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 plays in scientific exchange and data generation. This thought-provoking entirely online program encompasses the most comprehensive overview of the integral concepts necessary to be successful as a medical affairs professional in the pharmaceutical, biotechnology, and medical device industries. The program also includes important topics such as health economics outcomes research, regulatory affairs, clinical trial design, and presentation and communication skills.

The BCMAS program connects you to the clinical knowledge, real-world experience, and leadership skills needed to be successful within the pharmaceutical industry’s clinical and medical affairs space. The Accreditation Council for Medical Affairs (ACMA) offers this important course content using an asynchronous learning method. 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.
- Acquire knowledge of medical affairs practices that are necessary to guide in the development, implementation, and evaluation of both data dissemination and presentation strategies: this will enhance HCP knowledge and 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

Who Can Take the Course?
- The program is recommended for medical affairs professionals/MSLs and clinical development/clinical operations professionals.

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 dedicated to raising the bar in Medical Affairs Professional Development?

Contact us to learn more about the BCMAS program.
Course Listing & Topics

**The Pharmaceutical Industry**

**Medical Device Industry**

**Diagnostics Industry**
The Diagnostics Industry, Segments of In Vitro Diagnostics (IVDs), Molecular Diagnostics, Point-of-Care (POC) Diagnostics, Regulation of IVDs, Classification of IVDs, Pharmacogenomics, Diagnostics and Medical Affairs

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

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

**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**

**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**

**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; Digital Technology & CRM for Medical Affairs

**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 Ensure Safe Use (ETASU)

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

**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

**Earn CME/CE in Association with ScientiaCME**

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