

VALIDATE SPECIAL PROCESSES.

BUILD DEFENSIBLE EVIDENCE.

Validation strategy, protocols & technical documentation for cleaning, passivation, packaging, sterilization and reprocessing.

Build scientifically justified, traceable validation evidence supporting consistent process control and regulatory compliance.

YOUR CHALLENGES



STANDARDS & VALIDATION COMPLEXITY How to translate applicable ISO, ASTM and regulatory requirements into a coherent validation strategy?



SAMPLING & PROTOCOL DESIGN How to establish scientifically justified sampling strategies, acceptance criteria and validation protocols?



NOTIFIED BODY SCRUTINY How to ensure validation evidence is complete, consistent and traceable under regulatory review?

OUR APPROACH

01 ASSESS

- Definition of validation strategy, applicable standards, product families, and worst-case scenarios
- Gap analysis across ISO/ASTM standards (ISO 11607:2019, ISO 17664:2021, ISO 19227:2018, ISO 11137, ASTM F1980,)
- Validation Master Plan (VMP) formalization and sampling plan design



02 IMPLEMENT

- Protocol drafting and execution for cleaning, passivation, and packaging validations
- Sterilization, stability (accelerated & real-time), and transport testing protocols (ISTA 3A)
- Turnkey reprocessing validation files and complete validation report authoring



03 ASSURE

- Targeted team training on special processes and normative expectations
- Remediation of gaps and documentation findings
- Direct technical support and defense during Notified Body interactions

YOUR BENEFITS



CLEAR VALIDATION STRATEGY

Applicable requirements translated into defined validation parameters, acceptance criteria and evidence needs



SCIENTIFICALLY JUSTIFIED PROTOCOLS

Sampling strategies and protocols supported by clear technical rationale and predefined acceptance criteria.



DEFENSIBLE VALIDATION EVIDENCE

Complete, traceable documentation structured to demonstrate process control and support regulatory review.

READY TO VALIDATE YOUR SPECIAL PROCESSES?

WWW.EFOR-GROUP.COM



Committed to **Excellence**