Onsite Education: Presentation, Q&A Session and Consultation
One day or multi-day onsite consult includes two technical resources (example): • Onsite training of cleaning validations for newly manufactured devices including regulatory guidance, recommended best practices and practical applications (4 hrs) • Tour of client facility to assess key manufacturing areas and possible sources of contaminants during product specific consultation. • Written report detailing the observations and recommendations for process changes, test methods and validation approaches for newly manufactured device(s) reviewed. **DELIVERABLE:** Program Binder, Product-Specific Consult (based on client need)
Travel Expenses, estimated *Airfare, hotel, car, per diem – billed as incurred*

Facilities & Process Validation including Residual Manufacturing Materials
Onsite education session, facility tour and development of process validation procedures, acceptance criteria or test plan based on client need. • 3 Hour Education Session Environmental monitoring, water system validation, cleaning processes and residual manufacturing materials • 1 Hour Facility Tour Apply education session learning, observation & discovery • 1.5 Hour Procedure Review & Development Based on client need establish family groupings for cleaning, environmental monitoring plan or acceptance criteria. **DELIVERABLE:** Education session binder; best practices summary, establishment of acceptance criteria and family groupings based on product/process for validation.
Travel Expenses, estimated *Airfare, hotel, car, per diem – billed as incurred*

EO Master Validation Protocol - Sterilization & Product Acceptance
Full product validation review, summary report to include all testing and pass/fail criteria and data summary and acceptance. • 4 Hour Protocol & Test Plan Development Includes product bioburden resistance data review, development of PCD and supporting data with full/half cycle development plan. • 2 Hours Validation Oversight Review of laboratory data and monitoring of study. • 1.5 Hour Summary Report Preparation Written conclusion and validation statement. **DELIVERABLE:** Sterilization Validation Summary Protocol & Acceptance Report
Travel Expenses, estimated *Airfare, hotel, car, per diem – billed as incurred*

Nelson Labs
A Sotera Health company

Radiation Sterilization Validation & Family Grouping
Product review and assessment for up to 2 family groupings of 5-7 product types based on materials, manufacturing processes and bioburden loads. • Selection of worse case representative device for validation and verification. Development of family grouping justification. • Test plan for validation of VDmax or Method 1 radiation study. • Written justification for family grouping and test plan. • Regulatory support for 510(k) or CE mark **DELIVERABLE:** Radiation Validation Summary & Family Grouping Justification
Travel Expenses, estimated *Airfare, hotel, car, per diem – billed as incurred*

Reusable Device Validations, Test Plans, IFUs/DFUs
Study design review and validation plan for reprocessed medical devices including: • Product design for sterilization, cleaning and disinfection • Assessment of clinical use (patient contact and biomarker selection) • Selection of worse case representative device for validation and verification. • Development or modification of instructions/directions for use (IFUs/DFUs) • Development of family grouping justification. • Validation test plan and justification. • Regulatory support for 510(k) or CE mark **DELIVERABLE:** Reprocessing Validation Protocol, IFUs/DFUs, Written Justifications
Travel Expenses, estimated *Airfare, hotel, car, per diem – billed as incurred*

Biocompatibility & Toxicological Reviews
Study design review and biocompatibility assessment following ISO 10993 and current US FDA regulatory guidance. • Chemical characterization test plan design following ISO 10993 • Biocompatibility test plan design following ISO 10993 • Biological and toxicological risk assessments • Custom test and protocol development for novel devices • Written justifications for test plan selection • Written biocompatibility assessments for product/material changes • Regulatory support for 510(k) or CE mark **DELIVERABLE:** Test plan design, written justifications, test alternatives
Travel Expenses, estimated *Airfare, hotel, car, per diem – billed as incurred*

Packaging Design & Validation
Full review of product packaging design, test plan selection based on porous or nonporous properties, development of complete validation protocol. • Shelf Life - Aging for both accelerated and real time plan • Strength & Integrity test plan • Transportation & Distribution test plan • Selection of family groupings for packaging sets • Written justifications for test plan selection • Master validation protocol for packaging configuration • Regulatory support for 510(k) or CE mark **DELIVERABLE:** Test plan design, written justifications, test alternatives
Travel Expenses, estimated *Airfare, hotel, car, per diem – billed as incurred*