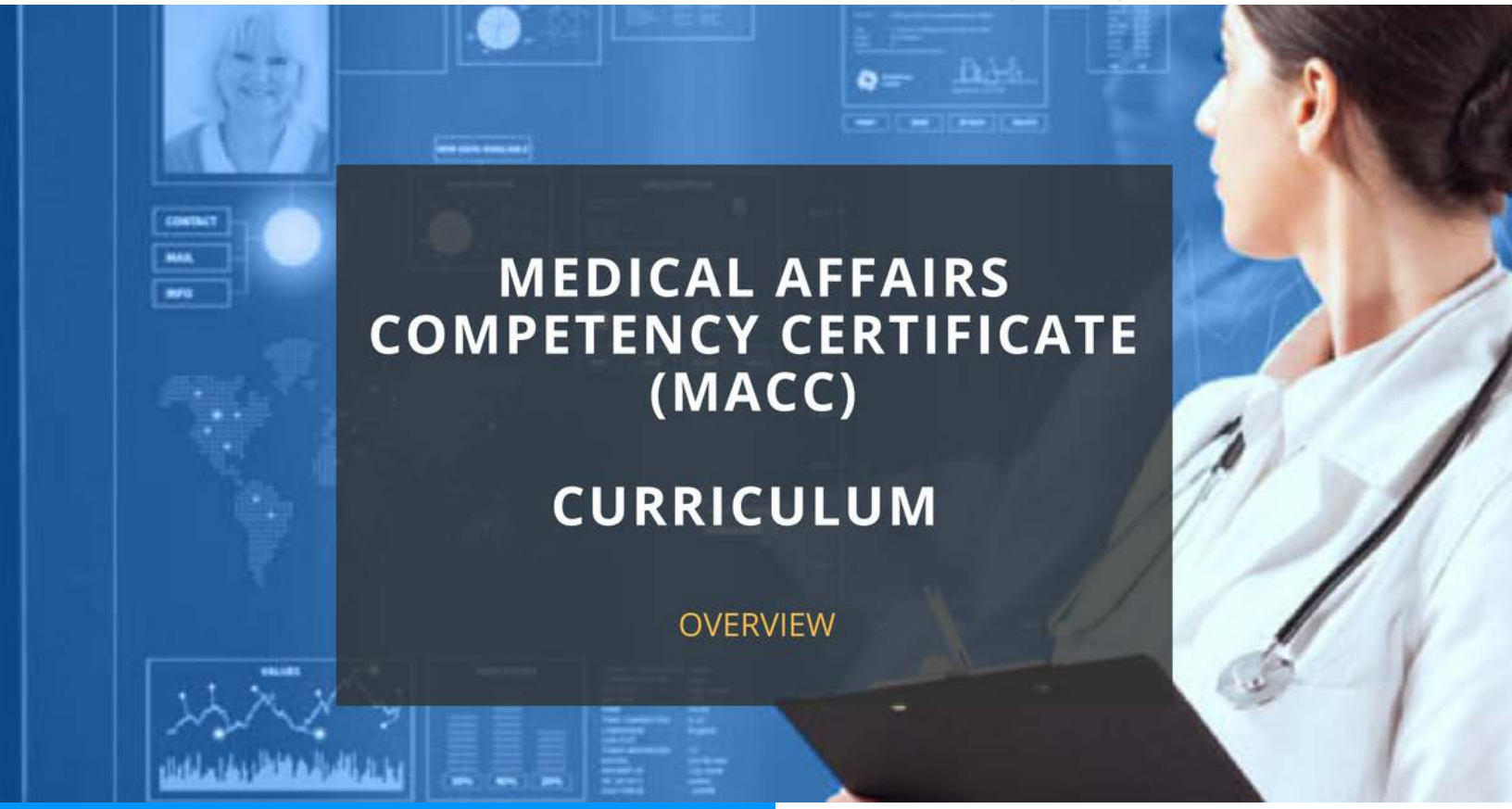
ACMA
Accreditation Council for Medical Affairs

Medical Affairs Competency Certificate (MACC) Curriculum



Influence the Future of Medical Affairs, Today

The Medical Affairs Competency Certificate (MACC) offers a competency assessment for students & professionals with an interest in the field of Medical Affairs. This online program encompasses an introduction of the most integral concepts necessary to be successful as a medical affairs professional in the pharmaceutical and biotechnology industries. The program includes important topics such as an overview of the pharmaceutical industry, regulatory affairs, compliance, and the drug development process.

The MACC introduces you to the clinical knowledge and real-world experience you will need to become familiar with the pharmaceutical industry's clinical & medical affairs space. The Accreditation Council for Medical Affairs (ACMA) in partnership with AG -The Apotheker Group is the first in the country to offer this important course content using an asynchronous learning mode.

What Does the MACC Indicate?

-Competency in medical affairs
-Your commitment to continued professional development
-Thorough understanding of Pharma industry & 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.

-Enhance knowledge in both regulatory and compliance issues related to drug development and interactions with health care providers.

-The program is an online, self paced program which includes case studies.

-There is no examination to complete the program.

Who Can Take the Course?

-Anyone with an interest in the field of Medical Affairs.

-There are no specific degree or license requirements for the program.

Cost

-Certificate Program Fee: $699

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 MACC 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

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

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)

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 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

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The Accreditation Council for Medical Affairs (ACMA) is an IACET/ANSI accredited provider

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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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