



Life Sciences and Safety 2017 Course Updates

December 2017 Course Updates

Update Type	Course Code	Course Title	Industry	Course Library	Version	Update Details
Minor	EHS17	DOT Employee Drug and Alcohol Awareness	General Industry	Environmental Health and Safety	1.2	Case studies and statistics, drug listings.
Minor	EHS46	Hoists and Rigging	General Industry	Environmental Health and Safety	2.1	Content restructure, grammatical changes.
Minor	EHS55	Ladder Safety	General Industry	Environmental Health and Safety	2.1	Content restructure, grammatical changes.
Major	GCP27	Administrative Roles of the Clinical Research Coordinator	Life Science	Clinical: Medical Device, Clinical: Pharmaceutical	2.0	Update to include 45 CFR Part 56 Subpart A, ICH E6 (R2).
Major	GCP29	Recruitment and Retention of Study Participants	Life Science	Clinical: Medical Device, Clinical: Pharmaceutical	2.0	Update to HHS regulations, 45 CFR part 46, " Common Rule " – the final rule enhancing human subject protections, revisions to Informed Consent Document, Local IRB and Advertising Material sections.
Minor	PHA77	European Union Good Distribution Practices for Medicinal Products	Life Science	Global Regulatory, Pharmaceutical GMPs	1.1	Updates include final draft of Drug Chain Securities Act, reissue of EU Guidelines on GDP for Medicinal Products.
Major	QSR02	QS Regulation 2: Quality System Requirement	Life Science	FDA Inspections and Enforcement, Medical Device GMPs	2.0	Inclusion of FD&C Act Chapter 5: Drugs and Devices.
Minor	QSR03	QS Regulation 3: Design Controls	Life Science	FDA Inspections and Enforcement, Medical Device GMPs	1.4	Case Study updates, FDA 483s regulation updates per 21 CFR Part 820.
Minor	QSR09	QS Regulation 9: Records	Life Science	FDA Inspections and Enforcement, Medical Device GMPs	2.1	Grammatical changes. update case studies.

November 2017 Course Updates

Update Type	Course Code	Course Title	Industry	Course Library	Version	Update Details
New	Aseptic04	Isolators for Aseptic Processing	Life Science	Program Only – Aseptic Processing: Advanced Series	1.0	New title in the Aseptic Processing: Advanced Series Program. This course describes critical operating principles for the successful operation of an isolator for aseptic processing. Topics in this course include: Prepare, Leak Test, Decontaminate, Setup, Operate, Monitor, Clean, and Maintain. After completing this course, learners will be able to recognize the major process steps for isolator processing.
New	Aseptic07	Dos and Don'ts of Aseptic Environments	Life Science	Program Only – Aseptic Processing: Advanced Series	1.0	New title in the Aseptic Processing: Advanced Series Program. This course introduces best practices for aseptic technique and behavior for use with conventional cleanroom aseptic processing. Topics in this course include: Dos and Don'ts (including Personnel Requirements, Gowning and Gloves, Cleanroom Integrity, Behavior, Critical Area Interactions, and Culture). After completing this course, learners will be able to recognize best practice aseptic behaviors and techniques as well as specific examples of what to do and what not to do in the cleanroom.
Minor	EHS29	Fire Extinguishers	General Industry	Environmental Health and Safety	3.1	Content restructure, grammatical changes.
Minor	EHS34	Forklift Safety	General Industry	Environmental Health and Safety	2.1	Content restructure, grammatical changes.
Minor	EHS48	Hydrogen Sulfide (H ² S)	General Industry	Environmental Health and Safety	2.1	Content restructure, grammatical changes.
Minor	EHS56	Lead	General Industry	Environmental Health and Safety	3.1	Content restructure, grammatical changes.
Minor	EHS57	Lockout/Tagout — Affected	General Industry	Environmental Health and Safety	2.2	Content restructure, grammatical changes.
Minor	EHS58	Lockout/Tagout — Authorized	General Industry	Environmental Health and Safety	2.3	Content restructure, grammatical changes.
Minor	EHS98	Walking and Working Surfaces – Affected Person	General Industry	Environmental Health and Safety	1.6	Content restructure, grammatical changes.

Update Type	Course Code	Course Title	Industry	Course Library	Version	Update Details
Minor	GCP02	ICH GCP Obligations of Investigators Conducting Clinical Trials	Life Science	Clinical: Pharmaceutical	4.1	Content refinements in accordance with <i>Step 4</i> version of ICH E6(R2).
Major	LAV22	Harassment Avoidance Training for California	General Industry	Ethics & Corporate Responsibility	3.0	Updates to California law re-training requirements, include training and scenarios regarding gender identity and sexual orientation (SB-396).
Major	PARTD08	Medicare Part D: Medication Therapy Management and Quality Improvement Program	Healthcare	Medicare Part D	7.0	Updates include incorporation of CMS guidance relating to the MTM program, adding a more detailed comparison to the most recent CMS guidance, corrected PDE requirements, inclusion of patient safety reports, STAR ratings, and updated quiz questions.
Major	PHA81	Computerized Systems Inspections in the Pharmaceutical Industry	Life Science	FDA Inspections and Enforcement	4.0	Inclusion of GAMP 5 Risk Management guidance, tips on cybersecurity, and refinements to sections on 21 CFR Part 11.

October 2017 Course Updates

Update Type	Course Code	Course Title	Industry	Course Library	Version	Update Details
Minor	EHS18	DOT Hazardous Materials Training – General Awareness	General Industry	Environmental Health and Safety	3.1	Content restructure, grammatical changes.
Minor	EHS67	Personal Protective Equipment	General Industry	Environmental Health and Safety	2.1	Content restructure, grammatical changes.
Minor	FDA24	Recalls of FDA-Regulated Products	Life Science	FDA Inspections and Enforcement	2.2	Course format change to EduFlex, grammatical changes.
Minor	FDA25	Special Investigations	Life Science	FDA Inspections and Enforcement	2.1	Course format change to EduFlex, grammatical changes.
Minor	FDA38	Basics of Inspections: Beginning an Inspection	Life Science	FDA Inspections and Enforcement	1.2	Course format change to EduFlex, grammatical changes.
Minor	LAV04	Hiring and Firing	General Industry	Ethics & Corporate Responsibility, HR Compliance & Risk Management	1.2	Course format change to EduFlex, grammatical changes.
Major	MA36	Medicare Advantage: Plan Benefit Package and Bid Pricing Tool	Healthcare	Medicare Advantage	4.0	Summary of Benefits (SB) removed, as requirements have been updated, SB is no longer generated from the PBP software, Medicare Personal Plan Finder updated to Medicare Plan Finder, and PBP software screenshots updated.
Minor	OIG03	OIG Compliance Program Guidance for Medical Device Manufacturers – Field Force	Life Science	Medical Device – Sales & Marketing	2.1	Clarification of distinction between kickbacks and illegal remuneration, inclusion of TRICARE, course format change to EduFlex, grammatical changes.