Workshop on Medical Device Cleanliness: How Clean is Clean Enough?

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Why do we clean?

- Healthcare-associated infections*
  - 2 million infections
  - 90,000 deaths
  - $4.5 Billion in excess health care costs
- Single use and reusable devices
  - Manufacturing residues
  - Cleaning agents
  - Bacteria
  - Endotoxins
- FDA Recalls
  - FDA has launched 64 recall for medical devices within the last 7 years among them are 26 due to process contamination

*Weinstein, Emerg Infect Dis, 1998

A corollary to the 2nd law of thermodynamics

IMBESI'S LAW OF THE CONSERVATION OF FILTH*

"Whenever something becomes clean, something else becomes dirty."

Cleaning is the process of moving residues from one location to another

* *Ken Kesey, "One flew over the cuckoo's nest"*

Four Laws of Cleaning

1. Whenever something becomes clean, something else becomes dirty
2. Soil is like entropy–never destroyed, always created
3. One can never get something completely clean
4. To get a particle off a surface, first you have to find both

cleaning is soil management

John Durkee "*Management of Industrial Cleaning Technology and Processes"*

Design to Minimize Cleaning

- Design components for simple, effective cleaning
  - Blind spots
  - Mixed materials
  - Sharp corners, fine features
- Design components for simple manufacturing
  - Fewest manufacturing steps
  - Fewest number of processing compounds (grit blast, polish, masking)
- Design simplest cleaning operation
  - Omnidirectional cleaning vs. directional
  - Avoiding redepositing removed soil on clean parts
  - Cleaning your clean-line
  - Cross-contamination of different components cleaned in the same clean-line
- Design with cleaning validation in mind
  - How to assess how clean your parts are?

Challenges of Cleaning

- Adequate removal of soils without introducing new residues
  - Cleaning agents
  - Migration of residues from one location to another
  - Elution/extraction
- Damage to component
  - Mechanical, thermal, chemical
- Validation of cleaning process
- Cost and process time

ASTM Activities in Device Cleanliness (F04.15.17)

- Workshop on Device Cleanliness (May, 2003)
- Symposium on Device Cleanliness (May, 2005)
- Passed first standard on assessing cleanliness (ASTM F2459-05)
- WK15532: Guide for Assessment of Contamination and Residues on Medical devices
  - Compilation of known assays for residues, including endotoxins
- WK13292: Standard Practice/Guide for Shipping Possibly Infectious Materials, Tissues, and Fluids

Upcoming Topics

- Cleaning and analysis methods
- Cleaning reusable devices
  - Endoscopes
  - Cannula
  - Arthroscopic shavers
- Establishing cleanliness limits

Reusable Devices

- Exposure of components to tissue and fluids
- Cleaning and disinfection require access to surfaces
  - Design for disassembly and cleaning
- Adequate instructions for reprocessing
  - Potential damage to component during cleaning
  - How many times can it be reprocessed?

How Clean is Clean Enough?

Agenda

- Regulatory and Legal Implications
- Cleaning and Testing (Part 1)
- Lunch
- Cleaning and Testing (Part 2)
- Establishing Residue Limits
- General Discussion

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