



Consulting, LLC

Quality Validations, Experience, & Training

Establishing and Justifying Limit Values for Residual Analysis

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

Between a Rock and a Hard Place



Regulatory Limits?

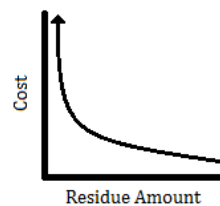
- ▶ Contaminant Toxicity
- ▶ Quantity Used
- ▶ Patient Exposure

- ▶ It's up to YOU!



Establishing Limit Values

- ▶ Zero?
- ▶ I don't think so...



- ▶ Validate your cleaning process
 - Choose test method
 - High and low parameters
 - Nominal parameters



Expressing Residue Amounts

- ▶ mg/cm^2 or $\mu\text{g}/\text{cm}^2$
- ▶ mg/device or $\mu\text{g}/\text{device}$
- ▶ Limit values in same units

Surface Area



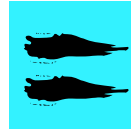
Statistical Comparison

- ▶ Average and Standard Deviation
- ▶ T-test
- ▶ ANOVA
- ▶ Confidence Intervals
- ▶ Uncertainty of Test Method



Baseline Comparison

- ▶ Test “Off the Shelf” Devices
- ▶ Compare to Freshly Cleaned Devices



Biocompatibility

- ▶ Biocompatible Clean Device

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- ▶ Biocompatible Residues

- ▶ Cytotoxicity
 - Sensitive In-Vitro Method
 - Pass/Fail Criteria



Other Testing

- ▶ Endotoxin
 - Not removed by sterilization
 - Better to prevent or limit contamination
 - Pass/Fail Criteria

- ▶ Bioburden
 - Primarily removed by sterilization
 - Can be removed during cleaning process
 - 3 log reduction



Risk-Based Assessment

- ▶ Patient Exposure
 - How long
 - Where

- ▶ Percent or Log Reduction
 - LD50
 - TDLO

MATERIAL SAFETY DATA	
SECTION 4 - FIRST AID	
irritation:	Flush with large amounts of water for at least 15 minutes. Do not
skin:	Wash affected area gently with soap and water. Skin cream or ointment
eyes:	Do not induce vomiting; drink plenty of water.
ingestion:	Remove affected person to clean fresh air.
SECTION 5 - FIRE FIGHTING MEASURES	
Flammability:	Non-combustible
Extinguishing media:	Use extinguishing media appropriate to the surrounding fire.
Hazards:	None
Special fire-fighting equipment:	Wear full bunker gear including positive pressure self-contained breathing apparatus.
SECTION 6 - ACCIDENTAL RELEASE MEASURES	
Prevention:	Avoid creating airborne dust. Follow routine housekeeping procedures for filtered equipment. If sweeping is necessary, use a dust suppressant. Do not use compressed air for clean-up. Personnel should wear approved respirator. Avoid clean-up procedures that could result in dust release.
SECTION 7 - HANDLING AND STORAGE	
Handling:	Limit use of power tools unless in conjunction with local exhaust. Frequently clean the work area with HEPA filtered vacuum or HEPA filtered air. Do not use compressed air for clean-up.
Storage:	This product is stable under all conditions of storage. Store in a cool, dry place.



Recommendations

- ▶ Clear and concise
- ▶ Re-evaluate as needed
- ▶ Justifiable with wiggle room



Questions?

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