Center for Communication Compliance™

Module	Description	Duration/Format	Cost
NEW TO HEALTHCARE AND ENTRY LEVEL			
Welcome to Healthcare	**BASICS FOR WORKING WITHIN THE REGULATED INDUSTRY OF HEALTHCARE**, including government agency oversight, role of diverse stakeholders (e.g. HCPs, payers, patients, caregivers, industry, government), importance of confidentiality (with 10-question quiz)	15-min webinar	90.00
Regulatory Approval	Overview of **REGULATORY PROCESS** by which drugs and medical devices are approved for marketing	15-min webinar	90.00
Functional Roles	Overview of **FUNCTIONAL ROLES** for ensuring compliance with regulations and brief descriptions of responsibilities for promoting drugs and medical devices	15-min webinar	90.00
Regulatory Environment	Overview of the **GOVERNMENT AGENCIES/TRADE ORGANIZATIONS** that "regulate" drug and medical device promotion: FDA; OIG; PhRMA; AMA; and ACCME.	30-min webinar	125.00
U.S. REGULATORY COMPLIANCE/PATIENT PRIVACY FUNDAMENTALS			
FDA Oversight	Comprehensive review of the **FOOD AND DRUG ADMINISTRATION**, the federal agency of the US Department of Health and Human Services with authority to regulate the promotion of prescription drugs, biologics, veterinary drugs, and restricted medical devices). Covers content do's and don'ts including comparative/superiority, charts/graphs, competitor information, "cherry-picking", disclaimers, references, market research data, quality-of-life claims, company spokespeople, accelerated drugs, REMS and boxed warning products.	30-min webinar	125.00
FDA Guidances	FDA Guidances relevant to a specific discipline (Ad Promo, Digital, Public Relations, or Promotional Med Education)	20-30 min webinar	90.00/each discipline
Ad Promo (Tactics, Scenarios)	Comprehensive review of the **DO'S AND DON'TS FOR AD/PROMO TACTICS**: covers types of drug and medical device advertising (disease state/unbranded, product/branded, reminder, institutional, recruitment), promotional labeling (booklets, brochures, direct mail, exhibit booths, file cards, monographs, publications, sales aids, videos)	Two 30-min webinars	125.00/each
Digital (Tactics, Scenarios)	Comprehensive review of the **DO'S AND DON'TS FOR DIGITAL TACTICS**: covers drug and medical device advertising, blogging, chat rooms, discussion forums, Facebook and Twitter, links, search (paid and organic) posts, videos, websites, mobile apps, YouTube	Two 30-min webinars	125.00/each
Public Relations (Tactics, Scenarios)	Comprehensive review of the **DO'S AND DON'TS FOR PUBLIC RELATIONS TACTICS**: covers drug and device promotion, including press releases, VNRs, media tours, web sites and webcasts, spokespeople, media training, sponsored content/advertorials	Two 30-min webinars	125.00/each
Promotional Med Ed (Tactics, Scenarios)	Comprehensive review of the **DO'S AND DON'TS FOR PROMOTIONAL MEDICAL EDUCATION TACTICS**: covers drug and device promotion, including speaker's bureaus, presentations at scientific meetings, contractual arrangements with speakers, consultants, ad board members, publication plans, speakers' fees, slide kits, gifts to HCPs, social events, sponsorships, MOA	Two 30-min webinars	125.00/each
PhRMA Code	Comprehensive review of the **PHARMA CODE** from the **PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA** (PhRMA) which represents research-based pharmaceutical and biotechnology companies. Covers selection, use and training of promotional education speakers and hiring of HCPs as consultants; comparative claims, promotional publications, videos and visuals, meeting venues, meals, events and gifts	15-min webinar	90.00
Sunshine Act	Overview of **PHYSICIAN PAYMENTS "OPEN PAYMENTS PROGRAM" (SUNSHINE ACT),** which requires manufacturers of drugs, medical devices/ biologicals that participate in U.S. federal health care programs to report certain payments/items of value given to physicians/teaching hospitals	30-min webinar	125.00
HIPAA	Overview of **FEDERAL HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT** (HIPAA). Primary goal of the law is to make it easier for people to keep health insurance, protect confidentiality/security of healthcare information and help the healthcare industry control administrative costs (with 10-question quiz)	30-min webinar	125.00

REST OF WORLD REGULATORY COMPLIANCE			
IFPMA Code	Overview of key elements in the **CODE OF PRACTICE ISSUED BY THE INTERNATIONAL FEDERATION OF PHARMACEUTICAL MANUFACTURERS & ASSOCIATIONS** (IFPMA). Covers range of activities for drugs and biologics including regulatory oversight, definition of promotion, general guidelines for compliant content, medicines advertising, fee for services, off-label promotion, interactions with patient organizations and internal training	15-min webinar	90.00
European Comparator UK, France, Germany, Spain, Italy (multi-channel marketing)	Comprehensive review of the **SIMILARITIES AND DIFFERENCES IN REGULATORY PROMOTIONAL GUIDELINES FOR FIVE EUROPEAN COUNTRIES**: United Kingdom, Italy, Spain, France and Germany. Covers range of activities for promotion of drugs and biologics, including regulatory authorities, industry associations and codes, pre-vetting, certification, content of promotional materials, artwork, websites for HCPs and general public, sampling, gifts, meetings and hospitality, press releases, media relations, disease awareness, communications with patient organizations, reprints of scientific articles (on- and off-label), national and international meetings, compliance programs and training	Two 30-min webinars	475.00
Ad/promo, Promo Med Ed, PR in Europe (multi-channel marketing by discipline)	Comprehensive review of **COUNTRY-SPECIFIC CONSIDERATIONS in UK, Spain, France, Germany and Italy:** Covers range of activities for promotion of drugs and biologics, including regulatory authorities, industry associations and codes, pre-vetting, certification, content of promotional materials, medicines advertising, sampling, artwork, websites for HCPs and general public, gifts, meetings and hospitality, press releases, media relations, disease awareness, communications with patient organizations, reprints of scientific articles (on- and off-label), national and international meetings, compliance programs and training	Two 30-min webinars	250.00
Social Media in Europe	Overview of **EUROPEAN SOCIAL MEDIA LANDSCAPE**: covers current perspectives for drugs and biologics, including rules and guidances, adverse events, product liability, patient privacy and best practices for execution	30-min webinar	125.00
PAC RIM	Overview of **COUNTRIES IN THE ASIA PACIFIC**: do's and don'ts related to industry oversight, definition of promotion, general guidelines for compliant content, medicines advertising fees for services, off-label promotion, interactions with patient organizations and internal training	30-min webinar	125.00
COMMUNICATIONS FOCUSED ON DATA			
Drug Development Primer	Comprehensive review of **DRUG DEVELOPMENT PROCESS**, including drug's life cycle, from discovery through post-marketing studies. Addresses non-clinical and clinical phases, and provides easy-to-understand definitions for commonly used terms (with 25-question test)	45-min webinar	250.00
Scientific Exchange/Safe Harbor	Overview of key elements of **SCIENTIFIC EXCHANGE** based on several FDA guidance documents including: responding to unsolicited requests for off-label information about prescription drugs and medical devices and distributing scientific and medical publications on unapproved new uses – recommended practices. Covers range of activities including definition of scientific exchange and safe harbor, general guidelines for compliant content, responding to unsolicited questions for off-label, and distribution of scientific and medical publications on unapproved new uses	30-min webinar	125.00
Publication Planning	Overview of **PUBLICATION PLANNING.** Covers range of activities for drugs and medical devices, including SWOT and gap analyses, congress strategy and initiatives for abstracts, posters, and presentations, manuscript development, authorship guidelines, journal selection, and publication management post publication	30-min webinar	125.00
Referencing 101	Overview of **REFERENCING** promotional materials for drugs and medical devices targeting consumers and healthcare professionals**.** Covers range of activities including reference types, reference selection, reference and promotional material annotating, reference citation guidelines, and guidelines for referencing material based on audience	30-min webinar	125.00

OTHER COURSEWORK			
Compliance Basics	Overview of **COMPLIANCE BASICS**: covers Anti-Kickback, Federal/state disclosure reporting, Foreign Corrupt Practices Act (FCPA), off-label (False Claims Act), PhRMA Code of Ethics, privacy, relationships with third-party groups, responsible business communications, sales/marketing practices	30-min webinar	125.00
Compliance for a Small Business	Overview of **COMPLIANCE EXPECTATIONS FOR SMALL BUSINESSES**: covers fair labor standards, discrimination, disabilities, Small Business Act, Section 8(d), FDA and OIG anticorruption, fraud, abuse [False Claims Act and Anti-Kickback Statute), PhRMA Code, HIPAA, confidentiality	Three 30-min webinars	375.00

Answers to Basic Questions about the Regulatory Compliance University

WHO DEVELOPS THE CCC CONTENT? CCC content is developed by members of the CCC Advisory Board, which is composed of national and international experts including former government officials and healthcare compliance officers, regulatory experts, and lawyers.

WHERE IS THE CONTENT HOUSED? Coursework is accessible through the CCC website using confidential passcodes.

HOW OFTEN IS THE CONTENT IN THE COURSEWORK UPDATED? Content is updated when there are changes in the regulatory compliance environment that are material to compliant execution of promotion.

ARE THERE VOLUME DISCOUNTS FOR THE COURSEWORK? Volume discounts are based on the total dollar purchased.

CAN THE COURSES BE CUSTOMIZED? CCC eLearning programs are modular, which makes customization quick, efficient, and cost-effective. Cost is based on extent of customization.

FOR HOW LONG DOES AN AGENCY HAVE ACCESS TO THE PURCHASED COURSEWORK? An agency has access for the period of one year from the date of first onboarding.

CAN ACCESS TO A COURSE BE TRANSFERRED FROM ONE PERSON TO ANOTHER? During the contract year, unused passcodes may be transferred to a new user.

IF A COMPANY PAYS FOR THE ELEARNING, CAN PARTICIPANTS WHO LEAVE THE COMPANY ACCESS THE COURSE? The coursework contract is between CCC and the purchaser. Therefore, it would be the company's decision whether to allow continued course access.

WHAT IS THE CCC CERTIFICATE OF MASTERY AND WHY IS IT IMPORTANT? Drug and medical device companies expect their account teams to demonstrate mastery of regulatory compliance fundamentals. CCC administers Regulatory Compliance Tests (RCTs) to confirm that employees understand compliance principles *in a practical way*, and are able to *actively apply them* to the design and execution of promotional marketing campaigns. Comprehensive reports include questions most frequently missed for professional development.

WHO SHOULD I CONTACT IF I HAVE A QUESTION ON COURSEWORK OR THE CERTIFICATE OF MASTERY?

CCC president and founder, Ilyssa Levins (ilevins@CommunicationCompliance.com; 212-361-9868) or Linda Matus, CCC Chief Operating Officer (lmatus@communicationcompliance.com, 704.737.5051)

Coursework Curricula: Suggestions for Instructional Packages

When employee responsibilities include content development, tactical execution or oversight, client interface

(All modules can be purchased independently; Certificate Programs are $475/per person)

Employees responsible for US drug and medical device ADVERTISING

Ad/Promo Certificate Program Modules + Mastery Test
Regulatory Environment; FDA Oversight; FDA Guidances for Ad/Promo; Ad/Promo Tactics/Scenarios

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Employees responsible for US drug and medical device PUBLIC RELATIONS

PR Certificate Program Modules + Mastery Test
Regulatory Environment; FDA Oversight; FDA Guidances for PR; PhRMA; PR Tactics/Scenarios

Plus: Scientific Exchange, if employee is involved in communication activities where investigational data will be utilized or discussed

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Employees responsible for Pan European drug/biologics ADVERTISING AND SOCIAL MEDIA

Dual Certificate Program Modules + Mastery Test
European Comparator and European Social Media

Employees responsible for US drugs and medical device DIGITAL PROMOTION

Single Certificate Program Modules + Mastery Test
Regulatory Environment**;** FDA Oversight; FDA Guidances for Digital**;** Digital Tactics/Scenarios

Plus: HIPAA, if employee needs to understand patient privacy requirements

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Employees responsible for US drugs and medical devices PROMOTIONAL MED ED

Promo Med Ed Certificate Program: Modules + Mastery Test
Regulatory Environment; FDA Oversight; FDA Guidances for Promo Med Ed; PhRMA; Promo Med Ed Tactics/Scenarios

Plus: Open Payments/Sunshine Act, if employee is involved with physician consulting agreements and speaking expenses