



NATIONAL COMPETENCY STANDARDS
FOR
BIOPHARMACEUTICAL MEDICAL
REPRESENTATIVES

Developed by

Medical Representatives Certification Commission

Derived from the [MRCC Job Analysis Study](#)

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Company and Board Recognition

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CMR Institute, an independent, not-for-profit 501(c)(3) professional development organization founded by physicians in 1966, provided initial funding through a loan to MRCC and facilitated the creation of the initial Commission. CMR Institute has no role or influence in MRCC programs or processes except through support services as needed during the start up phase.

Introduction

This introduction of the National Standards for Biopharmaceutical Medical Representatives explains the context in which the standards were developed, documents the process of development and suggests ways that the standard should be used by stakeholders.

MRCC was founded in 2009 to create and maintain a competency standard for medical representatives and to validate those competencies through certification examination and recertification requirements. MRCC is governed independently by a volunteer board of commissioners comprised of national healthcare leaders. By setting the standard for professional and ethical competency for medical sales representatives, MRCC seeks to improve patient outcomes and protect the public. Consistent with its mission, MRCC awards certification to individuals who satisfy eligibility criteria and pass a national examination.

What are the Standards?

National standards are a set of guidelines that define the knowledge and skills that are required by biopharmaceutical representatives to provide competent service to healthcare providers.

What are the eligibility criteria?

The requirements are as follows:

Option 1: A baccalaureate degree granted by a United States regionally accredited college/university or foreign equivalent and at least six months of experience in the medical representative or related role (e.g. sales representative, manager, training) actively providing service/information to healthcare providers.

Option 2: At least two years of related experience working as a medical representative and/or managing, educating, or training medical representatives.

MRCC further requires that, once certified, individuals undertake continuing education or pass the certification examination; however, all certification renewal candidates must renew certification by examination at least once during every six-year period.

Why are they needed?

The healthcare system is at a crossroads in its relationship with the pharmaceutical, biotechnology, medical device and diagnostics industries and the road taken will have a critical long-term effect on patient care in this country. The healthcare industry increasingly is demanding transparency, competency, attention to value, and commitment to improving patient outcomes in all its actions. Most prescribers rely on representatives of manufacturers for approved evidence-based information to aid their prescribing decisions. However, to assure competency, representatives must be held to the same assessment validations and ethics protocols of other healthcare professionals in order to fully gain the trust and respect of the medical community.

A clear understanding of the representatives' competencies needed to support patient care is necessary to meet the needs of the healthcare industry. In addition, an independent assessment of that competency and proven value through an accredited certification process is also necessary.

How were they developed?

Medical Representatives Certification Commission (MRCC) followed a standardized process to develop the competency standards for biopharmaceutical medical representatives. The basis of the standard is formed from a [national job analysis study](#) conducted by MRCC in the fall of 2009 and winter of 2010 to delineate the responsibilities and knowledge base required of the biopharmaceutical representative. The job analysis defines logical, practice-related, and research-based content to support various elements of MRCC certification. The domains, tasks, and topics described in this document were identified for the job analysis by a panel of experts, which was comprised of biopharmaceutical representatives, trainers and other executives throughout the United States. A full copy of the study may be obtained on the MRCC website.

As the primary process for identifying the competency areas and knowledge needed for proficient performance in a profession or specialty, job analysis studies offer a clear and useful basis for defining the essential components of licensure and certification examinations. This is because such studies provide the basis for job-relatedness, which is the most commonly applied and accepted validation strategy for licensure and certification tests. Validation through systematic job analysis studies helps to document that the competence to be inferred when a candidate passes the examination bears a sound link to the significant elements of work that characterize the profession. This was the underlying intent of the study.

In conducting the job analysis, MRCC desired to adhere to established standards within the professional licensure and certification community because of the high stakes nature of MRCC certification. The standards have their foundation in logically sound and legally defensible procedures drawn from psychometric literature and case law. These principles and procedures are outlined in federal regulation (*Uniform Guidelines on Employee Selection Procedures*) and manuals, such as *Standards for Educational and Psychological Testing* (published by the American Educational Research Association, 1999). CastleWorldwide, Inc. employed these standards, as well as those of the National Commission for Certifying Agencies (NCCA, 2006), in all phases of the study on behalf of MRCC.

In this study, performance domains, content domains, tasks, and topics were validated using scales for importance, criticality, and frequency. The importance scale offered insight into how essential the domain is for the medical representative. Criticality (potential for harm) and frequency (how often) scales also supplied support for decision making about the job analysis, which should be considered when making decisions about the MRCC examination. Data collected in the validation study portion of the job analysis study give clear evidence that the performance domains, content domains, tasks, and topics are accurate elements of practice for the medical representative working in the biopharmaceutical field.

How should the standards be used?

These national competency standards were developed to serve as the basis of the MRCC Certification for Biopharmaceutical Representatives in the US. They are further intended for use by medical representatives, their employers and their customers to measure capability, performance and to map growth and professional development needs.

Employers and medical representatives will utilize these standards to evaluate training and professional development initiatives to assure participants are gaining knowledge and skills that meet the requirements of certification and the needs of patient care.

These standards are intended to be taken as a whole. While each domain is important, the defined standards of competency for medical representatives encompass all five domains and their associated task and topic statements.

The Competency Standards

Five performance and content domains (major elements of practice and major bodies of knowledge) form the basic organizational structure for the standard.

Domains

Performance domains are the major responsibilities or duties that define the role of medical representatives in the biopharmaceutical field. Content domains are the major topics or bodies of knowledge that medical representatives in the biopharmaceutical field must possess in order to offer competent service.

Compliance and Ethical Conduct

- I. Regulatory Compliance and Ethical Conduct
- II. Customer Interaction
- III. Administration
- IV. Clinical and Therapeutic Knowledge
- V. Marketplace Knowledge

Tasks and Topics

Task Statements: Task statements within each performance domain and topics within each content domain supply essential detail. In essence, task statements define the domain operationally by identifying what is done, how, and why.

Full Description: Domains, Tasks and Topics

Domain I Regulatory Compliance and Ethical Conduct: *The medical representative must protect the interests of patients and other stakeholders by complying with federal, state, and local laws, regulations, guidelines, and policies. This includes completing compliance training, conducting business activities in an ethical manner, providing appropriate product information, and documenting and managing resources.*

- A. Complete required compliance training and certification using approved sources to protect the interests of patients and other stakeholders.
- B. Conduct daily business activities in an ethical manner in order to protect the interests of patients and other stakeholders.
- C. Build trust with customers by understanding and complying with federal, state, and local laws, regulations, guidelines, and policies in order to protect the interests of patients and other stakeholders.
- D. Ensure appropriate and timely delivery of product information by complying with federal, state, and local laws, regulations, guidelines, and policies in order to facilitate the proper use of products by customers.
- E. Document the use of resources using established procedures in order to demonstrate compliance with federal, state, and local laws, regulations, guidelines, and policies and to manage resources effectively.

Domain II: Customer Interaction: *The medical representative must support informed decision making in accordance with customer and patient needs, customer and patient feedback, settings, and applicable federal, state, and local laws, regulations, guidelines, and policies. The medical representative must identify appropriate product options, address payer-access challenges, provide fair, balanced, and accurate information, and maintain the physical integrity of the product and its packaging.*

- A. Interact with customers in compliance with federal, state, and local laws, regulations, guidelines, and policies and in accordance with the setting, applicable laws, regulations, guidelines, policies, and ethical requirements to identify customer needs.
- B. Identify diagnostic or therapeutic options that address patient and customer needs (e.g., medical conditions, treatment needs, payer policies) through collaboration with the customer in order to support informed decision making.
- C. Address payer-access challenges for customers in compliance with federal, state, and local laws, regulations, guidelines, and policies in order to support appropriate diagnostic and therapeutic options.
- D. Provide customers with approved fair, balanced, and accurate information consistent with applicable federal, state, and local laws, regulations, guidelines, and policies to validate appropriate diagnostic or therapeutic options and support informed decision making by the customer and the patient.
- E. Use product resources (e.g., educational materials and programs, samples) in accordance with their intended purposes to support appropriate product use and indication.
- F. Maintain the physical integrity of the product and packaging by adhering to all federal, state, and local laws and regulations in order to protect the interests of customers, their patients, and other stakeholders.
- G. Gather feedback from the customer through regular interaction to understand the diagnostic or therapeutic experience, identify additional needs, and comply with reporting obligations.

Domain III: Administration: *The medical representative must complete organizational and administrative tasks in accordance with federal, state, local, and corporate laws, regulations, guidelines, and policies. This includes implementing corporate strategies, adapting to market conditions, maintaining business relationships, recording activities, and promoting product utilization.*

- A. Implement business plans in accordance with corporate strategy in order to promote appropriate product utilization and adapt to market conditions.
- B. Communicate effectively and responsibly with all internal stakeholders using appropriate media in order to maintain business relationships and achieve business plans.
- C. Record activities (e.g., distribution of samples, leave behinds) using established procedures in order to demonstrate compliance with federal, state, and local laws and regulations.

Domain IV: Clinical and Therapeutic Knowledge: *Clinical and therapeutic knowledge is essential to effective consultation with customers and includes broadly applicable concepts and terminology*

- A. Prescribing Information and Safety (e.g. product labeling, adverse events, reporting, product safety, post-marketing surveillance data)
- B. Anatomy and Physiology (Drug Interaction with the Body) (e.g. body structure, cells and cell function, components and basic functions of major body systems)
- C. Medical Ethics (Within Practice of Medicine) (e.g. risk/benefit analysis, quality of life, mortality, morbidity)
- D. Pharmacology (e.g. pharmacodynamics, pharmacokinetics, absorption, distribution, metabolism, elimination, half life, impact of drugs on cell functions, dosage administration, method of action)
- E. Diagnostic Tests and Evaluation Procedures (e.g. diagnostic process)
- F. Clinical Trials and Research (e.g. evidence-based medicine, phases of clinical trials, standard components of trial)
- G. Product Lifecycle (e.g. phases of lifecycle from research to generics, distribution channels)

Domain V: Marketplace Knowledge: *Knowledge of the marketplace ensures the medical representative's ability to interact effectively and appropriately in the environments in which they work.*

- A. Concepts in Managed Care (e.g. payers, providers, distributors, managed market channels, Medicare, Medicaid, commercial, employers, GPOs, cost-containment methods, influence of delivery of healthcare and delivery settings)
- B. Formulary Status (e.g. types, pharmacy and therapeutic committee process)
- C. Healthcare Settings (e.g. types of settings, prescribing differences)
- D. Medical Training and Scope of Practice for Various Healthcare Providers
- E. Role of Standard Setting Organizations and Their Impact on Customers

Examination Content

The validation process within the job analysis study determined the blueprint for the certification examination. The following weights were approved and reflect the measurements of importance, criticality and frequency within the validation study. These weights will be applied to the examination question bank as examinations are created and delivered.

Domains:

I.	Regulatory Compliance and Ethical Conduct	25.9%
II.	Customer Interaction	30.4%
III.	Administration	7.9%
IV.	Clinical and Therapeutic Knowledge	24.8%
V.	Marketplace Knowledge	11.0%

Key Terms

Company policies: MRCC makes the key assumption that medical representatives adhere to the policies and rules of their employer. As MRCC certification is a minimum competency program, meant to be nationally and uniformly representative of this role, company policies will not be tested, but participants will be expected to know their importance to the role.

Content Domain: Content domains are the major topics or bodies of knowledge that medical representatives in the pharmaceutical and biotechnology fields must possess in order to offer competent service.

Customer and Healthcare Professionals: Customers and healthcare professionals are defined broadly to include the person or group involved in the access, delivery and receipt of healthcare products or services (consumable or non-consumable). Healthcare professional are those people who provide healthcare products and services to patients and/or their legal representatives and families.

Media: Media refers to the approved methods of communication between medical representatives and customers, such as visual aids, patient education materials, speaker programs, etc.

Medical Representatives: Medical representatives are defined as those people who, representing manufacturers, as part of their usual and customary role, call on healthcare professionals or patients for the purpose of providing educational content and/or promoting a product.

Performance Domain: Performance domains are the major responsibilities or duties that define the role of medical representatives in the pharmaceutical and biotechnology fields.

Prima facie ethical principles: beneficence (do good), non-maleficence (do no harm), veracity (honest), loyalty to ethical principles, justice, autonomy (individual choice of patient and prescriber/provider).

Regulations and Guidelines: Federal, state, and local laws, regulations, guidelines, and policies include but are not limited to Federal Drug Administration, anti-kickback, fraud and abuse, PDMA, HIPAA, state and local restrictions on promotions and interactions with healthcare professionals, medical testing, office visit restrictions, industry guidelines, Continuing Medical Education, grants, and sponsorships.

Task: Tasks are activities that the individual completes within a performance domain. Each performance domain consists of a series of tasks that collectively form a comprehensive and detailed description of the performance domain.