

Board Certified Medical Affairs Specialist (BCMAS)

Curriculum Overview

The Pharmaceutical Industry

Introduction to the Pharmaceutical Industry, History and Development, Publicly Traded vs. Private Companies, Global Needs Driving the Growth of the Pharma Industry, The Different Functions Within the Pharmaceutical Industry (Drug Manufacturing, Supply Chain, Regulatory Agencies, International Regulatory Bodies), Pharmaceutical Industry Organizational Structure and Organization Function, Drug Discovery: Research and Development (R&D), The Drug Development Process - Path to Drug Approval, Drug Advertising, Generic Drugs, Problem Reporting, Active Surveillance, Staying Competitive

Medical Device Industry

Introduction to the Medical Device Industry, Market Segmentation Categories, The Device Business Market, Exportation of Medical Devices, Global Market Growth Drivers, US Medical Device Industry Constraints, Medical Device Regulatory High Points, Medical Device Pathway

Diagnostics Industry

The Diagnostics Industry, Segments of In Vitro Diagnostics (IVDs), Molecular Diagnostics, Point-of-Care (POC) Diagnostics, Regulation of IVDs, Classification of IVDs

Rules Governing Interactions with Healthcare Professionals

The Importance of Interactions of Pharma Companies with Healthcare Professionals (HCPs), Rules Governing the Interactions with HCPs, Independence and Decision Making, Training and Conduct of Company Representatives, Physician Payments Sunshine Act, Impacts of Medical Affairs on the Interactions of Companies with HCPs

Health Economics Outcomes Research

Introduction to Health Economics Outcome Research (HEOR), Models of Pharmacoeconomics, Assessment of Costs and Outcomes, Conducting a Pharmacoeconomic Analysis, Health Outcome Research, Quality-of-Life Measures

Evidence-Based Medicine

What is Evidence-Based Medicine (EBM), Five Steps to Practice EBM, Study Designs, Evidence Hierarchy, Classification of Literature Resources

Clinical Trial Designs

Introduction to Clinical Trials, Importance of Clinical Trials, Clinical Trial Structural Designs, Clinical Trial Hypothetical Designs, Clinical Trial Parameters, Statistical Analysis, Diagnostics Tests, Bias and Confounding in Research

Presentation and Communication Skills

Importance of Presentation Skills, The People: Who is Your Audience, Presentation Preparation, Communication Skills, Emotional Intelligence (EI) vs Intelligence Quotient (IQ)

Regulatory Affairs

Introduction to Regulatory Affairs, Regulatory Affairs in the Medical Device Industry, Medical Device Classification, Performance Standards, Medical Device Filing Types, Regulatory Affairs in the US Pharmaceutical Industry, Regulatory Affairs in the EU and Canadian Pharmaceutical Industries

Compliance

Tiers of Compliance Regulations, First Tier Compliance Regulations and Subparts (FDA 21 CFR Parts 210 Current Good Manufacturing Practices for Manufacturing, FDA 21 CFR Parts 211 Current Good Manufacturing Practices for Finished Products, FDA 21 CFR Parts 280 Quality System Regulation for Good Manufacturing Practices), Second Tier Compliance Regulations and Subparts (FDA 21 CFR Part 50 Protection of Human Subjects, FDA 21 CFR Part 56 Institution Review Board, FDA 21 CFR Part 58 Good Laboratory Practice for Non-Clinical Laboratory Studies (GLPs)), Third Tier Compliance Regulations and Subparts (FDA 21 CFR Part 7 Enforcement Policy)

Abstract and Medical Writing

Introduction to Abstracts, Purpose of Writing an Abstract, Types of Abstracts, Effective Abstract Writing for Scientific/Research Papers, Components of the Abstract, Medical Writing in the Health Care Industry, Types of Medical Writing, General Steps in Writing Scientific Documents

Publication Practices

Introduction to Publications in Medical Affairs, Landmarks in Publications, Publications Work flow, The Scientific Platform, Working with Authors

Drug Development Process

Phases of Drug Development Process (Discovery, Pre-Clinical, Clinical), Regulatory Submission and Approval, Post-Market Research, Drug Approval Applications, Drug Life Cycle Management

Medical Information

Medical Information: Here and Now, Structure, Roles Within Medical Information, Medical Information Stakeholders, Medical Information Core Responsibilities, Scientific Review Committee, MI Key Challenges and Opportunities

Medical Science Liaisons and Field Based Medical Teams

Medical Science Liaisons: Here and Now, Introduction to Field Based Medical Teams and the Role of the MSL, Key Opinion Leaders, Geographic Coverage by MSL Teams, Roles Within an MSL Organization, Communication and Meeting Preparation, Networking and KOL Identification, Clinical Research Support, Maintaining Scientific Accuracy and Product Initiative Support, MSL Key Challenges and Opportunities

Grant and Investigator-Initiated Study Funding and Process

Grants Process, Investigator Initiated Studies (IIS), Funding Opportunities and Sources

Advisory Boards

Role of Advisory Boards, Challenges and Key Elements to the Success of Advisory Boards, Members of Advisory Boards, Value of Advisory Boards in Changing the Landscape of Medical Affairs

Phase IV/Post-Marketing Studies

Purpose of Post-Marketing Research, Advantages and Disadvantages of Post-Market Research, Types of Post-Marketing Studies, FDA-Mandated vs Non-FDA-Mandated, Roles of Medical Affairs in Post-Marketing Activities of Drugs

Risk Evaluation and Mitigation Strategies (REMS)

Introduction to REMS, Examples of the Types of Risk REMS Requirements Aim to Mitigate, Determining when a REMS is Needed, What the FDA Takes into Consideration When Identifying the Need for REMS, REMS Elements, Elements to Assure Safe Use (ETASU)

Medication Safety and Pharmacovigilance

Safety Signals, Adverse Events, Adverse Drug Reactions, FDA Pre-Market and Post-Market Safety