The Board Certified Medical Affairs Specialist Program

ACMA

The Future of Medical Affairs

ACMA
Accreditation Council for Medical Affairs

RAISE THE BAR

ACMA
Accreditation Council for Medical Affairs
About Us

Excellence
Establish benchmark of excellence in the industry for training & certification.

Experts
Team of subject matter experts dedicated to excellence and client success.

Accredited
US & Internationally recognized accreditation by the International Association for Continuing Education & Training.

Leadership
Trusted Circle of partners and seen as leaders within the medical affairs/MSL training sector.

Global
Learners in more than 35 countries

Transform
Our mission is to transform the healthcare ecosystem by raising the bar across the life sciences industry.

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"ACMA is the...starting point of excellence...in medical affairs"

European Medical Group, GOLD, September 2019 Issue

In the Press

"With a curriculum that includes best practices across the organization, the ACMA's aim is to reinforce an integrated approach to medical affairs that leads medical affairs to be viewed as a true partner by other departments."

PharmaVOICE - May 2019

"The ACMA is reshaping how we think about true transformation in medical affairs by elevating the field. They are the real experts.

-VP Medical Affairs, Pharma

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Exploring BCMAS

Pharmaceutical Industry

- Structure & Function
- Divisions Within Company
- Global Needs Driving Growth
- Summary of Drug Development & Approval
- Artificial Intelligence
- Blockchain Technology
- Intellectual Property
- Drug Advertising
- Supply Chain
- Generic Drugs

Medical Devices

- What is a Medical Device?
- Market Segmentation
- Positive & Negative Factors Influencing Industry
- Constraints on Medical Devices
- Regulatory Activities
- Device Classifications
- Export Challenges
- Supply Chain
- Pathway to Market
- Digital Technology & Medical Devices
- Combination Products
Diagnostics

- Segments of Diagnostic Industry
- Regulations
- Classification
- Pharmacogenomics
- Diagnostics & Medical Affairs

Regulations & Compliant Practices

- Rules Governing Interactions with Healthcare Professionals
- Regulatory Affairs
- Compliance
- Publication Practices
Rules Governing Interactions with Healthcare Professionals

- Purpose & Benefits of Interactions Between Industry and HCPs
- Different Rules Governing Interactions
- Impact of Medical Affairs on Relationship Between Industry and HCPs
- Proactive Vs. Reactive Interactions
- PHRMA Regulations
- Sunshine Act
- Prescription Drug Marketing Act

Regulatory Affairs

**Medical Devices**
- Performance Standards
- Filing Types & Definitions
- International Requirements

**Pharmaceuticals**
- FDA Review &

**Approval**
- Supplemental Applications
- Inspections & Advertising
- International Requirements
Compliance

- Quality System Related Requirements
- Protection of Human Subjects
- Institutional Review Boards
- Good Laboratory Practices
- Enforcement Policy

Publication Practices

- Goal of Publications and Scientific Communications in Medical Affairs
- Historical Overview of Publication Practices
- GPP3 Guidelines & Relevance to Medical Writers
- Publication Workflow & Approval Process
- Industry & HCPs Relationships
- Criteria for Authorship
Soft Skills

Presentation & Communication

- Constructing a Clear, Focused Presentation
  - Essentials of Successful Presentation
  - Improvisation & Active Listening

- Emotional Intelligence Vs. Intelligence Quotient
  - Impactful Communication
  - Handling Interruptions & Distractions
Core Technical Competencies

Health Economics Outcomes Research

- Models of Pharmacoeconomic Analyses
- Measuring & Assessing Costs
- Time Adjustments for Costs
- Measurement & Assessment of Outcomes
- Conducting a Pharmacoeconomic Analysis
- Health Outcomes Research
Clinical Trial Design

- Importance of Clinical Trials
- Different Types of Study Designs
- Parameters Used in Clinical Trials
- Key Statistical Concepts
- Sources of and Reducing Bias & Confounding Variables in Clinical Trials
- Difference Between Superiority, Equivalence, & Inferiority
- Specificity Vs. Sensitivity
- Relative Risk

Evidence Based Medicine

- Importance & Applicability of Evidence Based Medicine (EBM)
- Key Steps to Practicing EBM
- PICO Method
- Study Designs Used in EBM
- Ranking Levels of EBM
- Categorizing Literature Resources
- EBM Databases
Drug Development Process

- Phases of Drug Development Process
- Applications Required for Drug Approval
- Management of Drug Lifecycle
- Fast Track Drug Approvals

Processes

- Advisory Boards
- Grants & IIS
- Abstract & Medical Writing
Advisory Boards

- Purpose of Advisory Boards in Life Sciences Industry
- Elements of an Advisory Board
- Challenges & Key Elements to Success of Advisory Board
- Eligibility for Members of Advisory Boards
- Regulations & Compliance Aspects Governing Advisory Boards

Grant and Investigator-Initiated Study Funding and Process

- Purpose of Investigator-Initiated Studies (IIS)
- Grant Application Process
- Types of Grants
- Level of Involvement of Pharma in IIS
- Funding Opportunities and Sources for IIS
- “Hands off” Approach in IIS
Abstract and Medical Writing

- Purpose of Abstract Writing & Different Types of Abstracts
- Universal Format to Construct Concise Abstract
- Knowledge/Skills for Competent Medical Writing
- Types of Medical Writing
- Steps in Writing Scientific Documents

Roles Within Medical Affairs
### Medical Science Liaison / Field Medical

- Functions & Duties of Medical Science Liaison (MSL)
- Types of Key Opinion Leaders
- Rules Governing MSL, Sales, & Stakeholder Interactions
- Core Competencies Required for MSL
- Regulatory Guidelines Impacting MSLs
- Role of MSLs in IIS

### Overview of Medical Information

- Role, Function, & Responsibilities of Medical Information
- Rules Related to Providing Medical Information to HCPs
- Reporting Structure
- Identifying & Differentiating Sources of Information
- Standard Response Documents
- Regulatory Guidelines Impacting Medical Information
Safety Functions/Measures

- Post-Marketing Studies
- Risk Evaluation & Mitigation Strategies
- Medication Safety & Pharmacovigilance

Phase IV/Post-Marketing Studies

- Purpose of Post-Marketing Research
- Types of Post-Marketing Research
- Types of Non-FDA Mandated Studies
- Role of Medical Affairs in Phase IV Studies
Risk Evaluation & Mitigation Strategies

- Define REMS
- Situations Requiring REMS
- Intent of REMS
- REMS Process
- FDA Considerations
- Elements of REMS Program

Medication Safety & Pharmacovigilance

- Overview of Pharmacovigilance
- Safety Signals
- Terms Used in Drug Safety Evaluation
- Methods for Characterizing Adverse Drug Events
- Identifying Drug Safety Problems Pre- & Post-Approval
“As a patient advocate, mother of a child with a rare disease and a patient myself, I want the best of the best. This is why I and the patient advocate community are major supporters of the ACMA and the BCMAS program”

-Terri Ellsworth
Well known US Patient Advocate

Worth the investment

Earn the respect & trust of the medical & patient community
Broaden Your Skills
Distinguish Yourself