ELP 2017 Q1 Focus Areas

Table 1 - Office of Compliance (OC)

Focus Area	Specific Area of Interest	Focus Area Identifier
Electronic Systems to Support Quality in Manufacturing	Manufacturing Execution Systems (MES), Enterprise resource planning (ERP), Electronic Quality Management Systems (EQMS)	OC/ 1
Quality System in Manufacturing Environments	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.	OC/ 2
Combination Products	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.	OC/ 3
Management of Clinical Trials for Medical Devices	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. Would apply to ODE, OSB and OC/DBM.	OC/ 4
Management of Clinical Research	Conducting clinical research, observing the informed consent process, ensuring exclusion/inclusion criteria met. Observing organization and management of a clinical research site.	OC/ 5
Core Labs or CROs	Regulatory considerations for Core Labs or CROs conducting clinical research, monitoring data, or data	OC/ 6

	management for a sponsor or clinician.	
Implementation of Maturity Models	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.	OC/ 7
Medical Device Imports Point of Entrance	• Import Shipping Facilities (e.g., FedEx/UPS/DHL) imports processing division/brokerage • Charter Brokerage	OC/ 8
U.S. Agents for Foreign Firms	US agents in general, including those imbedded within large companies and stand-alone outfits.	OC/ 9

Table 2 - Office of the Center Director (OCD)

Focus Area	Specific Area of Interest	Focus Area Identifier
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)	OCD/ 1
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?	OCD/ 2

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Table 3 - Office of Device Evaluation (ODE)

Focus Area	Specific Area of Interest	Focus Area Identifier
Management of Clinical Trials for Medical Devices	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.	ODE/ 1
Management of Clinical Trials for Medical Devices	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.	ODE/ 2
Management of Clinical Trials for Medical Devices	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.	ODE/ 3
Reprocessing and Sterilization	Infection control-surgical and isolation gowns	ODE/ 4
Reprocessing and Sterilization	Sterilization and Packaging of Medical Devices	ODE/ 5
Combination Products	Devices coated with drug(s) or biologic(s); drug/biologic delivery products.	ODE/ 6
Combination Products	Total product life cycle for combination products	ODE/ 7

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Reprocessing and Sterilization	Sterilization and Reprocessing High level Disinfection	ODE/ 8
Emerging Manufacturing Methods	Production and calibration of innovative manufacturing Methods.	ODE/ 9
Biocompatibility Evaluation	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, bio absorbable, and in situ polymerized materials.	ODE/ 10
Standards Conformity Assessment	Medical Device [non-clinical] testing laboratories	ODE/ 11
Digital Health	Cybersecurity	ODE/ 12
Digital Health	Software Development	ODE/ 13

Table 4 - Office of In-Vitro Diagnostics and Radiological Health (OIR)

Focus Area	Specific Area of Interest	Focus Area Identifier
Quality Systems for Laboratory Developed Tests	Implementation of Quality System Requirements in an LDT (lab) environment as compared to a manufacturing environment.	OIR/ 1
Medical Device Software Development Practices	Development Practices and Methodologies in use by industry to develop medical device software over the course of the total product life cycle. Could apply to OC, ODE, OIR and OSEL.	OIR/ 2
Medical Device Software Testing	Software Testing types and practices used by industry to verify and validate medical device software.	OIR/ 3

Manufacturing of In-Vitro Diagnostic Devices	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.	OIR/ 4
Instrument Training of Medical Devices	Hands-on instrument and system training; clinical implication of common laboratory testing; hands on familiarization of medical imaging equipment in a hospital setting.	OIR/ 5
Quality System in Manufacturing Environments	Observation of implemented quality systems practices based on current Good Manufacturing Practices; the manufacturing of medical imaging or therapeutic radiology technologies.	OIR/ 6

Table 5 - Office of Surveillance and Biometrics (OSB)

Focus Area	Specific Area of Interest	Focus Area Identifier
Observe manufacturing processes for various medical devices	Site visit to a manufacturing site to observe manufacturing processes for various medical devices	OSB/ 1
Observe Usability Testing/ Risk Analysis	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	OSB/ 2
Stereotaxic Navigation Systems used in Cranial/Neuro, Ortho and/or ENT Procedures	Site visit to receive a demo of stereotaxic navigation systems used in cranial/neurological, orthopedic and/or ENT procedures	OSB/ 3

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