Biocompatibility		
Areas of Interest	**Anticipated Participants**	**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.	Cross Cutting	2020 A1

Clinical Trials/Clinical Research		
Areas of Interest	**Anticipated Participants**	**Identifier**
Specular microscopy provides important information regarding the health of the corneal endothelial cells. Permanent medical devices implanted in the eye may lead to endothelial cell loss (ECL). We request participation of stakeholders with experience in specular microscopy to describe endothelial cell morphology, techniques for determining the morphology parameters, how the images are collected and analyzed, and discuss factors impacting the endothelial cell density measure (aging, ocular surgical procedures, pharmaceutical exposure, and general health of the corneal endothelium.	OHT 1	2020 F1

Technology that uses machine learning and/or closed loop control to assist clinicians in diagnosing and/or treating patients. We're particularly interested in uses in anesthesiology and with ventilators.	OHT 1	2020 F2
Developing dermal fillers and aesthetic medical devices including product development aspects such as clinical trials: • Development/assessment of initial medical product concept, integrating customer needs and previous product experience • Development and completing pre-clinical testing including simulations, bench testing, and animal testing • Overcoming common obstacles to starting and completing clinical trials • Evaluating and responding to dermal fillers and aesthetic medical devices complaints, including enhancements and redesign.	OHT 4	2020 I2

Digital Health/Software		
Areas of Interest	**Anticipated Participants**	**Identifier**
AI/ML (Artificial Intelligence/Machine Learning)- Continuous learning, Adaptive algorithms, Reinforcement learning, Federated Learning, AI/ML in Virtual reality, Robotics, Surgery	Cross Cutting	2020 C1

Digital Diagnostics/Therapeutics or wearables- Novel Therapeutic paradigms/alternative therapies, Clinical Decision support, Digital biomarkers	Cross Cutting	2020 C2

Device Development/ Manufacturing/Device Demo

Areas of Interest	Anticipated Participants	Identifier
Manufacturing or Design Facilities for CDRH-lead Combination Products - Processes involved in the manufacturing or design of device/drug or device/biologic combination products with an emphasis on manufacturing and design controls involved to meet the Quality System requirements and GMP requirements for the finished combination product. CDRH-lead combination products that require a PMA typically include but are not limited to medical products like iontophoresis devices, drug-eluting stents, insulin pumps, and other drug coated or eluding devices.	Cross Cutting	2020 B1
Manufacturing or Design Facilities for traditional drug delivery systems that are regulated as Combination Products - Processes involved in the manufacturing or design of device/drug or device/biologic combination products with an emphasis on manufacturing and design controls involved to meet the Quality System requirements and GMP requirements for the finished combination product. Traditional drug delivery systems include but are not limited to medical products like syringes, auto injectors, transdermal patches, and inhalers.	Cross Cutting	2020 B2

Observe the testing set-ups for catheter based blood pumps in the test labs, understand the capabilities of these pumps and understand how these devices are used clinically in the real world (high risk PCI, Shock, right heart failure, pediatrics), understanding the manufacturing of these devices is key as these devices have many more manufacturing changes than the relatively stable long term VADs. It is also important to understand how manufacturers handle complaints and how they investigate complaints.	OHT 2	2020 G1
1)Didactic and hands on training on vascular anatomy, physiology, pathology and therapy, 2) A particular focus on the ascending aorta, aortic arch, and thoraco-abdominal aorta would be helpful, 3) Exposure to vascular surgery clinical practice (i.e., watching live surgical and endovascular procedures with narration), 4) Imaging Core laboratory exposure. It would be informative to understand the process and timeline for imaging review and adjudication.	OHT 2	2020 G2
FDA is interested in learning more about risk management activities of menstrual products, including tampons. These may include the manufacturing of tampons and menstrual products, the risk mitigation strategies employed by manufacturers, and how manufacturers address toxic shock syndrome risk mitigation and testing.	OHT 3	2020 H2

Robotic Surgical Assistive Device development through device use including: • Development/assessment of initial concept, integrating customer needs and previous product experience • Developing, building initial prototypes 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 • Developing, monitoring, and updating user training • Developing/refining the instructions for use to improve the use, performance, and benefits to patients and healthcare providers. • Evaluating and responding to medical device complaints, including enhancements and redesign	OHT 4	2020 I1
Neurointerventional therapeutics	OHT 5	2020 J1
Manufacturing of animal-derived tissue - Dura-mater devices	OHT 5	2020 J2
•Learn the complete process about patient matched guide manufacture and use including when and how a surgical case is planned, how the patient images are acquired and their quality is controlled, what software and interfaces are utilized, how the guides are created, verified by surgeon, manufactured, tested, and properly used in the surgery; • Improve our understanding of the roles of engineers, surgeons, manufacturers and other essential players in this process, critical steps in ensuring accuracy, and our knowledges of different software (e.g., cloud) and interfaces (e.g., web-based) used for this process and potential pros and cons (e.g., cybersecurity) •Discuss with the manufacturer about the manufacturing process (e.g., additive manufacturing process) and testing methods and visit the facility •Discuss with engineers and surgeons about the benefits and concerns in using these planning software and guides in surgeries	OHT 6	2020 K1

Plasma Spray Coating- • Learn about different types of coating processes (e.g., plasma spray Ti, HA and Ti/HA coatings, PVD, etc.) and see a manufacturing facility • Learn how different coating methods and parameters impact coating microstructure and properties and performance of the coated medical devices • Learn about post-processing manufacturing and processing steps (machining, cleaning, sterilization) • Discuss the common material characterization tests performed on the coating or the coated devices	OHT 6	2020 K2
Postmarket Surveillance/Signal Detection- Adverse Event and Complaint Handling, Recalls and Safety Surveillance for Medical Devices- • Complaint Handling including MDR reporting and vigilance • Complaint Handling Metrics, thresholds and reporting systems • Complaint Handling Training (in house for safety vigilance staff and sales staff) • Recall and CAPA assessments • Risk Assessments (evaluation, HRA, root cause and outcomes) • Safety Signals	Cross Cutting	2020 M1
Submission preparation for medical device manufacturers when following eSTAR template	Cross Cutting	2020 M2

Innovation/ Health Technology Assessment/ Market Access

Areas of Interest	Anticipated Participants	Identifier
Medical Device Innovation and Development – Review of the process of medical device development from ideation to patient access from the viewpoint of the innovator/manufacturer including a focus on the non-regulatory aspects such as the process of obtaining coding, coverage, and payment (commonly referred to as reimbursement), buy-in of physician professional societies, provider groups, health technology assessment groups, and others in the medical device ecosystem.	Cross Cutting	2020 D1
Medical Device Reimbursement	Cross Cutting	2020 D2

InVitro Diagnostics		
Areas of Interest	**Anticipated Participants**	**Identifier**
Manufacturers involved with development of NGS, ddPCR, digital pathology, artificial intelligence based diagnostic devices, IHC reagents, or digital pathology devices that are commonly used in pathology labs.	OHT 7	2020 L3
Total Lab Automation in Microbiology- Laboratory automation is gaining more penetrance in clinical microbiology. Several innovative approaches have been applied by integrating various technological advances to streamline and automate a wide range of complex, manual/visual processes in microbiology ranging from specimen culturing to digital reading and interpretation of growth. Many clinical microbiology labs are adopting these technologies and are finding many advantages including improvements in laboratory efficiency. At CDRH, the division of microbiology devices has seen growth in the number of submissions received from interested sponsors. It will be a valuable experience for scientific reviewers to visit a clinical microbiology lab to observe the total lab automation in practice.	OHT 7	2020 L4

Radiological Health

Areas of Interest	Anticipated Participants	Identifier
Diagnostic Radiologist image review – Wide variety of clinical use cases (small clinic, hospital, academic) to understand how radiologists prioritize the image review queue (which patient images to view next) with particular emphasis on integration of any computer aided triage devices that would impact clinical case prioritization. Preferred sites would review a wide variety of cases from routine to emergent.	OHT 7	2020 L1
Radiation therapy clinical physics and safety- Emerging technologies in Radiation Therapy (e.g., Light ion therapy treatment systems, FLASH-RT, radioactive microsphere dosimetry, novel image guidance and planning methods)	OHT 7	2020 L2

Reprocessing and Sterilization

Areas of Interest	Anticipated Participants	Identifier
Risk control and mitigation in scope design, manufacturing, surveillance and reprocessing. Scopes include duodenoscopes, gastroscopes, ureteroscopes, cystoscopes, choledochoscopes, laparoscope, hysteroscopes. FDA is interested in understanding use and reprocessing of endoscopes in a clinical or simulated clinical setting.	OHT 3	2020 H1

Reprocessing of scopes used in medical procedures to include the initial cleaning stage through final reprocessing is important. Interest is centered around types of disinfectants, material compatibility, and reprocessing including drying of the scopes after cleaning and reprocessing. Validation of the cleaning and reprocessing of the scopes is important. In addition to validating the cleaning and reprocessing of the device, monitoring the reprocessing procedures to include sampling and culturing would be beneficial in understanding the reduction in risk of infection.	Cross Cutting	2020 O1
Sterilization of medical devices is important in reducing the risk of infection from contaminated medical devices. There are many different ways of sterilizing medical devices to include dry heat, radiation, steam (moist heat), vaporized hydrogen peroxide, ethylene oxide gas, and other sterilization methods (for example, vaporized peracetic acid, chlorine dioxide gas, and nitrogen dioxide). While many medical devices can only be sterilized using ethylene oxide due to device material compatibility, alternative methods are being explored to sterilize medical devices. Training is needed to learn about alternative ways to sterilize medical devices with lower levels of currently used agents, and/or new agents or alternatives that can be used while maintaining device safety and effectiveness. Areas of interest include radiation, vaporized peracetic acid, vaporized hydrogen peroxide, chlorine dioxide gas, nitrogen dioxide, flexible chamber ethylene oxide, reduced ethylene oxide and etc.	Cross Cutting	2020 O2

Office of Regulatory Affairs		
Areas of Interest	**Anticipated Participants**	**Identifier**
Material Used in Medical Device Manufacturing: Plastics- Training (and possible demonstrations) on plastics technology and their associated process validation considerations. Areas of interest include molding (e.g. Injection, Compression and/or Extrusion), tooling, mold design (e.g. Cavities, Layouts and Parting Lines, Sprue and Runner Systems, Venting), resin flow characteristics, thermoplastics, thermosets, adhesives, coatings, recycled/regrind/reworked polymers, materials testing, ultrasonic welding, sterilization and laser etching.	ORA	2020 ORA 1
Material Used in Medical Device Manufacturing: Ceramic and Glass- Training (and possible demonstrations) on ceramic and/or glass technologies and their associated process validation considerations. Areas of interest include machining, polishing, reaction bonding, grinding, blowing, firing, and glazing.	ORA	2020 ORA 2
Material Used in Medical Device Manufacturing: Metals- Training (and possible demonstrations) on metallurgy technologies and their associated process validation considerations. Areas of interest include casting, extrusion, machining (e.g. lathes, mills, drills, stamping presses, CNC), plating, ultrasound welding, annealing, radiofrequency welding, and spot continuous welding.	ORA	2020 ORA 3

In-Vitro Diagnostics Device Manufacturing- Training (and possible demonstrations) on manufacturing of In-Vitro Diagnostics medical devices and their associated process validation considerations. Areas of interest for manufacturing include vialing/filling, antibody/nucleic acid purification, lyophilization, mixing and sterilization. Areas of interest for process validation include packaging (e.g. glass, paper, Tyvek; foils; laminates; pouches; bags; vials; ampules) and test methods for IVDs, including IQ/OQ/PQ.	ORA	2020 ORA 4
Electronics/Electromechanical: Welding/laser etching/ultrasound cleaning- Training (and possible demonstrations) on manufacturing of electronics/electromechanical components of medical devices and their associated process validation considerations. Areas of interest include welding, laser etching, and ultrasound cleaning processes.	ORA	2020 ORA 5
Electronics/Electromechanical: Surface Mount Technology (SMT) Training (and possible demonstrations) on manufacturing electronics/electromechanical components of medical devices and their associated process validation considerations. Areas of interest include the Surface Mount Technology (SMT) Board Assembly Process and SMT Test Method validations: Automatic Testing Equipment (e.g. in-circuit test system; functional test system); Vibration Testing; and Burning.	ORA	2020 ORA 6

ELP Participation Structure Key

OHT 1 – Ophthalmic, Anesthesia, Respiratory, ENT & Dental Devices
OHT 2 – Cardiovascular Devices
OHT 3 – Reproductive, Gastro-Renal, Urological, General Hospital Device & Human Factors
OHT 4 – Surgical & Infection Control Devices
OHT 5 – Neurological & Physical Medicine Devices
OHT 6 – Orthopedic Devices
OHT 7 – In Vitro Diagnostics & Radiological Health
OCEA – Office of Clinical Evidence and Analysis
ORP – Office of Regulatory Programs
OSEL - Office of Scientific Engineering Labs
ORA - Office of Regulatory Affairs
Cross Cutting – Potentially including multiple offices within CDRH
***** -** This entry appears in multiple categories.