MARSHA STEED

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PROFESSIONAL SUMMARY

Ambitious and driven Quality/Microbiology expert who successfully creates and deploys strategic contamination control programs ensuring global regulatory compliance standards are met. Leader with a proven track record for building and retaining high performing teams and developing microbial awareness across cross functional departments, peers, and teams. Leader in external engagement in microbiology/sterility assurance through PDA and industry forum activities and leadership roles including board memberships, technical report writing and training of peers and regulators. Aseptic processing expert with strong knowledge of worldwide regulations and standards.
Over 30 years of pharmaceutical and medical device experience working for various companies on a wide range of drug, biologic, medical device and drug/device combo products. Expert in Microbiology, Sterilization and USP, FDA and AAMI/ISO requirements. Notified Body Assessor BSI ISO 13485, 9001 & Microbiology Expert. Expert in EU Annex 1 Aug 2022, EU Guidelines on Good Manufacturing Practices Specific to Advanced Therapy Medicinal Products Nov 2017, FDA Sterile Drug Products Produced by Aseptic Processing Guideline Sep 2004

Current USP Microbiology Expert Committee Member

SKILLS

- Regulatory Compliance Expert
- Microbiology Expert
- Contamination Control Expert
- CDMO Manufacturing
- Rapid Microbial Methods (RMM) Expert
- Notified Body Auditor

EXPERIENCE

Jan 2024 - Current

Senior Associate/Sterility Assurance Expert — July 2021 - Current
Jeff Yuen Associates | Remote
Founder and CEO/President of Steed MicroBio LLC
Microbial Control/Sterility Assurance Senior Consultant specializing in:

- Aseptic Processing, Aseptic Technique, Aseptic Process Simulations, Isolators/RABS
- Contamination Control Strategy (CCS)/EU Annex 1
- Cell and Gene Therapy Manufacturing/EU Guidelines on Good Manufacturing Practices Specific to Advanced Therapy Medicinal Products Nov 2017
- Development of Environmental Monitoring Programs
- Microbial Risk Assessments and Cross Contamination Risk Assessments
- Facility Design/Contamination Control
- Microbial Control AuditingMicrobial Contamination Investigations

July 2021 – Jan 2024

Head of Corporate Microbial Contamination Control & Viral Safety
Resilience, Inc | Remote

- Responsible for leadership of Corporate Microbial Control for Resilience
- Responsible to own and lead the global microbiology strategy for all Resilience CDMO manufacturing sites
- Responsible for driving standardization and harmonization between the manufacturing sites
- Responsible for creation and management of centralized microbiology and contamination control standards and procedures
- Leads and/or supports microbiology contamination investigations at Resilience sites
- Ensures alignment of Resilience's network regarding global microbiological/aseptic standards and regulatory/compendial requirements
- Provides technical support to Resilience sites regarding aseptic processing and microbiology challenges
- Provides support for regulatory inspections (pre, during and post) EU Annex 1, EU ATMP, FDA CFRs
- Leads external engagement in microbiology, sterility assurance, cleanroom management, contamination control and ATMP related forums

Head of Global Microbiology (formerly Site Microbiology) June 2020 - July 2021
Takeda Pharmaceutical Company | Thousand Oaks, CA

- Responsible for leadership of the Takeda Global Microbiology team of experts
- Responsible to own and lead the global microbiology strategy for all Takeda manufacturing sites worldwide (multi-site, multi-product)
- Responsible for driving standardization and harmonization between the manufacturing sites
- Responsible for creation and management of global microbiology and contamination control policies and procedures
- Leads and/or supports microbiology contamination investigations at Takeda sites
- Ensures alignment of Takeda's network regarding global microbiological/aseptic standards and regulatory/compendial requirements
- Leads the Takeda Micro Alliance and Contamination Control Communities of Practice (CoP)
- Provides technical support to Takeda sites regarding aseptic processing and microbiology challenges
- Provides support for regulatory inspections (pre, during and post) EU, Rest of World, FDA
- Leads external engagement in microbiology, sterility assurance, cleanroom management, contamination control and ATMP related forums
- Benchmarks industry trends and standards with industry groups such as BPOG, PDA and ISPE
- Responsible to lead strategy for Quality Risk Management and microbial risk assessments for sites
- Head of Microbiology responsible for determining the strategy and directing the activities of Microbiology and Raw Materials & Utilities laboratories at the Thousand Oaks facility
- Member of the Quality Leadership Team (QLT) at the site and responsible for developing a mid- and long-term strategy
- Partners with the manufacturing business leaders to drive improvements in safety, quality, compliance, financial performance, employee development, customer satisfaction, and continuous improvement initiatives consistent with the plant strategic plan and Takeda values

Head of Microbial Contamination Control March 2019 - June 2020

bluebird bio | Cambridge, MA

- Internal sterility assurance expert supporting global sterility assurance and compliance at bluebird's global contract manufacturing locations
- Leadership role supporting the commercialization and globalization of cell and gene therapy manufacturing compliance programs for bluebird bio
- Driving microbial control strategies with use of quality risk management (QRM) tools
- Leading sterility assurance compliance at global CMO locations as expert in compliance and sterility assurance for small molecule, lentiviral vector (LVV) and ATMP drug product manufacturing Oversite of CMO compliance audits and audit responses Deploying a quality risk management program for sterility assurance; conducting microbial

Senior Consultant/Senior Director August 2013 - March 2019

ValSource | Remote

- My extensive knowledge of compliance, cGMPs, and regulations for clinical and commercial manufacturing allowed me to provide expert advice on quality and compliance solutions for pharmaceutical, biologic and medical device manufacturing companies in this consulting role
- Expert in Cell and Gene Therapy/ATMP who specialized in microbiology, risk, aseptic processing, environmental monitoring, packaging, validation, sterilization and auditing support for biopharmaceutical, pharmaceutical and medical device companies
- Expert in establishment of quality risk management programs
- Specialized in environmental monitoring (EM) program risk assessments, microbial HACCPs, raw materials/equipment/process microbial risk assessments
- Expert in establishment of microbial control strategies for low bioburden, cell therapy/CAR-T, gene therapy and aseptic processes
- Preparation of regulatory submissions for FDA and global regulatory entities

Senior Manager Corporate Quality Control September 2010 - January 2012

Dendreon | Seattle, WA

Dendreon was the pioneer of ATMP manufacturing and established the way for many other successful ATMP products to come to market.

- Responsible for Corporate Quality Control Lab Services including Raw Material Testing, Product Testing, Specifications, Lab Investigations, as well as Corporate Microbiology
- Responsible for alignment and best practices across Dendreon manufacturing facilities
- Provided leadership and management of Microbiology laboratory operations
- Establishment of Rapid Microbial Methods (RMM) for Dendreon product testing

Notified Body Auditor/Microbiology Expert February 2009 - May 2010

bsi | Remote

- Responsible for performing ISO 9001:2000, ISO 9001:2008, ISO 9001:13485 Quality Management System Assessments as well as CE and CMDCAS assessments for medical device manufacturers in the USA
- ISO Lead Auditor Certified, MDD/CE Certified, CMDCAS Certified
- Microbiology Product Expert responsible for performing microbiology, sterilization, packaging and contamination control ISO assessments for sterile medical device manufacturers

EDUCATION

Bachelor of Science - Biology May 1993
Western New England College, Springfield, Massachusetts

ACCOMPLISHMENTS

- USP Microbiology Expert Committee Member current
- USP Microbiology Expert Committee Sterility Assurance Team Lead current
- PDA ATMP Advisory Board Member current
- PDA Scientific Advisory Board Member
- PDA Education Advisory Board Member
- PDA 2012 Annual Program Co-Chair & 2011 Vice Chair
- PDA Annual Planning Committee
- PDA Task Force Leader
- PDA Cell and Gene Therapy Planning Committee
- PDA ATMP Planning Committee
- Presented at numerous PDA, ISPE, IVT and other worldwide technical organization meetings and webinars
- Hosts numerous global webinars for Executive Conference
- Author of numerous PDA book chapters
- Instructor for PDA TRI for USA and Europe
- Johnson & Johnson Standards of Leadership Award Recipient
- PDA Distinguished Service Award

CERTIFICATIONS

Six Sigma Green Belt ISO 9001:2000 Lead Auditor with Medical Device Focus (ISO13485:2003) RAB Certified BSI Notified Body ISO MDD Assessor

AFFILIATIONS

PDA
BioPhorum
ISPE
USP Microbiology Expert Committee Member