## 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
<table>
<thead>
<tr>
<th><strong>Radiation Sterilization Validation &amp; Family Grouping</strong></th>
<th></th>
</tr>
</thead>
</table>
| 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 |

<table>
<thead>
<tr>
<th><strong>Reusable Device Validations, Test Plans, IFUs/DFUs</strong></th>
<th></th>
</tr>
</thead>
</table>
| 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 |

<table>
<thead>
<tr>
<th><strong>Biocompatibility &amp; Toxicological Reviews</strong></th>
<th></th>
</tr>
</thead>
</table>
| 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*