Quality & Compliance Essentials

COURSE LIST (AS OF 02/12/16)

Courses in the Quality & Compliance Essentials represent eLearning courses that meet SCORM compliance and can be taken from a desktop, laptop, or a mobile device (e.g., iPad, iPhone).

In this course list, courses are categorized by course set name, in alphabetical order.

The Quality & Compliance Essentials courses include multi-touch features, allowing the learner to simply tap, swipe, pinch or zoom in on objects on the screen. In addition, learners can employ automatic screen rotation to display the course in either portrait or landscape mode.

This brochure lists all the courses available in the Quality & Compliance Essentials sets, and also indicates if languages are available other than English. For courses available in five primary languages (French (FR), German (GR), Spanish (SP), Simplified Chinese (CH), and Japanese (JP)), then "All 5" is noted.

At a client's request, any course can be translated into one of 34 specific languages, which are listed on Page 5.

This course list is current as of February 12, 2016, and is being updated on a quarterly basis.

Set Name	Course Title	Course Code	Languages
Corporate Compliance - Medical Device	Basics of the AdvaMed Code	MDSM01	All 5
	Eucomed Guidelines on Interactions with Healthcare Professionals	MDSM04	FR, GR, SP
	HIPAA and Privacy Guidelines for Medical Device Sales Representatives	PRIVACY01	English
	Introduction to Medical Device Health Care Compliance	MDSM05	English
	Massachusetts Pharmaceutical and Medical Device Manufacturer Conduct Regulation (MA Regulation)	MDSM03	English
	National Patient Safety Goals	MDSM07	English
	Operating Room Conduct	PHA68	English
	Physician Payment Sunshine Act	PHSM11	English
	Reporting Adverse Events for Medical Devices	MDSM02	English
Corporate Compliance - Pharmaceutical	Basics of PhRMA Code	PHSM01	English
	HIPAA and Privacy Guidelines for Pharmaceutical Sales Representatives	PRIVACY02	English
	Interactions with Healthcare Professionals – Field	PHSM07	English
	Interactions with Healthcare Professionals – In-House	PHSM06	English
	Introduction to Pharmaceutical Compliance	PHSM09	English
	Medical Education for Healthcare Professionals	PHSM03	English
Corporate Compliance - All Industries	Code of Business Conduct	LAV15	English
	Detecting and Preventing Fraud	ETHICS13	All 5
	Doing the Right Thing: Anti-bribery	ETHICS09	English
	E-mail and Corporate Communications	ETHICS20	English
	Foreign Corrupt Practices Act	ETHICS16	All 5 + 4 languages
	Global Anti-Bribery	ETHICS14	All 5 +4 languages
	Handling Confidential Information	ETHICS10	All 5
	Making Ethical Decisions	ETHICS17	English
	Physical and Network Security	ETHICS21	CH, JP, SP
	Privacy and Data Protection	ETHICS15	All 5
	Recognizing and Avoiding Conflicts of Interest	ETHICS11	English
	Safeguarding Intellectual Property	ETHICS12	English
	Sarbanes-Oxley Act: An Overview	ETHICS07	English
Corporate Compliance - Harassment	Discrimination and Harassment Free Workplace	ETHICS19	English
	Harassment in the Workplace	LAV21	English
	Preventing Sexual Harassment	ETHICS18	English
	Sexual Harassment Awareness for Employees	LAV08	English
	Sexual Harassment Awareness for Managers	LAV09	English
Dietary Supplements GMPs	Dietary Supplements -- Packaging, Labeling, Holding, & Distribution	Dietary01	English
	Dietary Supplements -- cGMP Requirements for Quality Control	Dietary05	English

Set Name	Course Title	Course Code	Languages
EH&S	Asbestos Awareness	EHS04	English
	Bloodborne Pathogens -- General Industry	EHS08	English
	Bloodborne Pathogens – Healthcare Workers	EHS09	English
	Electrical Safety	EHS23	English
	Emergency Preparation, Recognition, Control, Communication, and Response	OSHA61	English
	Fire Extinguishers	EHS36	English
	Glutaraldehyde	EHS29	English
	HAZWOPER Awareness	EHS42	English
	Hazardous Waste Disposal	EHS39	English
	Office Safety	EHS65	English
	Preventing Back Injuries	PHDV52	English
	Process Gauge Radiation	EHS69	English
	Process Safety Management: Process Hazard Analysis	EHS78	English
	Scaffold Safety	EHS93	English
	Safe Driving	PHDV41	English
	Toxic Substance Control Act (TSCA) Reporting	EHS102	English
Energy Operations	Emergency Response: Hazardous Spill	OSHA62	English
	Incident Command System: Responsibilities	OSHA78	English
	Incident Command System: Structure and Components	OSHA77	English
	Safety Hazards and Equipment	OSHA90	English
	Spill Prevention and Response Procedures	OSHA95	English
GMP Basics	A Step-by-Step Approach to Process Validation	PHDV79	All 5
	Combination Products – cGMP Requirements	PHDV93	All 5
	FDA Training and Qualification Requirements	PHA67	All 5
	GMP Principles for Batch Records	PHA60	All 5
	GMP Principles of SOP's	PHA64	All 5
	High Purity Water Systems	PHDV82	English
	Key Concepts of Process Validation	PHDV77	All 5
	Laboratory Safety	PHDV67	SP
	Meeting GMP Training Requirements	PHDV76	All 5
	Orientation to GMP Compliance	PHDV73	All 5 + Dutch
	Pharmaceutical and Medical Device Supplier Quality Management	PHDV85	All 5
	Principles of Sterilization	PHDV81	GR, JP, SP
	Understanding the Practices and Principles of Process Controls	PHA47	JP
	Validation of Analytical Laboratory Procedures	ISPE08	All 5
	Writing and Reviewing SOPs	PHA48	All 5
	Writing Validation Protocols	PHA51	English

Set Name	Course Title	Course Code	Languages
GMP Facility & Equipment Compliance	Collecting Samples and Establishing Limits for Cleaning Validation	PHA54	FR, JP, SP
	Environmental Control and Monitoring	PHDV87	All 5
	Essentials of an Effective Calibration Program	PHA75	CH, JP, KO
	Gowning for Sterile Manufacturing	PHA63	FR, GR, SP
	Maintenance and Cleaning of Drug Manufacturing Equipment	PHA44	FR, JP, SP
	Understanding GMPs for Facilities and Equipment	PHDV75	CH, JP, KO, SP
GMP Medical Device	An Introduction to ISO 13485 for Medical Devices	DEV48	All 5
	A Guide to ISO 13485 — The Quality Management Systems for Medical Devices	DEV50	All 5
	Good Documentation Practices for Medical Device Manufacturers	DEV56	CH, JP, KO
	Failure Investigations for Medical Devices	DEV45	CH, JP, KO
GMP Pharmaceutical	Batch Record Reviews	PHA53	FR, GR, SP
	Change Control	PHA35	All 5
	DEA Compliance	PHA40	All 5
	Documenting Validation Activities	PHA55	All 5
	EU: Role of the Qualified Person	PHA76	All 5
	EU: Good Distribution Practices for Medicinal Products	PHDV95	All 5
	GMP Principles for Batch Records	PHA60	All 5
	GMP Principles of SOP's	PHA64	All 5
	Principles of Good Documentation	PHA74	All 5
Global Clinical (Medical Device and Pharmaceutical)	Administrative Roles of the Clinical Research Coordinator	GCP02	English
	Financial Disclosure by Clinical Investigators	GCP24	English
	GCP/ICH Obligations of Sponsors, Monitors, and Investigators	GCP01	English
	Good Clinical Practices (GCPs) for New Product Investigations	PHA36	English
	Informed Consent	GCP13	English
	Obligations of Investigators in Conducting Drug and Biologic Trials	GCP27	English
	Obligations of Investigators in Conducting Medical Device Trials	GCP03	English
Global Regulatory Library	Introduction to CFDA and CFDA Registration (China)	PHDV97	CH
	Regulatory Requirements for Medical Devices in the Republic of Korea	DEV58	KO
	ICH Q7: Introduction and Quality Management	ISPE05	English
	ICH Q7: Resources and Materials Management	ISPE06	English
Health Plans	Introduction to Specialty Pharmacy Management	GHC09	English

Set Name	Course Title	Course Code	Languages
HR Compliance	Affirmative Action in the Workplace (for Employers)	LAV02	English
	Diversity in the Workplace	LAV06	SP
	Family Medical Leave Act	LAV08	English
	Fair Labor Standards Act (FLSA) and Equal Pay Act (EPA)	LAV03	English
	Substance Abuse	LAV10	English
	Violence in the Workplace	LAV11	English
IT Validation	Approach to Computerized Systems Validation and Compliance	ISPE02	All 5
	Computerized Systems Inspections in the Medical Device Industry	ISPE04	All 5
	Computerized Systems Inspections in the Pharmaceutical Industry	ISPE03	All 5
	EU: GMP Requirements for Computerised Systems	PHDV75	All 5
	Part 11: Electronic Records and Signatures -- Application	FDA61	CH, JP, KO
	Part 11: Electronic Records and Signatures -- Changes in Enforcement Policy	FDA57	CH, JP, KO
	Part 11: Electronic Records; Electronic Signatures	FDA31	CH, JP, KO
	Requirements for Computerized Systems Validation and Compliance	ISPE01	All 5
	The Design and Development of Software Used in Automated Process Controls	PHDV80	English
Inspection Readiness	Awareness of FDA Inspections for Pharmaceutical Manufacturers	PHA65	CH, FR, JP, SP
	EU Directives and Inspection Readiness	PHDV96	All 5
	FDA 483s: Inspectional Observations	FDA30	English
	Failure Investigations for Pharmaceutical Manufacturers	PHA59	All 5
	Handling an FDA Inspections	PHDV74	All 5
	Pre- and Post-Approval FDA Drug Inspections	PHA75	All 5
	Quality Systems Inspection Technique (QSIT)	DEV42	CH, JP
	QSIT 1 -- Beginning the Inspection	FDA50	CH, JP
	QSIT 2 -- QSIT 2 -- The Management Controls Subsystem	FDA51	CH, JP
	QSIT 3 -- The Design Controls Subsystem	FDA52	CH, JP
	QSIT 4 -- The Corrective and Preventive Actions Subsystem	FDA53	CH, JP
	QSIT 5 -- The Production and Process Controls Subsystem	FDA54	CH, JP

Set Name	Course Title	Course Code	Languages
Medical Device Quality System Regulation (QSR)	Introduction to Quality System Regulation	DEV43	All 5
	QS Regulation 1: Overview and General Provisions	QSR01	CH,JP,KO
	QS Regulation 2: Quality System Requirements	QSR02	CH,JP,KO
	QS Regulation 3: Design Controls	QSR03	CH,JP,KO
	QS Regulation 4: Document and Purchasing Controls	QSR04	CH,JP,KO
	QS Regulation 5: Identification, Traceability; Production and Process Controls	QSR05	CH,JP,KO
	QS Regulation 6: Acceptance Activities; Nonconforming Product	QSR06	CH,JP,KO
	QS Regulation 7: Corrective and Preventive Action	QSR07	CH,JP,KO
	QS Regulation 8: Labeling and Packaging Control; Handling, Storage, Distribution, and Installation	QSR08	CH,JP,KO
	QS Regulation 9: Records	QSR09	CH,JP,KO
	QS Regulation 10: Servicing; Statistical Techniques	QSR10	CH,JP,KO
Medical Device Reporting (MDR)	MDR Regulation 1: Overview and General Provisions	FDA63	CH,JP,KO
	MDR Regulation 2: Device User Facility, Importer, and Manufacturer Reporting Requirements	FDA65	CH,JP,KO
	MDR Regulation 3: Requirements for Individual Adverse Event Reports	FDA66	CH,JP,KO

Courses Can Be Translated into 34 Languages:

Arabic
Chinese (Simplified)
Chinese (Traditional)
Czech
Danish
Dutch Nederlands
English
Finnish
Flemish
French (Canada)
French (France)
German
Greek
Hebrew
Hindi
Hungarian
Indonesian
Italian
Japanese
Korean
Malaysian (Malay)
Norwegian
Polish
Portuguese (Brazil)
Portuguese (Portugal)
Romanian
Russian
Slovak
Spanish (Spain)
Spanish (Latin America)
Swedish
Thai
Turkish
Vietnamese

About UL EduNeering

UL EduNeering is a business line within UL Life & Health's Business Unit. UL is a premier global independent safety science company that has championed progress for 120 years. Its more than 10,000 professionals are guided by the UL mission to promote safe working and living environments for all people.

UL EduNeering develops technology-driven solutions to help organizations mitigate risks, improve business performance and establish qualification and training programs through a proprietary, cloud-based platform, ComplianceWire®.

For more than 30 years, UL has served corporate and government customers in the Life Science, Health Care, Energy and Industrial sectors. Our global quality and compliance management approach integrates ComplianceWire, training content and advisory services, enabling clients to align learning strategies with their quality and compliance objectives.

Since 1999, under a unique partnership with the FDA's Office of Regulatory Affairs (ORA), UL has provided the online training, documentation tracking and 21 CFR Part 11-validated platform for ORA-U, the FDA's virtual university. Additionally, UL maintains partnerships with leading life science industry trade organizations and software providers, including AdvaMed, the Drug Information Association, and MasterControl Inc.

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