



# Life Sciences and Safety 2019 Course Updates

## December 2019 Course Updates

Update Type	Course Code	Course Title	Industry	Course Library	Version	Update Details
New	PS5-102771	Ammonia Awareness	0	0	1.0	Take this course to learn how to safely identify, store and handle ammonia. You will also learn what to do in the event of an ammonia exposure or leak.
New	PS5-102862	Hearing Conservation (Canadian French)	0	0	1.0	Dans ce cours, vous en apprendrez davantage sur les risques liés à l'exposition au bruit en milieu professionnel ainsi que sur les mesures à prendre pour la protection de votre audition.
New	PS5-30109	Welding, Cutting and Brazing for Construction, Parts 1-3	0	0	1.0	Welding, cutting and brazing can be dangerous to your health and safety, but there are steps you can take to work safely. Take these courses to learn about health and safety considerations for various welding, cutting and brazing methods.
Major	EHS09	Bloodborne Pathogens — Healthcare Workers	EHS	Healthcare: General (LS) Medical Device – Sales & Marketing (LS) Pharmaceutical – Sales & Marketing (LS)	4.0	Hepatitis C section was revised to include more recent treatment regimen to the virus.
Major	EHS37	Hazard Communication	EHS	N/A	7.0	Updated images to match current use chemical container labels.
Major	GCP26	Administrative Roles of the Clinical Research Associate	Pharmaceutical Medical Device	Clinical: Medical Device (LS) Clinical: Pharmaceutical (LS)	2.0	Update regulation information, simplified text, and update websites. Integrated Addendum to ICH E6(R1): Guidance for Industry.....//Clarification of various clinical research roles in the clinical trial study center. Update monitoring roles and responsibilities.
Major	GHC02	HP: Compliance Program General Session	Health Plans	Healthcare: General (LS)	5.0	Final Rule Updates – CMS-4182-F

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Major	MA27	Administration and Management	Health Plans	Medicare Advantage (LS)	6.0	Updated FDR training requirements and associated test questions based on Final Rule changes
Major	MA34	Medicare Advantage: Provider Compliance	Health Plans	Medicare Advantage (LS)	7.0	Final Rule Updates – CMS-4182-F
Major	MAPD01	Medicare Health Plan and PDP: Fraud, Waste, and Abuse	Health Plans	Medicare Advantage (LS) Medicare Part D (LS)	6.0	Final Rule Updates – CMS-4182-F
Major	MSALES02	Medicare Plan: Broker and Agent Training — Medicare Basics	Health Plans	Medicare Broker/Agent Training (LS)	9.0	Update agent/broker training modules to meet 2020 requirements.
Major	MSALES03	Cost Plan Enrollment and Disenrollment	Health Plans	Medicare Broker/Agent Training (LS)	6.0	Update agent/broker training modules to meet 2020 requirements
Major	MSALES04	Medicare Plan: Broker and Agent Training — Beneficiary Protections	Health Plans	Medicare Broker/Agent Training (LS)	8.0	Update agent/broker training modules to meet 2020 requirements
Major	MSALES05	Medicare Plan: Broker and Agent Training — Marketing Communication and Compensation	Health Plans	Medicare Broker/Agent Training (LS)	7.0	Update agent/broker training modules to meet 2020 requirements
Minor	EHS63	Managing Job Stress	EHS	N/A	2.2	0
Minor	GCP04	GCP/ICH Obligations of Sponsors and Monitors	Pharmaceutical	Clinical: Medical Device (LS) Clinical: Pharmaceutical (LS)	3.1	Update references and review based on Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC

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						and 93/42/EEC and ISO 14155:2011 Clinical investigation of medical devices for human subjects — Good clinical practice, February 2011. Review based on Medical Device mfr and EU perspective.
Minor	MSALES01	Medicare Plan: Broker and Agent Training — Broker/Agent Requirements	Health Plans	Medical Device GMPs (LS)	6.1	Update agent/broker training modules to meet 2020 requirements
Minor	PHA68	Operating Room Conduct and Protocol	Medical Device	Medical Device – Sales & Marketing (LS)	1.2	Revised edition approved by AORN for continuing education credit. Updated terminology, and wording where necessary. No major content changes.
Minor	PHDV74	Handling an FDA Inspection	Medical Device Pharmaceutical	FDA Inspections and Enforcement (LS)	3.2	Modernized content and bring course into more consistent design aspect. No major content changes.
Minor	PS5-102015	Confined Space Awareness for Construction (US)	0	0	1.0	Post test updates
Minor	PS5-00867	Crane Operator Safety	0	0	1.0	SME review
Minor	PS5-100516	Fall Protection	0	0	1.0	Text, audio, test updates
Minor	PS5-102575	HAZWOPER Refresher Training – Module 2 – Environmental Issues for HAZWOPER (US)	0	0	1.0	Image and functionality updates
Minor	PS5-102266	Introduction to OSHA (US)	0	0	1.0	Update text, VO, functionality, images. SME Review
Minor	PS5-100555	Lab Safety	0	0	1.0	SME review
Minor	PS5-100812	Materials Handling and Storage	0	0	1.0	SME review
Minor	PS5-01345	Stormwater and Erosion Control for Construction	0	0	1.0	SME review and remove Awareness

Update Type	Course Code	Course Title	Industry	Course Library	Version	Update Details
Minor	PS5-102736	Walking/Working Surfaces (Canadian French)	0	0	1.0	Image update
Minor	PS5-101730	Walking/Working Surfaces (Chinese)	0	0	1.0	Image/test update
Minor	PS5-101724	Walking/Working Surfaces (Czech)	0	0	1.0	Image update
Minor	PS5-101725	Walking/Working Surfaces (Dutch)	0	0	1.0	Image update
Minor	PS5-101726	Walking/Working Surfaces (German)	0	0	1.0	Image/test update
Minor	PS5-101727	Walking/Working Surfaces (Japanese)	0	0	1.0	Image/test update
Minor	PS5-101728	Walking/Working Surfaces (Polish)	0	0	1.0	Image/test update
Minor	PS5-101729	Walking/Working Surfaces (Portuguese)	0	0	1.0	Image/test update
Minor	PS5-102240	Walking/Working Surfaces (Spanish)	0	0	1.0	Image update
Minor	PS5-101731	Walking/Working Surfaces (Thai)	0	0	1.0	Image update
Retiring	PS5-00671	Ammonia Awareness (US)	0	0	1.0	Replaced by PS5-102771 Ammonia Awareness
Retiring	PS5-01429	Lab Safety (US)	0	0	1.0	Replaced by PPS5-100555 Lab Safety
Retiring	PS5-102390	Ladder Safety for Construction (US) (Spanish)	0	0	1.0	Replaced by PS5-30103 Ladder Safety for Construction, Parts 1-2 (Spanish)
Retiring	PS5-01028	Welding, Cutting and Brazing for Construction	0	0	1.0	Replaced by PS5-30109 Welding, Cutting and Brazing for Construction, Parts 1-3

**November 2019 Course Updates**

<b>Update Type</b>	<b>Course Code</b>	<b>Course Title</b>	<b>Industry</b>	<b>Course Library</b>	<b>Version</b>	<b>Update Details</b>
Major	GCP05	HIPAA — The Impact on Clinical Research	Pharmaceutical & Medical Device	Clinical: Medical Device & Clinical: Pharmaceutical	4.0	Updated past tense of GDPR terminology to reflect current terminology. Questions updated to better match content.
Major	GHC06	Introduction to Specialty Pharmacy Management	Healthcare: Specialty Pharmacy	Healthcare: General	3.0	Updated to include updated definitions, updated Classification Criteria, updated references and tables, and updated all questions to match. Added Specialty Tier information.
Major	GCP21	Clinical Trial Audits and Consequences of Noncompliance	Pharmaceutical & Medical Device	Clinical: Medical Device & Clinical: Pharmaceutical	4.0	Updates related to FDA Guidance: Clinical Investigator Regulatory Sanctions – Information Sheet, and BIMO Compliance Program Guidance Manual 7348.811. Clarified references to Form FDA 483. Added reference to Debarment List. Additional formatting throughout course.
Minor	PHA38	Introduction to cGMPs	Pharmaceutical	Medical Device GMPs & Pharmaceutical GMPs	3.2	Course underwent a Graphic refresh. No content changes were made.
Minor	PHDV61	GxPs	Medical Device & Pharmaceutical	Clinical: Medical Device & Clinical: Pharmaceutical GMPs	1.5	Updated labeling of GXP/Life cycle development graphics. Minor wording updates for clarification purposes.
Minor	ETHICS14	Global Anti-Bribery	All Industries	Ethics & Corporate Responsibility	1.2	Updated to reflect recent legislation in various countries. Add information relating to the most recent Corruptions Perceptions index information..
Minor	PHDV71	Principles of Aseptic Processing	Medical Device & Pharmaceutical	Pharmaceutical GMPs	6.1	Added content based on current cGMPs and EU Annex 1 revisions
Minor	PHA73	Tools and Techniques for Effective CAPA Systems	Pharmaceutical	Pharmaceutical GMPs	1.2	Removed older ASQ references, updated definitions, added information pertaining to non-conformance to better match CAPA data sources. And CAPA tools. References updated.
Minor	DEV60	An Introduction to ISO 9001:2015 — The Quality Management System Requirements	Medical Device	Medical Device GMPs	1.1	Updated information to reflect current year 2019. Content edited for clarity. Links and references verified.

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Minor	ICHreg06	Quality Systems Approach	Pharmaceutical	Global Regulatory	3.1	Updated references to match current FDA guidance and links updated to match current FDA web addresses

**October 2019 Course Updates**

Update Type	Course Code	Course Title	Industry	Course Library	Version	Update Details
New	DP03	California Consumer Protection Act	0	0	1.0	This course describes the general requirements of the California Consumer Privacy Act (CCPA) of 2018.
New	MDSAP07	Chapter 7 Process – Purchasing	0	0	1.0	This Course verifies that the manufacturer's processes ensure that products are in conformance with specified purchase requirements.
New	MDSAP_Canada	Health Canada – MDSAP Country-Specific Tasks	0	0	1.0	This course describes the Health Canada country-specific tasks for the Medical Device Single Audit Program (MDSAP).
Major	EHS23	Electrical Safety	n/a	n/a	3.0	Updated Equipment section to include AFCIs and TRRs.
Minor	MAPD03	MAPD/PDP: Communications and Marketing	Health Plans	Health Plans	12.1	Course has been updated to include changes to the MCMG on 8/6/19.
Major	GHC04	Fraud and Abuse Awareness	Health Plans	Health Plans	5.0	Updated to clarify the FDRs are not required to complete FWA training.
Major	FDA57	Part 11: Electronic Records and Signatures – Enforcement Policy	“Pharmaceutical Medical Device”	“Pharmaceutical Medical Device”	4.0	Updated to recognize that the guidance document was issued in 2003. Added examples of FDA Warning Letters.
Major	GCP11	Overview of the Clinical Research Process	“Pharmaceutical Medical Device”	“Pharmaceutical Medical Device”	4.0	Course updated to include clarifications to Post Marketing – Phase 4, revised text of phase 3 clinical trials.
Major	PARTD01	Medicare Part D: Administration and Management	Health Plans	Health Plans	5.0	Course updated to include most recent Final Rule update – CMS-4182-F.
Minor	ETHICS19	Discrimination and Harassment Free Workplace	All Industries	All Industries	1.2	Course updated to include references to sexual orientation, stereotyping, available remedies, and investigation.
Minor	PARTD05	Medicare Part D: PDP Enrollment	Health Plans	Health Plans	12.1	Updated verbiage, revised SEPs for clarity, revised questions.

**September 2019 Course Updates**

<b>Update Type</b>	<b>Course Code</b>	<b>Course Title</b>	<b>Industry</b>	<b>Course Library</b>	<b>Version</b>	<b>Update Details</b>
New	ETHICS25	Work Secure: Security Measures for Employees	All Industries	Ethics and Corporate Responsibility	1.0	This course offers all employees ways to ensure they are helping to protect against theft, sabotage, or harm to themselves, their fellow employees, and their company.
Major	GCP15	Drug Safety & Adverse Event Reporting	Pharmaceutical	Clinical: Pharmaceutical	6.0	This course was updated to cover regulatory changes to Directive 2010/84/EU of the European Parliament and of the Council of 15 December 2010 and Directive 2001/83/EC on the Community code relating to medicinal products for human use.
Major	MDSM04	MedTech Europe Code of Ethical Business Practice	Medical Device	Medical Device – Sales & Marketing	4.0	This course was updated to reflect updates to the MedTech Code encompassing consolidation of the EucoMed and EDMA codes and guidelines regarding implementation periods.
Major	PHDV93	Combination Products – cGMP	Medical Device Pharmaceutical	Medical Device GMPs Pharmaceutical GMPs	2.0	This course was updated to include new versions of FDA Guidance documents and new Guidance documents relating to Combination Products.
Minor	LAV24	Sexual Harassment Awareness for California Employees	All California Industries	Ethics & Corporate Responsibility HR Compliance & Risk Management	1.1	Content added to further satisfy all CA requirements. Narration delay removed.
Minor	EHS41	Uniform Hazardous Waste Manifest Completion	EHS	EHS for Life Science	2.2	Course references updated.
Minor	EHS51	Environmental Management Systems	EHS	EHS for Life Science	2.1	Course references updated.
Revision	LAV22	Harassment Avoidance Training for California	All California Industries	Ethics & Corporate Responsibility HR Compliance & Risk Management		Course adjusted to correct delays in narration and the flow of the course.
Retired	CWIRE_AC E_01	ComplianceWire Administrator Certification Exam — Basic	N/A	N/A	N/A	This course is being retired because of FLASH incompatibilities. No replacement has been designated due to low usage.



Update Type	Course Code	Course Title	Industry	Course Library	Version	Update Details
Retired	CWIRE_ACE_02	ComplianceWire Administrator Certification Exam – Advanced	N/A	N/A	N/A	This course is being retired because of FLASH incompatibilities. No replacement has been designated due to low usage.
Retired	CWIRE_Adv_ACE	ComplianceWire Advanced Administrator Certification	N/A	N/A	N/A	This course is being retired because of FLASH incompatibilities. No replacement has been designated due to low usage.
Retired	CWIRE_Base_ACE	ComplianceWire Basic Administrator Certification	N/A	N/A	N/A	This course is being retired because of FLASH incompatibilities. No replacement has been designated due to low usage.
Retired	EHS36	Glutaraldehyde	N/A	N/A	N/A	This course is being retired because of FLASH incompatibilities. No replacement has been designated due to low usage.
Retired	EHS81	Quality Management Refresher	N/A	N/A	N/A	This course is being retired because of FLASH incompatibilities. No replacement has been designated due to low usage.
Retired	FDA47	Photography for FDA Enforcement	N/A	N/A	N/A	This course is being retired because of FLASH incompatibilities. No replacement has been designated due to low usage.
Retired	LAVP01	Sexual Harassment Policy	N/A	N/A	N/A	This course is being retired because of FLASH incompatibilities. No replacement has been designated due to low usage.
Retired	MDSM06	Ethical Third Party Sales and Marketing Intermediary (“SMI”) Relationships	N/A	N/A	N/A	This course is being retired because of FLASH incompatibilities. No replacement has been designated due to low usage.
Retired	MSales06	Broker and Agent Training Exam	N/A	N/A	N/A	This course is being retired because of FLASH incompatibilities. No replacement has been designated due to low usage.
Retired	PHDV90	A Tour of Health Europe	N/A	N/A	N/A	This course is being retired because of FLASH incompatibilities. No replacement has been designated due to low usage.

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Retired	PHDV97	Introduction to CFDA and CFDA Registration	N/A	N/A	N/A	This course is being retired because of FLASH incompatibilities. No replacement has been designated due to low usage.
Retired	SECURE06	WorkSecure: Security Measures for Employees	N/A	N/A	N/A	This course is being retired and replaced with Ethics25. Contact Client Services for information regarding replacement or equivalency settings.

**August 2019 Course Updates**

Update Type	Course Code	Course Title	Industry	Course Library	Version	Update Details
New	MDSAP_Australia	Australia Therapeutic Goods Administration (TGA) MDSAP Specific	Medical Device	Medical Device GMPs, Global Regulatory	1.0	This course covers Australia's Therapeutic Goods Administration (TGA) requirements specific to all seven chapters in the Medical Device Single Audit Program (MDSAP).
New	MDSAP_Brazil	Brazil Therapeutic Goods Administration (TGA) MDSAP Specific	Medical Device	Medical Device GMPs, Global Regulatory	1.0	This course covers Brazil's Agência Nacional de Vigilância Sanitária (ANVISA) requirements specific to all seven chapters in the Medical Device Single Audit Program (MDSAP).
New	MDSAP_Japan	Japan Therapeutic Goods Administration (TGA) MDSAP Specific	Medical Device	Medical Device GMPs, Global Regulatory	1.0	This course covers Japan's Ministry of Health, Labour and Welfare (MHLW) requirements specific to all seven chapters in the Medical Device Single Audit Program (MDSAP).
New	MDSAP05	MDSAP Chapter 5: Process: Design and Development.	Medical Device	Medical Device GMPs, Global Regulatory	1.0	This course covers Chapter 5 of the Medical Device Single Audit Program (MDSAP) — Process: Design and Development.
New	MDSAP06_01	MDSAP Chapter 6: Process – Production and Service Controls – Part 1	Health Plans	PPACA	1.0	This course covers the first 15 tasks of Chapter 6 of the Medical Device Single Audit Program (MDSAP) — Production and Service Controls.
Major	EHS50	Infection Prevention and Control	EHS	EHS for Life Science – Basics	2.0	References have been added to the course.
Major	FDA42	Import Operations 2: The Process	"Pharmaceutical Medical Device Food and Beverage"	FDA Inspections and Enforcement	3.0	Content updated for clarity and additional resource references have been added.
Minor	EHS25	EPA Inspections	EHS	EHS		Course visuals have been refreshed. Content edited for formatting, spelling, and grammar.
Minor	ETHICS13	Detecting and Preventing Fraud	All Industries	Ethics & Corporate Responsibility	1.1	Course Visuals have been refreshed. Content edited for formatting, spelling, and grammar.

Update Type	Course Code	Course Title	Industry	Course Library	Version	Update Details
Minor	ETHICS16	Foreign Corrupt Practices Act (FCPA)	All Industries	Ethics & Corporate Responsibility		Course visuals have been refreshed. Content edited for formatting, spelling, and grammar.
Minor	FDA31	Part 11: Electronic Records; Electronic Signatures	Pharmaceutical, Medical Device	FDA Inspections and Enforcement, Pharmaceutical GMPs	4.2	Updated the section on bio-metric signatures to include other forms of bio-metric recognition beyond fingerprints such as facial recognition and retinal scanning technologies.
Minor	GCP23	Investigational Product Development	Pharmaceutical, Medical Device	Clinical: Pharmaceutical	1.5	Updated information relating to Medical Device trials and classifications, updated the MDUFMA reference. Content edited for formatting, spelling, and grammar.
Minor	GCP25	Laboratory Specimens for Clinical Research	Pharmaceutical, Medical Device	Clinical: Medical Device, Clinical: Pharmaceutical	1.4	Updated lab requirements related to 21 CFR -211. Added details on CLIA for IVDs and added references to FDA Guidance for Industry: Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Applications for Manufacturers of In Vitro Diagnostic Devices.
Minor	PARTD08	Medicare Part D: Medication Therapy Management and Quality Improvement Program	Health Plans	Medicare Part D	9.1	Updated information on Over-utilization Monitoring specifics, Formulary Changes, and updated references. Content edited for formatting, spelling, and grammar.

**July 2019 Course Updates**

<b>Update Type</b>	<b>Course Code</b>	<b>Course Title</b>	<b>Industry</b>	<b>Course Library</b>	<b>Version</b>	<b>Update Details</b>
New	MDSAP06_01	MDSAP Chapter 6: Process – Production and Service Controls – Part 1	Health Plans	PPACA	1.0	This course covers the first 15 tasks of Chapter 6 of the Medical Device Single Audit Program (MDSAP) — Production and Service Controls.
New	MDSAP06_02	MDSAP Chapter 6: Process – Production and Service Controls – Part 2	Health Plans	PPACA	1.0	This course covers Tasks 16–29 of Chapter 6 of the Medical Device Single Audit Program (MDSAP) — Production and Service Controls.
Major	PHSM05	Promotion of Pharmaceutical Products – Field Facing	Pharmaceutical	Pharmaceutical – Sales & Marketing	3.0	Update of course content.
Major	EHS75	Process Safety Management: Operating Procedures	EHS	Process Safety Management	2.0	Update of course content.
Major	FDA43	Import Operations 3: Other Activities	Pharmaceutical, Medical Device, Food and Beverage	FDA Inspections and Enforcement	8.0	Changed OASIS system name and description to PREDICT. Edited script for clarity.
Major	GCP04	GCP/ICH Obligations of Sponsors and Monitors	Pharmaceutical	Clinical: Medical Device, Clinical: Pharmaceutical	3.0	Update of course content.
Major	MA40	Medicare Advantage: Provider Networks	Health Plans	Medicare Advantage	8.0	Update of course content.
Major	MA41	MA Quality Management and Utilization Management	Health Plans	Medicare Advantage	8.0	Update to include all needed changes in the QI/CCIP requirements effective January 1, 2019.
Major	PARTD01	Medicare Part D: Administration and Management	Health Plans	Medicare Part D	4.0	Update of course content.
Minor	EHS79	Process Safety Management:	EHS	Environmental Health and Safety	1.2	Update of course content.

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		Process Safety Information				
Minor	GCP16	European Union Clinical Trial Regulation	Pharmaceutical, Medical Device	Clinical: Medical Device, Clinical: Pharmaceutical	4.0	Update of course content.
Minor	LAV23	Sexual Harassment Awareness for New York Employees and Supervisors	All Industries	HR Compliance & Risk Management Ethics & Corporate Responsibility	1.1	Update of course content.

**June 2019 Course Updates**

<b>Update Type</b>	<b>Course Code</b>	<b>Course Title</b>	<b>Industry</b>	<b>Course Library</b>	<b>Version</b>	<b>Update Details</b>
Major	BIMO03	Introduction to Medicaid	Medical Device, Pharmaceutical	FDA BIMO Course Series	3.0	Update to reflect current changes to regulations (2018), removed History section to reduce course time, minor grammatical edits.
Major	DATA02	Audit Computer System Validation to Ensure Data Integrity	Medical Device, Pharmaceutical	FDA BIMO Course Series	2.0	Update to include ALCOA+, Providing definition and explanation of SDLC, and updated references.
Major	MA29	Medicare Advantage: Overview of the Medicare Program	Health Plans	Medicare Advantage	5.0	Update of training material and course content.
Major	PARTD05	Medicare Part D: PDP Enrollment	Health Plans	Medicare Part D	12.0	Revised course objectives, reorganized section and added new SEPs in Chapter 3, reorganized information in Chapter 4, made minor revisions to application dates on page 26, and revised conclusion.
Major	PARTD10	Medicare Part D: Coordination of Benefits and True Out-of-Pocket Facilitation	Health Plans	Medicare Part D	8.0	Incorporate new 2019 information from section 50.2 of Part D Chapter 14 into Chapter 3, updated limits in Chapter 4 to reflect 2019 amounts.
Major	PHA77	EU Good Distribution Practices	Pharmaceutical	Pharmaceutical GMPs & Global Regulatory	3.0	Updated to current changes to regulations (2018), removed History section to reduce course time, minor grammatical edits.
Major	PPACA03	Introduction to Medicaid	Health Plans	PPACA	5.0	Update of training material and course content.
Minor	PHA74	Principles of Good Documentation	Pharmaceutical GMPs & Global Regulatory	Pharmaceutical GMPs & Global Regulatory	1.2	Update and clarification of the QC and QA roles to align with current industry practices.
Revision	PHA78	European Union GMP Requirements	Pharmaceutical GMPs & Global Regulatory	Pharmaceutical GMPs & Global Regulatory	1.0	Update of minor typographical and grammatical errors.

**May 2019 Course Updates**

<b>Update Type</b>	<b>Course Code</b>	<b>Course Title</b>	<b>Industry</b>	<b>Course Library</b>	<b>Version</b>	<b>Update Details</b>
Minor	LAV08	Sexual Harassment Awareness for Employees	General Industry	Ethics & Corporate Responsibility HR Compliance & Risk Management	2.2	Version Verification, Minor Technical Corrections
Minor	LAV09	Sexual Harassment Awareness for Managers	General Industry	Environmental Health & Safety	3.2	Included Course References, Clarified Responsibility of Investigating Complaints
New	EHS62	Managing Conflict	General Industry	Ethics & Corporate Responsibility HR Compliance & Risk Management	1.5	Conversion to EduFlex
Minor	LAV21	Sexual Harassment Awareness for Employees	General Industry	HR Compliance & Risk Management Ethics & Corporate Responsibility	1.5	Version Verification, Minor Technical Corrections



**April 2019 Course Updates**

<b>Update Type</b>	<b>Course Code</b>	<b>Course Title</b>	<b>Industry</b>	<b>Course Library</b>	<b>Version</b>	<b>Update Details</b>
<b>Minor</b>	BIMO06	BIMO: In Vivo Bioequivalence Program Part I	Life Science	FDA BIMO Course Series	2.1	Conversion to EduFlex
<b>Major</b>	EHS69	Process Gauge Radiation	General Industry	Environmental Health & Safety	3.0	Conversion to EduFlex, MSDS to SDS.
<b>Major</b>	EHS71	Process Safety Management: Contractors	General Industry	Environmental Health & Safety	2.0	Conversion to EduFlex, MSDS to SDS.
<b>Major</b>	EHS72	Process Safety Management: Incident Investigation	General Industry	Environmental Health & Safety	2.0	Conversion to EduFlex, MSDS to SDS.
<b>Major</b>	MA38	Medicare Advantage: Claims Processing	Healthcare	Medicare Advantage	7.0	Changes reflect 2019 CMS updates as set forth by Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance (Released February 2019) guidelines.
<b>Minor</b>	DEV56	Good Documentation Practices for Medical Device Manufacturers	Life Science	Medical Device GMPs, Global Regulatory	1.2	Visual Refresh.
<b>Minor</b>	DEV59	Computerized Systems in the Medical Device Industry	Life Science	FDA Inspections & Enforcement, Medical Device GMPs	3.1	Visual Refresh.

**March 2019 Course Updates**

<b>Update Type</b>	<b>Course Code</b>	<b>Course Title</b>	<b>Industry</b>	<b>Course Library</b>	<b>Version</b>	<b>Update Details</b>
<b>New</b>	ETHICS 26	Doing Business with the US Government	General Industry	Ethics & Corporate Responsibility	1.0	Replaces RH011
<b>New</b>	ETHICS 27	US Trade Controls	General Industry	Ethics & Corporate Responsibility	1.0	Replaces RH0025
<b>New</b>	ETHICS 28	Trade Secrets	General Industry	Ethics & Corporate Responsibility	1.0	Replaces RH0034
<b>Major</b>	MA41	Medicare Advantage: Quality Management and Utilization Management	Healthcare	Medicare Advantage	7.0	Changes to Final Rule, Quality Improvement Projects (QIPs) removed.
<b>Major</b>	BIMO01	Overview of FDA's Bioresearch Monitoring Program	Life Science	Clinical: Medical Device, Clinical: Pharmaceutical, FDA BIMO Course Series	4.0	Conversion to EduFlex, regulatory updates.
<b>Major</b>	MAPD03	MAPD/PDP: Communications and Marketing	Healthcare	Medicare Advantage, Medicare PART D	12.0	Regulatory updates.
<b>Major</b>	PHDV87	Environmental Control and Monitoring	Life Science	Medical Device GMPs, Pharmaceutical GMPs	5.0	Regulatory Updates: Eudralex Vol. 4 EU Guidelines for GMP Medicinal Products for Human and Veterinary Use – Annex 1.
<b>Major</b>	GCP17	The Role of the Clinical Research Associate	Life Science	Clinical: Medical Device, Clinical: Pharmaceutical	2.0	Update to include EU Clinical Trials Register (EU CTR).
<b>Major</b>	BIMO05	BIMO: Sponsor/Monitor Responsibilities	Life Science	FDA BIMO Course Series	3.0	Regulatory update: 21 CFR 312, 21 CFR 812, and 21 CFR 511.
<b>Major</b>	EHS115	DOT Hazardous Materials Training – Security Awareness	General Industry	Environmental Health and Safety	2.0	Update to reflect establishing/maintaining Security Plan – 49 CFR 172.800(b).
<b>Major</b>	GCP18	The Role of the Clinical Research Coordinator	Life Science	Clinical: Medical Device, Clinical: Pharmaceutical	4.0	Update to include EU CTR.

**February 2019 Course Updates**

Update Type	Course Code	Course Title	Industry	Course Library	Version	Update Details
Major	GCP01	GCP/ICH Obligations of Sponsors, Monitors, and Investigators	Life Science	Clinical: Medical Device, Clinical: Pharmaceutical	5.0	Regulatory changes due to ICH E6 (R2) revision published in March 2018.
Major	MDR03	CE Certification for Medical Devices	Life Science	Medical Device GMPs, Global Regulatory	3.0	Regulatory update focused on the finalization of EU MDR 2017/745.

**January 2019 Course Updates**

Update Type	Course Code	Course Title	Industry	Course Library	Version	Update Details
Minor	BIMO07	BIMO: In Vivo Bioequivalence Program Part II	Life Science	FDA BIMO Course Series	2.1	Conversion to EduFlex, grammatical changes.
Minor	ETHICS14	Global Anti-Bribery	All Industries	Ethics & Corporate Responsibility	1.1	Incorporate concepts from RH0041-UK, updated Corruptions Perception Index, and regional regulation update.
Minor	PHSM03	Contracting with and Providing Medical Education for Healthcare Professionals	Life Science	Pharmaceutical – Sales & Marketing	2.1	Grammatical and contextual updates.
Minor	PRIVACY01	HIPAA and Privacy Guidelines for Medical Device Sales Representatives	Life Science	Medical Device – Sales & Marketing	2.2	Application of HIPAA to contemporary Medical Devices, focus content on medical device sales community.