IMDRF International Medical Device Regulators Forum

Final Document

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Competence, Training, and Conduct Requirements for Regulatory Reviewers

AUTHORING GROUP

IMDRF Good Regulatory Review Practices

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Preface

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Introduction

This is one document in a collection of documents produced by the International Medical Device Regulators Forum (IMDRF) intended to improve the efficiency and effectiveness of the regulatory review of medical devices.

IMDRF/GRRP WG/N47 (Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices) and IMDRF/GRRP WG/N52 (Principles of Labeling for Medical Devices and IVD Medical Devices) are complementary documents. These two documents are focused on the fundamental design, manufacturing, and labeling requirements for medical devices that, when met, provide assurance the device is safe and performs as intended, offers significant benefits to, among others, manufacturers, users, patients/consumers, and Regulatory Authorities.

This document, IMDRF/GRRP WG/N40 (Competence, Training, and Conduct Requirements for Regulatory Reviewers) is complementary to IMDRF/GRRP WG/N59 (Requirements for Medical Device Conformity Assessment Bodies for Regulatory Authority Recognition) and IMDRF/GRRP WG/N71 (Medical Device Regulatory Review Report: Guidance Regarding Information to be Included).

IMDRF/GRRP WG/N40 provides a common set of conduct, education, experience, competence, and training requirements that shall be established and maintained by the Regulatory Authorities and/or their recognized Conformity Assessment Body(ies) (CAB) for individuals who perform regulatory reviews of medical devices. Depending on individual legislations within various jurisdictions, additional requirements beyond those in this document may apply.

This document is intended to develop confidence in the consistency of regulatory reviews by Regulatory Authorities and/or their recognized CAB. Implementation of these practices is intended to provide an opportunity to rely on regulatory reviews performed by other Regulatory Authorities and/or their recognized CAB.

IMDRF/GRRP WG/N59 is focused on requirements for organizations conducting regulatory review(s) of medical devices and in vitro diagnostic (IVD) medical devices and individuals performing regulatory reviews and other related functions under their respective medical device legislation, regulations, and procedures required in their regulatory jurisdiction.

IMDRF/GRRP WG/N71 expands upon section 7.5.2 of IMDRF/GRRP WG/N59 by articulating exactly the type of information a regulatory review report should include to address the requirements of section 7.7 of IMDRF/GRRP WG/N59.

IMDRF GRRP WG/N61 (Regulatory Authority Assessment Method for Recognition and Surveillance of Conformity Assessment Bodies Conducting Medical Device Regulatory Reviews) is complementary to IMDRF/GRRP WG/N63 (Competence and Training Requirements for Regulatory Authority Assessors of Conformity Assessment Bodies Conducting Medical Device Regulatory Reviews) and IMDRF/GRRP WG/N66 (Assessment and Decision Process for the Recognition of a Conformity Assessment Body Conducting Medical Device Regulatory Reviews). Together, these three documents IMDRF/GRRP WG/N61, IMDRF/GRRP WG/N63, and IMDRF/GRRP WG/N66 are focused on how Regulatory Authorities and their Assessors will evaluate or “assess” medical device Conformity Assessment Bodies’ (CAB) compliance to the requirements of IMDRF/GRRP WG/N59 and IMDRF/GRRP WG/N40.

This collection of IMDRF GRRP documents will provide the fundamental building blocks by providing a common set of requirements to be utilized by the Regulatory Authorities for the recognition and surveillance of entities that perform regulatory reviews and other related functions. It should be noted that in some jurisdictions the recognition process is called designation, notification, registration, or accreditation.

IMDRF developed these GRRP documents to encourage and support global convergence of regulatory systems, where possible, seeking to strike a balance between the responsibilities of Regulatory Authorities to safeguard the health of their citizens as well as their obligations to avoid placing unnecessary burdens upon medical device CABs or the regulated industry. IMDRF Regulatory Authorities may add additional requirements beyond this document when their legislation requires such additions.

1. Scope

This document applies to individuals performing regulatory reviews and making decisions associated with the regulatory review for IVD and non-IVD medical devices, on behalf of Regulatory Authorities and/or their recognized CABs. This document recognizes the use of Regulatory Reviewers and Technical Experts in the regulatory review process and provides separate training and competency requirements for each.

This document does not establish competency and training requirements for MDSAP Auditors and MDSAP Regulatory Authority Assessors. These requirements are already addressed in the MDSAP working group documents (IMDRF/MDSAP WG/N4:2021 and IMDRF/MDSAP WG/N6:2021).

2. References

- GHTF/SG1/N78:2012 Principles of Conformity Assessment for Medical Device
- GHTF/SG1/N71:2012 Definition of Terms Medical Device and In Vitro Diagnostic Medical Device
- IMDRF/GRRP WG/N47:2024 Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices
- IMDRF/Standards WG/N51:2018 Optimizing Standards for Regulatory Use
- IMDRF/GRRP WG/N52:2024 Principles of Labeling for Medical Devices and IVD Medical Devices
- IMDRF/GRRP WG/N59:2024 Requirements for Medical Device Conformity Assessment Bodies for Regulatory Authority Recognition
- IMDRF/GRRP WG/N61:2024 Regulatory Authority Assessment Method for Recognition and Surveillance of Conformity Assessment Bodies Conducting Medical Device Regulatory Reviews
- IMDRF/GRRP WG/N63:2024 Competence and Training Requirements for Regulatory Authority Assessors of Conformity Assessment Bodies Conducting Medical Device Regulatory Reviews
- IMDRF/GRRP WG/N66:2024 Assessment and Decision Process for the Recognition of a Conformity Assessment Body Conducting Medical Device Regulatory Reviews
- IMDRF/MDSAP WG/N4:2021 Competence and Training Requirements for Auditing Organizations
- IMDRF/MDSAP WG/N6:2021 Regulatory Authority Assessor Competence and Training Requirements
- ISO 9000:2015 Quality management systems — Fundamentals and vocabulary

3. Definitions

3.1. *Competence:* Ability to apply knowledge and skills to achieve intended results. (ISO 9000:2015 clause 3.10.4)

3.2. *Medical device*: any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury,
- investigation, replacement, modification, or support of the anatomy, or of a physiological process,
- supporting or sustaining life,
- control of conception,
- cleaning, disinfection, or sterilization of medical devices,
- providing information by means of in vitro examination of specimens derived from the human body;

and does not achieve its primary intended action by pharmacological, immunological, or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.

NOTE 1: Products which may be considered to be medical devices in some jurisdictions but not in others include:

- disinfection substances,
- aids for persons with disabilities,
- devices incorporating animal and/or human tissues,
- devices for in-vitro fertilization or assisted reproduction technologies.

(Modified from GHTF/SG1/N71:2012)

NOTE 2: For clarification purposes, in certain regulatory jurisdictions, devices for cosmetic/aesthetic purposes are also considered medical devices.

NOTE 3: For clarification purposes, in certain regulatory jurisdictions, the commerce of devices incorporating human tissues is not allowed.

3.3. *Regulatory Review:* A review of a medical device that is conducted to assess conformity with regional regulations or standards.

NOTE 1: A regulatory review is performed by Regulatory Reviewer(s), and on occasion, the Regulatory Authority and/or recognized Conformity Assessment Body may consult with Technical Expert(s) to assist in specific aspects of the regulatory review process.

NOTE 2: Depending on the complexity of the medical device, it may be necessary for a team of regulatory reviewer(s) and/or technical expert(s) to conduct the regulatory review to ensure all required competencies are addressed.

NOTE 3: A regulatory review consists of an assessment of documentation and/or evaluation/testing of physical medical devices and includes the recommendation and associated decision making processes. The scope of the review is dependent on the regulatory authority's requirements.

3.4. *Regulatory Reviewer:* An individual from a Regulatory Authority and/or their recognized CAB responsible for routinely performing regulatory reviews of medical devices. This may include for example, premarket reviewers, product specialists, assessors, etc.

3.5. *Regulatory Authority:* A government body or other entity that exercises a legal right to control the use or sale of medical devices within its jurisdiction, and that may take enforcement action to ensure that medical products marketed within its jurisdiction comply with legal requirements. (GHTF/SG1/N78:2012)

3.6. *Conformity Assessment Body (CAB):* A body other than a Regulatory Authority engaged in determining whether the relevant requirements in technical regulations or standards are fulfilled. (GHTF/SG1/N78:2012)

3.7. *Technical Expert:* For the purposes of this document, a technical expert is an individual who is consulted on an *ad hoc* basis to provide specific technical knowledge or expertise to the regulatory review process. This may include an individual employed by the Regulatory Authority or their recognized CAB or external to these organizations, as permitted by the Regulatory Authority.

NOTE: Areas of expertise could include, for example, clinical, design, manufacturing, etc.

4. General Requirements for Regulatory Review

Fully competent Regulatory Reviewers and Technical Experts are able to perform regulatory reviews independently and produce review documentation that:

- Is completed in accordance with current regulations, guidance, standards, and/or policy, as applicable;
- Is impartial, comprehensive, and scientifically-based on the current body of knowledge;
- Demonstrates in-depth knowledge of the medical device including the intended use, product development, manufacturing, and technology; and
- Is administratively complete and understandable.

The following sections outline the conduct, education, experience, competence, and training requirements that shall be met for a Regulatory Reviewer and/or Technical Expert to progress to independent regulatory review.

5. Responsibilities of the Regulatory Authority and/or their Recognized CAB

The Regulatory Authority and/or their recognized CAB shall apply its own procedures for formally selecting, training, approving, and assigning personnel involved in regulatory reviews using the specified requirements contained within this document. It is the responsibility of the Regulatory Authority and/or their recognized CAB to collect and maintain evidence that demonstrates that personnel involved in regulatory review activities meet the specified requirements contained within this document.

The Regulatory Authority and/or their recognized CAB shall have documented processes to:

- Initially qualify personnel involved in regulatory reviews to the specified competence, training, and conduct requirements contained within this document;
- Ensure that the specified requirements are met on a continual basis by personnel involved in performing regulatory reviews;
- Provide personnel with appropriate support and resources where needed;
- Maintain records of these activities including evidence of adherence to a code of conduct for each individual involved in the regulatory review process;
- Ensure the confidentiality of information which comes into its possession, and the observance of professional secrecy by Regulatory Reviewers with regard to information obtained in carrying out their tasks with respect to regulatory reviews; and
- Manage perceived, actual, or potential conflicts of interest and any breaches of confidentiality.

6. Commitment to Impartiality and Confidentiality

The Regulatory Authority and/or their recognized CAB are to ensure that Regulatory Reviewers and other personnel involved in regulatory reviews understand the importance of a code of conduct in maintaining integrity. Regulatory Reviewers and other personnel involved in regulatory reviews shall commit to a code of conduct, that includes a commitment to confidentiality, and disclose any perceived, actual, or potential conflicts of interest. These individuals are to reaffirm their commitment to the code of conduct on an annual basis. Evidence of this commitment should be kept on file by the Regulatory Authority and/or their recognized CAB.

The Regulatory Authority and/or their recognized CAB shall also implement appropriate arrangements to manage perceived, actual, or potential conflicts of interest and any breaches of confidentiality. External Technical Experts may not be subject to the same requirements for adherence to a code of conduct but shall at a minimum, declare any perceived, actual, or potential conflicts of interest.

It is recommended that a code of conduct address the items listed below. Some Regulatory Authorities and/or their recognized CABs may have other regulatory or legislative mechanisms that also address these principles.

Code of Conduct

1. To act in a professional and ethical manner at all times.
2. To faithfully represent the interests of the Regulatory Authority or their recognized CAB.
3. Not to act in any way prejudicial to the interests or reputation of the Regulatory Authority and/or their recognized CAB.
4. Not to act in any way prejudicial to the integrity or objectives of the Regulatory Authority and/or their recognized CAB.
5. To disclose any relationship, or financial interest, past or present, that may create a conflict of interest, or the appearance of a conflict of interest, and to notify their management of any new conflicts of interest or potential conflicts of interest as soon as the case may arise.
6. Not to participate in any activity or relationship that may impair, or may appear to impair, one's objectivity, impartiality, or professional judgment.
7. Not to accept any inducement, gift, commission, discount or any other benefit not available to the general public from medical device manufacturers, their agents, their representatives, or economic operators.
8. To record and report truthfully and accurately review assessments performed in an impartial and unbiased way.
9. To record and report truthfully and accurately any material facts that may affect the regulatory review process.
10. Not to provide any compensated consulting services related to a regulatory application (or equivalent).
11. Not to disclose, verbally or written, any information obtained in the course of the regulatory review to any third party unless authorized in writing or required by law.

12. Not to use information obtained in the regulatory review activities for any personal gain.
13. Not to undertake regulatory reviews for which one does not possess the required skills, knowledge or experience, formal designation or responsibility.
14. To continually improve one's knowledge, proficiency, effectiveness, and quality of work.
15. To disclose to management, without delay, any breach of this statement by oneself or a colleague and to cooperate fully in the investigation of such a breach.

7. Competence Requirements

Three broad categories of competencies are required for Regulatory Reviewers and not all may be required for Technical Experts. For example, it may not be necessary for a clinical technical expert to be knowledgeable about medical device regulatory requirements in order to provide relevant clinical input into a regulatory review. It is the responsibility of the Regulatory Authority and/or their recognized CAB to determine applicable competencies for Technical Experts.

- **Foundational Competencies:** those generic skills, personal attributes, and behaviors applicable to all personnel and developed through experience (e.g. adaptability, diligence, critical and analytical thinking, communication, etc.)
- **Functional Competencies:** those generic skills applicable to all personnel developed through experience and required to perform regulatory reviews (e.g. time management, teamwork, effective use of information technology, etc.)
- **Technical Competencies:** those unique skills developed through experience and specific knowledge applicable to personnel depending on the scope of activities needed to address the assigned tasks (e.g. regulatory requirements, risk assessment, device subject matter expertise, etc.)

The knowledge and skills described in the three categories of competence for Regulatory Reviewers as well as the applicable competencies identified for Technical Experts are to be evaluated and assessed through training and other recognition activities. At entry point it may not be possible to evaluate or fulfill all three categories. In this case, the Regulatory Authority and/or their recognized CAB shall establish methods for evaluating and fulfilling these competencies so that the Regulatory Reviewer or Technical Expert possesses the requisite competencies prior to the assignment of responsibility for any regulatory review that requires those competencies. This does not prohibit the involvement of a Regulatory Reviewer, in training, or a Technical Expert, in training, from participating in a regulatory review that is under supervision by a fully trained Regulatory Reviewer or Technical Expert.

7.1. Foundational Competencies

Adaptability: Demonstrates the ability to use or consider non-traditional methods; makes changes in response to demands, new scientific findings, and circumstances.

Attitude: Has a sense of mission to protect the life and health of people and to serve the public.

Critical and Analytical Thinking: Seeks relevant, reliable, and competent information for use in problem solving and decision-making. Uses sound logic and reasoning to identify strengths and weaknesses of alternative solutions, conclusions, or approaches. Uses reasoning to analyze, compare, and interpret information to draw conclusions.

Cultural Sensitivity: Is observant and respectful to different cultures.

Integrity: Abides by a strict code of ethics and behavior; chooses an ethical course of action and does the right thing, even in the face of opposition; encourages others to behave accordingly. Treats others with honesty, fairness, and respect; makes decisions that rely on relevant objective evidence and reflect the just treatment of others. Takes responsibility for accomplishing work goals within accepted timeframes; accepts responsibility for one's decisions and actions and for those of one's group, team, or department; attempts to learn from mistakes. Understands and respects the confidential nature of regulatory information.

Interpersonal Skills: Establishes and maintains positive working relationships with a diverse group of contacts. Works effectively as a team member during the assessment process. Recognizes and considers input from all assessment program stakeholders.

Objectivity: Makes a balanced assessment of the relevant circumstances and is not unduly influenced by their own interests or by others in forming judgments.

Perception: Is instinctively aware of and able to understand complex regulatory situations.

Tenacity: Is persistent and focuses on achieving objectives.

7.2. Functional Competencies

Autonomy: Has the ability to work independently and adjust to unforeseen circumstances with minimal assistance.

Business Processes: Has the willingness and ability to apply current policies, procedures, work instructions, and other business processes of the organization to complete work objectives.

Conflict Resolution: Recognizes the potential and actual sources of personal conflict from various stakeholders. Achieves results through diplomatic handling of disagreements and potential conflict. Works effectively and cooperates with others to resolve conflicts.

Communication: Expresses or presents ideas, both orally and in writing, in a clear, concise, accurate and logical fashion, taking into consideration the target audience. Has a good command of language(s) and uses an appropriate business writing style. Creates clear and concise reviews that are based on objective evidence. Uses correct spelling, grammar, and punctuation to produce logical, unambiguous, and accurate written documentation and correspondence. Communicates ideas, information, and messages, which may contain technical material, in a logical, organized, and coherent manner.

Information Technology: Has the willingness and ability to apply electronic technology to complete work objectives, to use new techniques, and/or technologies as a routine part of assessments and has a working knowledge of how to use regulatory and functional databases and systems.

Project Management: Plans, organizes, directs, monitors, and evaluates their work and the work of others, as applicable, and according to established policies and procedures

Records Management: Maintains accurate and objective records of the regulatory review process outputs. Maintains records to ensure transparency of regulatory decisions or recommendations.

Teamwork: Possesses the ability to work collaboratively while respecting different points of view and working towards a common goal.

Time Management: Monitors progress against objectives and completes duties in timely and effective manner.

7.3. Technical Competencies

Guidance Documents: Applies knowledge of relevant guidance documents issued or recognized by the Regulatory Authority.

Medical Devices: Applies knowledge of medical devices including their intended use; the types of medical devices including their complexities, technologies, and risk classifications; the safety and risks of medical devices; and other related areas, as required by the assigned role, such as:

- Design verification and validation methods
- Performance and stability
- Manufacturing processes
- Biocompatibility
- Sterility
- Clinical
- Software
- Electrical Safety

Regulatory Requirements: Applies knowledge of the medical device regulatory requirements of the Regulatory Authority(s) to enable an assessment of the applicability and compliance with such laws and regulations.

Voluntary Consensus Standards: Applies knowledge of the Regulatory Authority's recognized medical device vertical and horizontal standards commonly used in product realization (design and manufacturing) for the medical devices under regulatory review, as applicable based on the assigned tasks.

8. Education Requirements

Regulatory Reviewers and Technical Experts should hold a degree or diploma from a university or technical college in health, medicine, science, engineering, or another relevant discipline. In exceptional cases, a demonstration of equivalent knowledge and skills may be acceptable. In such cases, the Regulatory Authority and/or their recognized CAB shall justify and document the reasons for accepting alternatives to the education requirements.

Technical experts shall typically have additional education in their particular area of expertise.

9. Experience Requirements

The Regulatory Authority and/or their recognized CAB shall define any prerequisite experience requirements depending on the assigned role. Any gaps in these requirements can be addressed by the Regulatory Authority and/or their recognized CAB through training. For example, some Regulatory Authorities may hire an engineer with an undergraduate degree with no experience, while others may require a clinician to have a minimum number of years of experience.

Technical Experts shall typically have advanced experience in their particular area of expertise.

10. Training Requirements

The Regulatory Authority and/or their recognized CAB shall maintain documented and implemented training plans for their Regulatory Reviewers and Technical Experts to ensure required competencies are met. The plan shall include initial training and maintenance training. The following training requirements are to be used to establish initial competence and to maintain proficiency. The Regulatory Authority and/or their recognized CAB may also implement additional training based on specific requirements within their jurisdictions.

10.1. Initial Training

The following subsections outline the initial training requirements for Regulatory Reviewers and Technical Experts. Some of these requirements may not apply depending on an individual's previous experience and training. In these cases, the Regulatory Authority and/or their recognized CAB shall document the justification for an individual not completing the initial training requirements outlined below. Successful completion of initial mandatory training must be documented.

10.1.1. Regulatory Reviewers

At a minimum, Regulatory Reviewers shall have successfully completed the following training prior to performing independent work for the Regulatory Authority and/or their recognized CAB:

- 32 hours of training in medical device law, regulations, and policy applicable to the particular jurisdiction for which the regulatory review is being conducted. The Regulatory Authority and/or their recognized CAB shall verify that the Regulatory Reviewer can explain the Regulatory Authority's role and authority and has adequate knowledge of the relevant statutes, regulations, guidelines, and range of enforcement measures.
- 40 hours of training in scientific/technical issues related to the assigned tasks they are responsible for such as relevant product standards, product technology, clinical indications of the product, etc. This training should also include at least 8 hours of cross-cutting (horizontal) disciplines applicable to the product area such as risk management, sterilization, biocompatibility, software validation, stability, quality management systems, etc. The Regulatory Authority and/or their recognized CAB shall verify that the Regulatory Reviewer understands the medical device lifecycle; apply basic scientific knowledge to assess conformity with regulations and guidance; and recognize the role of national and international standards.
- 8 hours of training on good regulatory review practices such as written and oral communication skills, technical writing, etc. The Regulatory Authority and/or their recognized CAB shall verify that the Regulatory Reviewer is able to provide reviews supported by appropriate regulatory and scientific justification in a clear and concise manner.

This training can be a combination of on-the-job, online, classroom, and/or experiential training.

10.1.2. Technical Experts

The Regulatory Authority and/or their recognized CAB shall determine requirements for the initial training of Technical Experts. This may be in the form of training in relevant regulatory requirements or processes of the Regulatory Authority and/or their recognized CAB. The Technical Expert shall receive training commensurate with the assigned tasks. Technical knowledge is implied and initial training in these technical aspects may not be required for the Technical Expert.

10.2. Maintenance Training

In accordance with the code of conduct, individuals involved in regulatory reviews shall commit themselves to continually improve their proficiency, effectiveness, and quality of work by acquiring further knowledge. Regulatory Reviewers shall receive training to maintain their regulatory review skills. This training should address changes to regulatory requirements, new and updated relevant guidance documents, or standards. Training should also address changes to internal policies, procedures, or business support systems.

These requirements may not apply to Technical Experts because they are consulted on an *ad hoc* basis. The Regulatory Authority and/or their recognized CAB may define requirements as appropriate for the maintenance of Technical Expert status.

10.3. Continual Professional Development (CPD)

In addition to maintenance training, Regulatory Reviewers shall fulfill a requirement for CPD of a minimum of 16 hours of professional development per year. Mandatory annual training or re-training on the internal procedures and processes of the Regulatory Authority and/or their recognized CAB shall not count toward CPD hours (See initial and maintenance training above). Reviews performed shall not count towards CPD hours. In order to count toward CPD hours, training shall maintain or augment existing technical competencies, or be provided for the acquisition of new technical competencies relevant to the roles and responsibilities in regulatory reviews. Regulatory Reviewers with a broad scope of recognized competence may require more CPD hours per year to maintain their competence. The Regulatory Authority and/or their recognized CAB shall not permit additional hours of CPD in a year carried forward to count as CPD hours in future years. CPD may include, for example, attendance at internal seminars or teleconferences; attendance, participation, and/or presentation at scientific/technical, regulatory, and professional meetings; or continuation of practical work in professional field (e.g. clinical practice) where applicable.

These requirements may not apply to Technical Experts because they are consulted on an *ad hoc* basis. The Regulatory Authority and/or their recognized CAB may define requirements as appropriate for the maintenance of Technical Expert status to ensure the quality and usability of the advice provided or the regulatory review performed by the Technical Expert.

11. Competence Evaluation

The Regulatory Authority and/or their recognized CAB shall assess and periodically monitor the competence of Regulatory Reviewers and Technical Experts. The Regulatory Authority and/or their recognized CAB shall evaluate Regulatory Reviewers and Technical Experts against updated or current competence criteria for continued recognition of competence at least every year. Records of the evaluation shall be maintained.

11.1. Methods of Evaluation

The Regulatory Authority and/or their recognized CAB shall evaluate the competence of Regulatory Reviewers and Technical Experts using a combination of evaluation and monitoring methods that may include:

- Review of records of regulatory reviews, education, training, etc.
- Feedback from peers, supervisors and stakeholders
- Interviews
- Observation of performance
- Testing

11.2. Competence Evaluation Criteria

The Regulatory Authority and/or their recognized CAB shall evaluate the Foundational, Functional, and Technical competencies (Section 7.0) against the minimal criteria established below. The Regulatory Authority and/or their recognized CAB may choose to include additional criteria.

Table 1. Evaluation Criteria for Foundational Competencies

Foundational Competencies	Evaluation Criteria
Adaptability	Accepts feedback as an opportunity to learn and improve their skills.
Attitude	Personally adheres to the laws, regulations, and policies of the Regulatory Authority.
	Understands the potential impact of the regulatory review decisions that are made.
Critical and Analytical Thinking	Demonstrates the ability to solve problems and make decisions based on sound logic and reasoning.
	Utilizes reasoning to analyze, compare, and interpret information to solve problems.

Foundational Competencies	Evaluation Criteria
Cultural Sensitivity	Respects cultural differences.
Integrity	Demonstrates ethical behavior by ensuring integrity in personal actions and in administering the Regulatory Authority and/or their recognized CAB's business practices.
	Prevents and resolves any perceived, actual, or potential conflicts of interest.
	Preserves confidentiality of classified information when applicable.
	Is accountable for their own behavior and actions.
Interpersonal Skills	Connects and relates well with a diverse group of individuals including stakeholders and other individuals at all levels within the organization.
Objectivity	Demonstrates the ability to judge fairly without partiality or external influence.
Perception	Raises and escalates, as appropriate, any ethical issues.
Tenacity	Accepts challenging work assignments.

Table 2. Evaluation Criteria for Functional Competencies

Functional Competencies	Evaluation Criteria
Autonomy	Requires supervision commensurate with the individual's competency.
	Takes initiative in problem solving.
Business Processes	Adheres to the Regulatory Authority and/or their recognized CAB's internal and external policies and processes.
	Participates in training on internal policies, procedures, or business support systems and effectively demonstrates the application of these policies, procedures, and systems.
Communication	Communicates in an accurate, clear, organized, concise, grammatically correct, and responsive manner, both orally and in writing.
	Uses written communications that are adequately supported, logical, and effectively convey the intended message.
	Uses oral communications that are adequately supported, logical, and effectively convey the intended message.
Conflict Resolution	Uses effective listening and negotiation skills.
Information Technology	Applies available electronic technology to complete regulatory reviews.
Project Management	Allocates time and resources to efficiently accomplish all tasks.
Records Management	Maintains accurate records.
Teamwork	Coordinates and/or participates in regulatory reviews with appropriate individuals and team members to ensure a thorough regulatory review.
	Fosters/facilitates cooperation, communication and consensus to accomplish a common goal both individually as well as a part of a team.
	Represents the team consensus with respect to regulatory review recommendations, actions, and decisions.
Time Management	Completes reviews within applicable timeframes.

Table 3. Evaluation Criteria for Technical Competencies

Technical Competencies	Evaluation Criteria
Guidance Documents	Keeps abreast of applicable guidance documents.
	Provides information and guidance to stakeholders on current and new guidance documents.
Medical Devices	Keeps abreast of and assesses the scientific and/or clinical advances, relevant to medical devices through activities such as training, literature reviews, etc.
	Establishes, maintains, and further develops medical device knowledge by completing initial training and CPD and is able to apply the skills/knowledge acquired towards regulatory review.
Regulatory Requirements	Keeps abreast of applicable regulatory requirements.
	Demonstrates regulatory knowledge of the Regulatory Authority to enable an assessment of the applicability and compliance with such laws and regulations.
	Provides information and guidance to stakeholders on current and new regulatory requirements.
	Establishes, maintains, and further develops regulatory knowledge by completing initial training and CPD and is able to apply the skills/knowledge acquired towards regulatory review.
Voluntary Consensus Standards	Keeps abreast of applicable voluntary consensus standards.

The following may serve as a guide for rating an individual's competence level for each of the competencies outlined in the tables above. The Regulatory Authority and/or their recognized CAB shall record the evidence to support any rating applied to a particular competency during an evaluation.

Table 4. Sample Competence Rating Scale

Competence Level	Rating
Fully Demonstrated	3
Partially Demonstrated	2
To be Developed	1
Not Applicable	0

12. Establishing Independent Regulatory Review

Before undertaking independent regulatory reviews, the Regulatory Reviewer shall operate under direct oversight until sufficient competencies are established. Oversight may be required for each medical device type as well as for each review type for a minimum number of regulatory reviews. Oversight shall be provided by (an) individual(s) with appropriate technical and regulatory knowledge for the medical device type or review type being reviewed and may be accomplished through mentoring activities and/or co-reviews provided by supervisors, peers, or others.

The following outlines the minimal criteria for evaluating the ability of a Regulatory Reviewer to perform independent regulatory review:

- Appropriately assesses the adequacy of quality, safety, preclinical and/or clinical documentation to demonstrate conformity with applicable regulations, guidance, standards, and/or policy;
- Applies scientific and analytical skills to define any problems, identify potential solutions, make relevant inferences, and articulate these clearly, when developing review recommendations;
- Maintains accountability by providing adequate documentation to support a decision recommendation and prepare correspondence and any potential deficiencies identified within the submission with minimal oversight;
- Demonstrates the need for minimal oversight by seeking input only when new or unique issues arise, overcomes day-to-day problems independently, etc.;
- Sustains regulatory review workload of a complexity commensurate with the individual's experience level; and
- Continues to perform sufficient numbers of regulatory reviews within the applicable medical device type or review type to maintain competency.

The Regulatory Authority and/or their recognized CAB shall record the evidence demonstrating the ability of the Regulatory Reviewer to undertake independent regulatory reviews.

13. Records of Competence, Training, and Conduct

The Regulatory Authority and/or their recognized CAB shall maintain current and accurate records associated with the evaluation and maintenance of competencies, training received, signed statements of adherence to a code of conduct (that includes a commitment to confidentiality), and any records of remediation. Records shall demonstrate how Regulatory Reviewers and Technical Experts meet the requirements contained in this document and are to include:

- Regulatory Reviewer or Technical Expert name, position, and contact information;
- Initial and subsequent education;
- Results of evaluation of the Regulatory Reviewer's competence in the role of Regulatory Reviewer or Technical Expert according to the requirements in this document;
- Training participation and outcomes to meet both CPD and on-going training requirements;
- Scope of demonstrated competence to perform independent regulatory reviews;
- Any perceived, actual, or potential conflicts of interests; and
- A log of regulatory reviews performed.

14. Remediation

In the event that a Regulatory Reviewer or Technical Expert fails to meet the requirements for the maintenance of competence, the Regulatory Authority and/or their recognized CAB shall prepare a remediation plan in order to bring the individual back into compliance. When a Regulatory Reviewer or Technical Expert is under remediation, he or she may not undertake independent regulatory reviews except where it is necessary as part of the remediation plan and under appropriate oversight. The remediation plan may include additional training, oversight and re-evaluation of competencies to return the Regulatory Reviewer or Technical Expert to independent regulatory reviewer status. Records of remediation shall be maintained.

IMDRF International Medical Device Regulators Forum

Please visit our website for more details.

www.imdrf.org