IPhO and CCC Industry Regulatory Compliance eLearning Experience

SYLLABUS

Module	Description of Module	Duration/Format
FDA Intro	**OVERVIEW of 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.	~15-min webinar
FDA Oversight	Comprehensive discussion of **DO'S AND DON'TS FOR MAKING PROMOTIONAL CLAIMS**	~30-min webinar
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
Product Claims	More detailed definitions and examples of **DO'S AND DON'TS FOR PRODUCT CLAIM COMMUNICATIONS** including samples of relevant warning letters	~30-min webinar
Product Risk	Overview of **GENERAL REQUIREMENTS FOR RISK COMMUNICATION** that are important to understand when developing material for promotional use.	~15-min webinar
Scientific Exchange/Safe Harbor	Overview of **KEY ELEMENTS FOR SCIENTIFIC EXCHANGE** based on several FDA guidance documents relating to the communication of off-label information	~30-min webinar
Ad Promo Scenarios	Comprehensive review of the **DO'S AND DON'TS FOR ADVERTISIING AND PROMOTIONAL TACTICS**, including covers disease state/unbranded, product/branded, reminder, institutional, and recruitment advertising	~30-min webinar
Digital Scenarios	Comprehensive review of the **DO'S AND DON'TS FOR DIGITAL TACTICS**, including paid and user-generated content (UGC)	~30-min webinar
FDA Guidances for Ad Promo	**FDA GUIDANCES** relevant to Ad Promo	~30 min webinar
FDA Guidances for Digital	**FDA GUIDANCES** relevant to Digital	~30-min webinar