The following table contains the Fall Fiscal Year 2023 Experiential Learning Program (ELP) Areas of Interest. Important items to note for this proposal solicitation period include:

1. Virtual Site Visits: The ELP is now implementing virtual site visits. This will allow greater flexibility in selecting staff for site visits, selecting proposals, and helping to increase exposure to the program. If your organization can accommodate a virtual site visit for any of the Areas of Interest for which a proposal is being submitted, please make sure to check the box with the Site Visit Request Sample.
2. Patient Engagement: If your organization would like to submit a proposal for any Areas of Interest stated in the Fall 2023 table below, please consider including Patient Engagement as a potential supplemental topic to the Area of Interest for which you are applying. You may do this by checking the "Patient Engagement Relevant" box in the Site Visit Request Sample linked at the bottom of the ELP webpage.

Combination Products		
Areas of Interest	**Anticipated Participants**	**Identifier**
Drug Delivery Devices – 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	Cross Cutting	2023 C2

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.		

Digital Health/Software		
Areas of Interest	**Anticipated Participants**	**Identifier**
Novel Digital Health Technologies and Therapy – Innovations in digital health technologies and therapies have accelerated medical device advancements. Technologies such as mobile platforms, wearables, virtual and augmented realities (VR/AR), and other computing platforms have increasingly been adapted to deliver healthcare to patients. Many of these applications are novel and present new opportunities for patients and health care providers to measure, treat, diagnosis, and/or manage diseases and conditions. Furthermore, advanced algorithms (such as artificial intelligence, machine learning), have enhanced the capabilities of digital health technologies and provide for new opportunities to improve performance from real-world use and experience. The novelty of these innovative digital health technologies and therapies often raise new questions of safety and effectiveness. Therefore, it is important to fully understand these products, as described by the software development and deployment processes, clinical validation, risk and cybersecurity management, lifecycle requirements, and other activities that demonstrate responsible and high-quality digital health innovation.	Cross Cutting	2023 B1
Real World Data and Evidence (RWD & RWE) – The FDA currently defines real-world data (RWD) as the data relating to patient health status and/or the	Cross Cutting	2023 B2

delivery of health care routinely collected from a variety of sources, such as electronic health records, registries, medical claims, and data from wearables and other digital health technologies. Improvements in interoperability and increasing availability of computers, cloud computing, mobile devices, wearables, and other digital health technologies to measure, collect, and/or store large amounts of health-related data has been accelerating the opportunities leverage RWD/RWE throughout health care. Additionally, innovations in medical devices, including mobile apps, have also resulted in novel data sources, including the device itself. Through advancements in RWD and analysis methods (for example, artificial intelligence, machine learning), there is growing potential to generate robust real-world evidence (RWE) to further support FDA regulatory decisions. It is important for FDA to understand, foster, and harness the increasing power of RWD/RWE to accelerate medical product development and bring new innovations faster and more efficiently to the patients who need them, without compromising patient safety. Furthermore, it is important to understand and advance the potential use RWD/RWE to support solutions that address health disparities and promote health equity.

Innovation/ Health Technology Assessment/ Market Access

Areas of Interest	Anticipated Participants	Identifier
Promoting Innovation in the Medical Device Ecosystem – Patient access, the primary mission of CDRH, to novel, safe and effective medical devices usually require more than regulatory approval or clearance. For most devices, patient access requires approval or buy-in of others in the medical device ecosystem, such as payors, and professional societies. Often the evidence needed by others to support their decision is different from the market authorization requirements. Innovators need to learn the requirements of these non-FDA stakeholders and develop a plan on how they will generate the data needed to meet the various stakeholder needs.	Cross Cutting	2023 A1

Innovators that develop and manufacture leading edge-medical devices frequently are small start-up companies, small businesses, and non-traditional medical device innovators (such as students, nurses, caregivers, and patients). Understanding the unique needs of these innovators will help CDRH staff better assist them during the review process. For this training, please include a shadowing/matching component with the start-up companies in your incubator/accelerator so each participant can meet 1:1 with a start-up to learn directly from them the unique regulatory challenges faced.	Cross Cutting	2023 A2

OCEA - Office of Clinical Evidence Analysis

Areas of Interest	Anticipated Participants	Identifier
Leveraging data from real-world experience is critical to bringing medical diagnostics and therapeutics to US patients first in the world. Evaluating the strengths and limitations of those data depends on understanding how the data move through the eco-system from the point of care to a reviewer's desk. This includes understanding of how clinical data are entered into various systems (such as electronic health records, claims, and registries) as part of the clinical workflow and for what purposes, which can shed light into the quality of the data submitted. This also includes understanding considerations for who can access those data and for what purposes, which provides context for whether certain data can be used, and how quality might be impacted by any processing of the data that might need to occur as a result of data ownership considerations. This also involves understanding of the entities involved in transforming the data (such as data visualization, governance, aggregation, linkage, analytics, and curation,) to understand where quality of those data might be impacted.	Cross Cutting	2023 P1

OHT 1 - Ophthalmic, Anesthesia, Respiratory, ENT & Dental Devices

Areas of Interest	Anticipated Participants	Identifier
Manufacturing; Design Controls; Device Labeling and Real-World Evidence – The FDA is interested in the total product lifecycle of dental implant systems including installation and production qualifications for the entire manufacturing stream of medical devices, as well as the assessments for device failures and malfunctions leading to adverse patient events such as dental implant failure due to lack/loss of osseointegration. This information would be beneficial in understanding the significant number of MDRs received for dental implant systems. The FDA is interested in the development of clinician training, and the associated device labeling, provided by dental implant manufacturers. Hands on training in patient selection and dental implant placement would be beneficial in understanding the design of dental implant systems, the accompanying device surgical instructions, and those features/instructions which may be specific to the device design and not applicable across all dental implant systems.	OHT 1	2023 D1
Device Fabrication and Process Validation – Dental therapeutic or prosthetic devices – The FDA has seen an increase in devices that are fabricated using biometric data such as patient scans to fabricate a patient-matched device to treat a medical condition. Conventional technology has involved the use of patient impressions and thermoforming techniques. In recent years, there has been an increase in the use of automated additive or subtractive (Computer Assisted Design and Manufacturing) manufacturing systems to fabricate the patient matched device. This would include the use of a scanner, software, printer or milling apparatus, and a post-curing unit. To ensure the patient-matched device fabricated by these systems meet design specifications, it is important that this system be validated. Device quality, such as feature geometry, overall dimensions, and material characteristics, may be affected by any one of the components of the device fabrication system. Process validation will ensure that the end user will receive a device that meets user needs.	OHT 1	2023 D2

OHT 2 – Cardiovascular Devices		
Areas of Interest	**Anticipated Participants**	**Identifier**
Non-Clinical Cardiovascular Medical Device Testing – This training will provide hands-on/in-person experience on the following topics to augment staff's knowledge on various ISO testing, development of silicone models for in vitro analyses, in-person knowledge on common testing equipment used for cardiac and cardiovascular device testing systems, and development/implementation of simulated use systems. The experience will also include knowledge on how standard test methods may be adapted and developed to address testing needs for device specific applications, which is common practice to address regulatory submission requirements.	OHT 2	2023 E1

OHT 3 - Reproductive, Gastro-Renal, Urological, General Hospital Device & Human Factors		
Areas of Interest	**Anticipated Participants**	**Identifier**
Reprocessing and Sterilization – Flexible Endoscopes – The FDA continues to work to improve the effectiveness of reprocessing of various scopes, including duodenoscopes. Reprocessing of scopes used in medical procedures, from the initial cleaning stage through final reprocessing, is vital toward reducing the risk of infection for patients. Scope reprocessing includes several products and processes, for example automated rinsing devices, disinfectants, and drying and storage practices. The FDA would like to visit a reprocessing facility to	OHT 3	2023 F1

improve our holistic understanding of scope reprocessing and how each aspect impacts the safety of these reusable devices.		
Implantable Neurostimulation Devices – Manufacturing and Post-market Surveillance – The FDA reviews neurostimulation devices for urinary and fecal incontinence, deep brain stimulation, spinal cord stimulation, and other applications. These are complex systems with many components and with evolving technologies. The FDA would like to learn more about the manufacturing and post-market surveillance for these high-risk class III devices.	OHT 3	2023 F2

OHT 4 - Surgical & Infection Control Devices		
Areas of Interest	**Anticipated Participants**	**Identifier**
Robotically-assisted Surgical Devices (RASD) – RASD are complex teleoperated devices which feature multiple interconnected subsystems. Design decisions made early in development can have significant impact on device usability and performance. Interest is in learning more about the RASD design and design validation process with a specific emphasis on how user and bedside interface design decisions effect device usability and performance.	OHT 4	2023 G1

OHT 5 - Neurological & Physical Medicine Devices		
Areas of Interest	**Anticipated Participants**	**Identifier**
Neurological Stereotactic Navigation Systems – Clinical observation of stereotactic neurosurgery procedures and research and development of neurological stereotactic systems.	OHT 5	2023 H1
Prosthetics/Neuromodulation Medical Devices – Prosthetics development is a rapidly advancing area that can potentially serve both civilian and military service personnel patient populations where amputee and spinal cord injury represents broad US public health challenges. Neurostimulation devices have the potential for substantial public health impact on mental or physical impairments because of the high incidence in psychiatric and neurological conditions. Several types of marketing submissions in the prosthetic and neuromodulation sector include pre-submissions, 510K, de novo, and Premarket Approval (PMA) regulatory paths. Moreover, several potential Sponsors may have competitive submissions for this call for ELP proposals. In addition, other Offices may have staff interested in these topics areas with related technologies in the orthopedics and cardiovascular technology sectors.	OHT5	2023 H2

OHT 6 - Orthopedic Devices		
Areas of Interest	**Anticipated Participants**	**Identifier**
Patient matched implants and cutting guides (Imaging Modality, Segmentation, Device Design, Final Device) – Personalized medicine is being explored throughout the medical device ecosystem and is no stranger to use in Orthopedic devices (patient matched devices have been authorized for use in both implants and instruments). The patient matched device design process can require heightened interactions with the clinical care team, and on the manufacturer's, end requires specialized expertise to ensure imaging scan segmentation is performed correctly and that the device design will fit the patient's anatomy and patients need. Moreover, there can be much variability in this process due to the differences in imaging modality, technology utilized by manufacturers and their specific clinical expertise and training/standard operating procedures. The FDA is interested in learning about the types of software used and how they are applied to the process. The FDA is also interested in learning the specifics of the patient matched process, including who needs to perform each step of the process, how the engineer is trained, what the necessary expertise are for each program type/approach, how patient matching process is best employed and monitored, when patient matched devices are more valuable to employ compared to off the shelf solutions, what the limitations are for matching a device to fit both the patients surrounding bony anatomy or a patient's pre-existing implants (for example, device intended to mate with existing ankle replacements). Some examples of this process include patient matched arthroplasty replacements, patient matched cutting guides and additively manufactured custom devices.	Cross Cutting	2023 I1
Biomechanical protocol design, testing, and data analysis – Biomechanical testing can be a very useful tool to assess orthopedic implants and can produce valuable data to support safety and effectiveness of Orthopedic devices. But this requires a well-designed study, robust protocol, and appropriate data analysis. As there are no standard methods or testing guides for biomechanical testing, there can be a lot of variability in these studies making it difficult to interpret the study results and understand how the data can support safety and	OHT 6	2023 I2

effectiveness. Interest is centered around understanding decisions that go into designing a biomechanical protocol, observing testing, understanding data collection and processing, and considerations regarding strengths and limitations of biomechanical testing.		

OHT 7 - In Vitro Diagnostics		
Areas of Interest	**Anticipated Participants**	**Identifier**
Clinical Laboratory Tour – A. Clinical laboratory workflow, patient sample testing workflow, clinical lab analyzers and instrumentation - B. Next generation sequencing laboratory workflow, preanalytical and analytical processing, sequencers, bioinformatic processing, clinical interpretation	OHT 7	2023 J2

OHT 8 - Radiological Health		
Areas of Interest	**Anticipated Participants**	**Identifier**
Radiology Image Reading – Radiology workflow involves radiologists analyzing images to help diagnose a patient. This often involves reviewing many images from patients with varying diseases. Software devices can aid in the radiology workflow by helping to automatically locate, identify, or triage images. Therefore, there is interest in academic or hospital-related sites that target diagnostic devices for patient management to facilitate our understanding of patient workflows and the roles the radiologic imaging devices (hardware and software) and, where possible, in the diagnostic setting or in actual clinical use. Preferred sites would be clinical sites with live cases included (for example, cath lab, interventional radiology suite), and/or the live use of Computer Aided-Diagnostic (CAD) software in the interpretation workflow, and educational instructional sessions, to understand the workflow from diagnosis to patient treatment.	OHT 8	2023 K2

ORP – Office of Regulatory Programs		
Areas of Interest	**Anticipated Participants**	**Identifier**
Evaluating sources of data for adverse event and signal identification – Medical Device associated events, their evaluation, escalation, investigation and actions a manufacturer may take to improve performance. Including in this focus is their connection with other data sources (internal and external), utilization of AI and other signal detection logics.	Cross Cutting	2023 L2

OSEL - Office of Scientific Engineering Labs		
Areas of Interest	**Anticipated Participants**	**Identifier**
3D Printing in a Healthcare Setting – The Center for Devices and Radiological Health (CDRH) is committed to assuring that patients and providers have timely and continued access to safe, effective, and high-quality medical devices and safe radiation-emitting products. As part of providing this assurance, CDRH recognizes that innovations in manufacturing and product delivery are as important as innovations in device design and functions. 3D printing in a healthcare setting may serve an important public health purpose and may provide for rapid and agile production of devices, including but not limited to patient-matched devices2 and anatomical models for surgical planning. This technology has the potential to help a healthcare facility (HCF) quickly respond to patient needs, bring personalized care to patients in a timely manner, and lead to new innovations in patient care and treatment. Areas of interest include healthcare settings engaged in 3D printing to support patient care, especially those working under a quality management system.	Cross Cutting	2023 M1
Producing Metallic Feedstock for Additive Manufacturing – While medical device manufacturers are adopting a range of additive manufacturing technologies, metal powder bed fusion (PBF) has been the predominant technology used for several years. While different PBF machines have different requirements for the metallic feedstock, all systems generally have tight tolerances for allowable material and standard bodies have focused significant efforts on developing standards for these metallic feedstocks. Of specific interest are smelting or powder atomization facilities that are focused on making metallic feedstock for PBF systems.	Cross Cutting	2023 M2

Patient Engagement		
Areas of Interest	**Anticipated Participants**	**Identifier**
Patient Engagement during all phases of medical device total product life cycle – Patient engagement is defined as intentional, meaningful interactions with patients that provide opportunities for mutual learning and effective collaborations. The FDA/CDRH is interested in learning how medical device innovators, developers, manufacturers, distributors, investigators, and others incorporate patient input into a phase or phases of a device's life cycle. These phases may include discovery and ideation, invention and prototyping, pre-clinical testing, pre-market clinical testing (for example, trial design and conduct), product launch, and post-market activities (such as post-market study design, labeling, and recalls).	Cross Cutting	2023 Q1

Reprocessing and Sterilization		
Areas of Interest	**Anticipated Participants**	**Identifier**
Reprocessing, Disinfection, and Sterilization – The FDA takes the risk of patient infection very seriously and continually works to take steps to help improve the effectiveness of reprocessing, disinfection, and sterilization of various medical devices. Reprocessing of reusable medical devices includes the initial cleaning stage through final reprocessing through disinfection or sterilization, depending on the overall risk of contamination of the device. Interest is centered around types of cleaning agents/disinfectants and their effectiveness, material compatibility, overall effectiveness of reprocessing including adequate log reduction of bioburden (disinfection), support of achieving an appropriate Sterility Assurance Level (sterilization) and drying of the medical	Cross Cutting	2023 N1

devices after cleaning and reprocessing through validation of reprocessing instructions proposed by the sponsor. 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.

ELP Participation Structure Key

Combination Products
Digital Health
Innovation
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
OHT 8 - Radiological Health
OCEA – Office of Clinical Evidence and Analysis
ORP – Office of Regulatory Programs
OSEL - Office of Scientific Engineering Labs
Patient Engagement
Reprocessing

Cross Cutting – Potentially including multiple offices within CDRH