Medical Device Testing "Framework"

QUALITY ASSURANCE, REGULATORY AFFAIRS, & COMPLIANCE ASSURANCE CONSULTING

VALIDATION TESTING

Biological Evaluation
(ISO 10993)

- Biological Evaluation Plan
- In vitro biocompatibility
- In vivo biocompatibility
- Chemical Characterization (E&L)
- Toxicology Assessment

Facility & Process Validation
- Cleanroom Validation
- Water System Validation
- Process Validation (RMM, Surfaces)

Sterilization Validation
(single-use device)

Radiation Validation
- Product Sterility
- Verification Dosing
- Bioburden
- BET/Particulates*
- Dose Mapping°

EO Validation
- BI Sterility
- Product Sterility
- Bioburden
- EO Residuals
- BET/Particulates*
- PCDs*

OR

Re-Use Validation
(multiple-use device)

- Cleaning
- Disinfection
- Sterilization
- Clinical Monitoring
- Simulated Use/Lifecycle Testing

Packaging Validation

- Aging (real-time)
- Aging (accelerated)
- Strength & Integrity
- Distribution Studies
- Thermal & RH Cycling
- Stability Testing

ROUTINE TESTING

Sterility Assurance

QDA (Radiation)
- Product Sterility
- Verification Dosing
- Bioburden
- BET/Particulates*

EO Lot Release
- BI Sterility
- EO Residuals
- BET/Particulates*
- PCDs*

Other Sterility Assurance
- Bioburden
- Organism IDs
- Cytotoxicity

Environmental Monitoring

- Air & Environmental
- Water Systems
- People & Process
- Process Verification

°Contract Sterilizer
*Optional