Life Sciences and Safety 2018 Course Updates

December 2018 Course Updates

Update Type	Course Code	Course Title	Industry	Course Library	Version	Update Details
Minor	DATA04	Data Integrity for Quality Control Laboratories	Life Science	Data Integrity	1.1	Inclusion of ALCOA+.
New	LAV24	Sexual Harassment Awareness for California Employees	General Industry	HR Compliance & Risk Management, Ethics & Corporate Responsibility	1.0	New title.
Major	MA34	Medicare Advantage: Provider Compliance	Healthcare	Medicare Advantage	6.0	Regulatory updates.
Major	MAPD01	Medicare Health Plan and PDP: Fraud, Waste, and Abuse	Healthcare	Medicare Advantage, Medicare Part D	5.0	Regulatory updates, beneficiary inducement limits and FWA monitoring and identification strategies updated.
Major	PHDV78	Application of cGMPs to Analytical Laboratories	Life Science	Medical Device GMPs, Pharmaceutical GMPs	5.0	Regulatory updates.
New	PHDV105	Australian Therapeutic Goods — Medical Device Regulations Overview	Life Science	Global Regulatory, Medical Device GMPs	1.0	New title.

November 2018 Course Updates

Update Type	Course Code	Course Title	Industry	Course Library	Version	Update Details
Minor	BIMO04	BIMO: Clinical Investigator (CI) Responsibilities	Life Science	FDA BIMO Course Series	2.1	Conversion to EduFlex. Regulatory updates: 21 CFR Part 812 and 21 CFR Part 511.
Minor	DATA01	Introduction to Data Integrity	Life Science	Data Integrity	2.1	Inclusion of ALCOA+.
Minor	EHS95	Overcoming Negativity in the Workplace	General Industry	Ethics & Corporate Responsibility, HR Compliance & Risk Management	2.3	Conversion to EduFlex, grammatical changes.
Minor	FDA01	Food and Drug Law: FDA Jurisdictions	Life Science	FDA Inspections & Enforcement	1.3	Conversion to EduFlex, grammatical changes.
Minor	FDA02	Food and Drug Law: Prohibited Actions	Life Science	FDA Inspections & Enforcement	1.2	Conversion to EduFlex, grammatical changes.
Minor	FDA03	Food and Drug Law: Judicial Actions	Life Science	FDA Inspections & Enforcement	1.2	Conversion to EduFlex, grammatical changes
Minor	FDA04	Food and Drug Law: Criminal Acts Violations	Life Science	FDA Inspections & Enforcement	1.2	Conversion to EduFlex, grammatical changes
Minor	FDA05	Food and Drug Law: Imports and Exports	Life Science	FDA Inspections & Enforcement	2.2	Conversion to EduFlex, grammatical changes
Major	MAPD02	MAPD: Enrollment	Healthcare	Medicare Advantage	9.0	Regulatory Updates: Medicare Managed Care Manual, Chapter 2 — Medicare Advantage Enrollment and Disenrollment.
Major	MAPD06	MAPD: Disenrollment	Healthcare	Medicare Advantage	2.0	Regulatory Updates: Medicare Managed Care Manual, Chapter 2 — Medicare Advantage Enrollment and Disenrollment.
Major	MDSM07	National Patient Safety Goals: HCIR Credentialing	Life Science	Medical Device – Sales & Marketing	2.0	Regulatory updates.
Major	OIG03	OIG Compliance Program Guidance for Medical Device Manufacturers – Field Force	Life Science	Medical Device – Sales & Marketing	3.0	Updated case studies, various regulatory changes and refreshed to current industry trends.

Update Type	Course Code	Course Title	Industry	Course Library	Version	Update Details
Major	PHSM06	Interactions with Healthcare Professionals – In-House	Life Science	Pharmaceutical – Sales & Marketing	2.0	Clarifications and enhancements to guidance regarding promotional materials and product communications; HCP training programs, other consulting engagements, and recent enforcement themes.

October 2018 Course Updates

Update Type	Course Code	Course Title	Industry	Course Library	Version	Update Details
Minor	EHS61	Making Meetings Work II: Leadership	General Industry	HR Compliance & Risk Management	1.2	Course update to EduFlex, grammatical changes.
Major	MA38	Medicare Advantage: Claims Processing	Healthcare	Medicare Advantage	6.0	Combined content from Medicare Contractor chapter into Claims Processing chapter, added notice requirements for non-contracted providers.
Major	MAPD03	MAPD/PDP: Communications and Marketing	Healthcare	Medicare Advantage, Medicare Part D	11.0	Medicare Communications and Marketing Guidelines (MCMG) updates.
Major	MDSM03	Massachusetts Pharmaceutical and Medical Device Manufacturer Conduct Regulation (Mass. Code) and Similar State-Level Requirements	Life Science	Medical Device -Sales & Marketing	3.0	Updated to reflect current regulations.
Major	MSALES01	Medicare Plan: Broker and Agent Training — Broker/Agent Requirements	Healthcare	Medicare Broker/Agent Training	6.0	Medicare Managed Care Manual Chapter 3 — Medicare Communications and Marketing Guidelines (MCMG) regulation updates.
Major	MSALES02	Medicare Plan: Broker and Agent Training – Medicare Basics	Healthcare	Medicare Broker/Agent Training	8.0	Updated 2019 Part D limits/amounts.
Major	MSALES03	Medicare Advantage and Part D Plan: Broker and Agent Training – MA-PD, PDP, and Cost Plan Enrollment and Disenrollment	Healthcare	Medicare Broker/Agent Training	5.0	Added information about the Medicare Advantage Open Enrollment Period (OEP) and requirements for the short enrollment form and telephonic enrollment.
Major	MSALES04	Medicare Plan: Broker and Agent Training – Beneficiary	Healthcare	Medicare Broker/Agent Training	7.0	Job aid additions for Part C and D Decisions and Appeals.

Update Type	Course Code	Course Title	Industry	Course Library	Version	Update Details
Major	MSALES05	Medicare Plan: Broker and Agent Training — Marketing Communication and Compensation	Healthcare	Medicare Broker/Agent Training	6.0	Course updated to reflect changes to Medicare Marketing Guidelines (now called Medicare Communication and Marketing Guidelines (MCMG)).
Major	MSALES06	Medicare Plan: Broker and Agent Training — Exam	Healthcare	Medicare Broker/Agent Training	4.0	Updated to reflect changes made in the MSALES series.
Major	PARTD05	Medicare Part D: PDP Enrollment	Healthcare	Medicare Part D	11.0	Updated to reflect 2019 requirements.
Major	PARTD11	Medicare Part D: PDP Disenrollment and Transaction Processing	Healthcare	Medicare Part D	2.0	Updated to reflect 2019 requirements.

September 2018 Course Updates

Update Type	Course Code	Course Title	Industry	Course Library	Version	Update Details
Minor	EHS06	Basics of Business Finance	General Industry	HR Compliance & Risk Management	1.2	Course update to EduFlex, grammatical changes.
Minor	EHS49	Improving Productivity	General Industry	HR Compliance & Risk Management	1.2	Course update to EduFlex, grammatical changes.
Minor	EHS60	Making Meetings Work I: Purpose and Preparation	General Industry	HR Compliance & Risk Management	1.2	Course update to EduFlex, grammatical changes.
Minor	EHS66	Personal Leadership Power	General Industry	HR Compliance & Risk Management, Ethics & Corporate Responsibility	2.3	Course update to EduFlex, grammatical changes.
Minor	LAV14	Antitrust Law and Competitor Relationships	General Industry	HR Compliance & Risk Management	1.3	Clayton Act annual limits updated.
Major	MA34	Medicare Advantage: Provider Compliance	Healthcare	Medicare Advantage	5.0	Updates pertaining to Contract Year 2019 Final Rule and Call Letter.
Major	MA38	Medicare Advantage: Claims Processing	Healthcare	Medicare Advantage	5.0	Updates pertaining to Contract Year 2019 Final Rule and Call Letter.
Major	MA41	Medicare Advantage: Quality Management and Utilization Management	Healthcare	Medicare Advantage	6.0	Updates pertaining to Contract Year 2019 Final Rule and Call Letter.
Major	PARTD03	Medicare Part D: Bid and Benefit Package	Healthcare	Medicare Part D	4.0	Updates pertaining to Contract Year 2019 Final Rule and Call Letter.
Major	PARTD07	Medicare Part D: Pharmacy Network	Healthcare	Medicare Part D	4.0	Updates pertaining to Contract Year 2019 Final Rule and Call Letter.
Major	PARTD10	Medicare Part D: Coordination of Benefits and True Out-of-Pocket Facilitation	Healthcare	Medicare Part D	7.0	Updates pertaining to Contract Year 2019 Final Rule and Call Letter.
Major	MAPD04	MAO/PDP: Compliance Program Guidelines	Healthcare	Medicare Part D	4.0	Removal of general compliance training requirement for FDR’s.

Update Type	Course Code	Course Title	Industry	Course Library	Version	Update Details
New	MAPD_MIC02	Member Issue Classification – Part C	Healthcare	Premium Content Only	1.0	New Course Offering. This course covers real-life scenarios and requires learners to apply knowledge of Medicare Advantage Organization (MAO) procedures in order to classify Part C member issues appropriately. Topics in this course include: Member Issues. After completing this course, learners will be able to identify the correct classification of member issues based on a brief summary of each situation.
New	MAPD_MIC03	Member Issue Classification – Part D	Healthcare	Premium Content Only	1.0	New Course Offering. This course covers real-life scenarios and requires learners to apply knowledge of procedures in order to classify member Part D issues appropriately. Topics in this course include: Member Issues. After completing this course, learners will be able to identify the correct classification of member issues based on a brief summary of each situation.

August 2018 Course Updates

Update Type	Course Code	Course Title	Industry	Course Library	Version	Update Details
New	DEV64	Canadian Medical Device Regulations	Life Science	Global Regulatory, Medical Device GMPs	1.0	New Course Offering. This course introduces the Canadian medical device regulations. This course identifies the scope and applicability of the Canadian Medical Devices Regulation (CMDR) that was last amended on February 13, 2017. Topics in this course include: Regulatory Agencies, Definition, Medical Device Licensing, Post Approval, and CMDR vs ISO 13485. After completing this course, learners will be able to identify the requirements to market devices in Canada.
Minor	EHS64	Managing Transitio ns to Teams	General Industry	HR Compliance & Risk Management	1.3	Course update to EduFlex, grammatical changes.
Minor	EHS94	Self-Motivation	General Industry	Ethics & Corporate Responsibility, HR Compliance & Risk Management	1.3	Course update to EduFlex, grammatical changes.
Minor	ETHICS15	Privacy and Data Protection	General Industry	Ethics & Corporate Responsibility	3.1	Inclusion of GDPR.
New	LAV23	Sexual Harassment Awareness for New York Employees and Supervisors	General Industry	HR Compliance & Risk Management, Ethics & Corporate Responsibility	1.0	New Course Offering. Sexual harassment is a serious issue facing employers. This course is designed to educate you about New York & federal laws regarding sexual harassment as well as to present information on identifying harassing behavior, avoiding harassment, and what steps to take should harassment issues arise involving the workplace. Topics in this course include: Guidelines, Confrontation, Reporting Incidents, Supervisor Responsibilities, and Rights and Remedies. Learners will be able to recognize that harassment is a personal issue and that definitions of offensive behavior may differ amongst coworkers. Learners also will be able to identify behaviors that are considered inappropriate and recognize how to avoid engaging in inappropriate behaviors.
Major	MA28	Medicare Advantage: Member Services	Healthcare	Medicare Advantage	8.0	Updates pertaining to Contract Year 2019 Final Rule and Call Letter.
Major	MA29	Medicare Advantage:	Healthcare	Medicare Advantage	4.0	Updates pertaining to Contract Year 2019 Final Rule and Call Letter.

Update Type	Course Code	Course Title	Industry	Course Library	Version	Update Details
		Overview of the Medicare Program				
Major	MAPD01	Medicare Health Plan and PDP: Fraud, Waste, and Abuse	Healthcare	Medicare Advantage, Medicare Part D	4.0	Updates pertaining to Contract Year 2019 Final Rule and Call Letter.
New	MAPD_MIC01	Member Issue ClassificationTraining	Healthcare	Premium Content Only	1.0	New Course Offering. This course provides an overview of the different types of member issues to provide Call Center, Appeals and Grievance, Utilization Management, and Pharmacy staff with guidance on how to appropriately classify the issues so that they are handled under the appropriate procedure(s). Topics in this course include: Importance, Types of Member Issues, Multiple Processes, and Copays. After completing this course, learners will be able to identify the key terms used by CMS related to inquiries, grievances, organization determinations, and appeals. Learners will be able to recognize the types of member issues that are classified in these categories. Learners will also be able to recognize how to apply this knowledge to member issues so they can be handled by the appropriate department.

July 2018 Course Updates

Update Type	Course Code	Course Title	Industry	Course Library	Version	Update Details
Major	GHC02	HP: Compliance Program General Session	Healthcare	Healthcare: General	4.0	Updates pertaining to Contract Year 2019 Final Rule and Call Letter.
Major	GHC04	Fraud and Abuse Awareness	Healthcare	Healthcare: General	4.0	Updates pertaining to Contract Year 2019 Final Rule and Call Letter.
Major	MA35	MAPD: Risk Adjustment and Data Validation	Healthcare	Medicare Advantage	4.0	Updates pertaining to Contract Year 2019 Final Rule and Call Letter.
Major	MA36	Medicare Advantage: Plan Benefit Package and Bid Pricing Tool	Healthcare	Medicare Advantage	5.0	Updates pertaining to Contract Year 2019 Final Rule and Call Letter.
Major	MAPD02	MAPD: Enrollment	Healthcare	Medicare Advantage	8.0	Updates pertaining to Contract Year 2019 Final Rule and Call Letter.
Major	MAPD03	MAPD/PDP: Communications and Marketing	Healthcare	Medicare Advantage	10.0	Updates pertaining to Contract Year 2019 Final Rule and Call Letter.
Major	MDR03	CE Certification for Medical Devices	Life Science	Medicare Device GMPs, Global Regulatory	2.0	Update to reflect final rule of EU MDR.
Major	PARTD01	Medicare Part D: Administration and Managements	Healthcare	Medicare Part D	3.0	Updates pertaining to Contract Year 2019 Final Rule and Call Letter.
Major	PARTD05	Medicare Part D: PDP Enrollment	Healthcare	Medicare Part D	10.0	Updates pertaining to Contract Year 2019 Final Rule and Call Letter.
Minor	PHDV72	Application of cGMPs to Microbiology Laboratories	Life Science	Pharmaceutical GMPs	3.0	Update for 21 CFR 211 Part 160 – calibration procedures, Data Integrity guidance, EU guidance, and cGDP for laboratories.

June 2018 Course Updates

Update Type	Course Code	Course Title	Industry	Course Library	Version	Update Details
Major	ADVAMED-MINI-02	AdvaMed Guidance: Modest Meals	Life Science	Medical Device – Sales & Marketing	2.0	Update regarding applicability to transparency requirements.
Minor	EHS63	Managing Job Stress	General Industry	HR Compliance & Risk Management	2.1	Course update to EduFlex, grammatical changes.
Minor	EHS99	SMART Goal Setting	General Industry	HR Compliance & Risk Management	1.4	Course update to EduFlex, grammatical changes.
Major	LAV03	Fair Labor Standards Act (FLSA) and Equal Pay Act (EPA)	General Industry	Ethics & Corporate Responsibility, HR Compliance & Risk Management	5.0	Rewrite refocusing on content relevant to the learner.
Major	MA27	Medicare Advantage: Administration and Management	Healthcare	Medicare Advantage	5.0	Updates pertaining to Contract Year 2019 Final Rule and Call Letter.
Major	MA34	Medicare Advantage: Provider Compliance	Healthcare	Medicare Advantage	4.0	Updates pertaining to Contract Year 2019 Final Rule and Call Letter.
Major	MA37	Medicare Advantage: Grievances, Organization Determinations, and Appeals	Healthcare	Medicare Advantage	8.0	Updates pertaining to Contract Year 2019 Final Rule and Call Letter.
Major	PARTD02	Medicare Part D: Grievances, Coverage Determinations and Appeals	Healthcare	Medicare Part D	7.0	Updates pertaining to Contract Year 2019 Final Rule for Medicare Advantage and Part D.
Major	PARTD08	Medicare Part D: Medication Therapy Management and Quality Improvement Program	Healthcare	Medicare Part D	8.0	Updates pertaining to Contract Year 2019 Final Rule.

Update Type	Course Code	Course Title	Industry	Course Library	Version	Update Details
Major	PHA63	Gowning for Sterile Manufacturing	Life Science	Medical Device GMPs, Pharmaceutical GMPs, Global Regulatory	3.0	Added additional detail on contamination control, sections for gown and glove replacements requirements and gowning qualification, and updated case studies and graphics.
Minor	QSR07	QS Regulation 7: Corrective and Preventive Action	Life Science	FDA Inspections and Enforcement, Medical Device GMPs	1.3	Updates in accordance with 21 CFR 820.

May 2018 Course Updates

Update Type	Course Code	Course Title	Industry	Course Library	Version	Update Details
New	Aseptic06	Media Fills for Aseptic Processing	Life Science	Program Only: Aseptic Processing: Advanced Series	1.0	New title in the Aseptic Processing: Advanced Series Program. Media fills allow manufacturers to evaluate if their aseptic processes are capable of reliably producing sterile products that are free from contamination and are safe and effective for patients. This course describes the process of designing and executing media fills. Topics in this course include: Purpose and Design, Study Considerations, Execution, and Monitoring and Results. After completing this course, learners will be able to recognize the purpose of a media fill. Learners will also be able to identify the elements to consider while designing a media fill.
Major	DEV43	Introduction to the Quality System Regulation (QSR)	Life Science	FDA Inspections and Enforcement, Med Device GMPs	3.0	Case Study update, regulation updates to 21 CFR Part 820.
New	DEV61	A Guide to ISO 9001:2015 — Quality Management Systems Requirements	Life Science	Med Device GMPs	1.0	New course offered in the Med Device GMPs library. This course serves as a guide to ISO 9001:2015 — the international quality management system requirements standard. This standard specifies requirements to demonstrate an organization's ability to consistently provide products and services that meet customer satisfaction and applicable statutory and regulatory requirements. Topics include: System and Process, Leadership, Planning, Support, Operation, Performance Evaluation, and Improvement. Learners will be able to recognize the specific requirements of ISO 9001:2015 and identify management's role in implementation and maintenance. Learners will also be able to recognize the requirements for quality management system Clauses 4–10 and how to ensure compliance with the standard.
New	DEV62	Introduction to the Medical Device Single Audit Program (MDSAP)	Life Science	Medical Device GMPs	1.0	New course offered in the Med Device GMPs library. This course introduces the Medical Device Single Audit Program, which conducts audits of medical device manufacturers that satisfy the relevant requirements of five regulatory authorities

Update Type	Course Code	Course Title	Industry	Course Library	Version	Update Details
						participating in the program as well as those of ISO 13485:2016. Topics in this course include: Program, Audit Types, Structure, and Nonconformity Grading and Audit Responses. After completing this course, learners will be able to recognize the structure of the MDSAP as well as grading and follow-up requirements.
New	DEV63	Brazil's Technical Regulations for Medical Devices: RDC 16/2013, 67/2009, and 23/2012	Life Science	Medical Device GMPs	1.0	New Course Offering – This course discusses Brazil's technical regulations for medical devices, including RDC 16/2013 for Good Manufacturing Practices (GMPs) of Medical Devices and In Vitro Diagnostic Devices (IVDs), RDC 67/2009 for Technovigilance Requirements for Registration Holders, and RDC 23/2012 for Field Action Requirements. Topics in this course include: Background, Elements, and Applications. After completing this course, learners will be able to identify each of these regulations and recognize the practical actions to use in the normal course of business to ensure that the regulations are adhered to.
Major	EHS42	HAZWOPER Awareness	General Industry	Environmental Health and Safety	4.0	MSDS (Material Safety Data Sheet) to SDS (Safety Data Sheet) updates.
Major	PHA46	Protection of Human Subjects in Clinical Trials	Life Science	Clinical: Pharmaceutical	4.0	Update to include ICH E6(R2).
Major	PARTD05	Medicare Part D: PDP Enrollment	Healthcare	Medicare Part D	4.0	Addition of Special Enrollment Periods (SEPs), updates to retiree drug subsidies, incomplete enrollments, and premium payments.
Major	PHDV89	A Tour of Health Canada	Life Science	Clinical: Pharmaceutical, Clinical: Medical Device	3.0	Course rewritten to reflect current regulatory needs. After a brief introduction, the course will focus on the Health Products and Food Branch (HPFB) of Health Canada, which directly affects pharmaceutical manufacturers. Topics in this course include: Purpose, Organization, HPFB, TPD, BGTD, and HPFBI. After completing this course, learners will be able to identify the major branches of Health Canada, the HPFB, and its directorates. Learners will also be able to identify the unique roles and responsibilities of the three HPFB directorates that most directly affect the pharmaceutical industry.

Update Type	Course Code	Course Title	Industry	Course Library	Version	Update Details
Major	PHDV94	Japanese Medical Device and Pharmaceutical Regulations	Life Science	Global Regulatory	2.0	Regulation updates to the Japanese medical device regulations required full rewrite of content. This course explores the scope and applicability of Japan's new Act on Medical Devices (PMD Act). Topics in this course include: History, Agencies, Approval Process, PMD vs ISO 13485, and Labeling. After completing this course, learners will be able to recognize the general structure of PMD and its requirements for the manufacture and distribution of medical devices to the Japanese market.
New	PHDV104	CFDA Order No. 25 — Good Clinical Practices for Medical Devices	Life Science	Global Regulatory	1.0	New Course Offering – China Food and Drug Administration (CFDA) Order No. 25 — Good Clinical Practice for Medical Devices was enacted to strengthen the administration, supervision, and management of clinical trials medical devices. Topics in this course include: General Provisions, Preparation Before Clinical Trials, Guarantee of Rights and Interests of Subjects, Clinical Trial Protocol, Responsibilities of Ethics Committee, Responsibilities of Sponsors, Responsibilities of Clinical Trial Institutions and Investigators, Recording and Reporting, and Management of Investigational Medical Devices. After completing this course, learners will be able to identify participating regulatory agencies. Learners will also be able to identify the rights of clinical trial subjects and the responsibilities of investigators, sponsors, the administrative department, and the ethics committee. Lastly, learners will be able to recognize the documentation and reporting requirements for clinical trials.
Major	PPACA03	Introduction to Medicaid	Healthcare	PPACA	4.0	Information added on eligibility and benefits, added chapter on enrollment, removed chapters on prescription drugs, quality improvement and dual eligibles. Also streamlined and clarified information throughout course.

April 2018 Course Updates

Update Type	Course Code	Course Title	Industry	Course Library	Version	Update Details
New	DEV60	An Introduction to ISO 9001:2015 – The Quality Management System Requirements	Life Science	Medical Device GMPs	1.0	New Course Offering – This course serves as an introduction to ISO 9001:2015 — the international quality management system requirements standard. This standard specifies requirements to demonstrate an organization's ability to consistently provide products and services which meet customer satisfaction and applicable statutory and regulatory requirements. Topics in this course include: Scope, Principles, Certification, Auditing, and Resources. After completing this course, learners will be able to identify the quality management principles and be able to recognize considerations for selecting a certification body as well as appropriate preparations for certification audits.
New	Aseptic08	Cleanroom Cleaning, Sanitization, and Disinfection	Life Science	Program Only: Aseptic Processing: Advanced Series	1.0	New title in the Aseptic Processing: Advanced Series Program. In order to achieve safe and effective products, manufacturers of sterile product must employ various contamination control methods, such as cleaning, sanitization, and disinfection in the cleanroom. Topics in this course include: Contamination, Cleaning, Sanitization and Disinfection, and Additional Considerations. After completing this course, learners will be able to recognize why cleaning and sanitization are critical to contamination control in the cleanroom. Learners will also be able to identify the differences between cleaning, sanitizing, and disinfecting. Lastly, learners will be able to recognize proper basic cleaning procedures as well as critical parameters for effective sanitization.
Minor	FDA33	Deconstruction and Reconditioning	Life Science	FDA Inspections and Enforcement	1.4	Course update to EduFlex, grammatical changes.
Minor	HIPAA09	HIPAA Privacy: Role-Based Training IV	Healthcare	HIPAA	1.2	Course update to EduFlex, grammatical changes.

Update Type	Course Code	Course Title	Industry	Course Library	Version	Update Details
Major	MA40	Medicare Advantage: Provider Networks	Healthcare	Medicare Advantage	3.0	Removed of Application Process – submission of HSD tables changed, added chapter on Network Adequacy with current HSD table guidance, and deleted chapters on monitoring tools and provider network maintenance.
Major	MSALES05	Medicare Plan: Broker and Agent Training – Marketing	Healthcare	Medicare Broker/Agent Training	5.0	Regulatory updates from Medicare Managed Care Manual, Chapter 3, Medicare Marketing.
Major	MSALES06	Medicare Plan: Broker and Agent Training – Exam	Healthcare	Medicare Broker/Agent Training	3.0	Exam rewritten due to regulatory changes in MSALES01-MSALES05.
Major	PHDV86	Testing for Bacterial Endotoxins	Life Science	Medical Device GMPs, Pharmaceutical GMPs	2.0	Inclusion of guidance material: Guidance for Industry: Pyrogen and Endotoxins Testing: Questions and Answers, June 2012; Endotoxin Testing Recommendations of Single-Use Intraocular Ophthalmic Devices, August 17, 2015; Recommendations for Microbial Vectors used for Gene Therapy, September 2016.

March 2018 Course Updates

Update Type	Course Code	Course Title	Industry	Course Library	Version	Update Details
New	DP01	General Data Protection Regulation	General Industry	Premium Content	1.0	This course covers the European Union's (EU's) General Data Protection Regulation (GDPR), a harmonized data privacy law across Europe. Topics include: General Provisions and Principles, Rights of the Data Subject, Data Processors and Controllers, and Other Considerations. Learners will also be able to recognize the general provisions of the GDPR, and identify data subject rights under the Regulation, and identify controller and processor obligations related to data privacy and security.
Minor	EHS11	Building Customer Loyalty	General Industry	HR Compliance & Risk Management	1.2	Course update to EduFlex, grammatical changes.
Major	EHS12	Flammable Liquids	General Industry	Environmental Health & Safety	5.0	Removal of combustible liquid references per OSHA regulatory updates, inclusion of OSHA's 4 categories of flammable liquids.
Major	ETHICS09	Doing the Right Thing: Anti-Bribery	General Industry	Ethics & Corporate Responsibility	3.0	Regulation changes in reference to Vietnam, South Korea, Indonesia, Thailand, and the Philippines.
Minor	FDA27	Interviewing Techniques	Life Science	FDA Inspections & Enforcement, Pharmaceutical GMPs	1.3	Course update to EduFlex, grammatical changes.
Major	MSALES01	Medicare Plan: Broker and Agent Training — Broker/Agent Requirements	Healthcare	Medicare Broker/Agent Training	3.0	Regulatory updates including Medicare Managed Care Manual Chapter 21, Prescription Drug Benefit Manual Chapter 9, and Medicare Managed Care Manual Medicare Marketing Guidelines Chapter 3.
Major	MSALES03	Medicare Advantage and Part D Plan: Broker and Agent Training – MA-PD, PDP, and Cost Plan Enrollment and Disenrollment	Healthcare	Medicare Broker/Agent Training	4.0	Nomenclature update of "Medicare Plans" to "Medicare Advantage and Part D plans", update to verification requirements, election period, and clarity for POA requirements. Inclusion of Medicare Beneficiary Identifier (MDI).
Major	MSALES04	Medicare Plan: Broker and Agent Training —	Healthcare	Medicare Broker/Agent Training	6.0	Part C and Part D appeals process updated to reflect 2018 Managed Care appeals process.

Update Type	Course Code	Course Title	Industry	Course Library	Version	Update Details
		Beneficiary Protections				
Major	PHA36	Good Clinical Practices (GCPs) for New Product Investigations	Life Science	Clinical: Medical Device, Clinical: Pharmaceutical	4.0	Update includes revisions of ICH E6(R2).
Major	PHDV68	Biotechnology: An Overview of Compliance Considerations	Life Science	Pharmaceutical GMPs	3.0	Rewrite to align to current GMP manufacturing processes.
Major	PHDV78	Application of cGMPs to Analytical Laboratories	Life Science	Medical Device GMPs, Pharmaceutical GMPs	4.0	Inclusion of Aseptic Technique and data requirements.
Major	QSR01	QS Regulation 1: Overview and General Provisions	Life Science	FDA Inspections & Enforcement, Medical Device GMPs	3.0	Update to reflect revised sections of 21 CFR Part 821 & 820, additional case studies and content related to the FD&C Act/Preamble of the QS Regulations.
Minor	QSR04	QS Regulation 4: Document and Purchasing Controls	Life Science	FDA Inspections & Enforcement, Medical Device GMPs	1.4	Case study updates, charts related to FDA 483s, and clarifications related to 21 CFR Part 821.
Major	QSR06	QS Regulation 6: Acceptance Activities; Nonconforming Product	Life Science	FDA Inspections & Enforcement, Medical Device GMPs	2.0	Regulation and definition updates per 21 CFR Part 812 & 820, and the FD&C Act. Additional case studies added.
Minor	QSR10	QS Regulation 10: Servicing; Statistical Techniques	Life Science	FDA Inspections & Enforcement, Medical Device GMPs	1.3	Updates to case studied, definition and test question refinements.
Minor	QSR11	QS Regulation 11: Application and Inspection of QS Regulation Requirements	Life Science	FDA Inspections & Enforcement, Medical Device GMPs	1.4	Regulation and definition updates per 21 CFR Part 820, addition of charts outline FDA Inspectional Data Findings.

February 2018 Course Updates

Update Type	Course Code	Course Title	Industry	Course Library	Version	Update Details
New	ASEPTIC05	RABS for Aseptic Processing	Life Science	Program Only – Aseptic Processing: Advanced Series	1.0	New title in the Aseptic Processing: Advanced Series Program. Users will be able to identify the key benefits of RABS for aseptic processing, recognize the major process steps for aseptic processing using RABS technology and recognize the importance of proper glove use and aseptic technique in a RABS environment. Users will also be able to identify methods for material transfer with a RABS unit and recognize the environmental monitoring techniques applicable to RABS.
Major	ETHICS15	Privacy and Data Protection	General Industry	Ethics & Corporate Responsibility	3.0	Removal of Safe Harbor, inclusion of EU Privacy Shield provisions and options for compliance.
Minor	FDA26	FDA Establishment Inspection Report Writing	Life Science	FDA Inspections and Enforcement	6.1	Course update to EduFlex, grammatical updates.
Minor	PARTD02	Medicare Part D: Grievances, Coverage Determinations and Appeals	Healthcare	Medicare Part D	6.1	Added generic substitution to formulary management controls, tier exceptions to exception requests, requirements of an investigation of grievance issues and notice requirements, updatedrecord keeping requirements, AIC limits updated, and AOR representative language.
Minor	PARTD05	Medicare Part D: PDP Enrollment	Healthcare	Medicare Part D	8.1	Original course split into two offerings, PARTD05 (Enrollment) and PARTD11 (Disenrollment). Content updates include Chapter 3, Section 40.4.1, Enrollment Form requirements, and Chapter 3, Section 10 and Appendix 3 on OEC application changes.
New	PARTD11	Medicare Part D: PDP Disenrollment and Transaction Processing	Healthcare	Medicare Part D	1.0	Content split from PARTD05. Please couple training of PARTD05 with PARTD11.
Major	QSR05	QS Regulation 5: Identification and Traceability; Production and Process Controls	Life Science	FDA Inspections & Enforcement, Medical Device GMPs	2.0	Case Study updates, FDA 483s regulation updates per 21 CFR Part 820.

January 2018 Course Updates

Update Type	Course Code	Course Title	Industry	Course Library	Version	Update Details
Minor	ETHICS18	Preventing Sexual Harassment	General Industry	Ethics & Corporate Responsibility	1.1	Addition of workplace bullying.
Minor	ETHICS19	Discrimination and Harassment Free Workplace	General Industry	Ethics & Corporate Responsibility	1.1	Addition of workplace bullying.
Minor	FDA46	Courtroom Testimony	Life Science	FDA Inspections and Enforcement	1.3	Course format change to EduFlex, grammatical changes.
Minor	HIPAA06	HIPAA Privacy: Role-Based Training I (Incidental PHI Contact)	Healthcare	HIPAA	1.1	Course format upgrade to EduFlex.
Minor	HIPAA07	HIPAA Privacy: Role-based Training II (Internal Uses of PHI)	Healthcare	HIPAA	1.1	Course format upgrade to EduFlex.
Minor	HIPAA08	HIPAA Privacy: Role-Based Training III (Uses and Disclosures of PHI)	Healthcare	HIPAA	1.1	Course format upgrade to EduFlex.
Minor	LAV08	Sexual Harassment Awareness for Employees	General Industry	Ethics & Corporate Responsibility, HR Compliance & Risk Management	2.1	Addition of workplace bullying.
Minor	LAV09	Sexual Harassment Awareness for Managers	General Industry	Ethics & Corporate Responsibility, HR Compliance & Risk Management	3.1	Addition of workplace bullying.
Minor	LAV21	Harassment in the Workplace	General Industry	Ethics & Corporate Responsibility, HR Compliance & Risk Management	1.4	Addition of workplace bullying.
Major	MSALES02	Medicare Plan: Broker and Agent Training — Medicare Basics	Healthcare	Medicare Broker/Agent Training	7.0	Course format change to EduFlex, adding info on CFR, Title 45 on Lawfully Present Regulation, changes in benefit summary requirements, and call center requirements.