Biocompatibility	
Areas of Interest	**Identifier**
Biocompatibility - 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 E1

Combination Products	
Areas of Interest	**Identifier**
Manufacturing Facilities for CDRH-lead Combination Products - Manufacturing processes involved in the manufacturing 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.	Q1 A2
Manufacturing Facilities for traditional drug delivery systems that are regulated as Combination Products - Manufacturing processes involved in the manufacturing 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.	Q1 A3/ E2

Clinical Trials/Clinical Research	
Areas of Interest	**Identifier**
Clinical Trials - Conducting clinical trials for medical devices as a sponsor (medical device manufacturers, contract research organizations, and/or sponsor-investigators), 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 C3
Clinical Trials - 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 C4
Clinical Trials - 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 C5
Diabetes Clinical Trial Sites - Research centers dedicated to executing clinical trials for future treatments to cure diabetes and related health conditions.	Q1 D7

Animal Studies - Learn about the sites compliance with GLP regulations and what differences there are between non-GLP and GLP studies at their facility. Attend an invasive cardiac clinical procedure and necropsy to better understand how cardiac procedures are modified for the animal model, the type of monitoring done during and after the study, and the equipment/facilities being utilized. Tour the facility to better understand the equipment and personnel involved with GLP animal studies.	Q1 C1

Device Development/ Manufacturing/Device Demo

Areas of Interest	Identifier
Manufacturing Processes and Quality Controls- Manufacturing processes and the use of quality controls in the manufacturing environment to ensure high quality medical devices. Specific areas could include, but are not limited to, incoming acceptance activities, manufacturing processes, in-process controls, and final acceptance activities.	Q1 A1
Manufacturing Facilities for CDRH-lead Combination Products - Manufacturing processes involved in the manufacturing 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.	Q1 A2

Manufacturing Facilities for traditional drug delivery systems that are regulated as Combination Products - Manufacturing processes involved in the manufacturing 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.	Q1 A3
Good Laboratory Practice/ Non-Clinical - Visit non-clinical laboratory sites that are involved in animal studies for medical device studies.	Q1 A5
Automated External Defibrillator (AED) Design - Manufacturing, Returned Product, Reconditioning, and Quality Control.	Q1 C2
Medical Device Development - 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.	Q1 C6
Cell-Free DNA Collection Tubes - Manufacturing, in-process and finished device testing.	Q1 D1
Chemistry Reagents/Analyzers - Manufacturing, in-process and finished device testing.	Q1 D2
Clinical Laboratory Tour - Clinical laboratory workflow, patient sample testing workflow, clinical lab analyzers and instrumentation.	Q1 D3

Continuous Glucose Monitoring Systems and Insulin Pumps - Manufacturing, in-process and finished device testing.	Q1 D4
CTC (Circulating Tumor Cells) - Manufacturing, In-process testing, or finished device testing.	Q1 D5
Cytology - Pap Smear Imaging Systems.	Q1 D6
Diagnostic Ultrasound Devices - Diagnostic ultrasound device manufacturing procedures and performance evaluation.	Q1 D8
Glucose Test Strips and Meters - Manufacturing, In-process and finished device testing.	Q1 D10
Home use urine tests - Manufacturing, in-process and finished device testing.	Q1 D11
Immunohistochemistry - Opportunities to visit manufacturers of Immunohistochemistry (IHC) reagents and/or automated IHC equipment.	Q1 D12
Liquid Biopsy - Liquid Biopsy-Opportunities to visit manufacturers or users of liquid biopsy tests (either circulating tumor cell assays or circulating tumor DNA assays).	Q1 D13
Next-Generation Sequencing - Next-Generation Sequencing Variant Calling - 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.	Q1 D14
POC diagnostic devices and accessories - Manufacturing, in-process and finished device testing.	Q1 D15

Urine Test Strips and Readers - Manufacturing, in-process and finished device testing.	Q1 D18
Diagnostic ultrasound devices - Diagnostic ultrasound device manufacturing procedures and performance evaluation.	Q1 D8

Digital Health/Software

Areas of Interest	Identifier
Digital Health Software as a Medical Device (SaMD) - Software intended for one or more medical uses that may run on different operating systems or in virtual environments. Software run on a hardware medical device is a SaMD when not part of the intended use of the hardware medical device. Software is not SaMD if it drives or controls the hardware medical device. This can include standalone software that is intended to run on general purpose computers or mobile platforms (e.g., smartphone, tablet). Other examples include: •SaMD that uses the microphone of a smart device to detect interrupted breathing during sleep and sounds a tone to rouse the sleeper. •SaMD that analyzes heart rate data intended for a clinician as an aid in diagnosis of arrhythmia."	Q1 B1

Digital Health/ Advanced Analytics – A device or product that can identify, analyze, and use big data and large complex data sets from a variety of sources. The product extracts new and relevant information or patterns to use for medical purposes. Required for artificial intelligence devices.

Advanced Analytics may include the use of statistical modeling and analytical techniques that provide insights, predictions, and recommendations based on its analysis. In that respect, devices including Advanced Analytics may have an overlap with those including Artificial Intelligence. However, Advanced Analytics techniques typically analyze large and varied datasets that cannot normally be analyzed by humans without specialized software tools, and often discover new patterns in data.

Q1 B2

Examples include:
•An imaging system conducts an analysis of a patient's melanoma by comparing it to a repository of data from past melanoma cases (including images, diagnosis, treatment plans). The system then provides a diagnosis and generates a treatment plan for the patient.
•A software program uses data from a standard CT to create a personalized 3D model of the coronary arteries and analyzes the impact that blockages have on blood flow.

Digital Health/ Artificial Intelligence – A device or product that can imitate intelligent behavior or mimics human learning and reasoning. Artificial intelligence includes machine learning, neural networks, and natural language processing. Some terms used to describe artificial intelligence include: computer-aided detection/diagnosis, statistical learning, deep learning, or smart algorithms. One rapidly growing area of Artificial Intelligence is machine learning. Machine learning is used to design an algorithm or model without explicit programming but through the use of automated training with data (e.g., a regression function or deep learning network). Devices that include Adaptive Algorithms, i.e., algorithms that continue to learn and evolve in time, are also another area of Artificial Intelligence. Terms or jargon used to describe artificial intelligence include computer-aided detection/diagnosis, statistical learning machines/algorithms, classifier, indicator/index/indices, support vector machine, deep learning, and smart algorithm.

Q1 B3

Examples include:
•An imaging system that uses algorithms to provide diagnostic information for malignant melanoma or skin cancer in patients.
•A smart ECG device that estimates the probability of acute cardiac ischemia (ACI), a common form of heart attack.

Digital Health/ Cloud - A device or product with internet-based computing that provides computer processing resources and data on demand. The cloud is a shared pool of configurable resources (e.g., computer networks, servers, storage, applications, and services). Computing and data storage resources include: servers, operating systems, networks, software, applications, services, and storage equipment.

Q1 B4

Examples include:
•SaMD being executed in the cloud.
•A mobile colposcope that stores images taken on the cloud for future retrieval and review in the doctor's office.
•A picture archiving and communications system consists of cloud-based, web-accessible software that analyzes cardiovascular images acquired from magnetic resonance (MR) scanners.

Digital Health/ Cybersecurity - A device or product that can prevent unauthorized access, modification, misuse, or denial of use, or the unauthorized use of information which is stored, accessed, or transferred from a medical device to an external recipient.

Examples of security functions for protection include:
•Limited access to devices or products through the authentication of users (e.g. user ID and password, smartcard, biometric).
•Use of automatic timed methods to terminate sessions within the system where appropriate for the use environment.

Q1 B5

Digital Health/ Interoperability - A device or product that can exchange and use information through an electronic interface with another medical/non-medical product, system, or device.

Examples include:
•An infusion pump has been designed to receive patient data from any pulse oximeter and uses this data to change infusion pump settings.
•A centralized patient monitoring system receives patient data from several devices and uses this data to command and control a ventilator to adjust pressure, volume, and flow settings that are appropriate for the patient."

Q1 B6

Digital Health/ Medical Device Data System (MDDS) - Hardware or software that can transfer, store, convert data formats, or display medical device data without controlling or altering the functions or parameters of any connected medical device.

Examples include:
•The electronic transfer or exchange of medical device data. For example, this would include software that collects output from a ventilator about a patient's CO2 level and transmits the information to a central patient data repository.
•The electronic storage and retrieval of medical device data. For example, software that stores historical blood pressure information for later review by a healthcare provider.
•The electronic conversion of medical device data from one format to another in accordance with a preset specification. For example, software that converts digital data generated by a pulse oximeter into a digital format that can be printed.
•The electronic display of medical device data. For example, software that displays a previously stored electrocardiogram for a particular patient.

Please note that MDDS does not include devices intended for active patient monitoring (i.e., any device that is intended to be relied upon in deciding to take immediate clinical action or where a timely response is required).

Q1 B7

Digital Health/ Mobile Medical App (MMA) - A software application that meets the definition of a medical device. The MMA transforms a mobile platform into a regulated medical device or is an accessory to a regulated medical device.

Examples include:
•Mobile apps that transform the mobile platform into a regulated medical device by using attachments, display screens, or sensors or by including functionalities similar to those of currently regulated medical devices
•Mobile apps that area an extension of one or more medical devices by connecting to such device(s) for the purposes of controlling the device(s) or for use in active patient monitoring or analyzing medical device data
•Mobile apps that become a regulated medical device (i.e. SaMD) by performing patient-specific analysis and providing patient-specific diagnosis, or treatment recommendations

Q1 B8

Digital Health/ Wireless - A device or product that uses wireless communication of any form (e.g., Wi-Fi, Bluetooth, NFC) to perform at least one function.	Q1 B9
Digital Health/ "Novel Digital Health - A device or product that includes new, unfamiliar, or unseen digital health technology never submitted, cleared, or approved by FDA. The technology could potentially be a de Novo, have a new intended use, or have different technological characteristics. This also includes digital health technology or topic areas that have no agreed upon or established definition by industry or FDA. Examples of novel digital health technologies include but are not limited to: •Virtual Reality •Gaming •Medical Body Area Network (MBAN) wearable or implanted wireless devices	Q1 B10
Digital Health/Software - Cybersecurity and software development. Software Testing types and practices used by industry to verify and validate medical device software. The cybersecurity features and needs of these systems, development practices and methodologies over the total product life cycle. Also, the software testing types and practices used by industry to verify and validate these medical device software	Q1 E3

Innovation/ Health Technology Assessment/ Market Access

Areas of Interest	Identifier
Innovation - Innovators that develop and manufacturer leading-edge medical devices must satisfy the needs of many different stakeholders in the healthcare ecosystem: FDA is just one of those stakeholders. Innovators typically conduct extensive bench testing and might conduct multiple clinical trials as part of the overall development process. Data from these tests and trials provide scientific evidence that is used to support FDA review and approval/clearance of the device. In addition, innovators might need to consider other hurdles to patient and market access such as coding, coverage, and payment: together these elements are commonly referred to as reimbursement. FDA staff would benefit from a better understanding of how innovators consider the needs of and engage with professional societies, healthcare providers, healthcare technology assessment groups, and payors. Innovators must consider these groups in their overall strategic planning process that includes gathering, analyzing, and presenting clinical evidence and healthcare economic information, as well as the publication of these results in peer-reviewed scientific journals.	Q1 B11

InVitro Diagnostics

Areas of Interest	Identifier
Cell-Free DNA Collection Tubes - Manufacturing, in-process and finished device testing.	Q1 D1

Chemistry Reagents/Analyzers - Manufacturing, in-process and finished device testing.	Q1 D2
Clinical Laboratory Tour - Clinical laboratory workflow, patient sample testing workflow, clinical lab analyzers and instrumentation.	Q1 D3
Continuous Glucose Monitoring Systems and Insulin Pumps - Manufacturing, in-process and finished device testing.	Q1 D4
CTC (Circulating Tumor Cells) - Manufacturing, In-process testing, or finished device testing.	Q1 D5
Cytology - Pap Smear Imaging Systems.	Q1 D6
Diabetes Clinical Trial Sites - Research centers dedicated to executing clinical trials for future treatments to cure diabetes and related health conditions.	Q1 D7
Urine Test Strips and Readers - Manufacturing, in-process and finished device testing.	Q1 D18
Home use urine tests - Manufacturing, in-process and finished device testing.	Q1 D11
Immunohistochemistry - Opportunities to visit manufacturers of Immunohistochemistry (IHC) reagents and/or automated IHC equipment.	Q1 D12

Liquid Biopsy - Liquid Biopsy-Opportunities to visit manufacturers or users of liquid biopsy tests (either circulating tumor cell assays or circulating tumor DNA assays).	Q1 D13
Next-Generation Sequencing - Next-Generation Sequencing Variant Calling - 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.	Q1 D14
POC diagnostic devices and accessories - Manufacturing, in-process and finished device testing.	Q1 D15
Public Health Laboratories that are in charge of implementing programs in compliance with Federal/State rules and regulations (for example newborn screening program) – Public Health Laboratory operation, patient education, patient specimen testing workflow, abnormal result follow-up, specimen retention.	Q1 D16
Ultrasound transducer reprocessing - Catheter ultrasound transducer reprocessing procedures and quality assurance.	Q1 D17

Quality Management/Quality Systems

Areas of Interest	Identifier
Manufacturing Processes and Quality Controls - Manufacturing processes and the use of quality controls in the manufacturing environment to ensure high quality medical devices. Specific areas could include, but are not limited to, incoming acceptance activities, manufacturing processes, in-process controls, and final acceptance activities.	Q1 A1
Manufacturing Facilities for CDRH-lead Combination Products - Manufacturing processes involved in the manufacturing 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.	Q1 A2
Quality Management - Use of Quality manufacturing processes and methods, as well as controls, used to manufacture devices in a way that incorporates continuous process feedback into the manufacturing processes. This will allow review of actual acceptance criteria and controls.	Q1 E4
Statistical Methodology - Understanding the statistical methods used in risk based decisions and sample determinations as it pertains to quality control of verification and validation of production systems.	Q1 E6

Standards Conformity Assessment Testing	
Areas of Interest	**Identifier**
Standards Conformity Assessment Testing - Evaluation of processes validated against recognized standards criteria, specifically medical device manufacturing and related activities that rely on standards for sterilization of medical devices, controlled environments used for processing or testing devices, and methods of stability testing and evaluation related to device sterility and in vitro diagnostics.	Q1 E5