

ACMA

Accreditation Council for Medical Affairs

**BOARD
CERTIFIED
MEDICAL
AFFAIRS
SPECIALIST
(BCMAS)
PROGRAM**



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1 About the Accreditation Council for Medical Affairs

The Accreditation Council for Medical Affairs (ACMA) is a self-governing entity which administers the only accredited certification for the Medical Affairs function. The ACMA is a joint provider of CME/CE in conjunction with ScientiaCME accredited by the Accreditation Council for Continuing Medical Education (ACCME) and the Accreditation Council for Pharmacy Education (ACPE). The ACMA is also a member organization of the Institute for Credentialing Excellence and is accredited by the International Association for Continuing Education and Training (IACET/ ANSI) a globally recognized accrediting body (#6565093).

The council works collaboratively with other academic & industry organizations to ensure that there are adequate educational and professional development opportunities for professionals involved in the pharmaceutical industry within Medical Affairs as well as clinical & scientific students with an interest in Medical Affairs.

1.1 Mission Statement

The Mission of the ACMA is to establish, certify, and maintain the competencies of qualified medical and scientific professionals who have a focus in Medical Affairs within the pharmaceutical & biotechnology industries.

2 Board Certified Medical Affairs Specialist (BCMAS) Program Information

The Board Certified Medical Affairs Specialist (BCMAS) program is a comprehensive, 20-module, online program and is designed to foster the development of Medical Affairs professionals. ACMA Board Certification demonstrates that professionals have met rigorous standards through intensive study, self-assessment and evaluation.

Achieving the BCMAS demonstrates the highest standards of knowledge, and excellence in the medical affairs profession. It also sets the stage for continual professional development through values centered on lifelong learning.

The curriculum serves to provide intermediate level material which is meant to establish a minimum level of core competencies we believe are important for all medical affairs professionals. The curriculum focuses on 5 key areas:

- I. Life Sciences Understanding-The curriculum covers traditional pharma, medical devices, and diagnostics as well as newer areas such as artificial intelligence (AI) and blockchain technology.
- II. Regulatory & Compliance-A key focus on ethical and compliance issues relevant to any medical affairs professional.
- III. Core Technical Competencies-The program ensures a comprehensive understanding of pharmacoeconomics, clinical trial design, evidence based medicine, drug development, REMS, and pharmacovigilance.
- IV. Process-The curriculum covers important functional areas within medical affairs such as compliant publication practices, advisory board, CME, investigator sponsored research and post-marketing studies.
- V. Soft-Skills-The program covers basic presentation and communication skills essential for any effective medical affairs professional.



2.1 Program Goals

- Provide a solid foundation within various areas in Medical Affairs to increase the chance of success.
- Offer the most comprehensive certification to allow Medical Affairs professionals the opportunity to work within a variety of areas within the pharmaceutical industry.

2.2 Program Learning Outcomes

- Align the basic direction and goals of a medical affairs organization by better understanding the cross functional areas that relate to medical affairs such as regulatory affairs, clinical development, marketing, compliance and drug development.
- Understand health economics outcomes research as it relates to medical affairs.
- Review clinical trial design, evidence based medicine, and become an expert at interpreting medical literature.
- Broaden your knowledge in diagnostics and medical devices as well as better understanding publication planning and regulations.

2.3 Program Format

The BCMAS program is online and self-paced. Individuals are given access to all program materials for six months.

The program consists of twenty modules (See curriculum overview on pages 12-14). Each module contains a pre-quiz, post-quiz, learning objectives, module chapters, and a module summary. The pre and post-quizzes are meant as progress indicators. The individual is not required to achieve a certain score on the quizzes in order to sit for the final examination.*

The program also includes case studies, a question bank, and a glossary of terms.

*Pharmacists and Physicians are eligible for CME/CPE credits. To obtain CME/CPE credits, you must pass the post-quizzes with a score of at least 80%.

2.4 CME/CPE Credit

For Physicians - maximum of 5.00 AMA PRA Category 1 Credit(s)TM

This CME activity has been planned and implemented in accordance with the Essential Areas and Policies of the Accreditation Council for Continuing Medical Education through ScientiaCME. ScientiaCME is accredited by the ACCME to provide continuing medical education for physicians.



ScientiaCME designates this educational activity for a maximum of [5] AMA PRA Category 1 Credits™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

To receive AMA PRA Category 1 Credit™, the individual must receive a minimum score of 80% on the post-quiz.

For Pharmacists - maximum of 5.00 contact hour(s) (0.5 CEUs).

ScientiaCME designates the following modules within the BCMAS program for continuing education activity for a maximum of 5.00 contact hour(s) (0.5 CEUs). These modules are listed below:

- Pharmaceutical Industry Overview: 0574-9999-19-040-H04-P: 2.00 contact hours (0.2 CEUs)
- Diagnostics Industry: 0574-9999-19-041-H04-P: 1.00 contact hour (0.1 CEU)
- Health Economics Outcomes Research: 0574-9999-19-042-H04-P: 1.00 contact hour (0.1 CEU)
- Compliance: 0574-9999-19-043-H03-P: 1.00 contact hour (0.1 CEU)*

*May be used to satisfy pharmacy law CEU requirements in states that require it.

To receive CPE credits, the individual must receive a minimum score of 80% on the post-quiz.

2.5 Value of Accreditation

Demonstrating that your medical affairs organization has met independent and accredited standards of excellence communicates to both, your external and internal stakeholders that your company is committed to raising the bar in your profession. Medical affairs plays a critical role in educating healthcare providers and collaborating with academic research centers to generate valuable data to inform the most optimal use of pharmaceutical therapeutics.



2.6 Payment Options

Fee Structure

Individuals who are accepted into the program are required to pay all associated program fees. Please reference the table below (Table 1) for a specific fee breakdown.

Please visit <https://www.medicalaffairsspecialist.org/terms-and-conditions/> to read all payment and service terms and conditions.

Table 1. Total Program Cost in USD

Type	Fee
Application Fee (Non-refundable)	\$49.00
Board Certified Medical Affairs Specialist Program Fee	\$1,000.00
Credentialing Fee	\$150.00
Examination Fee	\$800.00
Total	\$1999.00

Individuals applying by online application:

Individuals applying online will be required to input payment information prior to submitting an application. Individuals who apply by using the online application will be eligible to pay in full payment type or in partial payment type.

Individuals applying by manual application (Email/Fax):

While we encourage applicants to apply using the online application, there are instances when applicants may request for a manual application by emailing info@medicalaffairsspecialist.org. Individuals who submit their application by email or fax will be required to complete and submit a payment form with the application.

Company partnerships

The ACMA partners with pharmaceutical companies to offer board certification to entire organizations. The pricing is based on a sliding scale dependent upon the number of employees the company wishes to train and certify. For more information please contact info@medicalaffairsspecialist.org



Payment Options

Applicants will be required to select between two payment types: Full payment or Partial Payment.

(1) Full payment: The individual will be charged the applicable fees (Board Certified Medical Affairs Specialist Program fee, Credentialing Fee, and Examination Fee) in full (\$1,999.00 USD).

(2) Partial payment: A partial payment type is only available for individuals who apply using the online application. An applicant who selects 'Partial Payment' will pay in three monthly installments. Upon acceptance into the program, the individual will be charged the first installment (\$700.00 USD)*. The individual will be charged for the second and third installments in the two subsequent months.

a. For individuals who are accepted into the program between the 1st and 15th of each month, the second and third payments will be charged on the 12th day of the two subsequent months

b. For individuals who are accepted into the program between the 16th and 31st of each month, the second and third payments will be charged on the 26th day of the two subsequent months

(3) A \$50.00 USD processing fee will be assessed for each partial payment transaction. **If this date falls on a weekend or holiday, the individual will be charged on the following regular business day.

Associated Fees:

(1) Proctoring Fee: The Board Examination is proctored by ProctorU. ProctorU, a third-party online proctoring service, assesses a separate fee from all individuals. For more information regarding ProctorU, please visit

https://www.proctoru.com/?gclid=EAlaIQobChMImeDGxr7f1wIVyUwNCh0ZOOQ-2EAAYASAAEgLLfD_BwE.

Program Extension Procedure and Fees:

Individuals have six months to complete the program and successfully pass the Board Examination. Individuals who require an extension beyond the six month time period may submit an extension request to info@medicalaffairsspecialist.org. The ACMA will make the final determination regarding whether or not extensions will be granted.

Please reference the table below (Table 2) for extension fee structure.

Table 2. Extension Fees in USD

Type	Fee
6 month extension	\$399.00
Premium yearly access to content (available only to BCMAS graduates)	\$799.00/year

Refunds and Cancellation Policy:

Regardless of its action on any application, the ACMA will retain a \$49.00 USD non-refundable application fee and will require candidates to pay all fees and meet eligibility criteria applicable at the time of application. Once an individual has been accepted into the program, there are no refunds.

3 Application Process

3.1 Eligibility Criteria

In order to be certified, you must:

- Hold an MD, PharmD, PhD, DO, MBBS, DNP, NP, PA, BPharm, PsyD, or other relevant degree from an accredited college, university or institution.**

OR

- Have completed at least a bachelor's degree and have 2 years of relevant professional experience(ie., pharmaceutical industry experience, clinical and/or research experience).
- Pass the certification examination

Who should enroll?

- Current medical affairs professionals (this includes: medical science liaisons, medical directors, VP Medical Affairs, Medical Information Specialists, Pharmacovigilance, HEOR professionals)



-Current professionals working in promotional or non-promotional medical education agencies which support pharmaceutical companies.

-Current professionals working within clinical research organizations (CROs).

-Those professionals working within clinical development, research & development and are transitioning to a medical affairs role.

(*Note: Each applicant will be carefully considered based on a combination of their professional, clinical and educational background.

Foreign Medical Graduates:

Foreign medical graduates may be eligible for the BCMAS program as long as they have graduated from an ECFMG accredited medical school.

3.2 International Applicants

Approximately 30% of BCMAS candidates are outside of the United States. We encourage all international applicants to consider the Board Certified Medical Affairs Specialist Program. All international physician graduates must provide evidence that the university is certified by the Educational Commission for Foreign Medical Graduates (ECFMG).

Note: **The Board will also consider professionals who do not hold doctorate level degrees but who have significant experience working within the space of Medical Affairs or significant clinical experience.



3.3 How to apply

Applications may be submitted online or via E-mail/Fax.

Online Application Procedure - TWO STEPS

1. Step One: Register
 - a. Visit https://training.medicalaffairsspecialist.org/register.html?redirectURL=package_detail.html?id=1 and create an account.
2. Step Two: Apply
 - a. Read all pages of this information packet.
 - b. Visit the BCMAS application page: https://training.medicalaffairsspecialist.org/package_detail.html?id=1
 - c. Complete the online application form and attach all required documentation(E.g. CV/resume).
 - d. Input payment information prior to submission.

Email/Fax Application Procedure - TWO STEPS

1. Step One: Request
 - a. Read all pages of this information packet.
 - b. Request for a manual application by emailing BCMAS@medicalaffairsspecialist.org
2. Step Two: Apply
 - a. Submit the program application materials by email to BCMAS@medicalaffairsspecialist.org or by fax to(201)297-7720.

3.4 Admissions Process

The applicant must submit all of the items listed on the program application, including a \$49.00 USD non-refundable application fee. The Board will review the program application materials. Applications are reviewed on a rolling or continuous bases.



4 Board Certification Exam

After reviewing the 20 preparatory modules, the individual will sit for the Board Examination. The Board Certified Medical Affairs Specialist Examination is proctored online by ProctorU (<https://www.proctoru.com/>). To take the exam, you will need access to a computer with a web camera enabled.

4.1 Scheduling

The Board Examination is taken online within the BCMAS program learning management system. The examination tab will be enabled once the individual completes all 20 modules of the course. The individual will be given detailed instructions on scheduling once the exam tab has been enabled. Unless a specified extension has been granted to an individual, the individual will be required to schedule and take the Board Examination within the six-month program access period.

The individual will create an account with ProctorU and schedule a time and date to take the exam, at least 72 hours before testing. More information on creating an account and scheduling can be found at <https://www.medicalaffairsspecialist.org/wp-content/uploads/2017/10/ProctorU-How-it-Works-TEST-TAKER.pdf>.

4.2 Format

Individuals have three hours to complete the examination. No notes or study materials of any kind are allowed in the testing area. Individuals will be required to comply with all proctor instructions, including a process to ensure that the testing area is secure.

The examination is made up of a total of 90-100 questions. The questions are broken down into four sections:

- Section 1- Multiple Choice
- Section 2- True/ False
- Section 3- Select all that apply
- Section 4- Case Study

None of the exam sections have a designated time.; therefore, the individual will be able to navigate between the different sections.

4.3 Results

Pass/Fail results will be released via email 1-3 business days following the date of testing. In the event that a candidate fails the examination, the candidate will be required to schedule for a retake of the exam. In order to protect the integrity of the BCMAS program, no exam questions or the answer key will be released to any individual or organization.



4.4 Retakes

The BCMAS Exam can be taken up to four times. There is no additional fee to retake the exam. *

In the event that a candidate fails after the fourth attempt, the candidate will then have to file an application for additional retakes. There is a waiting period of one year before retaking the exam up to four more times. The reexamination fee is \$250.00 USD.

*While the ACMA assesses no fee for retakes, the candidate will be required to pay any associated proctoring fees to ProctorU.

4.5 Certificates

Individuals who successfully pass the Board Examination will be able to download a digital copy of their official Board Certificate. They may request to have a hard copy mailed via the United States Postal Service (USPS). Board Certificates are mailed out on a quarterly basis."

5 Credentialing

Upon completion of the BCMAS program and achievement of a passing score on the Board Examination, an individual will be registered as a Board Certified Medical Affairs Specialist (BCMAS).

Registered Board Certified Medical Affairs Specialists earn the professional title designation of 'BCMAS'.

6 Maintenance of Certification

Becoming a Board Certified Medical Affairs Specialist demonstrates your professional accomplishment and growth, and validates competence, knowledge, dedication, and commitment to best practices and standards in the field of Medical Affairs. Competence includes both cognition and behaviors, and can be defined as the ongoing ability to integrate and apply the knowledge, skills, judgment, and values to excel in Medical Affairs.

After initial certification, the ACMA encourages you to continue activities essential to the maintenance of knowledge and continuing competence required for their level of practice and certification. With new technology, strategies, and research comes change. Renewal of certification assures that those holding the BCMAS credential have maintained knowledge and competence, and are up-to-date with the latest advances in the field.



The ACMA requires that all BCMAS professionals renew their certification every 5 years to maintain active status. Those who do not renew their certification, must cease using the BCMAS credential after the associated expiration date. The cost for recertification is \$500.00 USD.

There are two options for re-certification:

- (1) Achieving a passing score on the re-certification examination, based on the content outline for the BCMAS program
- OR
- (2) Earning 20 hours of continuing education credits provided by a professional development program approved by the ACMA

7 Advising Information

Prospective candidates for the Board Certified Medical Affairs Specialist program should contact the Associate Director of Medical Affairs Capabilities and Excellence, Gabriela Gomez Rendon MD MBA BCMAS, at gabriela@acmainfo.org or +1 (201) 688-2230.



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, Artificial Intelligence, Blockchain Technology

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



BCMAS at a Glance

Remain competitive in today's global marketplace by building a solid understanding of key principles in medical affairs. Build Your Brand.

BCMAS Program Overview

- Online, self-paced program.
- Earn CME/CE Credits.
- Provides the most comprehensive professional development program in medical affairs with over 20 modules.
- Contains knowledge check questions, glossary of important terms, and case studies.
- Instant chat function for live support with content related & technical questions.
- Progress check indicators track your performance.
- Contains a question bank of over 100 question to prepare for the board exam.

About the Board Exam

- Online, proctored exam (requires a web camera).
- Candidates are given 3 hours to take the exam.
- Results are provided within 1-3 business days.

Key Learning Outcomes

- Align the basic direction and goals of a medical affairs organization by better understanding the cross functional areas that relate to medical affairs such as regulatory affairs, clinical development, marketing, compliance and drug development.
- Understand health economics outcomes research as it relates to medical affairs.
- Review clinical trial design, evidence based medicine, and become an expert at interpreting medical literature.
- Broaden your knowledge in diagnostics and medical devices as well as better understanding publication planning and regulations.

Eligibility Criteria

To meet the requirements for BCMAS, you must:

- Hold an MD, PharmD, or a PhD from an accredited university
- Individuals with several years of pharmaceutical industry experience will be considered.
- *ECFMG Foreign medical graduates are eligible.
- Candidates have 6 months to complete the BCMAS program.
- Most candidates complete the program in 6-8 weeks.

Maintenance of Certification

- The BCMAS Program must be renewed every 5 years. Renewal can be done either (1) by retaking the board exam and passing OR (2) completing 20 hours of continuing education approved by the ACMA.



Program Cost

- The program cost (including a \$49.00 USD non-refundable application fee) is \$1,999.00 USD.
- The ACMA offers 2 payment options.
 - Full payment upon acceptance into the program OR
 - Installment payment plan over 3 months

