Life & Health

Pharmaceutical Course Report

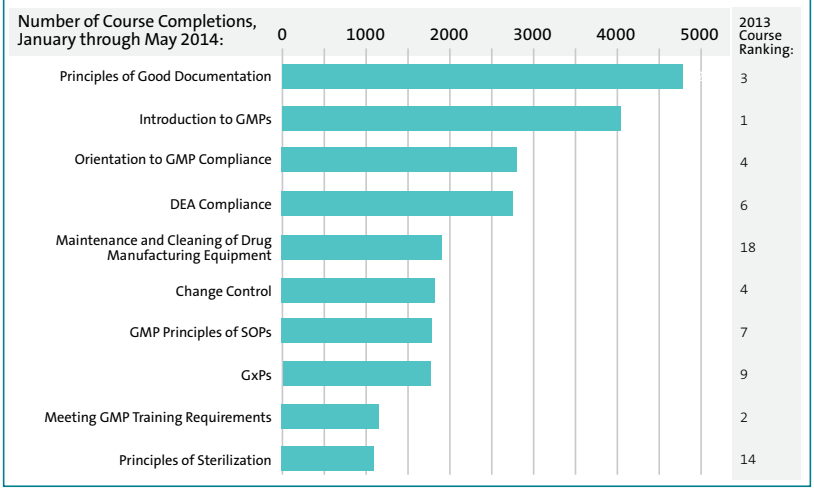
GMP: Critical Course Usage – January through May 2014

This report is designed to help Pharmaceutical QA teams identify today's most critical GMP 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 Pharmaceutical-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 Pharmaceutical 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 Pharmaceutical GMP 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	
	DEA Compliance	DEA40	
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	GMP Principles for Batch Records	PHA60	
	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	
Titles: Manufacturing and Equipment	Environmental Control and Monitoring	PHDV87	
	Essentials of an Effective Calibration Program	PHDV75	
	Gowning for Sterile Manufacturers	PHA63	
	Implementing an Equipment Qualification Program	PHDV88	
	Maintenance and Cleaning of Drug Manufacturing Equipment	PHA44	
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	

About UL EduNeering

UL EduNeering is a business line within UL Life & Health's Business Unit. UL is a global independent safety science company offering expertise across five key strategic businesses: Life & Health, Product Safety, Environment, Verification Services and Enterprise Services.

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 exclusive partnerships with leading regulatory and industry trade organizations, including AdvaMed, the Drug Information Association, the Personal Care Products Council and the Duke Clinical Research Institute.