PROPOSED DOCUMENT

International Medical Device Regulators Forum

Title: Competence, Training, and Conduct Requirements for Regulatory Reviewers

Authoring Group: IMDRF Good Regulatory Review Practices

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**Please note that the text of a new European Union Regulation on medical devices, which also contains new detailed requirements for Auditing Organizations/Conformity Assessment Bodies, was finalized in June 2016. The current version of "Competence, Training, and Conduct Requirements for Regulatory Reviewers" does not incorporate these requirements, as the Working Group was not able to take into account these latest developments given the timing. Therefore, the Working Group will ensure that all new EU requirements will be reviewed and reflected in the revised document, following the public consultation phase.*

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Preface

The document herein was produced by the International Medical Device Regulators Forum (IMDRF), a voluntary group of medical device regulators from around the world. The document has been subject to consultation throughout its development.

Introduction

This IMDRF Good Regulatory Review Practices document provides a common set of competence, training, and conduct requirements to be utilized by the Regulatory Authorities and/or their designated Conformity Assessment Body(ies) (CAB) for individuals who perform regulatory reviews of medical devices.

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

The purpose of this document is to specify basic competence, training, and conduct requirements that shall be demonstrated and maintained by Regulatory Authorities and/or their designated CAB for personnel involved in performing regulatory reviews and the associated decision-making processes. Regulatory Authorities may add additional requirements beyond this document when their legislation requires such additions within their jurisdictions.

The requirements include:

- Defining knowledge, skills, and attributes.

- Defining criteria for various degrees of competence based on roles in reviews and decision-making functions.

- Assisting in staff evaluation and development.

- Providing a basis for identifying training needs.

1.0 Scope

This document applies to individuals from Regulatory Authorities and/or their designated CAB who are performing technical regulatory reviews of medical devices including both IVD and non IVD devices. This document also recognizes the use of Technical Experts in the regulatory review process and provides separate training and competency requirements. Adherence to this document and its requirements will help mitigate the risk of inconsistent or ineffective assessments by ensuring that personnel from the Regulatory Authority and/or their designated CAB have the necessary commitment, competence, experience, and training prior to performing regulatory reviews. This document does not establish competency and training requirements for MDSAP Auditors and MDSAP Regulatory Authority Assessors already covered under the MDSAP working group documents (IMDRF/MDSAP WG/N4 FINAL:2013 and IMDRF/MDSAP WG/N6 FINAL:2013).

2.0 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/MDSAP WG/N4FINAL: 2013 *Competence and Training Requirements for Auditing Organizations*
- IMDRF/MDSAP WG/N6FINAL: 2013 *Regulatory Authority Assessor Competence and Training Requirements*
- ISO 9000:2015 *Quality management systems — Fundamentals and vocabulary*

3.0 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,
- disinfection 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: 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.

(GHTF/SG1/N71:2012)

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

3.3 *Regulatory Review:* A review of a medical device that is conducted to assess conformity with regional regulations or standards. A regulatory review is usually performed by a Regulatory Reviewer, but on occasion, the Regulatory Authority and/or designated Conformity Assessment Body may consult with a Technical Expert to assist in specific aspects of the regulatory review process.

3.4 *Regulatory Reviewers:* A person with demonstrated personal attributes, competence, and training to routinely perform regulatory reviews of medical devices. This applies to employees of Regulatory Authorities as well as their designated CAB, and may include for example, premarket reviewers, product specialists, etc. Regulatory Reviewers at a minimum shall possess broad knowledge of medical device use and technology and applicable regulatory requirements.

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 a person who is consulted on an *ad hoc* basis to provide specific technical knowledge or expertise to the regulatory review process. This may include a person employed by the Regulatory Authority or their designated CAB or external to these organizations, as permitted by the Regulatory Authority. Areas of expertise could include, for example, clinical, design, manufacturing, etc. Technical experts shall typically have additional education in their particular area of expertise.

4.0 Responsibilities

It is the responsibility of the Regulatory Authority and/or their designated 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 designated CAB shall have documented processes to:

1. initially qualify personnel involved in regulatory reviews to the specified requirements contained within this document;
2. ensure that the specified requirements are met on a continual basis by personnel involved in performing regulatory reviews;
3. provide personnel with appropriate support and resources where needed;
4. maintain records of these activities including a signed Code of Conduct (see clause 5.1.1) for each person involved in the regulatory review process;
5. 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
6. manage perceived, actual, or potential conflicts of interest and any breaches of confidentiality.

5.0 Commitment to Impartiality and Confidentiality

Regulatory Authorities and/or their designated 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 sign a Code of Conduct (see Section 5.1), 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. This should be in the form of a signed statement of adherence kept on file by the Regulatory Authority and/or their designated CAB. At a minimum, the signed statement shall attest the elements described in Section 5.1 below.

The Regulatory Authority and/or their designated CAB shall also implement appropriate arrangements to manage perceived, actual, or potential conflicts of interest and any breaches of confidentiality. 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.

5.1 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 designated CAB.
3. Not to act in any way prejudicial to the interests or reputation of the Regulatory Authority or their designated CAB.
4. Not to act in any way prejudicial to the integrity or objectives of the Regulatory Authority or their designated 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 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 to manufacturers who have submitted a regulatory application (or equivalent) for review.
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 any regulatory reviews for which one does not possess the required skills, knowledge or experience, formal designation or responsibility.
14. To continually improve one's 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.

6.0 Entry Level Requirements

Regulatory Reviewers shall be able to demonstrate through sufficient experience, education, or training to have acquired the requisite knowledge and skills to successfully perform assigned tasks. A Regulatory Authority and/or their designated CAB shall apply its own procedures for formally selecting, training, approving, and assigning personnel involved in regulatory reviews and the associated decision-making functions using the specified requirements contained within this document.

The following are the prerequisite education, experience, and competencies to be demonstrated and maintained by personnel involved in regulatory reviews and the associated decision-making functions. Any gaps in these requirements can be addressed by the Regulatory Authority and/or CAB through the mandatory initial training. The Appendix contains a tool for the evaluation of the competencies described below.

6.1 Education

Regulatory Reviewers and Technical Experts should hold a diploma from a university or technical college in medicine, science, engineering, or any other relevant health disciplines. Disciplines of interest may include, for example:

- Biology - microbiology, cell and molecular biology
- Microbiology
- Chemistry
- Biochemistry

- Hematology
- Immunology
- Computer hardware and software technology
- Material sciences
- Engineering - electrical, mechanical, biomedical, clinical, bioengineering, chemical, human factors
- Human physiology
- Medicine
- Dentistry
- Nursing
- Veterinary Medicine
- Pharmacy
- Physics and biophysics

In exceptional cases, a demonstration of equivalent knowledge and skills may be acceptable. In such cases, the Regulatory Authority and/or their designated 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.

6.2 Experience

The Regulatory Authority and/or their designated CAB shall define the prerequisite experience requirements depending on the assigned tasks. In some cases, prerequisite experiences may not be required.

Technical Experts shall typically demonstrate advanced experience and expertise in a particular process, medical device, or technology.

6.3 Competence Requirements

Three broad categories of competencies are required for Regulatory Reviewers and not all may be required for Technical Experts. It is the responsibility of the Regulatory Authority and/or their designated 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 attributes 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 as part of entry level requirements and 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 designated CAB shall establish methods for evaluating and fulfilling these prerequisite competencies at a later point.

6.3.1 Foundational Competencies

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

2. *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 are objective 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.

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

4. *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.

5. *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.

6. *Adaptability:* Demonstrates the ability to use or consider nontraditional methods; makes changes in response to demands and circumstances.

7. *Tenacity:* Persistent and focused on achieving objectives.

8. *Perception:* Instinctively aware of and able to understand situations.

9. *Cultural Sensitivity:* Observant and respectful to different cultures.

6.3.2 Functional Competencies

1. *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.

2. *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.

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

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

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

6. *Communication:* Expresses or presents ideas, both orally and in writing, in a clear, concise, accurate and logic 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 and accurate written documentation and correspondence. Communicates ideas, information, and messages, which may contain technical material, in a logical, organized, and coherent manner.

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

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

9. *Autonomy:* Ability to work independently and adjust to unforeseen circumstances with minimal assistance.

6.3.3 Technical Competencies

1. *Regulatory Requirements:* 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. NOTE: Technical Experts may not necessarily require full competency in regulatory requirements.

2. *Medical Devices:* 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
    - Manufacturing processes
    - Biocompatibility
    - Sterility

3. *Voluntary Consensus Standards:* 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.

4. *Guidance Documents*: Knowledge of applicable guidance documents issued or recognized by the Regulatory Authority.

7.0 Training Requirements

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

7.1 Initial Training

Initial training must be completed prior to undertaking regulatory reviews. Successful completion of initial mandatory training must be documented. Some of the following initial training requirements for Regulatory Reviewers and Technical Experts may not apply depending on an individual's previous experience and training. In these cases, the Regulatory Authority and/or their designated CAB shall document the justification for an individual not completing the initial training requirements outlined below.

7.1.1 Regulatory Reviewers

Regulatory Reviewers shall have successfully completed, at a minimum, the following training (or equivalent) prior to performing independent work for the Regulatory Authority and/or their designated CAB:

- 32 hours of training in medical device law, regulations, and policy applicable to the particular jurisdiction in which the medical device is proposed to be marketed. As a result of this training, the Regulatory Reviewer shall be able to explain the Regulatory Authority's role and authority including 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 disciplines applicable to the product area such as risk management, sterilization, biocompatibility, software validation, stability, quality management systems, etc. As a result of this training, the Regulatory Reviewer shall be able to understand the medical device lifecycle; apply basic scientific knowledge to assess conformity with regulations and guidance; understand how regulatory decisions are made using principles of risk management; 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. As a result of this training, the Regulatory Reviewer shall be able to provide reviews supported by appropriate regulatory and scientific justification in a clear and concise manner.

7.1.2 Technical Experts

The Regulatory Authority and/or their designated 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 or their designated 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.

7.2 Ongoing Training

In accordance with the Code of Conduct (see Section 5.1), personnel involved in regulatory reviews and the associated decision-making functions shall commit themselves to continually improve their proficiency, effectiveness, and quality of work.

7.2.1 Continual Professional Development (CPD)

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 designated CAB shall not count toward CPD hours. 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 or their associated decision-making functions. Regulatory Reviewers with a broad scope of recognized competence may require more CPD hours per year to maintain their competence. The Regulatory Authority 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 or their designated CAB may define requirements as appropriate for the maintenance of Technical Expert status.

7.2.2 Maintenance Training

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 or their designated CAB may define requirements as appropriate for the maintenance of Technical Expert status.

8.0 Competence for Regulatory Review

Regulatory Reviewers shall be required to demonstrate appropriate competence prior to undertaking independent regulatory reviews. Independent regulatory review is achieved with minimal supervision and results in review documentation that is:

- Completed in accordance with current regulations, guidance, standards, and/or policy,
- Comprehensive and scientifically-based on the current body of knowledge,
- Conducted in accordance with appropriate risk management principles, and
- Administratively complete.

The Regulatory Authority and/or their designated CAB shall determine the arrangements for developing competence which may be accomplished through the oversight of activities such as co-reviews, mentoring, or similar activities. The Regulatory Authority and/or their designated CAB shall record the evidence demonstrating the ability of the Regulatory Reviewer to undertake independent regulatory reviews and provide related advice. In addition, they will also record the evidence demonstrating the competency of Technical Experts providing advice or performing regulatory reviews. These records shall be maintained and kept current.

8.1 Regulatory Reviewers

The Regulatory Authority and/or their designed CAB shall establish minimal criteria for performing independent regulatory reviews and for the maintenance of these skills. Initial and maintenance criteria may include a minimum number of regulatory reviews that shall be performed. Skill maintenance could also be achieved through oversight activities.

Before undertaking independent regulatory reviews, the Regulatory Reviewer shall operate under direct oversight until sufficient competency is established. Oversight may be required for each medical device type as well as for each review type. Oversight shall be provided by an individual with appropriate technical and regulatory knowledge for the medical device type or review type being reviewed. This may be accomplished through mentoring activities and/or co-reviews provided by supervisors, peers, or others. The oversight activities shall establish that the

Regulatory Reviewer is sufficiently independent to provide recommendations based on sound scientific methodology; appropriate application of regulations, guidance, standards, and/or policy; and the use of appropriate risk management principles.

8.2 Technical Experts

The Regulatory Authority and/or their designated CAB shall establish specific requirements for the competence of Technical Experts contributing to or performing specific portions of the regulatory review. These requirements shall ensure that the Technical Experts have the appropriate advanced knowledge in a particular medical device type or other relevant areas as well as the basic knowledge in medical device regulations and policy. The Regulatory Authority and/or their designated CAB shall also have mechanisms for ensuring the quality and usability of the advice provided or the regulatory review performed by the Technical Expert.

In some cases, the Regulatory Authority and/or their designated CAB shall establish a process for periodic review of the maintenance of competency of Technical Experts.

9.0 Competence Evaluation

The Regulatory Authority and/or their designated CAB shall assess and periodically monitor the competence of Regulatory Reviewers and Technical Experts. The Regulatory Authority and/or their designated 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.

9.1 Methods of Evaluation

The Regulatory Authority and/or their designated 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 and supervisors
- Interviews
- Observation of performance
- Testing

A sample tool for this purpose is provided in the Appendix.

9.2 Competence Evaluation Criteria

The Regulatory Authority or their designated CAB shall evaluate the Foundational, Functional, Technical and Regulatory competencies against the minimal criteria established below. The Regulatory Authority or their designated CAB may choose to include additional criteria.

Foundational Competencies

- Demonstrates ethical behavior by ensuring integrity in personal and the Regulatory Authority and/or CAB's business practices.
- Raises and escalates, as appropriate, any ethical issues.
- Respects cultural differences.
- Is accountable for their own behavior and actions.
- Adheres to and upholds the laws, regulations, and policies of the Regulatory Authority.
- Prevents and resolves any perceived, actual, or potential conflicts of interest.
- Preserves confidentiality of classified information.
- Connects and relates well with a diverse group of individuals including stakeholders and other individuals within the organization.
- Accepts feedback as an opportunity to learn and improve their skills.
- Understands the impact of the regulatory review decisions that are made.
- Demonstrates the ability to judge fairly without partiality or external influence.
- 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.
- Accepts challenging work assignments.

Functional Competencies

- 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.
- Adheres to the Regulatory Authority or CAB's internal and external policies and processes.
- Represents the team consensus with respect to regulatory review recommendations, actions, and decisions.
- Reviews are completed within applicable deadlines.
- Time and resources are allocated to efficiently accomplish all tasks.
- Oral and written communications are accurate, clear, organized, concise, grammatically correct, and responsive.
    - Written communications support and lead to logical conclusions and effectively communicate the intended message.
    - Oral statements are adequately supported, logical, and effectively communicate the intended message.
- Effective listening and conflict resolutions skills are used.
- Applies available electronic technology to complete regulatory reviews.
- Participates in training on internal policies, procedures, or business support systems and effectively demonstrates the application of these policies, procedures, and systems.
- Requires supervision commensurate with the individual's competency.
- Takes initiative in problem solving.
- Maintains accurate records.

Technical Competencies

- Demonstrates regulatory knowledge of the Regulatory Authority to enable an assessment of the applicability and compliance with such laws and regulations.

- Keeps abreast of and assesses the scientific and/or clinical advances, relevant to medical devices through activities such as training, literature reviews, etc.
- Keeps abreast of applicable voluntary consensus standards, guidance documents, and regulatory requirements.
- Provides information and guidance to stakeholders on current and new regulatory requirements or guidance documents.
- Establishes, maintains, and further develops regulatory and medical device knowledge by completing initial training and CPD and is able to apply the skills/knowledge acquired towards regulatory review.

Regulatory Review Competencies

- Appropriately assesses the adequacy of quality, safety, preclinical and/or clinical documentation to demonstrate conformity with applicable regulatory requirements.
- In developing a review recommendation, individual applies scientific and analytical skills to define any problems, identify potential solutions, make relevant inferences, and articulate these clearly.
- Individuals maintain 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.
- Continues to perform sufficient numbers of regulatory reviews within the applicable medical device type or review type to maintain competency.

10.0 Records of Competence, Training, and Conduct

The Regulatory Authority and/or their designated 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
- A log of regulatory reviews performed

11.0 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 designated CAB shall prepare a remediation plan in order to bring the person 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.

Appendix

Appendix: Evaluation of Competencies

The Regulatory Authority and/or CAB shall assess the applicable foundational, functional, technical, and regulatory review competences for the Regulatory Reviewer and Technical Expert. The following tables may serve as a guide for evaluating those competencies.

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

Evaluation of Foundational Competencies

Foundational Competencies	Evaluation Criteria	Rating
Attitude	Adheres to and upholds the laws, regulations, and policies of the Regulatory Authority.	
	Understands the impact of the regulatory review decisions that are made.	
Integrity	Demonstrates ethical behavior by ensuring integrity in personal and the Regulatory Authority and/or CAB's business practices.	
	Prevents and resolves any perceived, actual, or potential conflicts of interest.	
	Preserves confidentiality of classified information.	
	Is accountable for their own behavior and actions.	
Objectivity	Demonstrates the ability to judge fairly without partiality or external influence.	
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.	
Interpersonal Skills	Connects and relates well with a diverse group of individuals including stakeholders and other individuals within the organization.	
Adaptability	Accepts feedback as an opportunity to learn and improve their skills.	
Tenacity	Accepts challenging work assignments	
Perception	Raises and escalates, as appropriate, any ethical issues.	
Cultural Sensitivity	Respects cultural differences.	

Evaluation of Functional Competencies

Functional Competencies	Evaluation Criteria	Rating
Information Technology	Applies available electronic technology to complete regulatory reviews.	
Business Processes	Adheres to the Regulatory Authority or 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.	
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.	
Conflict Resolution	Effective listening and conflict resolutions skills are used.	
Project Management	Time and resources are allocated to efficiently accomplish all tasks.	
Communication	Oral and written communications are accurate, clear, organized, concise, grammatically correct, and responsive.	
	Written communications support and lead to logical conclusions and effectively communicate the intended message.	
	Oral statements are adequately supported, logical, and effectively communicate the intended message.	
Time Management	Reviews are completed within applicable deadlines.	
Records Management	Maintains accurate records.	
Autonomy	Requires supervision commensurate with the individual's competency.	
	Takes initiative in problem solving.	

Evaluation of Technical Competencies

Technical Competencies	Evaluation Criteria	Rating

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.	
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.	
Voluntary Consensus Standards	Keeps abreast of applicable voluntary consensus standards.	
Guidance Documents	Keeps abreast of applicable guidance documents.	
	Provides information and guidance to stakeholders on current and new guidance documents.	

Evaluation of Regulatory Review Competencies

Regulatory Review Competencies	Evaluation Criteria	Rating
Regulatory Review	Appropriately assesses the adequacy of quality, safety, preclinical and/or clinical documentation to demonstrate conformity with applicable regulatory requirements.	
	In developing a review recommendation, individual applies scientific and analytical skills to define any problems, identify potential solutions, make relevant inferences, and articulate these clearly.	

	Individuals maintain 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.	
	Continues to perform sufficient numbers of regulatory reviews within the applicable medical device type or review type to maintain competency.	