Emily Mitzel, M.S., B.S.

Technical Consulting Manager
Sr. Scientist

Ph: 801-290-7899
M: 801-520-8040
emitzel@nelsonlabs.com

CONSULTANT INTRODUCTION

Emily Mitzel is the Senior Manager, Technical Consulting and Senior Scientist at Nelson Laboratories, a Sotera Health Company; a microbiological testing company specializing in improving the quality of life by ensuring medical products are safe, sterile, and functional.

Her expertise includes Reusable Device Reprocessing validations, Newly Manufactured Device validations, Sterilization, and Microbiology testing. Emily presents at Nelson Laboratories' seminars, tradeshows, ISO, FDA, AAMI, and client facilities across the U.S and internationally.

Emily is an active committee member of many working groups with the International Organization for Standardization (ISO), Association for the Advancement of Medical Instrumentation (AAMI) and American Society of Testing and Materials (ASTM).

Prior to her employment at Nelson Laboratories she was a microbiologist and managed research trials and training at Cargill, Inc. and managed all technical services including the laboratory at Minnesota Crop Improvements Association. Her other passions include ultra running, backcountry skiing, traveling, and spending time with friends and family.

AREAS OF EXPERTISE

- Reusable Device Cleaning, Disinfection and Sterilization Validations
  Validation of instructions for use (IFUs), cleaning, disinfection and sterilization of devices
- Device Family Groupings
  Determine Device Families, worst case devices for validation, and adoption of processing
- Failure Investigations
  Product test failures for sterilization, lot release, contaminants, residual materials
- Cleaning Validations of Newly Manufactured Devices
  Validation of the cleaning procedure after manufacturing
- Medical Devices
  Class I, II and II devices including orthopedic, cardiovascular, pulmonary, disposables

PROFESSIONAL ASSOCIATIONS

Member of AAMI Sterilization Standards Committee 2004-Present

US Delegate of:
- Working Group 12 - ISO 17664
- Working Group 13 - ISO 15883

Co-Chair of AAMI Working Groups:
- Working Group 13 – Washer-disinfectors, ISO 15883 Series
- Working Group 95 – Water Quality for Reprocessing Medical Devices

Member of AAMI and ASTM Working Groups:
- WG6 – Chemical Indicators – ANSI/AAMI/ISO 11140
- WG10 – Liquid Chemical Sterilization - ANSI/AAMI/ISO 14160
- WG12 – Instructions for Device Reprocessing – TIR12, ST81, ISO 17664
- WG13 – Washer-disinfectors - ISO 15883
- WG 40 – Steam Sterilization Hospital Practices - ST79
- WG 60 – EO Sterilization Hospital Practices – ST41
- WG61 – Chemical Sterilants Hospital Practices - ST58
- WG84 – Endoscope Reprocessing
- WG85 – Human Factors for Device Reprocessing
- WG93 – Cleaning of Reusable Medical Devices – TIR30
- WG94 – Rigid Sterilization Container Systems - ST77
- WK31799 – New Guide for Designing Medical Devices for Cleanability
- WK33439 – New Guide for Standard Test Soils for Validation of Cleaning Methods for Reusable Medical Devices

EDUCATION & CERTIFICATIONS

M.S., Microbiology
B.S., Microbiology

MASTERS PUBLICATIONS

Mitzel, E. Development of an Assay for the Detection of Mucoid and Nonmucoid Strains of *Clavibacter michiganensis* subsp. *sepedonicus*. North Dakota State University, Fargo, ND.

Baer, D., E. Mitzel, J. Pasche, N. Gudmestad, D. Mills, and B. Russell. Semi-quantitative detection of *Clavibacter michiganensis* subsp. *sepedonicus* using a DNA hybridization-based microtiter plate assay after PCR. North Dakota State University, Fargo, ND. .

Baer, D., E. Mitzel, J. Pasche, and N.C. Gudmestad. 2001. PCR Detection of *Clavibacter michiganensis* subsp. *sepedonicus* infected tuber samples in a plate capture assay. Amer J of Potato Res. 78:269-277.

PUBLISHED ARTICLES and WHITEPAPERS:

Considerations for Third-Party Reprocessing of Single-Use Medical Devices
QMed
By Emily Mitzel and Paul Littley
Published: 02/27/17

Validating IFUs for Reprocessed Medical Devices
Medical Device Technology
By Emily Mitzel
Published: 01 Dec 2016

Successful Medical Device Cleaning Validations: What You Need to Know
By Emily Mitzel, Alpa Patel, and Nick Workman

Justifying Family Groupings to Maximize Value for Cleaning and Sterilization
Orthopedic Design Technology
By Nick Workman and Emily Mitzel
Published: 23 May 2016

How Clean is Your Cardiovascular Device?
Medical Design Technology
By Emily Mitzel
Published: April/May 2016

Comments on "Reprocessing Guidance for Industry and FDA Staff", Issued March 17, 2015
Nelson MedTech Insights
By Emily Mitzel
March 2015

Learning from Superbug Deaths: Understanding Reprocessing Regulation
MD&DI Device Talk Blog
By Emily Mitzel and John Bolinder
April 13, 2015

Understanding Differences in 'Reprocessing Guidance for Industry and FDA Staff
MDTmag.com Blog Article, March 24, 2015
By Emily Mitzel

7 Criteria to Improve Reprocessed Medical Device Instructions
MDT Magazine Print Feature, March 2015
MDTmag.com Digital Feature, March 23, 2015
By Emily Mitzel, Alpa Patel, and Nick Workman

Validating Cleanliness Taking Human Factors Into Effect
MPO.com, October 17, 2014
By Emily Mitzel, Alpa Patel, and Nick Workman

Functionality vs. Simulated Use Testing for Processing Reprocessing of Reusable Scopes
MPO.com, September 12, 2014
By Alpa Patel, Emily Mitzel, and Nick Workman

"A Roundtable Discussion Toward a Cleaner Future", *AAMI Horizons*. Spring 2012.

WEBINARS and PRESENTATIONS:

Important Considerations in the Third-Party Reprocessing of Single-Use Medical Devices
Launch: 30 Mar 2017

New Trends in Cleaning Validations
Medica/Compamed
17 November 2016

Medtec Europe
May 2016

3M Sterilization Seminar
March 2016

Reprocessing Of Medical Devices In The Clinical Setting: Validations To Meet EU and US FDA Requirements
MEDTECH Europe
April 22, 2015

Learning From Healthcare Acquired Infections (HAIs): Understanding Current Reprocessing Regulations, Product Validation and Clinical Human Factors
BIOMEDevice Boston
May 6, 2015

Learning from Hospital Acquired Infections (HAIs): Understanding Current Reprocessing Regulations, Product Validation and Clinical Human Factors
May 19, 2015

Planning for Product Validations: Designing for Biocompatibility, Sterilization and Cleaning
MEDevice San Diego Conference & Technology Showcase
September 11, 2014

Managing Human Factors in Reprocessing of Reusable Devices – Validation Considerations
May 22, 2014

Healthcare Reprocessing of Medical Devices and Human Factors Debrief
February 11, 2014

New Trends in Cleaning and Disinfection Validations for Reusable Devices
June 18, 2013

Water Quality for CSSD 101
February 19, 2015
3M Webinar Guest Presenter

Cleaning Validations Webinar
Bal-Seal Webinar Guest Presenter