ACMA
Accreditation Council for Medical Affairs

BOARD CERTIFIED MEDICAL AFFAIRS SPECIALIST (BCMAS) CURRICULUM

OVERVIEW

Influence the Future of Medical Affairs, Today

The Board Certified Medical Affairs Specialist Program (BCMAS) offers an in depth perspective on the dynamic role medical affairs will play in the future of scientific exchange and data generation. This thought-provoking 100 percent online program encompasses the most comprehensive overview of the most integral concepts necessary to be successful as a medical affairs professional in the pharmaceutical and biotechnology industries. The program also includes important topics such as health economics outcomes research, regulatory affairs, clinical trial design and even presentation and communication skills.

The BCMAS program connects you to the clinical knowledge, real-world experience and leadership skills you'll need to become successful within the pharmaceutical industry's clinical & medical affairs space. The Accreditation Council for Medical Affairs (ACMA) offers this important course content using an asynchronous learning mode. We are paving the way by offering the first online graduate board certification program in medical affairs.

What Does the BCMAS Indicate?

-Improved professional stature & credibility
-Recognition as an advanced medical affairs professional
-Your commitment to continued professional development
-Qualified to lead medical affairs organizations
-Thorough understanding of Pharma industry ethics & compliance standards

Program Objectives

- Develop critical and strategic thinking that is necessary to understand how medical affairs operates and integrates with other functions such as clinical and commercial.
- Acquire knowledge of medical affairs practices that are necessary to guide in the development, implementation and evaluation of both data dissemination and presentation strategies which will enhance HCP knowledge & ultimately improve patient care.
- Develop the leadership and management skills necessary to facilitate socio-scientific and organizational change within your institution
- Enhance knowledge in both regulatory and compliance issues related to publications, clinical trials, drug development and interactions with health care providers.
- The program is an online, self paced program which includes case studies and interactive communication with subject matter experts.
- Successfully passing a final exam is required to become board certified.

Who Can Take the Course?

-The program is recommended for medical affairs professionals/MSLs and clinical development/clinical operations.

Given the shift towards specialty and rare disease (orphan) drugs, there is a growing demand for effective medical affairs professionals who can conduct meaningful scientific exchange with healthcare providers as well as carefully generate important clinical trial data.

Are you passionate about the pharmaceutical industry?

Contact us to learn more about the BCMAS program.

Course Listing & Topics

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 Outcome 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 Workflow, 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

Earn CME/CE in Association with ScientiaCME

SCIENTIACME

Eligibility Requirements

- Graduated with a PharmD, MD, DO or PhD from an accredited program
- Non doctoral-degree with relevant industry experience.

*All information provided will be verified by the ACMA

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Independent Credentialing in Medical Affairs
Be Prepared. Be Board Certified.

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NYU

Are you ready to actively shape the future of medical affairs?

Call us at 1-855-255-7137 or visit us at www.medicalaffairsspecialist.org

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