Life & Health

Medical Device Course Report

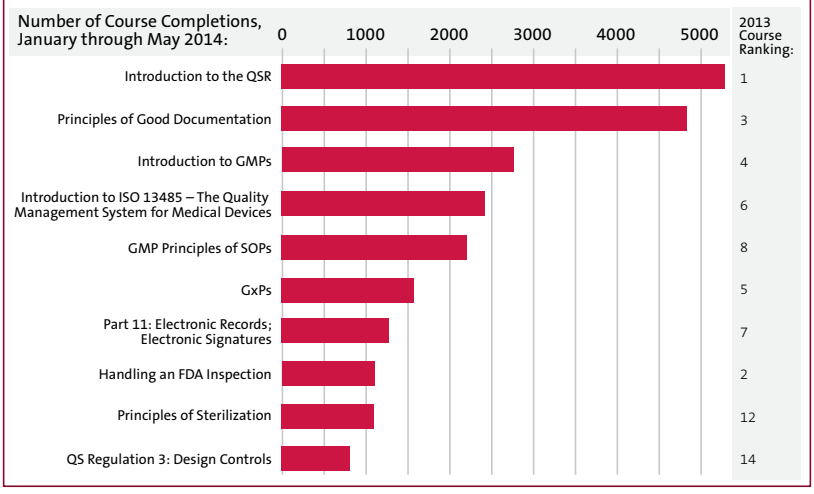
GMP/QSR: Critical Course Usage – January through May 2014

This report is designed to help Medical Device QA teams identify today's most critical GMP and QSR training topics, based on completions from more than 200 Life Science companies that subscribe to UL EduNeering's libraries.

On the next page you'll find the most completed Medical Device-focused UL EduNeering courses, from January to May 2014. In our analysis of client usage, we have categorized the courses by recommended curricula, which focus on specific job roles within the organization.

These courses are available to all Medical Device companies via a UL EduNeering subscription, and can run on most learning management systems. In addition, UL EduNeering can also provide onsite workshops related to many of these topics, including FDA Inspection Readiness, GMP Basics, CAPA, IT Validation and more. To learn more, e-mail us at EduNeeringInquiry@ul.com.

Ten Most-Demanded Medical Device GMP/QSR Courses
Trend Shows a Shift in Focus from 2013 to 2014



CURRICULUM	COURSE TITLE	CODE	COMMENTS
FDA Inspection Readiness:			
Roles: Auditors, QA, Management, SMEs	Pre- and Post-Approval FDA Inspections	PHDV66	
	Principles of Auditing	PHDV69	
	Handling an FDA Inspection	PHDV74	
	QSIT 4: The Corrective and Preventive Actions Subsystem	FDA53	Authored by US FDA
	Quality System Inspection Technique	DEV42	Overview of QSIT
GMP Basics:			
Roles: Production, Management	Principles of Good Documentation	PHA64	
	Introduction to GMPs	PHDV77	
	Orientation to GMP Compliance	PHDV75	
	Change Control	PHA67	
	GMP Principles of SOPs	PHDV87	
	GxPs	FDA29	Authored by US FDA
	Writing and Reviewing SOPs	PHDV76	
QA Compliance Basics:			
Roles: QA, Quality Control, Auditing	Introduction to the Quality System Regulation (QSR)	DEV43	
	A Step-by-Step Approach to Process Validation	PHDV79	
	FDA Training and Qualification Requirements	PHA67	
	Writing Validation Protocols	PHDV69	
	Principles of Auditing	PHDV69	
	Principles and Practices of Process Controls	PHA47	
	Key Concepts of Process Validation	PHDV77	
	Resolving Out Of Specification Test Results	PHA50	
	Meeting GMP Training Requirements	PHDV73	
Complaints, Recalls and Adverse Events			
Titles: Complaint Management, MDR Specialist	Handling a Product Recall	PHDV64	
	Failure Investigations for Medical Device Manufacturers	DEV45	
	Complaint Management for Medical Device Manufacturers	DEV46	
	MDR Regulation 1: Overview and General Provisions	FDA63	Authored by US FDA
	MDR Regulation 2: Device User Facility, Importer and Reporting	FDA65	Authored by US FDA
	MDR Regulation 3: Requirements for Individual Adverse Event Reports	FDA66	Authored by US FDA
Titles: Regulatory Affairs	The Approval Process for New Medical Devices in the US	DEV42	
	Medical Device Filings: 510(k), PMA, and IDE	DEV53	
	Global Regulatory Strategy and Planning Process	DEV54	
Titles: Designers and Engineers	Introduction to ISO 13485	DEV48	
	Guide to ISO 13485	DEV50	
	Design Control Regulations for Medical Device Manufacturers	DEV40	
Titles: IT Validation	Part 11: Electronic Records; Electronic Signatures	FDA31	Authored by US FDA
	Requirements for Computerized Systems Validation and Compliance	ISPE01	
	Approach to Computerized Systems Validation and Compliance	ISPE02	