Biocompatibility	
Areas of Interest	**Identifier**
Decision making process for biocompatibility evaluation and test selection (if needed); considerations for use of animal testing vs. in vitro testing; sample preparation of nanoscale, bioabsorbable, and in situ polymerized materials.	Q1 A1

Combination Products	
Areas of Interest	**Identifier**
Manufacturing processes involved in the manufacturing of device/drug or device/biologic combination device products with an emphasis on the manufacturing processes and controls involved including the Quality System for devices and GMPs for the drug component.	Q1 B1
Devices coated with drug(s) or biologic(s); drug/biologic delivery products.	Q1 B2
Total product life cycle for combination products.	Q1 B3

Clinical Trials/Clinical Research	
Areas of Interest	**Identifier**
Conducting clinical research, observing the informed consent process, ensuring exclusion/inclusion criteria met. Observing organization and management of a clinical research site.	Q1 C1
Conducting clinical trials for medical devices as a sponsor, overcoming common obstacles to starting and completing clinical trials, and interacting with various other stakeholders; preparing applications to request approval to conduct Investigational Device Exemption (IDE) clinical studies and responding to feedback received from FDA.	Q1 C2
Conducting clinical trials for medical devices as an investigational site, including the numerous responsibilities of investigators and research coordinators such as initial study planning, working through the IRB and contracting process, training staff, recruiting potential subjects, screening/enrolling subjects, completing testing required by the clinical protocol, interacting with sponsors, and various reporting requirements throughout the investigation.	Q1 C3
Reviewing clinical trials for medical devices as an institutional review board (IRB), including developing and establishing procedures as well as all activities related to human subject protection during research, reviewing clinical protocols, conducting ongoing reviews of clinical trials, handling various unanticipated situations, and notifying and interacting with FDA when necessary.	Q1 C4
Conducting clinical trials involving registries, study design and subject selection criteria, controls employed by sponsor to ensure no selection bias. Would like staff to learn about minimizing selection bias, as well as techniques and tools used to select subjects from registries.	Q1 C5

Regulatory considerations for Core Labs or CROs conducting clinical research, monitoring data, or data management for a sponsor or clinician.	Q1 G1

Digital Health/Software	
Areas of Interest	**Identifier**
Cybersecurity	Q1 D1
Software Development	Q1 D2
Development Practices and Methodologies in use by industry to develop medical device software over the course of the total product life cycle.	Q1 D3
Software Testing types and practices used by industry to verify and validate medical device software.	Q1 D4

Imports/US Agents	
Areas of Interest	**Identifier**
Import Shipping Facilities (e.g., FedEx/UPS/DHL) imports processing division/brokerage and Charter Brokerage.	Q1 E1
US agents in general, including those imbedded within large companies and stand-alone outfits.	Q1 E2

InVitro Diagnostics	
Areas of Interest	**Identifier**
Pre-analytical devices (i.e., blood tubes), pathogen collection devices, micro collection/transport devices; general reagents, manual reagents; general assays, common point-of-care devices.	Q1 F1
Hands-on instrument and system training; clinical implication of common laboratory testing; hands on familiarization of medical imaging equipment in a hospital setting.	Q1 G4

Implementation of Quality System Requirements in an LDT (lab) environment as compared to a manufacturing environment.	Q1 H2
IHC Reagents/ Automated IHC Equipment- Seeking opportunities to visit manufacturers of Immunohistochemistry (IHC) reagents and/or automated IHC equipment.	Q2 D1
Digital Pathology Devices- Seeking opportunities to visit manufacturers or users of digital pathology devices.	Q2 D2
Genetic Sequencing - Sequencing Systems, Interpretation Software, and/ or Genetic Counseling- Seeking opportunities to visit manufacturers or users of genetic sequencing systems, sequence interpretation software, and mock examples of how genetic counselors (or alternative medical personnel) convey results to patients.	Q2 D3

Device Development/ Manufacturing/Device Demo	
Areas of Interest	**Identifier**
Site visit to observe manufacturing of medical devices.	Q1 K3

Production and calibration of innovative manufacturing Methods.	Q1 G2
Site visit to receive a demo of stereotaxic navigation systems used in cranial/neuro, ortho and/or ENT procedures.	Q1 G6
Pre-analytical devices (i.e., blood tubes), pathogen collection devices, micro collection/transport devices; general reagents, manual reagents; general assays, common point-of-care devices.	Q1 F1
Mechanical Ventilation- Seeking an opportunity to visit the manufacturer of a Life-Sustaining Respiratory Device.	Q2 C1
Seeking opportunities to visit a laboratory that is doing innovative things that would allow the Anesthesia Devices branch to see Physiological Closed Loop Devices in person and allowing for sound feedback on the submissions received related to this innovative technology.	Q2 C3
Powder Materials- Seeking to visit a manufacturer of zirconia based CAD/CAM milling materials, Ti bases and various software programs utilized for forming abutments.	Q2 C4
Endosseous Implant Restoration/Repair- Seeking opportunities to visit a university/academic training center/hands-on training facility for placing and/or restoring implants.	Q2 C5

Innovative Pediatric Spinal Devices- Clinical Factors Important To Consider Regarding Innovative Spinal Devices Used To Treat Pediatric Patients With Scoliosis And Other Spinal Deformities. • Discuss benefits and risks of non-fusion approaches to treatment of early onset scoliosis patients (EOS), which are defined as patients with spinal deformities who are less than 10 years of age. • Discuss when treatment of pediatric patients with spinal deformities are better treated with traditional spinal fusion versus growth sparing treatment methods. • Gain an understanding of how different patient populations and spinal pathologies (ex. neuromuscular, congenital, idiopathic, and syndromic deformities) are indicated for treatment with specific spinal devices at various stages of spinal development. • Gain an understanding of recent advances related to the current understanding of spinal growth, thoracic growth, and pulmonary function in relation to pediatric spinal disorders.	Q2 E1
Patient Matched Orthopedic Implants- Learn the process of developing patient-matched orthopaedic implants and instruments for joints and/or fracture fixation (e.g. osteotomy). Learn about the software interface, image segmentation, pre-operative planning steps, surgeon interaction and how the final design of the patient-matched implant/instruments is determined. Learn about how the patient-matched instrument or implant is utilized intra-operatively.	Q2 E3
IHC Reagents/ Automated IHC Equipment- Seeking opportunities to visit manufacturers of Immunohistochemistry (IHC) reagents and/or automated IHC equipment.	Q2 D1
Digital Pathology Devices- Seeking opportunities to visit manufacturers or users of digital pathology devices.	Q2 D2

Genetic Sequencing - Sequencing Systems, Interpretation Software, and/ or Genetic Counseling- Seeking opportunities to visit manufacturers or users of genetic sequencing systems, sequence interpretation software, and mock examples of how genetic counselors (or alternative medical personnel) convey results to patients.	Q2 D3
Developing products as a medical device manufacturer including all aspects of the product development process such as development/assessment of initial concept; consideration of customer needs and previous product experience; building initial prototypes; performing failure mode effects analysis; developing and conducting pre-clinical testing including simulations, bench testing, and animal testing; considering anomalies identified during testing and use and whether to redesign or retest the device; manufacturing considerations; evaluating complaints and returned products to identify trends and assess product quality; and developing/refining the instructions for use to improve the use, performance, and benefits to patients and healthcare providers.	Q2 A1

Postmarket Assessment	
Areas of Interest	**Identifier**
Registry Data for Use in Orthopedics- Learn how registries function to collect and analyze clinical data. Learn how registries can be better utilized to support premarket applications and evaluate the performance of orthopaedic medical devices. • Gain an understanding of how Level-I data (patient, surgeon, and hospital identifiers as well as procedure data) may be used to monitor revision rates following implantation of orthopedic devices. • Gain an understanding of how Level-II data (patient factors, comorbidities, surgical data, perioperative data, adverse event data) may be used to assess outcomes for various orthopedic devices). • Gain an understanding of how Level-III data (patient reported outcome data) derived from a registry may be used to inform outcomes of various types of orthopedic implants. • Gain an understanding of how Level-IV data (radiographs and other imaging data) are collected in a registry setting and how this data could potentially be used to detect impending orthopedic implant failures • Assess the challenges related to collection of Level-V data (data from explanted devices) and explore the utility of this data to the understanding of device failure modes. • Gain an understanding of the strengths and limitations of orthopedic studies based on registry data in comparison to other study types including studies based on randomized controlled clinical trials.	Q2 E2

Quality Management/Quality Systems	
Areas of Interest	**Identifier**
Manufacturing Execution Systems (MES), Enterprise resource planning (ERP), Electronic Quality Management Systems (EQMS).	Q1 H1
Implementation of Quality System Requirements in an LDT (lab) environment as compared to a manufacturing environment.	Q1 H2
Observation of implemented quality systems practices based on current Good Manufacturing Practices; the manufacturing of medical imaging or therapeutic radiology technologies.	Q1 H3
Quality System applied to Manufacturing: Looking at the manufacturing processes and controls employed by firms to ensure quality medical devices from start to finish, such as incoming acceptance activities, manufacturing processes and in-process controls, and final acceptance activities. Would like staff to see actual manufacturing facilities and processes in action.	Q1 H4
Manufacturing processes involved in the manufacturing of device/drug or device/biologic combination device products with an emphasis on the manufacturing processes and controls involved including the Quality System for devices and GMPs for the drug component.	Q1 B1
Total product life cycle for combination products.	Q1 B3

Production and calibration of innovative manufacturing Methods.	Q1 G2
Use of Quality manufacturing processes and methods, to manufacture devices in a way that incorporates continuous process feedback into the manufacturing processes. Examples include continuous process monitoring to detect minor deviations in the process and address them before they become major deviations which require remediation activities.	Q1 G3
Site visit to observe usability testing for a medical device and understand how the testing relates to documents in the device's design history file, e.g. risk analysis.	Q1 G5

Reprocessing and Sterilization	
Areas of Interest	**Identifier**
Sterilization and Packaging of Medical Devices.	Q1 I1
Cleaning, and/or reprocessing of medical devices- Learn how the instruments are handled, disassembled or cleaned at the hospital. Observe the reprocessing of the following devices: Class I instruments and Class II instruments. Learn whether the above Class I and Class II instruments are separately reprocessed. Learn about flash sterilization techniques and under what circumstances they are used. Learn whether the hospitals utilize extended cycles for sterilization. Also, learn about potential reprocessing or cleaning of permanent orthopedic implants and under which circumstances (e.g. open but unused condition) the implants are reprocessed.	Q2 E5

Standards Conformity Assessment Testing	
Areas of Interest	**Identifier**
Medical Device [non-clinical] testing laboratories.	Q1 J1
* General testing processes and equipment used in a typical testing laboratory for medical devices . * Testing of high-impact safety and/or performance standards including electrical safety, electromagnetic compatibility, biocompatibility, sterility etc. * Testing of high-volume device-specific standards with clear acceptance criteria.	Q2 B1
Non-clinical Testing- Learn about the testing protocols for non-clinical wear testing of joint prosthesis. Gain knowledge on the considerations taken for development of test protocols (normal wear test and Mode-III wear test).	Q2 E4

Innovation	
Areas of Interest	**Identifier**
Health Technology Assessment Groups and Payers- How do HTAs and payers determine what data is needed for a positive coverage decision? Is there a way these groups can communicate with device developers to capture all of the data needed to expedite patient access?	Q1 K1
Medical Device Innovation and Development_- Unique regulatory challenges faced by small startup companies, small businesses, and non-traditional medical device innovators (e.g. students, nurses, patients).	Q1 K2