagher/c2a05712ba0b3917

In my nearly 6 years with several positions with Stryker, I worked in Global Operations and assisted all divisions for matters around biocompatibility, cleaning (implants and reusable instruments) and sterilization both internal and for our supply base on projects. I want to move back from auditing to more of the Subject Matter Expert role. Authorized to work in the US for any employer

WORK EXPERIENCE

Supplier Quality Engineer / Microbiologist

Stryker Orthobiologics - Malvern, PA - July 2012 to August 2015

Cleaning and sterilization sub team leader and subject matter expert for implant and instruments for Redwood City, CA transfer project. Coordinated work between 3 vendors to ensure requirements laid out and met.

• Coordinated and conducted Tissue audits and Malvern supplier audits upon integration of Malvern in order to document all Malvern suppliers regardless of risk classification. Classified all Malvern suppliers on the goods and
services they provide and streamlined from 255 to 123 suppliers.

• Validation Lead for Malvern Sterility Team in 2014 to lead the validations activities for MedPor in addition to support the team with the experience gained during career.

• Subject matter expert for issues of sterilization (EO, Gamma, E-beam) across all divisions of Stryker and with suppliers.

• Supplier Quality Engineer working on supplier NC and CAPA activities.

• Integration Auditor for CoAlign and UniVise integrations for review of the cleaning and sterilization requirements for the manufacturing transfers.

• Elected Vice Chair for NADCAP Task Force for Medical Device Sterilization - create audit checklists and work to provide team with the requirements and considerations for OEMs, sterilizers and contract manufacturers.

• Project Eagle - Sterility Sub Team Leader - Responsible for integration of sterility and biocompatibility activities of the MedPor integration from Georgia to Malvern, PA for standard, customized and non-porous polyethylene products. Coordination of testing, sterility, and related tasks with suppliers and the rest of the team. Integration for the simultaneous validations running through Malvern for customized and standard products in conjunction with coordination of Millstone Medical for the outsourced products. Coordination of the sterility of products manufactured at Millstone is being driven through the sterility validation in Malvern to save cost and control the process.

• Lead Human/Animal/GLP/Biological Supplier Auditor - Responsible to transfer the regulations required for Human Tissue/Animal Tissue and GLP to audit teams and created audit checklists for use to ensure supplier conformance to the regulations. Responsible for leading these audits and evaluation of suppliers for Stryker Orthobiologics, Spine and Joint Preservation, Osteosynthesis and Orthopaedics. Also working to develop suppliers to ensure environmental issues are addressed and guidance issued to educate the supplier to the regulations and expectations for Stryker compliance.

• Acted as Divisional Sterilization Microbiologist for Stryker Spine from July 2013 to January 2014 and Operations
Microbiologist up to August 2015 and performed biovalidations for Instruments and Implants, supported Regulatory Audits and internal audit activities in addition to performing Supplier Quality for GQO

Divisional Microbiologist, Sterilization Sciences

Stryker Orthopaedics - Mahwah, NJ - December 2009 to July 2012

New Product Development Sterilization Representative - Responsible for Instrument and Implant New product sterilization representation for 510 (k) submissions including product development and validations for cleaning and sterility. Projects have included Knee Instrumentation and Implants, Hip Instrumentation and Implants, Upper
Extremity Instrumentation, Customized Cranial Implants and Instrumentation as well as representing new integrations for environmental monitoring, cleaning and sterilization to meet Stryker standards.
• MedPor Integration Sterility Representative - Sterility lead for MedPor Customized Cranial Project Integration and
NPDP from Newnan, Georgia into Stryker. Responsible for coordination of sterility validation tasks for NPDP for a
combined Gamma/EtO Validation of customized cranial products. Worked with multiple departments and suppliers to complete the project. to serve as sterility lead for integration into Project Eagle to move the products and process to Malvern, PA.
• Liaison to suppliers such as Millstone Medical, Tegra Medical, Triangle to review and help improve products and processes through streamlining validations for cleanlines, cleanrooms for sterility and final packaging and also for
sterilization validations and instrument qualifications and provided guidance, support and instruction.
• Certified GLP Lead Auditor / ISO 13485 Certified Lead Auditor - Have conducted 3 GLP audits in 2011 and an ISO 13485 Audit in 2010. Have prepared reports, conducted the physical audits and prepared the follow ups with focus on the sterility, cleaning, document control, training and all the validation sections and have done so on all
audits.
• Microbiology/Chemistry/Validation Subject Matter Expert (SME) for Supplier Audits - Have participated in approximately 40 audits from 2010 acting in capacity as SME for critical Stryker suppliers (test laboratories, sterilization centers, and critical powder suppliers) to evaluate the suitability and compliance of the supplier for Stryker critical needs.
• Sterility Assurance representative for Change Management Board aiding to ensure that all cleaning, sterility and associated changes are made appropriate to Stryker and regulatory standards.
• Sterility liaison to sales, hospital central sterile supply and associated representatives both domestic and overseas seeking information about cleaning and sterilization of Stryker Instruments with a focus on Orthopaedics. Fluent in multiple sterilization methods: Gamma, Ethylene Oxide, E-Beam, Steam and Dry Heat Sterilization and chemical disinfections. Versed in nitric and citric acid passivation cleanlines in technical and troubleshooting efforts.

Product Assurance Specialist

Cardiac Dimensions, Incorporated - Kirkland, WA - October 2007 to September 2009

Developer of Cardiac Technology to Treat Mitral Valve Regurgitation
Product Development Specialist
• Sterile Load Coordinator - Responsible for preparation, product and process validation execution and coordination and release of all Ethylene Oxide Sterilization of product.
• Initiation and execution of sterility and cleaning validation protocols and reports with communication of any issues to senior management.
• Certified Lead Auditor - responsible for performing all supplier audits, internal audits and coordination of third party audits with notified bodies.
• Environmentally Controlled Area Microbiology Specialist - Responsible for all aspects of environmentally controlled rooms, cleaning, validation, cleaning and gowning systems and training of personnel. Improved level of cleanliness in room and reduced bioburden on product and environment significantly.

• Coordinated and hosted third party audits for DEKRA for ISO 9001 and 13485 Initiation and surveillance audits
• Documentation Control/Quality System Trainer/Standards Coordinator - Responsible for all aspects of documentation control and training including, database updates for training and new and archived documentation
including Standards.
• Safety Committee Leader - Duties included hazardous waste coordination, safety training, and leading safety committee meetings and follow up.

Quality Specialist

BioControl Systems, Incorporated - Bellevue, WA - October 1995 to October 2007

Bellevue, WA
October 1995-October 2007
Leading Developer of Rapid Pathogen Test Kits for the Food Industry
Quality Specialist
• QA Specialist/Document Control Specialist- Maintain Patent, Trademark, Controlled Documentation and BioControl Website Information. Initiate and execute document revisions, marketing translations of technical information translation of documentation into Spanish, French, German and Portuguese, including audits to ensure the integrity of Master Files for ISO and AOAC submission.
• ISO Trained Internal Auditor - Coordinated and led Internal audits of BioControl Quality Systems.
• Troubleshoot Microbiology of QA testing and functions during Testing Failures or Delayed Release. Able to solve the problems quickly and thoroughly with minimum effort and get product released and into inventory.
• Coordinate and facilitated method development from research to manufacturing for several new product lines. Performed validations on the methods to ensure robustness for transfer.
• Prepare Standard Operating Procedures, Standard Test Procedures, Application Notes, and Directions for Use,
Technical Manuals. Have working knowledge of technical French, Spanish and Italian languages when dealing with medical terms.
• Initiated and executed Quality Testing for all Pathogen and Quality Assurance Product lines from Initial to Final
Product Release, Validations, Stability and Bioburden testing as well as System Integrity testing for the Lab and
Manufacturing. Initiated and prepared Safety Data Sheets for all BioControl Products for use internationally.
Research/Development Microbiologist
• Assisted in development of VIP® for EHEC, Listeria and Salmonella Lateral Flow Devices. Purified antibody, particle coupling and nitrocellulose membrane preparation and optimization for VIP devices.
• Maintained Tissue Culture and Microbial Master and Working Cell Banks and Culture Collection integrity.
Microbiologist in charge of Murine Hybridoma Monoclonal Cell lines development of rapid Pathogen Detection Kits.
• Facilitated the development of the Assurance EIA Pathogen Detection kits. Performed both Antigen and Antibody
Enzyme Immunoassay validations and development evaluations to produce components for manufacturing.
Purified polyclonal antibody and prepared conjugate concentrates for the kits.
• Initiated and executed stability, functionality, and bioburden testing protocols for multiple lines of the SimPlate®
Binary Detection Technology System. Trained QA personnel in QA testing protocols for these lines.
• Main microbiologist for all standard Coliform and E. coli tests and Salmonella 1-2 Immunodiffusion testing.
• Facilitate and perform bioreactor equipment maintenance and qualification and system troubleshooting.

Research Associate

CellPro, Incorporated - Bothell, WA - 1992 to 1995

Developer of Stem Cell Therapy using Column Technology
Research Associate
• Coordinated and compiled a Phase I Clinical Trial Master Device File for FDA submission for use of Stem Cell separation in efforts to reset immunity for immunologically challenged children and trained outside collaborators in instrument and system troubleshooting to improve stem cell separation process of CEPRATE® SC and LC systems for Phase I Clinical Trial.
• Tissue Specialist -Developed Model System for standardization of biological testing, including Master and Working Monoclonal Cell banks, database compilation and Standard Operating Procedures for cell preparation.

EDUCATION

Master of Science in Microbiology
Idaho State University - Pocatello, ID
1989 to 1991

Bachelor of Science in Microbiology
Idaho State University - Pocatello, ID
1984 to 1989

SKILLS

Medical Device Biocompatibility, Cleaning, Sterility (10+ years), Human and Non-Human Tissue (6 years), ISO 13485 Lead Auditor (7 years)