Promoting the
QUALITY OF MEDICINES Plus

Competency Framework for Regulators of Biologicals Including Vaccines

Developing capacity for regulation of biologicals including vaccines to improve access of products

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Acronyms

ADR	adverse drug reaction
AE	adverse effects
AEFI	adverse event following immunization
ALCOA+	Accuracy, Legibility, Completeness, Originality, Authenticity
BA	bioavailability
BE	bioequivalence
CAPA	corrective and preventive action
CQA	critical quality attribute
GBT	Global Benchmarking Tool
GCF	Global Competency Framework
GCP	good clinical practices
GDP	good documentation practices
GLP	good laboratory practices
GMP	good manufacturing practices
GSDP	good storage and distribution practices
GVP	good pharmacovigilance practices
GxP	good practices
ICH	International Conference on Harmonization
IDP	institutional development plan
NRA	national regulatory authority
OCAT	Organizational Capability Assessment Tool
OOS	out of specification
PV	pharmacovigilance
RAPS	Regulatory Affairs Professionals Society
QMS	quality management system
SF	substandard and falsified
SPC	summary of product characteristics
SOP	standard operating procedure
TNA	training needs analysis
WHO	World Health Organization

1. Executive Summary

The *Competency Framework for Regulators of Biologicals Including Vaccines* is a complementary framework to the World Health Organization's (WHO's) Global Competency Framework for Regulators of Medicines[1] (November 2023) which aims to establish a benchmark for competencies needed for regulatory staff to manage the regulation of vaccines and other biologicals. It presents a model to describe the expected competencies for personnel working in the regulatory sector for managing the manufacturing, market authorization, and distribution of vaccines and other biologicals.

The objective of the framework is to define critical competencies for the biologics regulatory workforce and help national regulatory authorities (NRAs) establish a consistent approach for professional and organizational development aligned with the WHO Global Benchmarking Tool (GBT). The framework will help NRAs organize relevant training needs analyses (TNAs) and develop a long-term competence-based training strategy while systematically planning for staff recruitment, retention, performance management, and motivation. Application of this framework that translates into capacity building approaches will result in NRAs improving their regulatory capacity and ability to govern the regulation of biologicals including vaccines.

The framework describes four complementary and interconnected domains that should be considered collectively at an organizational level: i) core regulatory values, ii) foundational competencies, iii) core knowledge and skills, and iv) role-based competencies. As a complementary resource to the WHO's Global Competency Framework (GCF), this framework describes only the core regulatory values and role-based competencies in detail specifically toward the regulation of biologicals including vaccines. The foundational (or meta) competencies and core knowledge and skills remain the same as described in the WHO framework.

This framework provides detailed guidance and direction to NRAs on capacity building approaches that can be implemented at the organizational level. The competency framework has various applications within and beyond the NRAs, such as organizational planning, performance management, training and development, and links to academia, industry, and government for a shared vision of an ecosystem of skilled workforce. While the framework provides a benchmark for regulatory activities and competencies for them, each NRA needs to balance its unique needs relating to the national and local context. This global framework and the organizational context can guide the creation of an organization-specific competency framework.

The *Competency Framework for Regulators of Biological including Vaccines* is supplemented with a Microsoft Excel-based Organizational Capability Assessment Tool (OCAT) to further aid NRAs in effectively leveraging the competency framework for learning and development initiatives. This tool serves as a means to identify specific competencies requiring development within key departments such as Dossier Review, Inspection, Quality Control Laboratory, and Pharmacovigilance. By assessing all activities pertinent to the critical roles involved in biologicals and vaccines regulation, the OCAT empowers NRAs to swiftly identify areas for improvement. Subsequently, this assessment can inform the creation of targeted training and recruitment strategies and organizational training plans aimed at enhancing core competencies.

[1] Global Competency framework for regulators of medicines, World Health Organization 2023 available at https://iris.who.int/bitstream/handle/10665/374053/9789240078758-eng.pdf?sequence=1

2. Introduction

2.1 Background

A well-functioning national regulatory system builds public confidence in the healthcare industry and more importantly in the quality of products circulated in the public and private markets. Effective policies and strong enforcement protect the population from exposure to substandard and falsified (SF) products. It also ensures that the right products are distributed in the market and are available for use. Enabling national regulatory decision-making in a timely manner accelerates access to lifesaving biological products such as vaccines. It is critical therefore to systematically develop the capacity of NRAs by focusing on right and fit-for-purpose recruitment, professional skill development, strengthening the working conditions for the staff, and investing in mechanisms that improve staff motivation.

Biological products include a wide range of items, such as vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins. Biologic medications (biologicals), including vaccines, are complex products derived from living organisms that differ from the chemically derived small molecule ("conventional") drugs. The long and complex manufacturing processes and temperature sensitive nature of biologicals and vaccines require specifically designed good manufacturing practices (GMP) and good storage and distribution practices (GSDP), quality control, and quality assurance mechanisms to ensure consistency in quality, safety, and efficacy for public health use.

While the manufacturer has the primary accountability for the quality, safety, and efficacy of the biologicals they produce, the countries' NRAs, where the manufacture and distribution of vaccines occur also play a critical role in assuring product quality. NRAs are responsible for inspecting and issuing GMP/GSDP certification of manufacturing facilities, inspecting clinical trial sites, reviewing licensing applications, issuing marketing authorizations, performing lot release, and monitoring the quality and safety of the product in the country. Hence, NRAs must have the scientific competence and requisite skills to manage the essential processes and perform the regulatory functions leading to approvals of biologicals in the country, making those products available for the public.

The WHO started working on a harmonized regulatory benchmarking and development system in 2014, and in 2021 published the validated GBT (Revision VI) for evaluation of national regulatory systems. The GBT is used to objectively evaluate countries' regulatory systems. The tool and benchmarking methodology enable WHO and regulatory authorities to identify strengths and areas for improvement; formulate institutional development plans (IDPs) to address the identified gaps; and monitor progress in raising the maturity level of the regulatory authority overall, as well as specific regulatory functions.[2]

The GBT provides a systematic approach of defining and strengthening regulatory maturity and with continuous monitoring, evaluation, and development, NRAs can systematically develop their operational capacity. However, using the WHO GBT and subsequently developing regulatory capacity depend on the availability of appropriately qualified staff who can manage the regular regulatory operations while supporting capacity development initiatives. WHO reports[3] that a key reason for low regulatory capacity in low- and middle-income countries is the lack of appropriately qualified, trained, and experienced regulators. They also report an urgent need to establish a systematic approach for addressing the skills

[2] https://www.who.int/tools/global-benchmarking-tools
[3] Global Competency Framework for Regulators of Medical Products, World Health Organization 2023

gap, instead of ad hoc training programs. Hence, a regulatory competency framework must supplement the GBT to give NRAs visibility to the skills they need to effectively institute the GBT sustainably and effectively conduct their regulatory duties.

Competency[4] refers to the capability to apply or use a set of related knowledge, skills, and abilities required to successfully perform "critical work functions" or tasks in a defined work setting. Competencies are abilities that people possess to do their jobs or to fulfill their assigned functions. This requires knowledge, but the focus is on what people can do. Competencies also include qualities, skills, attributes, and traits that help people succeed. A framework goes beyond the traditional focus on academic qualifications, technical skills, and experience, and facilitates the development of a comprehensive and holistic set of competencies.

A competency framework is a model that broadly describes performance excellence within an organization or an area of work. Such a framework usually includes several competencies that are applied to multiple occupational roles within the organization or the sector they are in. Each competency defines, in generic terms, excellence in working behavior; this definition then establishes the benchmark against which staff can be assessed for learning requirements.

The *Competency Framework for Regulators of Biologicals Including Vaccines* is a complementary framework to the WHO GCF which aims to establish a benchmark for key skills needed for regulators to specifically manage the regulation of vaccines and other biologicals. In addition, the design of this competency framework has been inspired by various similar globally validated frameworks, such as:

- Regulatory Affairs Professionals Society (RAPS) regulatory competency framework (2021).[5]
- The WHO-ASPHER Competency Framework for the Public Health Workforce in the European Region (2020).[6]
- Rehabilitation Competency Framework by WHO (2020).[7]
- Global Competency Framework for Universal Health Coverage (2022).[8]
- WHO competency framework: Building a response workforce to manage infodemics (2021).[9]

2.2 Overview of the Competency Framework and Its Objectives

The *Competency Framework for Regulators of Biologicals Including Vaccines* presents and communicates the competencies expected of personnel who provide regulatory oversight for the dossier review and market authorization, lot release, inspection, laboratory testing, and pharmacovigilance of vaccines and other biologicals. This framework has been developed

[4] For the current purpose, we are using the definition of competency from a paper by the University of Texas School of Health: https://sph.uth.edu/content/uploads/2012/01/Competencies-andLearning-Objectives.pdf
[5] Regulatory Competency Framework, Regulatory Affairs Professionals Society, 2021, available at https://www.raps.org/resources/regulatory-competency-framework
[6] From the World Health Organization and the Association of Schools of Public Health in the European Region See https://www.aspher.org/who-aspher-competency-framework-phw.html and https://iris.who.int/handle/10665/347866.
[7] See https://www.who.int/teams/noncommunicable-diseases/sensory-functions-disability-and-rehabilitation/rehabilitation-competency-framework.
[8] See https://www.who.int/publications/i/item/9789240034686.
[9] See https://www.who.int/publications/i/item/9789240035287.

as a complementary resource to the WHO GCF for regulators, focusing specifically on the competencies required to regulate biologicals and vaccines.

The objective of this framework is to define critical competencies for the regulatory workforce that will help NRAs establish a consistent approach for professional and organizational development toward managing the market access for biologicals and vaccines. This includes control on the registration process, ascertaining the quality of products throughout the supply chain and managing the safety of the products. Developing these competencies at the professional and organizational levels will eventually improve the regulatory capacity and increase their maturity level as per the criteria listed in the WHO GBT.

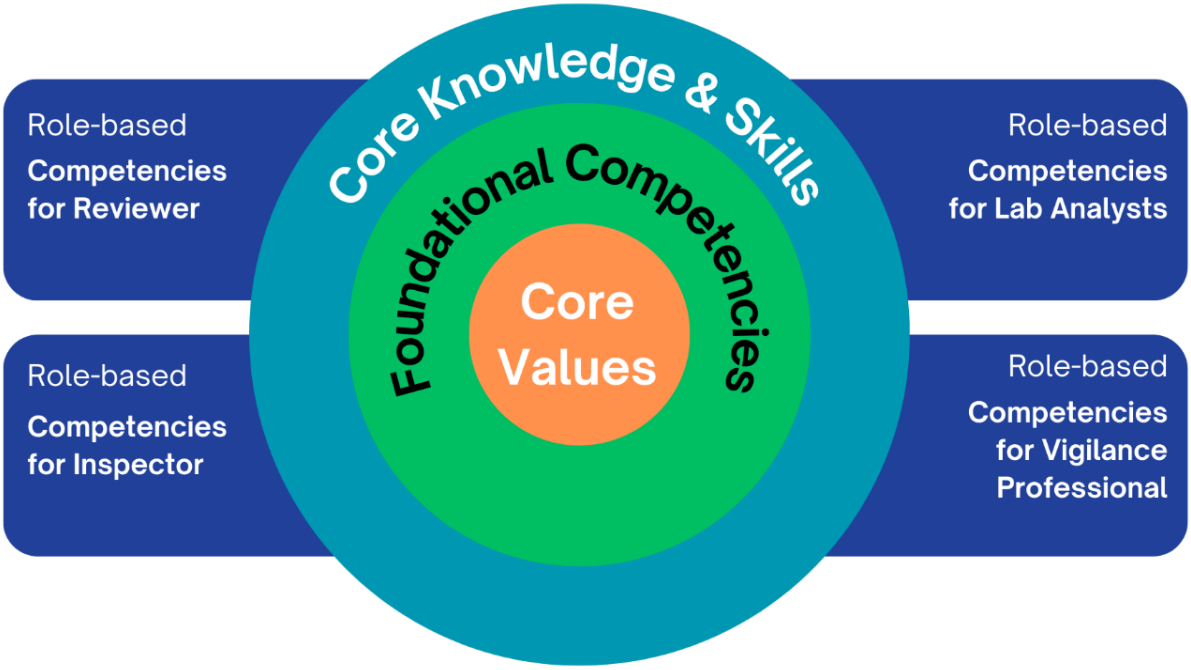
More specifically, the competency framework will also support how NRAs implement the IDPs originating from the WHO GBT assessments, as they will have better visibility on the competencies that needs to be developed in staff working in functional areas that are deemed to be weak. From the perspective of the regulatory personnel, the framework will help them understand their own career progression and identify competencies that they need to develop to move toward higher roles in their organization. The framework will help NRAs organize relevant TNAs, either following a more traditional approach where a detailed competency analysis is conducted at the personnel level or using the Organizational Capability Assessment Tool (OCAT) provided along with this competency framework. The TNA or OCAT will help NRAs identify which competencies are deficient / missing and hence, need to be developed using a long-term competency-based training strategy (which is also linked with IDPs), centered on individual organizational needs while systematically planning staff recruitment, retention, performance management, and motivation.

The framework describes four complementary and interconnected domains that should be considered collectively an organizational level (Figure 1):

- Core regulatory values
- Foundational competencies
- Core knowledge and skills
- Role-based competencies

This framework is designed to complement the WHO GCF, which organizes regulatory competencies into organizational and role-specific requirements. The organizational requirements are further segmented into meta-competencies, core activities, and core knowledge and skills, which must be standard at the organizational level. The role-specific requirements are presented for four distinct regulatory roles: Reviewers, Inspectors, Laboratory Analysts, and Vigilance Personnel. The objective of this framework is to align with that overall design and present specific requirements for biologicals including vaccines. Hence, this document describes only the core regulatory values and role-based competencies in detail. The foundational (or meta) competencies and core knowledge and skills that apply across all product categories remain the same as described in the WHO's framework. Therefore, this framework does not cover them.

Figure 1: Competency Framework Design (adapted from WHO GCF)



2.3 Scope of the Competency Framework

The competency framework is designed specifically for NRAs to use in organizational and staff development for regulating biologicals including vaccines, per the gaps identified using the WHO GBT model. As a supplement to the WHO GCF, this framework can support NRAs in organizing staff TNAs (specifically for biologicals) and developing a competency-based recruitment system and a comprehensive performance management system.

NRAs can use this framework to guide development of staff who work in the area of biologicals and vaccines, specifically a) ***reviewers/assessors*** involved in registration and marketing authorization processes, b) ***inspectors*** involved in regulatory and facility inspections, c) ***laboratory analysts*** involved in lot release program and quality control process for biologicals and vaccines, and d) ***vigilance personnel*** involved in receipt, analysis, conclusion, reporting, and feedback of the vigilance system.

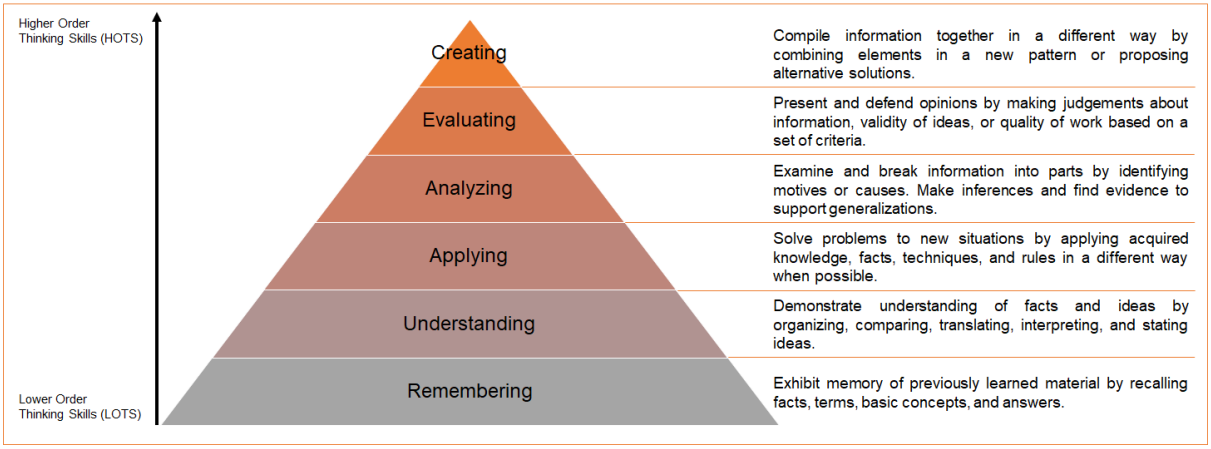
3. Design Principles for the Framework

The *Competency Framework for Regulators of Biological Products including Vaccines* is designed to support NRAs to plan employee training curricula with material and modules to implement a standard framework for career progression. The framework uses Bloom's Taxonomy to classify skills and learning objectives and draws on the Dreyfus Model of Acquisition to identify three levels of career progression.

3.1 Bloom's Taxonomy (Cognitive Domain)

The taxonomy of educational objectives, developed by Benjamin Bloom in the late 1950s and revised by Anderson and Krathwohl[10] in 2001, is a widely applied scheme to measure and explain learning objectives and activities. It proved helpful in delivering, analyzing, and assessing the integrated teaching and training programs across a broad spectrum of professional areas and academic disciplines. The advantage of using Bloom's Taxonomy for designing competency frameworks is that it focuses on gaining understanding and skills rather than only knowledge in a bid to achieve higher levels of learning *(to guide application)*. It helps gauge the level of mastery for an individual according to six hierarchical levels of learning actions, presented as a pyramid in Figure 2.

Figure 2: Bloom's Taxonomy for Cognitive Domain (adapted from A Revision of Bloom's Taxonomy of Educational Objectives, Anderson, LW, Krathwohl et al, 2001)

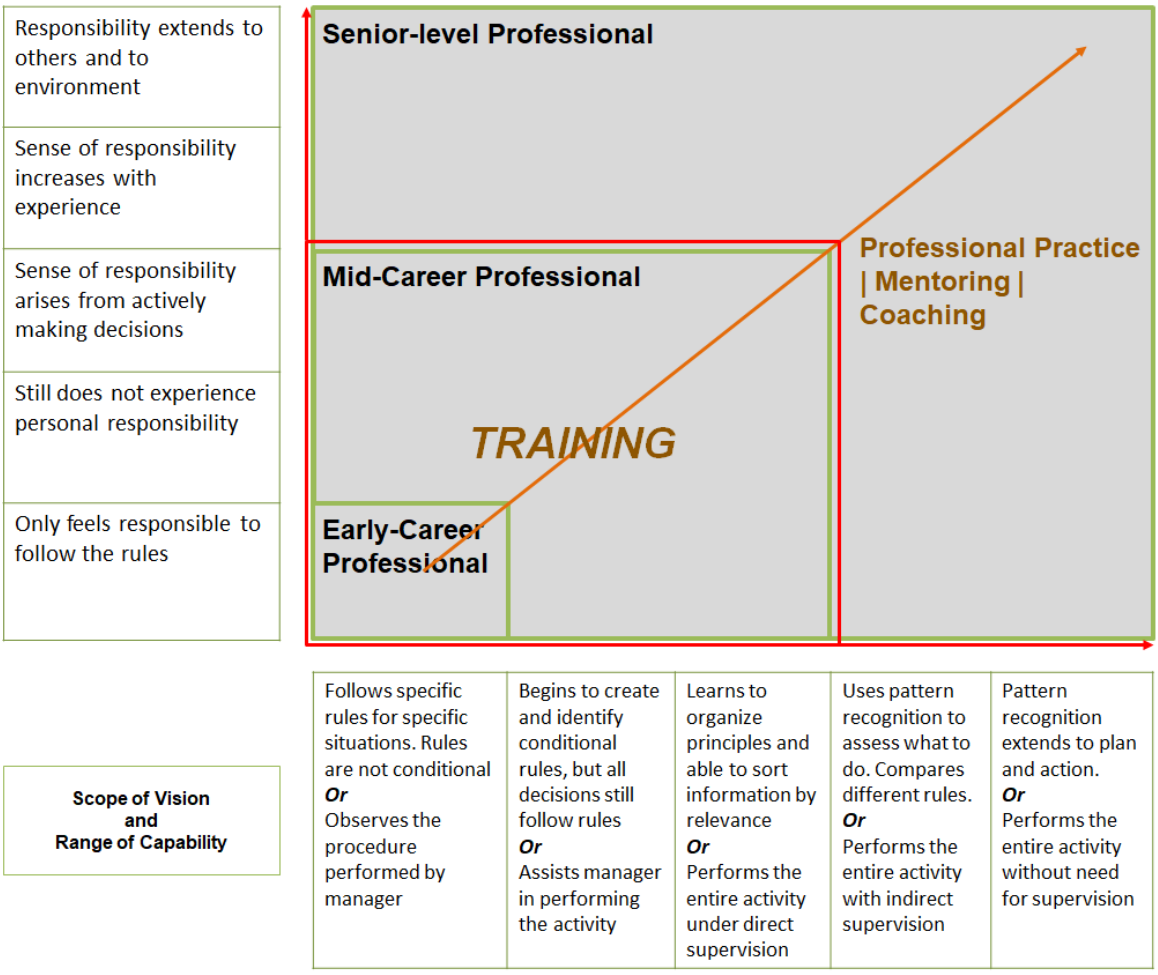


3.2 Dreyfus Skills Acquisition and Career Progression Matrix

A competency framework should be able to map progressive stages of professional development in any sector; in this case, for personnel working in the regulation of medical products. The model of skills acquisition, originally developed by Stuart and Hubert Dreyfus (2004), recognizes that the range of proficiency and level of expertise varies across groups and career stages. It suggests that in the process of acquiring skills, a learner passes through five stages of development, from novice to expert. In this process, an individual gradually progresses from context-free fact learning and rigid adherence to rules to the problem-solving "know-how" level of mastery, where skills are transformed due to experience with real situations. The model also emphasizes the best learning and development methods for each career stage, as Figure 3 depicts.

[10] Anderson, LW, Krathwohl, DR, Airasian, PW, Cruikshank, KA, Mayer, Richard, Pintrich, PR, Raths, J., and Wittrock, MC. (2001). A Taxonomy for Learning, Teaching, and Assessing: A Revision of Bloom's Taxonomy of Educational Objectives.

Figure 3: Adapted Dreyfus Skills Acquisition and Career Progress Matrix (adapted from Dreyfus and Dreyfus: A five stage model of the Mental Activities Involved in Directed Skills Acquisition, 1980)



The *Competency Framework for Regulators of Biological including Vaccines* draws on concepts of the Dreyfus Model to establish three levels of career stages for regulators. The three career stages defined in the framework combine the Dreyfus stages to create three career stages NRAs can use to identify and map competency needs: *early career professional, mid-career professional,* and *senior-expert professional.* As with the Dreyfus model, the career levels illustrate a cumulative progress of knowledge and skill usage related to NRA role activities. Categorizing the competencies in three career levels allows the NRAs to not only map their organograms easily but also create standardized role requirements linked with needed qualifications and demonstration of skills.

Table 1 details career levels and progression, relationship to the Dreyfus Model, and expected behavioral skills and competencies.

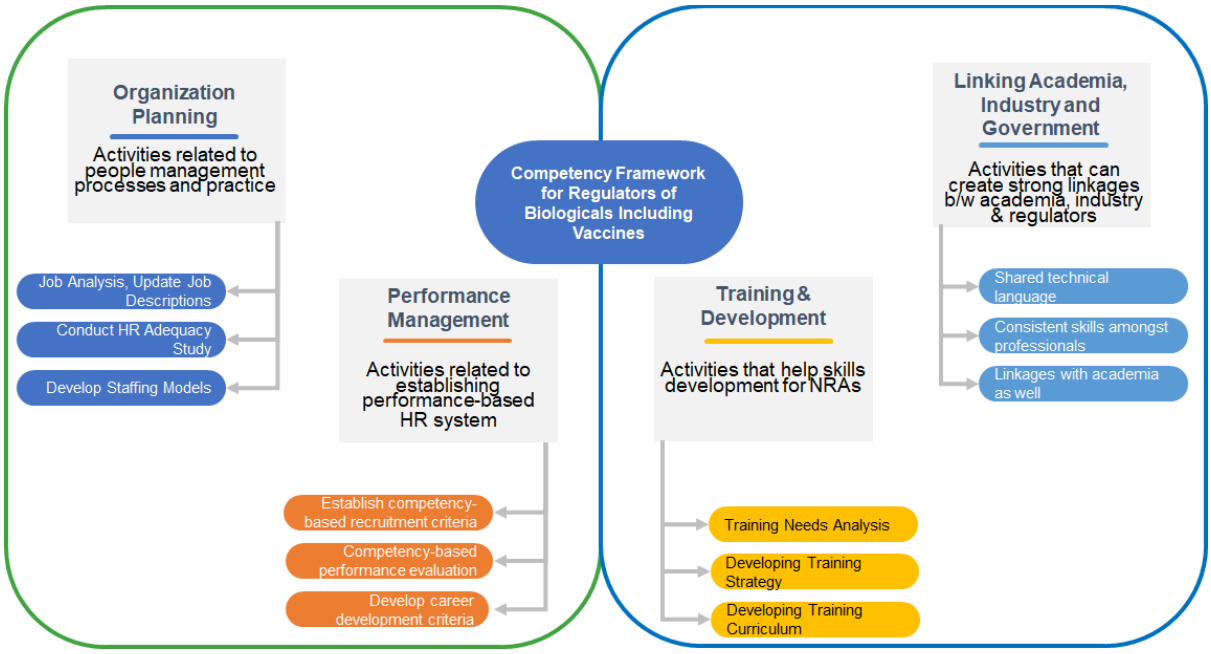
Table 1: Career Progression Matrix (Adapted from Dreyfus and Dreyfus five stages model)

	Early-Career Professional (Beginner)	Mid-Career Professional (Intermediate to Competent)	Senior-Expert Professional (Proficient to Expert)
Definition	Early-Career Professionals are capable of performing activities as defined in documented procedures and need close supervision.	Mid-Career Professionals perform activities consistently without supervision and are able to document processes and systems.	Senior-Expert Professionals are able to train and coach others on activities, manage critical problem solving, and oversee the development of systems and processes.
Attributes	- Has received foundation training in medical products regulation and quality assurance. - Relies heavily on their education. - Needs direct supervision from experienced staff. - Follows validated protocols and standard operating procedures (SOPs). - Manages administrative activities linked with the technical functions.	- Makes decisions via deliberation. - Has supervisory capability. - Functions without direct supervision. - Writes protocols and guidelines. - Assumes managerial to leadership roles when needed. - Displays consistent performance. - Manages variety of tools and techniques.	- Focuses on problem-solving. - Performs intuitively. - Reflects on the overall needs of the system. - Assumes leadership roles. - Supervises multiple layers of staff. - Develops strategies and policies. - Assesses the quality of work.

4. Application of This Competency Framework

This framework has various applications within and beyond NRAs. Figure 4 provides a high-level view of the application segmented into four categories: organization planning, performance management, training and development, and linkages among academia, industry, and government.

Figure 4: Application of the Competency Framework for Regulators of Biologicals Including Vaccines



4.1 Organizational Planning

NRAs can use the competency framework to plan their organizational structure, recruitment processes, and staffing policies in various departments. The framework can assist with redesigning job descriptions, conducting human resources analysis, and organizing competency-based recruitment to fill the skills gap within the organization.

4.2 Performance Management

Since the competency framework is designed to facilitate career progression, NRAs can use the framework to establish a performance management system that can appropriately recognize and reward staff who demonstrate competencies required for the next job level. This will create an objective method for career progression that motivates employees to perform appropriately to their functional benchmarks. The framework will allow NRAs to easily identify the behaviors that would drive successful performance and improve regulation and enforcement. It will provide a clear behavioral link to the IDPs they develop based on the findings from WHO GBT.

Competencies are performance indicators that an organization can expect from the staff on various activities and tasks. Competencies developed for the whole organization become a common language and benchmark when describing staff performance.

4.3 Training and Development

A key application of the competency framework is in establishing an organization-wide training and development system that aims to develop competencies required by staff to address any functional deficiencies identified through the WHO GBT. For each regulatory function, the WHO GBT is grouped into specific categories, one of which assesses the NRAs on their human resources. Hence, based on the result of the assessment and subsequent IDPs related to human resources, the competency framework and its application can be plugged into those IDPs.

A long-term training strategy can be built on a competency-based TNA. A TNA uses the competencies defined in the competency framework and assesses the proficiency of NRA staff on those competencies. Upon identifying the weaker competencies within the staff, a training strategy to develop those competencies and eventually, curricula can be designed that directly support the development of those competencies.

The *Competency Framework for Regulators of Biological including Vaccines* is supplemented with a Microsoft Excel-based Organizational Capability Assessment Tool (OCAT) which is a rapid TNA conducted at an organizational level that can be readily used by NRAs to assess existing capabilities, identify weaker areas, and create plans to develop them. The OCAT specifically focuses on Domain number 4 – Role-based competencies (listed in section 8) to identify the capacity gaps in the NRAs for those specific roles. Note that the competency statements included in the OCAT are written from an organizational rather than an individual perspective in a career progression matrix. More specifically, the tool will help NRAs:

a. To identify the roles that need more development (training and/or recruitment)

b. Per role, determine activities with weaker performance because of competency gaps, and link them with the pre-existing plans from the WHO GBT IDP *(if a GBT assessment is conducted)*

c. Per role, identify those competencies that must be part of any training curriculum for the development of those roles

In addition to the framework, the OCAT provides a practical resource to get a detailed understanding of the skills gap within the organization and carry out development initiatives. The OCAT can be modified according to each NRAs organizational system and changing needs, to add additional specific competencies. The results from this tool can be used in combination with the IDPs developed after WHO GBT assessment to initiate a comprehensive skills development program in the areas where they are needed. Periodic assessment, every 2 years or as deemed necessary by the NRA, of the organizational capabilities using the OCAT will allow NRAs to monitor and document progress over time.

4.4 Establish Linkages among Academia, Industry, and Government

The competency framework can support the establishment of a standard language for regulatory governance in a country. Hence, higher educational institutions, pharmaceutical manufacturers, industry associations, and regulators can all have similar understandings of the regulatory requirements for biologicals including vaccines. Using the competency framework at a national level can result in developing a skilled workforce ecosystem that can benefit all stakeholders equally.

5. Components of the Competency Framework

The framework uses various complementary and interconnected domains that should be considered as a whole by NRAs while strengthening their organizations. The framework includes four domains to help categorize its thematic areas.

5.1 Domains

The domains of the framework provide a thematic arrangement for the various competencies, activities, knowledge, and skill statements. As Figure 1 illustrates, each domain addresses an aspect of the regulatory function, yet all are interconnected and must interact to result in the successful performance of regulatory personnel. The four domains under which the competency framework is presented are:

- **Domain 1: Core regulatory values** are consistent with the regulatory profession and are universal. These values must be inherent in any regulatory personnel and must be adapted by any NRA that seeks to use this competency framework.
- **Domain 2: Foundational competencies** are essential for the whole organization's work environment and for performing specific regulatory functions. They form the foundation for organizational success. These competencies are termed "meta competencies" in the WHO GCF and should be used as written; therefore, they are not described in this document.
- **Domain 3: Core knowledge and skills** are competencies that are required to perform the core activities for the regulation of medical products including biologicals and vaccines. These competencies are common to all regulatory functions (such as organizational awareness, preparation of reports, quality management system, regulatory framework, surveillance, and enforcement). These competencies can also be used as written in the WHO GCF; therefore, they are not described in this document.
- **Domain 4: Role-based competencies** represent the core of this framework. Although they are adapted from roles presented in the WHO GCF (i.e., reviewer, inspector, lab analyst, and vigilance professional), the competencies presented in this document are specifically written for the regulation of biologicals including vaccines.

5.2 Activities and Tasks

Activities refer to applications of knowledge, skills, values, and beliefs conducted through a series of tasks that describe what the regulatory personnel do.

Tasks are the observable components of an activity; like behaviors, they may differ depending on the proficiency of the regulatory personnel (as described in the career progression matrix). Activities and tasks for regulatory personnel depend on their role and position within an NRA.

5.3 Competencies

Competencies are the observable abilities a person acquires by integrating knowledge, skills, and core values and beliefs into their performance of tasks. Competencies are durable, trainable, and measurable through the expression of behaviors.

6. Domain 1: Core Regulatory Values

Medical product regulatory professionals' work results in important decisions that affect public health. Hence, they need to demonstrate the highest standards of professional conduct while exercising duties that uphold and clarify the applicable laws and regulations. Regulatory personnel must always display values that uphold the standard of work in this area. The competency framework referred to various industry practices, existing publications from the RAPS competency framework, WHO (WHO Good Regulatory Practices) and others to define a set of six values that should be consistent across NRAs and part of their organizational culture, at minimum: trust, transparency, privacy, accountability, integrity, and innovation. Table 2 provides definitions for each of these core values.

Table 2: Core Regulatory Values

Value	Definition
Trust	Act with integrity and honesty to improve public health and build trust with customers and other related stakeholders.
Transparency	Maintain accurate records of all data submitted from manufacturers and any other stakeholders and ensure all relevant data are shared among stakeholders unbiasedly.
Privacy	Respect any privacy rights and maintain the confidentiality, as required, of personal or proprietary information related to patients or any other stakeholder.
Accountability	Be accountable for the actions you take and your decisions, including those related to licensing, product approvals, import or export, or distribution.
Integrity	Act responsibly, ethically, and professionally when conducting your work. Do not accept, offer, promise, or provide anything of value to inappropriately influence a decision. Avoid and declare all potential conflicts of interests.
Innovation	Keep sight of any possible innovative products and services that can improve public health while analyzing those products per the applicable policies and guidelines.

7. Domain 4: Role-based Competencies

This framework outlines competencies required for specific roles in the regulation of vaccines and biologicals. These role-based competencies are expressed as **role-based activities** and the underlying **role-based knowledge and skills**. This section outlines the key activities for four key roles: ***reviewers*** (for both clinical trials and marketing authorizations), ***inspectors***, ***laboratory analysts***, and ***vigilance personnel***. The activities

and competencies can be adapted or expanded based on the needs of a particular NRA. Section 8 expands these activities per role into the competencies (knowledge and skills) required to execute them at each career level.

7.1 Reviewers

It is recommended that before a medical product is marketed in any country, the responsible NRA should ensure that the product meets acceptable standards of safety, efficacy, and quality and that the manufacturer complies with GMP. Thus, the review of safety, efficacy, and quality data submitted in dossiers for approval of clinical trial applications, marketing authorization, or registration, as well as post-approval changes, are key regulatory functions. A reviewer in the context of this competency framework includes staff for assessing dossiers for both clinical trials and marketing authorizations of vaccines and biologicals.

Product approval is a multidisciplinary field that requires knowledge of, for example, drug discovery and development, pre-clinical and clinical development of medical products, chemistry, pharmaceutical manufacturing, analytical quality control, legal aspects, information technology, and public health. Table 3 outlines the key activities (or areas) for the reviewers. The required competencies are enumerated in section 8.1 Competencies for Reviewers.

Table 3: Key Activities for Reviewers

#	Key Activity	Explanation
7-1-I	Regulate investigational products (such as vaccines, biologicals), review bioavailability (BA) and bioequivalence /(BE) studies and clinical trials as per good clinical practice (GCP) requirements.	These activities include investigating the processes involved in BE studies or clinical trials for the products and assessing their compliance against relevant regulatory guidelines.
7-1-II	Review clinical trial results and confirm that the study was conducted according to GCP.	These activities include reviewing all the clinical trial data submitted by the manufacturer (phase-wise) such as data of safety, efficacy, and quality and issuing approvals for the next phase of trials.
7-1-III	Document and manage data (including statistical analysis) related to clinical trials.	These activities include documenting data originating from trial results, as submitted by the manufacturer, conducting independent analysis of the data, and documenting all data as per relevant guidelines.
7-1-IV	Manage a database of all product applications screened, received, approved, rejected, suspended or withdrawn along with their supporting documentation.	These activities include maintaining a database of approved products, including periodic renewal, and regulatory actions to suspend, withdraw or cancel registrations due to non-compliance with requirements.
7-1-V	Coordinate and manage the product review system/process between the relevant departments and agencies.	These activities include coordinating various processes and reviews related to product submissions for market authorization and clinical trial applications.
7-1-VI	Review the product labeling and information for the use of healthcare providers and patients.	These activities include reviewing each product information that is submitted for marketing authorization to publish relevant communication for health providers and the public *(summary of product characteristics (SmPC) and patient information leaflet (PIL) for compliance to the guidelines and publishing of the public assessment report for the approved products)*
7-1-VII	Evaluate product quality by reviewing submitted documentation.	These activities include evaluating quality of products (as per scientific and regulatory requirements) based on data submitted by manufacturer for marketing authorization.

#	Key Activity	Explanation
7-1-VIII	Make recommendations (approval, query, rejection) on product applications for clinical trial/registration/market authorization or emergency use authorization based on review of data submitted.	These activities include making final decisions regarding a product (trial progress, marketing authorization or other) based on all available data.
7-1-IX	Monitor clinical trials data, variants, amendments, or changes to registered products and review corrective and preventive action (CAPA) submitted by the applicants.	These activities include analyzing data originating from approved trial results, or amendments to product as submitted by the manufacturer. This also includes reviewing any CAPA reports submitted by the manufacturer post approval.

7.2 Inspectors

As manufacturers submit applications and dossiers for market authorization, NRAs need to carefully evaluate the safety, efficacy, and quality of the product under consideration while ensuring that the manufacturer follows the standards of GMP, and distributors follow GSDP. Thus, an inspection of the product's manufacturing facilities and warehouses where it is stored until distributed is a key regulatory function. NRAs must have dedicated inspectors for this role. Table 4 outlines the key activities (or areas) for the inspectors of vaccine manufacturing and distribution facilities. The required competencies are enumerated in section 8.2 Competencies for Inspectors.

Table 4: Key Activities for Inspectors

#	Key Activity	Definition
7-2-I	Perform GMP / GCP / good laboratory practice (GLP) / GSDP inspections as per applicable guidelines.	These activities include all the various tasks involved in performing an inspection of a manufacturing site, a clinical trial site, a quality control laboratory or a warehouse.
7-2-II	Document and manage data collected during inspections.	These activities include documenting, recording, and managing all data collected during an inspection for decision making and archiving them for future use.
7-2-III	Establish a quality management system for the inspectorate function.	These activities include managing the processes in the inspectorate division from maintaining a roster of inspectors, planning of inspections, coordination with manufacturers and communication of results.
7-2-IV	Evaluate processes and documentation that verifies quality of products (starting materials, intermediates, and finished products) during inspection.	These activities include evaluating processes and documentation from manufacturing, quality control tests, and visual inspection towards determining the quality of products.
7-2-V	Develop technical regulatory documents for inspections	These activities include developing technical documents such as inspection reports or technical advisory for stakeholders.
7-2-VI	Enforce good practices (GxP) guidelines for vaccines and biologicals	These include activities that are carried to enforce the GxP guidelines, such as random inspections, product sampling and testing from the market, and random checking at ports.

7.3 Laboratory Analysts

The role of the laboratory analyst in the regulation of biological products by the NRA must be clearly defined within the policies and procedures that govern the country's vaccine registration process, lot release program, and monitoring and control programs. In some cases, the role of the analyst can extend beyond analytical biological and/or chemical testing of biologics. The role of the laboratory analyst within the country context determines the

specific competencies required. This competency framework addresses activities only related to providing accurate and reliable measurements of product quality for biologicals including vaccines.

As part of the biological products regulatory process, NRAs test the quality of products against the pharmacopeial (compendial) and/or per manufacturers' methods as a prerequisite for issuing marketing authorization, lot release, and as part of market surveillance and control either within their agency or at external laboratories. Effective laboratory testing processes assure the efficacy, quality, and safety of biologicals before and after their distribution for use, specifically conducting lot release before vaccine batch distribution. Thus, laboratory testing plays a key role in assuring medicines quality and detecting SF medicines. In addition, data generated from laboratory testing informs regulatory actions and interventions to combat SF products.

Laboratory personnel at national quality control laboratories are responsible for quality control analysis of biologicals and vaccines (confirmatory or investigational testing), using appropriate methods and equipment and generating test reports/certificates to support regulatory actions and decisions. Table 5 outlines the key activities for laboratory analysts. The required competencies are enumerated in later section 8.3 Competencies for Laboratory Analysts.

Table 5: Key Activities for Laboratory Analysts

#	Key Activity	Explanation
7-3-I	Operate in a manner that facilitates a safe and hazard free work environment.	These activities include efforts to sustain the safety of the laboratory working environment. It involves tasks for daily operation, continuous monitoring, evaluation, and improvement of safety practices.
7-3-II	Use equipment that is suitable for accurate and reliable measurement of products.	These activities include appropriate use, operations, calibration, qualification, and maintenance of laboratory instruments and equipment, to include associated software.
7-3-III	Apply national and international standards, guidelines and best practices while assessing biological product quality and safety.	This includes activities to ensure the safety and quality of biologicals per the relevant guidelines published by WHO or a national regulatory authority.
7-3-IV	Use suitable analytical methods to analyze product quality.	This includes activities of method selection, verification, and validation, including statistical analysis and mathematical calculations when needed during analysis of a product.
7-3-V	Participate in investigation of out-of-specification (OOS) results and support implementation of corrective actions.	This includes activities of identification of test result anomalies, determination of root cause, and development and execution of CAPAs to prevent reoccurrence.
7-3-VI	Adhere to laboratory operational procedures and systems.	This includes activities related to the laboratory quality management system, sample, and inventory management.
7-3-VII	Verify analytical reports for tested products.	These activities include reviewing and verifying analytical reports generated for products to make regulatory decisions.
7-3-VIII	Participate in further research in pharmaceutical analysis or SF products.	These include activities conducted as research toward analysis of new products or to understand prevalence of SF products.

7.4 Vigilance Personnel

Vigilance is an overarching function for NRAs that requires careful management and oversight to ensure the safety of vaccines and biological products available in the market. It includes working closely with manufacturers, wholesalers, pharmacies, public supply organizations, healthcare professionals and other stakeholders. Pharmacovigilance (PV)

aims to improve patient care and safety. It supports public health programs by providing reliable and timely information about the risk-benefit profile of biologicals and vaccines throughout their life cycle. It assists supply organizations by ensuring the quality and integrity of biologicals and vaccines, as well as, identifying and reporting adverse events or quality issues related to those products in the supply chain. It encourages supply organizations to make informed decisions and promotes the safe, rational, and more effective (including cost-effective) use of products.

Vigilance is a wide area that requires knowledge of molecular mechanisms of adverse drug reactions (ADRs), adverse events following immunization (AEFIs), clinical medicine, pharmacoepidemiology, information technology, pharmaceutical manufacturing, legal aspects, and public health, among other areas. Table 6 outlines the key activities (or areas) for vigilance personnel. The required competencies are enumerated in later section 8.4 Competencies for Vigilance Personnel.

Table 6: Key Activities for Vigilance Personnel

#	Key Activity	Explanation
7-4-I	Establish procedures for reviewing product safety information during clinical trials.	These include activities that are conducted in coordination with manufacturers during clinical trials to establish a new product's safety.
7-4-II	Conduct post-marketing surveillance for biologicals and vaccines available in the market.	These include activities that are undertaken to ascertain the safety and efficacy of new (or existing) products launched in the market, such as reviewing submitted AEFIs or ADRs, reviewing and recording case safety reports, reviewing and compiling signals, and conducting causality assessments.
7-4-III	Establish a country-wide system for PV.	These include working with all relevant stakeholders in the country to establish a robust and operational PV system.
7-4-IV	Take regulatory actions and communicate product status with stakeholders.	These include regulatory activities and decisions based on data collected from the safety databases and other regulatory authorities, on safety and efficacy and coordinating with manufacturers and other stakeholders.

8. Library of Role-based Competencies (Knowledge and Skills)

8.1 Competencies for Reviewers

Domain	4-Role-based Competencies (I)		
Activity	**(7-1-I) Regulate investigational products (such as vaccines, biologicals), review BA/BE studies and clinical trials as per GCP requirements**		
Career Progression	Level 1 – Early Career Professional	Level 2 – Mid Career Professional	Level 3 – Senior Professional
Behavioral competencies per level *At each career level, personnel should be able to:*	• Explain clinical trials study design and purpose as per regulatory requirements. • Understand the principles and reasons for specifications. • Classify and record clinical trial protocols and related records as per SOPs. • Demonstrate processes involved in GCP inspection. • Summarize clinical trial protocol reports and supporting documentation to inform completeness. • Understand the potential safety issues associated with the product being investigated. • Summarize reports on reported adverse events related to an investigational product (e.g., vaccine, biological) • Explain various regulations that apply to conducting clinical research on human subjects • Demonstrate importance of institutional review board's approval and ethical guidelines for a clinical trial or a BE study on human subjects.	• Examine clinical study design and recommend modifications based on relevant regulatory or ethical guidelines • Assess compliance with GCP (WHO, International Conference on Harmonization [ICH], national guidelines) by carefully examining clinical study protocol, case report forms, study databases, as well as statistical analysis of study data. • Verify the protocol has been reviewed and approved by the IRB. • Analyze the integrity and accuracy of clinical trial study data submitted by the manufacturer. • Analyze the statistical analysis methods used in clinical trials study designs. • Analyze whether the data and information in the case report form and clinical trial protocol are aligned and appropriate. • Interpret clinical data submitted by manufacturer to understand the product life cycle.	• Approve clinical trial design / protocol as per GCP or relevant regulatory guidelines. • Formulate guidance for manufacturers on regulatory requirements for various product types (vaccines, biologicals, etc.) for clinical trial or BA/BE studies. • Apply risk assessment in determination of acceptability of clinical trial applications. • Participate in international scientific regulatory fora or discussion groups to develop clinical trials regulations, guidelines and standards. • Formulate and publish harmonized investigational product reporting requirements for manufacturers. • Verify submitted protocol for compliance with GCP. • Design mechanisms for effective review, retention, and storage of trial documentation submitted by manufacturers. • Deduce the ethical issues involved when dealing with vulnerable

Domain	4-Role-based Competencies (I)		
Activity	**(7-1-I) Regulate investigational products (such as vaccines, biologicals), review BA/BE studies and clinical trials as per GCP requirements**		
Career Progression	Level 1 – Early Career Professional	Level 2 – Mid Career Professional	Level 3 – Senior Professional
	• Demonstrate the reporting requirements of a serious adverse event. • Compare various statistical analysis processes related to data processing in a clinical trial. • Define and explain appropriate risk management policies related to a clinical trial.	• Examine the processes followed during clinical study to ensure that patient safety has been maintained. • Categorize various safety issues reported by manufacturer as observed during the conduct of the clinical trial. • Generate detailed scientific evaluation reports on reported serious adverse events during a clinical trial. • Assess safety report submitted by the clinical study investigators for conformance to regulatory guidelines and procedures. • Review the documentation and approvals related to ethical standards that ensure the privacy, rights, welfare, and well-being of the clinical subjects. • Evaluate whether the clinical study protocol describes how efficacy and safety will be assessed including the appropriate withdrawal criteria. • Assess whether the appropriate information as required under GCP's has been captured in the protocol (e.g., protocol's title name, address of sponsor name, address of monitor name, and address of responsible parties), including the appropriate inclusion and exclusion criteria.	populations. • Formulate additional safeguards for vulnerable populations to be included in clinical trials. • Assess and determine whether the research questions being asked in the protocol contribute to the overall scientific understanding of human health.

Domain	4-Role-based Competencies (I)		
Activity	**(7-1-I) Regulate investigational products (such as vaccines, biologicals), review BA/BE studies and clinical trials as per GCP requirements**		
Career Progression	Level 1 – Early Career Professional	Level 2 – Mid Career Professional	Level 3 – Senior Professional
		• Verify that all clinical research records have been stored in accordance with GCP requirements.	

Domain	4-Role-based Competencies		
Activity	**(7-1-II) Review clinical trial results and confirm that the study was conducted according to GCP**		
Career Progression	Level 1 – Early Career Professional	Level 2 – Mid Career Professional	Level 3 – Senior Professional
Behavioral competencies per level *At each career level, personnel should be able to:*	• Demonstrate competency to review clinical trials pharmacokinetics, pharmacodynamics, toxicity, safety, and efficacy data. • Explain the relevant national and international principles (and GCP) of subject safety and ethical considerations (Nuremberg code, declaration of Helsinki, Belmont report etc.) including that care and protection are maintained throughout the study. • Understand the concepts related to inclusion and exclusion criteria and appropriate communication to patients or subjects. • Explain the safeguards to be put in pace when including vulnerable populations in clinical trials.	• Evaluate clinical trial results with respect to its accuracy and completeness. • Evaluate pharmacokinetics, noninferiority, biosimilarity, and *in vitro* and *in vivo* studies with different endpoints. • Review regulatory requirement for labels. • Plan and coordinate the review process of clinical trial results. • Evaluate clinical data (safety and efficacy) for clinical trials (for approval of following phases or marketing authorization). • Review documentation related to compliance with ethical guidelines. • Develop relevant guidelines and standards for human subject protections and privacy throughout all stages of clinical study. • Contrast and compare existing guidelines and requirements for human subject protection and privacy under different national and international regulations. • Examine implementation of appropriate legislation, guidelines and scientific standards throughout all phases of a clinical study. • Review and analyze that the concept of clinical equipoise is applied to guarantee	• Analyze submitted data in specific disciplines/specialty areas. • Evaluate the impact of vaccines and biologics on clinical practice and public health. • Assess submitted applications within their field to understand a range of issues, both unique and complex, to ensure product and regulatory compliance. • Evaluate and approve / disprove clinical data (safety and efficacy) for clinical trials or for marketing authorization for all types (complexity) of products. • Develop ethical standards and additional safeguards to protect vulnerable populations during clinical trials. • Approve the reviews of clinical equipoise and therapeutical misconception on patient safety. • Determine the appropriateness of clinical trial protocol inclusion and exclusion criteria for patient protection. • Develop and design rules and standards to protect the population against coercion to participate in the clinical trial research study. • Determine the informed consent

Domain	4-Role-based Competencies		
Activity	**(7-1-II) Review clinical trial results and confirm that the study was conducted according to GCP**		
Career Progression	Level 1 – Early Career Professional	Level 2 – Mid Career Professional	Level 3 – Senior Professional
		safety of patients and avoid therapeutic misconception. • Examine and verify whether the inclusion and exclusion criteria were carefully followed during the execution of the clinical trial. • Examine the informed consent document and its compliance with all appropriate regulations and guidelines. • Analyze the various safeguards proposed for the vulnerable populations to be appropriate. • Present summary of clinical trial results during review meetings on clinical trial safety, efficacy, and quality data to facilitate regulatory decision.	documents have been reviewed and approved by the appropriate institutional review board. • Develop and design standards and principles to protect and safeguard vulnerable patient populations against any possible eventualities when participating in a clinical trial.

Domain	4-Role-based Competencies		
Activity	**(7-1-III) Manage and process data (including statistical analysis) related to clinical research**		
Career Progression	Level 1 – Early Career Professional	Level 2 – Mid Career Professional	Level 3 – Senior Professional
Behavioral competencies per level *At each career level, personnel should be able to:*	• Explain the processes involved in traceability of data from clinical trial protocol to case report forms to the clinical study report. • Classify records, documents, and reports toward assessment of the traceability of submitted clinical trial data. • Demonstrate knowledge to verify the data submitted in the clinical trial reports are the same data collected during a clinical study. • Explain ALCOA+ (Accuracy, Legibility, Completeness, Originality, Authenticity) principles for data management. • Understand the guidelines and standards for managing data integrity.	• Analyze compliance of submitted clinical trial documents against standards and best practices. • Conclude that the reporting of clinical trial information is carried out by the clinical trial principal investigator, as well as the study sponsor. • Assess whether the clinical trial data are reported to the appropriate oversight bodies, including the institutional review board, as well as local and global regulators where appropriate. • Identify the appropriate study personnel involved in the collection and handling of all study data. • Determine whether highly qualified and competent statisticians are engaged in the analysis and reporting of the data generated during the conduct of the clinical trial. • Examine the description of appropriate statistical methods in study protocol. • Verify that all data meet ALCOA+ principles. • Verify that all data are being stored according to GCP standards, local policies, guidelines and procedures. • Examine the traceability and retrieval of the entire data set when stored. • Conduct independent analysis of	• Develop and design quality assurance standards and principles for clinical trial data analysis. • Interpret and use submitted data to make informed regulatory decisions. • Bring any issues related to the data integrity to the clinical investigator or manufacturer. • Design and develop guidelines and standards for management of data integrity for clinical trials. • Develop and design data integrity policies, guidelines, and procedures and ensure implementation. • Develop policies and guidelines for the retention and retrieval of data. • Verify that the appropriate SOPs are in place that govern good documentation practices (GDP).

Domain	4-Role-based Competencies		
Activity	**(7-1-III) Manage and process data (including statistical analysis) related to clinical research**		
Career Progression	Level 1 – Early Career Professional	Level 2 – Mid Career Professional	Level 3 – Senior Professional
		clinical trial data using robust methods. • Assess those methods employed in the conduct of the clinical trial, such as randomization, stratification, or crossover design, to ensure they are appropriately executed and documented.	

Domain	4-Role-based Competencies		
Activity	**(7-1-IV) Manage a database of all product applications received, approved, rejected, suspended or withdrawn along with their supporting documentation.**		
Career Progression	Level 1 – Early Career Professional	Level 2 – Mid Career Professional	Level 3 – Senior Professional
Behavioral competencies per level *At each career level, personnel should be able to:*	• Develop basic documents based on review. • Utilize appropriate software for cataloguing and communication. • Communicate with various stakeholders on regulatory information. • Develop communications for manufacturers and other relevant stakeholders. • Compile status reports on the various applications managed in a data management system. • Classify various applications on the database as per their status. • Generate guidelines, SOPs, and templates for management of each application managed on the database.	• Address various problems and queries with both scientific and regulatory documents. • Address stakeholder needs and queries. • Organize communication on regulatory conclusions with peers and stakeholders. • Review and make recommendations on the status reports on the various applications managed in a data management system. • Plan the development of clinical trial management and maintenance data management systems. • Analyze generated guidelines, SOPs and templates for management of each application maintained in the data management system. • Compile technical specifications for regulatory data management systems.	• Develop complete and effective communication strategies. • Utilize best practices for communication strategies. • Formulate special considerations required for studies in vulnerable populations. • Evaluate status reports and develop improvement plans for the management of applications and data management systems. • Approve guidelines, SOPs, and templates for management of each application maintained in the data management system.

Domain	4-Role-based Competencies		
Activity	**(7-1-V) Coordinate and manage the product review system/ process among the relevant departments and agencies**		
Career Progression	Level 1 – Early Career Professional	Level 2 – Mid Career Professional	Level 3 – Senior Professional
Behavioral competencies per level *At each career level, personnel should be able to:*	• Review the approved product register and ensure it is up to date. • Coordinate timelines and processes for review cycles. • Coordinate and organize review meetings and generate reports where applicable.	• Develop templates and tracking systems for market authorization processes. • Organize review meetings and evaluate reports. • Review guidelines, SOPs, and templates to enhance the product review process for market authorization. • Create and draft guidelines, SOPs, and templates to enhance the product review process.	• Determine and formulate various policies and contribute to enhancement as well as maintenance of approved product registration.

Domain	4-Role-based Competencies		
Activity	**(7-1-VI) Review the product labeling and information for the use of healthcare providers and patients**		
Career Progression	Level 1 – Early Career Professional	Level 2 – Mid Career Professional	Level 3 – Senior Professional
Behavioral competencies per level *At each career level, personnel should be able to:*	• Know the basic labeling requirements applicable to vaccines and biological products. • Compare the product labeling against the innovator product for biosimilars. • Maintain product information databases or data management systems. • Generate status and monitoring reports for review of product labels and information. • Understand labeling variation requirements. • Explain requirements for changes on leaflets, package inserts, labelling (i.e., container and package), and summary of product characteristics (SPCs). • Illustrate basic technical understanding of different types of product labeling variations. • Technically interpret and classify the appropriate information to be included in the package inserts (i.e., inserts and patient information leaflets), SPC-like information (i.e., information leaflets for professionals or equivalent) and labelling of container packaging, including relevant supporting documentation including forms and records (e.g., samples of mock-ups and published product information).	• Develop labeling requirements for vaccines and biological products. • Evaluate the product labeling against the innovator product for biosimilars. • Examine product information databases or data management systems. • Apply guidelines, SOPs, and templates to enhance the product information system. • Evaluate status and monitoring reports and provide quality assurance of the reports. • Develop and apply guidelines and procedures that define the types and scopes of variations and the format and content to be used for documenting the variations. • Apply guidelines and SOPs to evaluate changes made on the leaflets, package inserts, labeling (i.e., container and package), and SPCs • Distinguish between different types of product labeling variations and categorize them in terms of requirements for regulatory approval, those that require only notification to the regulator before or during implementation, and those that do not require notification. • Organize the technical information to be included in the package inserts (i.e.,	• Appraise labeling requirements for vaccines and biological products. • Develop and design product information databases or data management systems. • Design guidelines, SOPs, and templates to enhance the product information system. • Assess status and monitoring reports and provide quality assurance of the reports. • Formulate guidelines that define the types and scope of variations, the format and content to be used for documenting the variations, and the identification of those variations that require prior approval or notification. • Develop guidelines and standard requirements on changes made to leaflets, package inserts, labeling (i.e., container and package), and SPCs. • Clearly communicate and appraise product labeling variations that require regulatory approval before implementation and those that require only notification to the regulator before or during implementation, and those that do not require notifying the NRA. • Formulate guidelines on the content of product information leaflets, SPC-like information, and product packaging and

Domain	4-Role-based Competencies		
Activity	**(7-1-VI) Review the product labeling and information for the use of healthcare providers and patients**		
Career Progression	Level 1 – Early Career Professional	Level 2 – Mid Career Professional	Level 3 – Senior Professional
	• Outline and technically illustrate the supportive documentation including forms and records for product labeling and information guidance on the MA application requirements. • Explain and support formulation of guidelines and/or SOPs for assessing product information on SPC-like information, packaging, and product labels. • Select and classify information and documents describing the registration or MA application processing flow for the stage or phase of the process in which review of the product information (i.e., SPC-like, packaging and labeling information) is conducted, including medical products registration or market authorization application assessment reports.	inserts and patient information leaflets), SPC-like information (i.e., information leaflets for professionals or equivalent) and labeling of container packaging, including relevant supporting documentation such as forms and records (e.g., samples of mock-ups and published product information. • Analyze and identify the relevant technical content of product information leaflets, SPC-like information, and product packaging and labeling for vaccines and biological products, to provide for guidelines that provide direction on the MA application requirements. • Develop guidelines and/or SOPs for assessing product information on SPC-like information, packaging, and product labels. • Develop documents describing the registration or MA application processing flow for the stage or phase of the process in which review of the product information (i.e., SPC-like, packaging and labeling information) is conducted, including medical products registration or MA application assessment reports.	labeling for vaccines and biological products. • Determine the technical information that should be included in the package inserts (i.e., inserts and patient information leaflets), SPC-like information (i.e., information leaflets for professionals or equivalent) and labeling of container packaging, including relevant supporting documentation such as forms and records (e.g., samples of mock-ups and published product information. • Evaluate and approve the documents describing the registration or MA application processing flow for the stage or phase of the process in which review of the product information (i.e., SPC-like, packaging and labeling information) is conducted, including medical products registration or MA application assessment reports.

Domain	4-Role-based Competencies		
Activity	**(7-1-VII) Evaluate product quality by reviewing submitted documentation**		
Career Progression	Level 1 – Early Career Professional	Level 2 – Mid Career Professional	Level 3 – Senior Professional
Behavioral competencies per level *At each career level, personnel should be able to:*	• Outline basic elements of the product quality sections as part of the market authorization dossier. • Understand the extent of safety and quality data on active substance (i.e., drug substance) and finished product (drug product). • Understand the critical quality attributes (CQA), such identity, purity, potency, and safety, that are applicable to drug substance and drug product. • Understand the compendial test methods (appearance, pH, bioburden, endotoxin, osmolality/osmolarity, container closure integrity, container content for injections, sterility, etc.) applicable to drug substance and drug product. • Classify the nonclinical aspects and toxicology for safety of the drug product. • Summarize evaluation reports on the submitted quality data for product authorization.	• Evaluate active ingredients data (for vaccine and biologicals) against relevant standards and guidance (e.g., ICH Q5C). • Assess the drug substance and drug product CQAs to determine whether they meet specifications. • Review the drug substance and drug product manufacturing processes and the ability of the processes to meet the established CQAs. • Evaluate the Certificate of Analysis of drug substance and drug product batches to verify their completeness and acceptability. • Review the manufacturer's procedures for lot release of vaccines and biologicals. • Evaluate the compliance status (verification, validation) of compendial test methods (appearance, pH, bioburden, endotoxin, osmolality/osmolarity, container closure integrity, container content for injections, sterility, etc.) used for testing of drug substance and drug product.	• Review development report on active substance and finished product to ensure quality. • Appraise development report for finished products and assess their fitness for purpose. • Review CQAs of the finished products (e.g., vaccines, biologicals). • Ensure that all CQAs of the biological product are identified and assessed in the specifications as appropriate. • Review manufacturing methods, data, and controls to ensure lot to lot consistency. • Approve procedures for lot release of vaccines and biologicals including the adequacy of the Certificate of Analysis. • Review how the sterility of the finished product is ascertained. • Review comparability protocols showing equivalence of finished product and active substance used in previously approved vaccines or biologicals. • Evaluate submitted procedures for monitoring of safety signals on marketed vaccines looking for known and unknown safety risks and review adequacy of these procedures.

Domain	4-Role-based Competencies		
Activity	**(7-1-VIII) Make recommendations (approval, query, rejection) on product applications for clinical trial / registration/ market authorization or emergency use authorization based on review of data submitted**		
Career Progression	Level 1 – Early Career Professional	Level 2 – Mid Career Professional	Level 3 – Senior Professional
Behavioral competencies per level *At each career level, personnel should be able to:*	• Demonstrate knowledge in pharmacology or toxicology, and relevant regulations and guidelines. • Explain relevant guidelines and standards used to evaluate the safety, quality, and effectiveness of products. • Demonstrate technical understanding of risk management plans, criteria and standards implemented in circumstances in which the routine regulatory processes may not have to be followed for MA in relation to crises and emergencies (e.g. outbreaks, force majeure, and medical product shortages). • Define internal technical approaches and supporting documents that should be followed during crises and emergencies (e.g., outbreaks, force majeure, and medical product shortages). • Examine product applications for waivers from some clinical trials/registration/market authorization requirements. • List technically relevant information for the compilation of guidelines, procedures and other related documents to assist in the efficient preparation of the registration and MA application dossier and in the	• Apply the regulatory framework to evaluate and make recommendation on product application for clinical trials and market authorization. • Critically evaluate scientific data, assess risk, and communicate their findings and recommendations effectively. • Assess that the operationalization of a clinical research study complies with WHO or ICH Clinical Practice Guidelines. • Develop guidelines that defines the types and scope of variations, format and content. • Apply a risk-based approach to MA in circumstances in which the routine regulatory processes may not have to be followed. • Organize processes for MA evaluation to be followed during crises and emergencies (e.g., outbreaks, force majeure, and medical product shortages). • Examine approved waivers from some clinical trials / registration / market authorization requirements without compromising patient safety or the risk-benefit balance for vaccines or biological products. • Identify guidelines, procedures and related documents such as forms and	• Organize risk benefit analysis of products to make informed decisions to balance the interests of public health and safety with the needs of industry. • Deduce that products that are approved for use are safe, effective, and of high quality. • Assess that regulatory decisions are made in a transparent, consistent, and scientifically rigorous manner. • Design a risk management plan to cover circumstances in which the routine regulatory processes may not have to be followed. • Evaluate and communicate appropriate internal crisis and emergency management procedures. • Apply discretionary powers to waiver some clinical trials/registration/market authorization requirements for some vaccines/biological products in exceptional cases during emergency situations for the public health interest. • Compile and approve guidelines, procedures and related documents such as forms and templates to promote the efficient preparation of the registration and MA application dossier and in the documentation of the receipt and evaluation of the dossier.

Domain	4-Role-based Competencies		
Activity	**(7-1-VIII) Make recommendations (approval, query, rejection) on product applications for clinical trial / registration/ market authorization or emergency use authorization based on review of data submitted**		
Career Progression	Level 1 – Early Career Professional	Level 2 – Mid Career Professional	Level 3 – Senior Professional
	documentation of the receipt and evaluation of the dossier. • Collate data and organize information to assist the establishment of effective registration and MA activities from receipt of registration applications to issuance of technical evaluation summary reports. • Compare various technical documentation and select appropriate information to aid the compilation of procedures that will provide consistency in the approval or rejection of applications through the application of defined requirements and criteria. • Interpret the supportive information submitted on proposed drug labels to determine whether they contain truthful claims about the product's effectiveness, appropriate warnings, precautions about the product's safety, and/or adequate directions for the product's use. • Contribute to the effective utilization of resources, planning strategies and promote efficient biological/vaccine products reviews based on risk-based approach. • Contribute to the assessment of preclinical (animal) studies submitted in support of investigational new vaccines and/or biologics	templates to support the efficient preparation of the registration and MA application dossier. • Create process mapping and categorize information to support the establishment of effective registration and MA activities. • Analyze information required to develop guidelines and standards for the review and evaluation of the different components of registration or MA applications. • Identify relevant documents to assist the compilation of procedures that will provide consistency in the approval or rejection of applications for MA. • Identify the link between developing a new intervention and the interrelated trial goals and design by reading and comprehending a clinical trial protocol. • Assess supportive information submitted on proposed drug labels to determine whether they contain truthful claims about the product's effectiveness, appropriate warnings, and precautions about the product's safety, and/or adequate directions for the product's use. • Organize allocated resources and implement effective planning strategies to ensure that reviews are effectively	• Design processes and steps to be followed, the resources required for effective registration and MA activities. • Develop guidelines for the review and evaluation of the different components of registration or MA applications; to facilitate the review and evaluation of the specific requirements of each product class; and to grant / reject MAs • Design procedures that will provide consistency in the approval or rejection of applications. • Formulate recommendations on trial protocols to ensure the links between the objective of developing a new intervention and the related trial goal and design are accurate. • Decide on proposed drug labels to determine whether they contain truthful claims about the product's effectiveness, appropriate warnings, and precautions about the product's safety, and/or adequate directions for the product's use. • Plan resources so that reviews are effectively performed based on the risk-based approach and resources are rationally allocated. • Appraise and provide recommendations on the results of preclinical (animal) studies submitted in support of

Domain	4-Role-based Competencies		
Activity	**(7-1-VIII) Make recommendations (approval, query, rejection) on product applications for clinical trial / registration/ market authorization or emergency use authorization based on review of data submitted**		
Career Progression	Level 1 – Early Career Professional	Level 2 – Mid Career Professional	Level 3 – Senior Professional
	• Classify pharmacokinetics, BA/BE, in vitro and / or in vivo studies with different end points. • Define requirements for a risk management plan in the vaccines/ biological products application. • Contribute to one or two specific disciplines / specialty area to the analysis and evaluation of data submitted for clinical trial approval, marketing authorization, or post approval decisions. • Explain statutory requirements and approved scientific references materials to analyze clinical data (safety and efficacy) and product quality data for clinical trials or for marketing authorization for all types (complexity) of products. • Demonstrate knowledge of how to review the various components of the clinical trial applications, including supportive checklists or clinical trials application review form, that are used to justify authorization, rejection or deferral of the clinical trials applications.	performed based on the risk-based approach and resource allocated. • Apply relevant guidelines and assessment tools to analyze the results of preclinical (animal) studies submitted in support of investigational new vaccines/biologics • Categorize pharmacokinetic, BA/BE data, in vitro and/or in vivo studies with different end points. • Analyze risk management plans and identify whether it meets applicable requirements. • Apply relevant guidelines and approved scientific references materials to assess clinical data (safety and efficacy) and product quality data for clinical trials or for marketing authorization for all types (complexity) of products. • Organize the review of the various components of the clinical trial applications, including supportive checklists or clinical trials application review form, that are used to justify authorization, rejection or deferral of the clinical trials applications.	investigational new vaccines and/or biologics • Appraise and make determination on pharmacokinetic, bioavailability / bioequivalence data, in vitro and/or in vivo studies with different end points. • Review risk management plans and make final recommendations. • Evaluate and make final recommendations on clinical data (safety and efficacy) and product quality data for clinical trials or for marketing authorization for all types (complexity) of products. • Develop review of the various components of the clinical trial applications, including supportive checklists or clinical trials application review form, that are used to justify authorization, rejection or deferral of the clinical trials applications.

Domain	4-Role-based Competencies		
Activity	**7-1-IX - Monitor clinical trials data, variants, amendments or changes to registered products and review CAPA submitted by the applicants**		
Career Progression	Level 1 – Early Career Professional	Level 2 – Mid Career Professional	Level 3 – Senior Professional
Behavioral competencies per level *At each career level, personnel should be able to:*	• Track and monitor clinical trial data and registered product changes. • Understand data variants and amendments. • Understanding of CAPA concepts. • Provide concise summaries of monitored data and changes.	• Apply analytical skills to assess clinical trial data for potential risks and deviations. • Evaluate the impact of registered product changes on regulatory compliance. • Have in-depth understanding of regulatory requirements related to clinical trials and registered product modifications. • Be proficient in interpreting CAPA submissions and assessing their effectiveness. • Actively contribute to process improvements in monitoring and CAPA review.	• Provide strategic oversight in monitoring complex clinical trial data and registered product changes. • Develop and implement strategies to enhance the efficiency of monitoring processes. • Lead cross-functional initiatives to improve overall regulatory processes. • Make informed decisions on complex issues related to clinical trial data and CAPA submissions. • Evaluate the long-term impact of registered product changes on public health and regulatory compliance.

8.2 Competencies for Inspectors

Domain	4-Role-based Competencies		
Activity	**(7-2-I) Perform GMP / GCP / GLP / GSDP inspections as per applicable guidelines**		
Career Progression	Level 1 – Early Career Professional	Level 2 – Mid Career Professional	Level 3 – Senior Professional
Behavioral competencies per level *At each career level, personnel should be able to:*	• Understand ICH Q5E. • Understand the product and laboratory control methods. • Explain vaccines and biologics manufacturing processes and control methods. • Understand the components of lot release protocols for vaccines and biologicals. • Infer the SOPs for summary protocol review. • Demonstrate basic legal and administrative aspects of clinical trials (GCP) inspections for vaccines and biologics. • Observe GxP inspection and summarize the process. • Classify various tools and templates as per relevant GxP inspection. • Demonstrate reading and interpretation of vaccine vial monitor device. • Explain national and international guidelines on GSDP for vaccines and biologics. • Explain national and international guidelines on GLP. • Explain national and international	• Apply the principles of ICH Q6B or other similar national guidelines during inspection of manufacturing facility. • Apply the principles of ICH Q5E or other similar national guidelines during inspection of manufacturing facility. • Assess requirements for clean rooms, controlled environments, and activities within clean rooms as per ISO 14644-1: 2015 are maintained. • Assess adequacy of cold chain and cold chain monitoring. • Analyze manufacturing processes and control methods during inspection. • Build inspection plan of a manufacturing facility, clinical trial site, laboratory, or warehouse to assess GxP compliance. • Examine the critical quality attributes (identity, potency, purity, concentration, integrity etc.) of the applicable product (inactivated, attenuated, subunit, DNA, mRNA, viral vector and VLP vaccines and other biologicals) from submitted documentation during inspection. • Assess applications for GCP inspection for vaccine and biologics by clinical research organizations performing clinical studies. • Assess applications of distributors and	• Evaluate the manufacturer's QMS that supports lot release of vaccines and biologics. • Develop checklist for summary protocol review. • Contribute to the establishment of procedure for selection of lots of vaccines/biologics for independent testing as part of lot release. • Develop procedure for review of summary protocol that describes the acceptance criteria for completeness. • Evaluate quality systems of the clinical trial for vaccines and biologics. • Coordinate inspections of approved facilities for compliance over time. • Evaluate the risks/ impact of facility non-compliances or deviations on clinical practice and public health. • Design the GCP inspection plan using various tools and checklists for vaccines and biologics. • Evaluate and approve inspection reports for GCP inspections. • Evaluate the inspections reports and determine / recommend CAPA for the manufacturers / clinical trials.

Domain	4-Role-based Competencies		
Activity	**(7-2-I) Perform GMP / GCP / GLP / GSDP inspections as per applicable guidelines**		
Career Progression	Level 1 – Early Career Professional	Level 2 – Mid Career Professional	Level 3 – Senior Professional
	guidelines on Good Manufacturing Practices for vaccines and biologics. • Understand legislation on vaccines and biologics licensing and inspection of manufacturers, importers, retailers/pharmacies, and healthcare facility dispensaries.	wholesalers for GCP inspection for vaccine and biologics. • Assess applications for GCP inspection for vaccine and biologics by laboratories in non-clinical research and drug development, and in bioanalytical laboratories. • Assess applications for inspection of biologics active substances and finished products. • Examine temperature measurement equipment used in monitoring vaccine storage for adequacy and utilization. • Examine manufacturer's SOPs for preparing summary protocol to assess compliance of the lot/batch against GMP requirements. • Analyze security of databases used to capture information for a particular test or section of the protocol. • Document and analyze any discrepancies, errors, or OOS results found during the inspection. • Analyze all critical quantitative data from quality control test results, especially potency test results from the manufacturer or other sources to perform trend analysis as an essential part of lot release. • Examine the clinical trials' safety reporting and its compliance to GCP	• Determine potential risks at each segment of cold chain for manufacturer. • Apply legal and regulatory frameworks to assess compliance to imports, exports, and shipments of vaccines at the national and regional levels. • Review corrective action reports submitted by manufacturers / distributors for approval. • Plan and design GLP inspections of drug development research laboratories for vaccines, biologics, and bioanalytical laboratories. • Assess performance of bioanalytical laboratories based on regulatory requirements. • Verify accreditation/ certification of bioanalytical laboratories to regional and international certifying bodies. • Determine any data integrity breach or documentation risks during GLP inspection. • Evaluate and approve inspection reports for GLP inspections and review corrective actions taken by the laboratory. • Evaluate quality risk management plans of vaccines and biologics manufacturing plants, control strategy to minimize variability and preventive measures to avoid contamination and

Domain	4-Role-based Competencies		
Activity	**(7-2-I) Perform GMP / GCP / GLP / GSDP inspections as per applicable guidelines**		
Career Progression	Level 1 – Early Career Professional	Level 2 – Mid Career Professional	Level 3 – Senior Professional
		principles. • Inspect clinical studies to assess compliance with GCP requirements. • Analyze documentations for clinical evaluation of vaccine especially for assurance of immunogenicity, efficacy and effectiveness, and safety in compliance with GCP. • Assess compliance with GSDP, including personnel, premises, equipment, environment, documentation, distribution systems, transport and handling systems and recommend for certification for GSDP compliance. • Inspect and examine facilities, personnel, study animals' management, study protocols, SOPs, test drug product, data collection, documentation of results and quality management system. • Analyze documentations for non-clinical evaluation of vaccine including assessment of all clinical quality assurance and compliance with GLP. • Identify GMP deficiencies and evaluate risk of the deficiency to the patient. • Classify necessary sanctions for violation of drug legislation during GxP inspection.	cross-contamination. • Evaluate purification and filtration techniques for vaccines and biologics. • Plan continuous assessment of approved vaccines and biologics manufacturing facilities to ensure their continued compliance to GMP requirements. • Identify non-compliances or deviations, evaluate their impact, and decide regulatory actions. • Award regulatory actions (issue, vary, suspend, or withdraw licenses) for vaccines and other biologic products. • Evaluate the overall approach to how quality risk management is used in the organization.

Domain	4-Role-based Competencies		
Activity	**(7-2-I) Perform GMP / GCP / GLP / GSDP inspections as per applicable guidelines**		
Career Progression	Level 1 – Early Career Professional	Level 2 – Mid Career Professional	Level 3 – Senior Professional
		• Plan all types of inspections such as routine, investigative, and ad hoc inspections for vaccine and biologics. • Refer the appropriate regulatory reference when making an observation of noncompliance. • Determine the overall approach for monitoring, investigations, and corrective actions during an inspection. • Analyze various methods of controlling contamination and mix-up to determine their effectiveness.	

Domain	4-Role-based Competencies		
Activity	**(7-2-II) Document and manage data collected during inspections**		
Career Progression	Level 1 – Early Career Professional	Level 2 – Mid Career Professional	Level 3 – Senior Professional
Behavioral competencies per level *At each career level, personnel should be able to:*	• Explain data governance system to ensure integrity of inspection data. • Demonstrate knowledge of data the lifecycle. • Explain various data vulnerabilities associated with inspection process. • Classify documentation using the principles of data integrity per ALCOA+ before and during a GxP inspection. • List and Explain facts and observations made during GxP inspection. • Understand the GDP. • Use computerized systems to create and manage inspection data.	• Analyze the facts and observations made during inspection. • Develop data risk assessment. • Apply GDP while collecting and recording data during inspection. • Categorize data and documents received from manufacturers in a format that can support review and decision making. • Record the processes linked with audit of clinical research operations. • Verify and conclude data collected during an inspection.	• Support provision of resources for storage of data / documents / records of facts and observations made during inspections. • Review and approve the manufacturer's policies, practices, and procedures for data lifecycle management. • Identify interoperability between systems to ensure easy transfer of data. • Develop a data governance system and organize data risks assessment. • Formulate audit trail system to track changes in data / documentation.

Domain	4-Role-based Competencies		
Activity	**(7-2-III) Establish quality system for the inspectorate function**		
Career Progression	Level 1 – Early Career Professional	Level 2 – Mid Career Professional	Level 3 – Senior Professional
Behavioral competencies per level *At each career level, personnel should be able to:*	• List completed, ongoing and upcoming inspections. • Demonstrate the quality management system for the inspectorate in managing various inspections and associated activities. • Classify inspections as per the risk management matrix. • Coordinate inspection activities within the inspectorate.	• Coordinate the schedule of GxP inspections related to vaccines and biologicals. • Organize the inspection and licensing system for vaccine and biologicals manufacturers. • Develop relevant GxP guidelines for public dissemination. • Maintain and organize a system of records related to each inspection and its outcomes. • Apply the risk management system by identifying the risks associated with each application.	• Develop quality manual for inspectorate system. • Review and support the maintenance of information repositories. • Develop a risk management matrix for inspection and its monitoring. • Plan and allocate resources.

Domain	4-Role-based Competencies(V)		
Activity	**(7-2-IV) Evaluate processes and documentation that verifies quality of products (starting materials, intermediates and finished products) during inspection**		
Career Progression	Level 1 – Early Career Professional	Level 2 – Mid Career Professional	Level 3 – Senior Professional
Behavioral competencies per level *At each career level, personnel should be able to:*	• Understand biosafety requirements and procedures for vaccine and biological manufacturing. • Explain requirements related to biomanufacturing equipment and facilities. • Demonstrate knowledge of all relevant QC and QA methods in manufacturing of vaccines and biologicals. • Understand the importance of batch records. • Understand the critical quality attributes (CQAs) for vaccines and biologics in the marketing authorization.	• Identify manufacturing procedures of vaccines and biologics, including mRNA technology. • Analyze bioanalytical techniques that assess variability and its impact on product quality and consistency. • Examine control strategies for environmental contamination levels for high-risk products or intermediates. • Infer stability data of reference samples or retention samples of biological starting materials and finished products. • Determine whether microbiological tests (sterility tests or purity checks) verify lack of contamination. • Determine that vaccines and biologics manufacturers have traceability plan for proper use and storage of reference standards and their stability • Examine lot-to-lot consistence of biological products and vaccines and review comparability protocols. • Analyze appropriateness of a given container to maintain product integrity under the different storage conditions. • Identify inconsistencies and problems with batch records.	• Evaluate pharmaceutical quality system of vaccines and biologics. • Assess quality risk management plans and control strategy. • Analyze bioburden and endotoxin control measures in entire aseptic manufacturing process (e.g., water sources, sterilization of final product). • Predict the potential quality issues given the characteristics of the starting materials and finished products. • Assess whether the analytical methods meet all applicable ICH (or other relevant) requirements for vaccines and biologicals. • Appraise relevant stakeholders on batch record inconsistencies.

Domain	4-Role-based Competencies (VII)		
Activity	**(7-2-V) Develop technical regulatory documents for inspections**		
Career Progression	Level 1 – Early Career Professional	Level 2 – Mid Career Professional	Level 3 – Senior Professional
Behavioral competencies per level *At each career level, personnel should be able to:*	• Understand regulatory frameworks, guidelines, SOPs and tools for regulation of vaccines and biologics. • Know various stakeholders involved in the development, manufacture, distribution and marketing of vaccines and biologics. • Explain the regulations related to quality, safety and efficacy of vaccines and biologics. • Interpret the guidelines and SOPs applicable to the GxP inspection for vaccines and biologics across the supply chain. • Classify the vaccines and biologics regulatory inspection outcomes that informs decision making. • Understand the SOPs for handling (receiving, documenting, investigating and preparation of final report) product quality complaints.	• Develop draft regulatory frameworks, guidelines, SOPs, and tools for regulation of vaccines and biologics. • Develop and apply SOPs for vaccines and biologics storage in the entire supply chain. • Examine the quality of regulatory reports and records against the set QMS. • Outline and review required documentation for import of vaccines and biologicals. • Assist in the development and implementation of SOP and CAPAs. • Contribute to updating the regulatory frameworks, guidelines, SOPs, and tools for regulation of vaccines and biologics in line with emerging issues. • Contribute to the development of information portal for the regulatory frameworks, guidelines, SOPs and tools for regulation of vaccines and biologics for public use. • Organize investigations into product quality complaints, prepare investigation reports, and advise on appropriate regulatory actions. • Conclude the regulatory decisions such as suspension, withdrawal, modification, or cancellation of license for vaccine and biological manufacturing premises	• Validate and approve regulatory frameworks, guidelines, SOPs) and tools for regulation of vaccines and biologics. • Assess adherence to the regulatory frameworks, guidelines, (SOPs) and tools for regulation of vaccines and biologics. • Approve the regulatory decisions such as suspension, withdrawal, modification, or cancellation of license for vaccine / biological manufacturing premises and clinical trial sites based on relevant inspection results and applicable regulatory guidelines. • Provide regulatory guidance to the leadership and the board/scientific committees. • Provide scientific evidence to inform on policy / regulatory reviews.

Domain	4-Role-based Competencies (VII)		
Activity	**(7-2-V) Develop technical regulatory documents for inspections**		
Career Progression	Level 1 – Early Career Professional	Level 2 – Mid Career Professional	Level 3 – Senior Professional
		and clinical trial sites based on relevant inspection results and applicable regulatory guidelines. • Outline regulatory guidance for the applicants, sponsors, and manufacturers during regulatory correspondence. • Coordinate and communicate the outcomes of inspections of facilities for vaccines and biologics with relevant stakeholders.	

Domain	4-Role-based Competencies		
Activity	**(7-2-VI) Enforce GxP guidelines for vaccines and biologicals**		
Career Progression	Level 1 – Early Career Professional	Level 2 – Mid Career Professional	Level 3 – Senior Professional
Behavioral competencies per level *At each career level, personnel should be able to:*	• Explain the GxP guidelines to the relevant stakeholders, if needed (manufacturers, Clinical Research Organizations, laboratories) • Classify various GxP guidance notes for the stakeholders as per their importance and risk profile • Define the policy, regulations, and procedures for waste disposal of vaccines, biologicals and other materials (e.g., starting materials) during manufacturing, storage and transport. • Understand the regulatory requirements and SOPs for inspection of vaccines and biologics at the port of entry. • Screen imports for vaccines and biologics towards identifying SF vaccine products. • Understand the guidelines and procedures for surveillance and sampling of vaccines and biologics in the supply chain. • Demonstrate the process of sampling of imported vaccines and biologicals and their handling, storage and transportation.	• Assess application of national policy, regulations, and procedures for the disposal of expired, substandard, and poorly stored vaccines. • Develop necessary templates, tools, checklists, SOPs and guidelines for manufacturers, clinical research organizations and distributors to follow in compliance to the GxP guidelines • Monitor and examine global alerts related to product quality • Develop procedures for screening and examination of imported vaccines and biologics. • Organize awareness campaigns and training materials towards industry self-regulation. • Develop public education programs on reporting product quality issues. • Plan surprise GxP inspections based on risk portfolio associated with products. • Apply the acceptance / rejection criteria for vaccines lot release from the manufacturer / Health Authority in determining vaccines for disposal / destruction. • Determine if the manufacturer, clinical site or distributor applies policies and procedures for waste segregation and collection.	• Develop a surveillance program to monitor SF products and disposal procedures adopted by manufacturers, clinical sites and others for biologicals and vaccines. • Validate the screening and sampling techniques for imported vaccines and biologics based on risk-based approach and intelligence information. • Design and evaluate control strategies to prevent dispensing of expired and substandard vaccines and other biological products in healthcare facilities. • Take regulatory actions based on the outcome of investigation of product quality complaints as appropriate. • Use reports of screening and examination of vaccines and biologics to alert other regulatory functions for monitoring compliance. • Formulate measures to seize and remove / recall SF vaccine or biological product from the market. • Collaborate with national or international authorities to identify and arrest suspects of falsification / counterfeiting.

Domain	4-Role-based Competencies		
Activity	**(7-2-VI) Enforce GxP guidelines for vaccines and biologicals**		
Career Progression	Level 1 – Early Career Professional	Level 2 – Mid Career Professional	Level 3 – Senior Professional
		• Gather information on SF products from a range of sources.	

8.3 Competencies for Laboratory Analysts

Domain	4-Role-based Competencies		
Activity	**(7-3-I) Operate in a manner that facilitates a safe and hazard-free work environment**		
Career Progression	Level 1 – Early Career Professional	Level 2 – Mid Career Professional	Level 3 – Senior Professional
Behavioral competencies per level *At each career level, personnel should be able to:*	• Participate in laboratory safety programs and demonstrate knowledge of relevant safety policies, guidelines, and regulations related to laboratory safety within the quality control labs. • Compile and report safety related incidents and reports to appropriate authorities. • Initiate an emergency incident response. • Choose relevant personal protective equipment while working in the quality control labs. • Apply established waste management program for disposal of all hazardous, biological, pharmaceutical, and chemical waste.	• Develop and implement SOPs for handling hazardous and biohazardous materials (laboratory safety program). • Analyze implementation of policies, guidelines, and procedures on laboratory safety and handling of biohazardous materials and sterile materials to ensure their effectiveness. • Organize appropriate safety information and documents, such as safety data sheets, are available on all chemicals, reagents, drugs, vaccines, biologics, and other applicable materials that are utilized in the quality control laboratories. • Develop emergency incident response measures. • Organize laboratory biosecurity protocols. • Analyze all safety-related documents. • Implement heightened control measures for working with hazardous chemicals and reagents.	• Categorize control measures (regular, heightened, and maximum) in a laboratory based on risk assessment of products. • Develop and implement policies, guidelines, and procedures on laboratory safety, and handling of biohazardous materials. • Design and implement a biological risk control strategy. • Design and maintain the safety program for quality control laboratories. • Develop relevant safety procedures, policies, guidelines, and regulations. • Evaluate newly emerging policies and procedures that impact laboratory, safety, and handling of biohazardous materials. • Assess implementation of policies, guidelines, and procedures on laboratory safety and handling of biohazardous materials. • Address any gaps in safety policies and procedures. • Develop and supervise the implementation of safety procedures required within the laboratory.

Domain	4-Role-based Competencies		
Activity	**(7-3-I) Operate in a manner that facilitates a safe and hazard-free work environment**		
Career Progression	Level 1 – Early Career Professional	Level 2 – Mid Career Professional	Level 3 – Senior Professional
			• Conduct laboratory biosecurity risk assessment and implement change control when needed.

Domain	4-Role-based Competencies		
Activity	**(7-3-II) Use equipment that is suitable for accurate and reliable measurement of products.**		
Career Progression	Level 1 – Early Career Professional	Level 2 – Mid Career Professional	Level 3 – Senior Professional
Behavioral competencies per level *At each career level, personnel should be able to:*	• Participate in equipment/instrument management program which includes qualification, calibration, preventative maintenance, and proper daily use. • Categorize instruments as per relevant guidelines, for example, USP 1058. • Follow annual preventive maintenance plan for specified equipment. • Adhere to the internal policies and/or manufacturers' recommendations and manuals to comply with international standards and regulatory requirements. • Understand national, regional, and international guidelines and procedures for qualification/validation of laboratory equipment. • Support the processes in post-preventive maintenance program. • Draft procedures and guidelines for qualification of category 1 and 2 laboratory equipment. • Demonstrate knowledge of calibration and verification process for category 1 and 2 laboratory equipment. • Document and maintain records of equipment qualification activities in an approved report. • Explain the steps to logical troubleshooting.	• Develop the process for performing and documenting preventive maintenance, performing calibration and verification of all equipment including instruments, systems, and test equipment used for testing in a laboratory. • Monitor the performance of key quality control laboratory equipment. • Develop annual preventive maintenance plan. • Organize troubleshooting of equipment when needed. • Plan a post-preventive maintenance program. • Organize change control systems for equipment. • Identify equipment malfunction and replacement of spare parts. • Analyze commissioning and validation/qualification of equipment used by subcontractors. • Analyze guidelines and procedures for qualification and validation of laboratory equipment. • Organize policy, guidelines, and procedures, and documentation to manage equipment qualification. • Plan design qualification activities for new equipment.	• Design a metrology equipment/instrument management program with defined guidelines, SOPs, accountability matrix, and tracking for performing calibrations, performance verifications. • Establish a system for equipment life-cycle management to include all stages between commissioning and decommissioning. • Collaborate with procurement department to ensure timely purchase and replacement of laboratory equipment and parts. • Audit laboratory measurements submitted by subcontracted laboratories. • Appraise and apply policy, guidelines, and procedures for qualification and validation of laboratory equipment. • Evaluate equipment needs. • Develop user requirements specifications. • Evaluate equipment qualification reports. • Design processes for equipment calibration, maintenance, and requalification.

Domain	4-Role-based Competencies		
Activity	**(7-3-II) Use equipment that is suitable for accurate and reliable measurement of products.**		
Career Progression	Level 1 – Early Career Professional	Level 2 – Mid Career Professional	Level 3 – Senior Professional
	• Troubleshoot non-sophisticated equipment as a facilitation to their verification process.	• Identify safety requirements and drafts procedure on safety rules followed during equipment handling and qualification exercise. • Identify inputs and utilities for equipment installation and qualification and ensure they are procured in a timely manner. • Troubleshoot sophisticated equipment and devises solutions to complex problems encountered during the equipment qualification process.	• Assess computer systems validation data, ensuring qualified equipment are run with appropriate computer systems. • Assess the troubleshooting processes and reports. • Evaluate factory acceptance and site acceptance inspection reports to ensure the requisitioned equipment is supplied.

Domain	4-Role-based Competencies		
Activity	**(7-3-III) Apply national and international standards, guidelines and best practices while assessing biological product quality and safety.**		
Career Progression	Level 1 – Early Career Professional	Level 2 – Mid Career Professional	Level 3 – Senior Professional
Behavioral competencies per level *At each career level, personnel should be able to:*	• Explain standards and best practices, including current GLP, good microbiological laboratory practices, and GMP as applicable to quality control laboratories for vaccines and biologics. • Define standards for specific products, such as mRNA vaccines, and align them regional as well as international best practices. • Demonstrate the principles of reliance and harmonization. • Define certification /accreditation scheme for assuring the safety, quality, and efficacy of vaccines and biologics. • Understand laws pertaining to the operation of quality control laboratories. • Infer information on safety, efficacy, and quality of vaccines and biologics received from other NRAs.	• Identify standards required for analysis of products. • Develop and retain documentation to comply with quality regulations. • Organize routine audits of quality control processes and systems. • Engage in the development of national standards to ensure they are based on sound scientific and regulatory guidance. • Apply the certification /accreditation process for quality control, laboratories, and personnel. • Apply laws pertaining to the operating principles and procedures of the quality control labs. • Analyze components of the laboratory information management system to ensure they are compliant with regulatory standards. • Discover areas where existing processes should change resulting from audit findings. • Organize improvements to processes by changing approaches and working practices, typically using recognized models and standards. • Apply relevant risk regulations, policies, and procedures to non-complex issues.	• Apply standards and best practices, including current GLP as applicable to quality control laboratories for vaccines and biologics. • Evaluate the use of standards and best practices. • Appraise national and international standards for those that apply to quality control laboratories. • Assess certification / accreditation process for quality control laboratories. • Evaluate compliance with laws pertaining to quality control laboratories. • Prioritize areas for quality improvement by considering strategy, business objectives, and results from internal and external audits. • Identify and plan systematic corrective action to reduce errors and improve the quality of the systems and services provided by quality control laboratories. • Develop innovative approaches to managing significant organization-wide risks effectively and efficiently. • Develop and implement appropriate risk mitigation for significant and unusual risks to which the organization is exposed. • Ensure the autonomy of the quality control laboratory to ensure independent, authoritative, and impartial

Domain	4-Role-based Competencies		
Activity	**(7-3-III) Apply national and international standards, guidelines and best practices while assessing biological product quality and safety.**		
Career Progression	Level 1 – Early Career Professional	Level 2 – Mid Career Professional	Level 3 – Senior Professional
		• Implement risk reporting systems to facilitate communications for decision makers.	decisions on safety, efficacy, and quality of vaccines and biologics.

Domain	4-Role-based Competencies		
Activity	**(7-3-IV) Use suitable analytical methods to analyze product quality.**		
Career Progression	Level 1 – Early Career Professional	Level 2 – Mid Career Professional	Level 3 – Senior Professional
Behavioral competencies per level *At each career level, personnel should be able to:*	• Understand national, regional, and international guidelines for analytical procedures and methods validation for vaccines and biologics. • Understand quality attributes of different vaccine types, such as live-attenuated, inactivated, protein subunit, recombinant, polysaccharide, conjugate, toxoid, nucleic acid (mRNA, DNA), inactivated viral vector, and virus-like particle vaccines. • Prepare guidance for the biopharmaceutical industry on analytical methods development for vaccines and biologics including critical parameters parameters based on method validation, verification, and technical transfer. • Understand various bioassays for potency determination applicable to vaccines (animal-based, cell culture-based, and biochemical assays). • Explain method, verification, qualification, and validation, and the technology transfer of analytical procedures. • Prepare protocol report for analytical methods for vaccines and biologics.	• Develop national and regional guidelines for analytical procedures and method validation for vaccines and biologics. • Develop toolkits for assessing quality attributes of various vaccines and biologics. • Organize the transfer / validation of new methods of analysis or manufacturers in-house test methods in accordance with a predefined protocol. • Evaluate robustness of analytical method for vaccines and biologics (scope, apparatus/equipment, operating procedures, reagents/standards, sample preparation, standards control solution preparation, procedure, system suitability, calculations, data reporting) and advise on any variations in method parameters that might occur. • Conduct and record revalidation (verification) of method performance in case of changes to materials. • Collate and interpret test results of method verification, qualification, and validation. • Extend training to NRA staff on how to conduct analytical methods for vaccines and biologics. • Develop tools and checklist to guide inspection of pharmaceutical industries	• Review and approve implementation of testing and re-testing policies. • Review and approve implementation of all validation procedures. • Assess revisions to validation procedures and protocols, including method transfer. • Provide technical guidance on advancement in technology for vaccines and biologics manufacturing. • Ensure that existing analytical methods and specifications align with current science and knowledge. • Assess technical reports and documentation such as deviation reports, testing protocols, and trend analyses, identifying root causes, and advise on corrective actions. • Determine the robustness of specifications and monographs for vaccines. • Approve the validation of analytical methods. • Elaborate analytical method verification and validation results. • Supervise the qualification, validation, and calibration program of analytical equipment.

Domain	4-Role-based Competencies		
Activity	**(7-3-IV) Use suitable analytical methods to analyze product quality.**		
Career Progression	Level 1 – Early Career Professional	Level 2 – Mid Career Professional	Level 3 – Senior Professional
		on analytical methods used for various vaccines and biologics.	

Domain	4-Role-based Competencies		
Activity	**(7-3-V) Participate in investigation of out-of-specification (OOS) results and support implementation of corrective actions.**		
Career Progression	Level 1 – Early Career Professional	Level 2 – Mid Career Professional	Level 3 – Senior Professional
Behavioral competencies per level *At each career level, personnel should be able to:*	• Follow laboratory procedures for identification and investigation of OOS test results. • Apply procedures related to OOS results investigations. • Support OOS and other out of expectation/trend investigations. • Demonstrate knowledge of implementing corrective action with the goal of eliminating recurrences.	• Develop plan to investigate OOS results. • Determine possible root cause using relevant techniques and apply corrective actions. • Identify CAPAs and perform effectiveness review of corrective action for OOS and trend analysis. • Summarize issues arising from the investigation of OOS results and execution failures. • Apply national, regional, and international regulations and guidelines on investigation of OOS results.	• Evaluate effectiveness of procedures to investigate OOS results. • Evaluate the effective actions implemented to address OOS. • Determine acceptability of test results. • Drive system improvements, if warranted. • Monitor and track corrective action and OOS investigations trending to identify potential repeat occurrences

Domain	4-Role-based Competencies		
Activity	**(7-3-VI) Adhere to laboratory operational procedures and systems**		
Career Progression	Level 1 – Early Career Professional	Level 2 – Mid Career Professional	Level 3 – Senior Professional
Behavioral competencies per level *At each career level, personnel should be able to:*	• Explain the importance of a quality management system. • List the quality management system essential elements. • Demonstrate relationship of quality model to relevant standards. • Describe practices to prevent or reduce risks. • Understand the quality system of an analytical laboratory. • Describe the requirements for a preventive maintenance program for equipment. • Explain the importance of documentation related to purchasing and inventory. • Explain the importance of maintaining sample integrity and assuring that all regulations and requirements are met when transporting samples. • Describe the process involved in the development of standards. • Adhere to International Organization for Standardization documents and quality manual. • Describe the hierarchy of documents and the role of each level. • Demonstrate methods and tools for safe storage of documents and records.	• Analyze general safety requirements for the laboratory. • Develop a monitoring plan for the inventory system. • Develop a system for sample handling, including collection, transport, storage, and disposal. • Ensure that laboratory analytical data are linked to the findings. • Analyze information and data and identify corrective and preventive actions. • Categorize instances on preventive action, remedial action, and corrective action. • Organize root cause analysis where needed.	• Utilize modern project management approaches to handle laboratory projects. • Decide on the selection and acquisition of new equipment. • Formulate the various process control systems. • Design tools to monitor laboratory processes so that problems can be identified and improved upon. • Plan and manage internal audits. • Perform statistical analysis and other data analysis as needed.

Domain	4-Role-based Competencies		
Activity	**(7-3-VI) Adhere to laboratory operational procedures and systems**		
Career Progression	Level 1 – Early Career Professional	Level 2 – Mid Career Professional	Level 3 – Senior Professional
	• Explain the purpose of a quality manual.		

Domain	4-Role-based Competencies		
Activity	**(7-3-VII) Verify analytical reports for tested products**		
Career Progression	Level 1 – Early Career Professional	Level 2 – Mid Career Professional	Level 3 – Senior Professional
Behavioral competencies per level *At each career level, personnel should be able to:*	• Understand the use of master data management processes for data analysis and reporting. • Maintain information handling procedures for analytical data. • Classify the analytical reports to ensure availability, integrity, and searchability of information. • Demonstrate knowledge of metadata structures and protection measures for data and reports.	• Develop master data management processes for all analytical reports. • Organize data management structures and metadata to support consistency of information retrieval, combination, analysis, pattern recognition and interpretation throughout the laboratory. • Analyze study processes and reports against set quality manual. • Plan effective data storage, sharing, and publishing within the organization. • Examine external information from multiple sources.	• Implement strategy of master data management that supports the development and secure operation of information and digital services. • Utilize the master data management strategy to approve all reports. • Develop organizational policies, standards, and guidelines for data management, and data collection, that align with ethical principles. • Formulate processes for regular and consistent access to external information from multiple sources.

Domain	4-Role-based Competencies		
Activity	**(7-3-VIII) Participate in further research in pharmaceutical analysis or SF products**		
Career Progression	Level 1 – Early Career Professional	Level 2 – Mid Career Professional	Level 3 – Senior Professional
Behavioral competencies per level *At each career level, personnel should be able to:*	• Understand the research and development processes involved in developing vaccines and biological products. • Demonstrate understanding of the regulations that govern the development of drugs, vaccines, and biological products. • Demonstrate understanding of scientific research methods, study designs, and the diverse sources of data utilized in the development of drugs, vaccines, and biological products. • Explain the purpose, concept, and topic of a scientific study. • Understand the issues related to SF products.	• Identify questions that need to be answered in the drug, vaccine, and biological product development process. • Design research protocols for use in the development of drugs, vaccines, and biological products • Conduct research as part of an overall development process. • Use appropriate tools and techniques for collecting, analyzing, and interpreting data. • Utilize peer review principles for studies conducted during the development of vaccines, and biological products and while analyzing prevalence of SF products. • Analyze quantitative and qualitative data related to a research question • Evaluate the design, conduct, and documentation of clinical studies for compliance. • Evaluate preclinical and clinical research methods, study designs, and the diverse sources of data (primary and/or secondary).	• Appraise research protocols to be utilized in the development of new drugs, vaccines, and biological products and analysis of SF products. • Evaluate the methodology and conduct of the research. • Develop descriptions, explanations, predictions, and models based on evidence. • Apply research results to inform regulatory decision. • Evaluate scientific evidence presented in publications or presentations. • Identify trends and anomalies within the biological development program. • Perceive issues early in the development or research phase that could impact regulatory strategy.

8.4 Competencies for Vigilance Personnel

Domain	4-Role-based Competencies		
Activity	**(7-4-I) Establish procedures for reviewing product safety information during clinical trials**		
Career Progression	Level 1 – Early Career Professional	Level 2 – Mid Career Professional	Level 3 – Senior Professional
Behavioral competencies per level *At each career level, personnel should be able to:*	• Compile safety signals. • Explain appropriate criteria for analysis of adverse events (such as Bradford Hill or ADR probability scale). • Demonstrate knowledge of common adverse events (AEs) in biologicals and AEFIs in vaccines. • Infer various techniques for causality analysis of adverse events. • Demonstrate the application of various adverse events reporting formats. • Compile data from substantiated case reports.	• Apply procedures for the investigation process for examination and substantiation of individual case reports. • Develop risk minimization and mitigation plans. • Compile appropriate reporting of AEs/AEFIs from vaccines and biologicals clinical trials. • Examine the adverse event data for its completeness when reported by the manufacturer. • Distinguish true safety signals from noise in ongoing event reporting. • Assess adverse event reports from clinical trials. • Identify risk factors and mechanisms for adverse events. • Evaluate the risk-benefit ratio on an ongoing basis. • Communicate any changes in the risk benefit calculation for a product to relevant stakeholders.	• Develop enforcement and compliance rules for submission of safety data during clinical trials of vaccines and biologicals. • Summarize and design relevant guidelines from appropriate international organizations (such as WHO, ICH, etc.) while drafting rules for monitoring and reviewing safety information. • Formulate clinical trial risk minimization and mitigation plans during any ADR. • Approve the adverse events reports, causality analysis, and risk-benefit ratio reports for each product.

Domain	4-Role-based Competencies		
Activity	**(7-4-II) Conduct post-marketing surveillance for biologicals and vaccines available in the market**		
Career Progression	Level 1 – Early Career Professional	Level 2 – Mid Career Professional	Level 3 – Senior Professional
Behavioral competencies per level *At each career level, personnel should be able to:*	• Classify ADRs/AEFIs from reports. • Find authentic vaccine or biologics adverse events from medical or patient data or reliable databases. • Interpret and report idiosyncrasies and new reactions associated with vaccines and biologics. • Maintain list of AEFIs and sources. • Conduct trend analysis of locally received AEs/AEFIs for identification of probable safety concerns and signal, report, and share data within and outside the NRA for further investigations. • Demonstrate processes related to checking data coding and completeness before entry and analysis. • Understand how to submit data to pharmacovigilance databases. • Enter all the necessary information on the patient, reporter, event, and suspected vaccine or biological product in individual case safety reports. • Understand pharmacovigilance systems and process for detecting errors related to vaccines and biologicals. • Demonstrate knowledge of risk management, tools, and techniques to	• Examine relevant data on vaccines and biologics while reviewing AEs. • Identify idiosyncrasies and rare reactions in vaccines and biologics. • Continuously monitor safety of vaccines and biological products. • Analyze individual case safety reports when submitted. • Review and analyze the appropriateness/completeness of periodic benefit-risk evaluation reports and periodic safety update reports as per national regulations and international standards (i.e., ICH). • Apply analytical methods to discern medication errors, substandard, and counterfeit drugs. • Create robust communication plan to communicate with medical professionals regarding medication errors • Distinguish adverse events caused by medication errors. • Implement, monitor, and analyze effectiveness of risk mitigation measures for specific products. • Maintain QMS for the management of risks/harms from vaccines and biological products. • Prepare SOPs to apply risk management policies and procedures.	• Assess the data collected for the reporting of any adverse events. • Recommend scientific and medical review for any adverse event prior to changing risk benefit, profiles. • Appraise and confirm new AEFIs. • Review each case narrative for information on the clinical course and therapeutic measures outcomes. • Formulate processes and mechanisms to gather adverse event data from a variety of different sources, including the medical and scientific literature. • Establish a quality system to manage risks and evaluate the overall approach to how quality risk management is used. • Formulate relevant regulatory policies and opinions or briefs on managing adverse events. • Develop a robust system for signal detection, validation, confirmation, analysis, and assessment. • Recommend decisions regarding potential risks and the communication of signals. • Review, formulate, and oversee the implementation of risk minimization / mitigation plans in relation to reported identified and potential risks. • Communicate risk/benefit evaluations to

Domain	4-Role-based Competencies		
Activity	**(7-4-II) Conduct post-marketing surveillance for biologicals and vaccines available in the market**		
Career Progression	Level 1 – Early Career Professional	Level 2 – Mid Career Professional	Level 3 – Senior Professional
	monitor safety and evaluate risk benefit ratios. • Monitor all vaccine and biological products in the market to evaluate drug safety. • Follow Good Pharmacovigilance Practices (GVP). • Update risk management plan as per risk-benefit ratio for a product on an ongoing basis as new risk information becomes available. • Collate and upload causality reports and the individual case safety reports casualty report to appropriate databases • Monitor AEFI/AE for vaccines and biological being circulated in the market. • Prepare appropriate communication to healthcare professionals and patients based on appropriate evaluation of adverse events. • Use various search engines, medical databases, and study registers to assist in the identification and processing of ADRs or AEFIs. • Compile promotional material related to vaccines and biological products. • Understand and interpret the regulatory/legal requirements in relation to safety, quality, efficacy, and effectiveness of products.	• Conduct initial reviews of risk management plans and summarize key components for further decision-making. • Utilize relevant data while analyzing signals for further recommendation or action. • Determine and classify signals that represent a risk from those that do not represent a risk. • Analyze signals obtained from various sources (e.g., pre-clinical studies, clinical trials, spontaneous reports, commercial complaints, social media, medical literature). • Examine the processes used for signal validation • Evaluate collected data to ensure that the data demonstrate sufficient evidence of the existence of a new safety signal. • Develop guidance for required action after the investigation of each signal. • Conduct quality assurance reviews on risk management data to ensure that periodic safety update reports contain the most recent risk evaluations. • Synthesize and summarize safety data presented in periodic benefit-risk evaluation reports and periodic safety update reports. • Draft regulatory responses to submit	the public and advise on the right course of action. • Approve updates to the patient information leaflets with the necessary risk/benefit information to inform the medicines users. • Formulate policies and guidelines that guide advertisement and promotional/ product labeling activities. • Develop processes for PV centers to identify, detect, and analyze medication errors. • Design studies and tools to evaluate the linkage between advertisement and use of vaccines/biologicals.

Domain	4-Role-based Competencies		
Activity	**(7-4-II) Conduct post-marketing surveillance for biologicals and vaccines available in the market**		
Career Progression	Level 1 – Early Career Professional	Level 2 – Mid Career Professional	Level 3 – Senior Professional
	• Demonstrate knowledge of medication errors, drug misuse, and drug abuse.	periodic benefit-risk evaluation reports and periodic safety update reports. • Develop guidelines and SOPs on how to review advertisements and promotional material. • Organize statistical analysis of adverse event data where appropriate.	

Domain	4-Role-based Competencies		
Activity	**(7-4-III) Establish country-wide system for pharmacovigilance**		
Career Progression	Level 1 – Early Career Professional	Level 2 – Mid Career Professional	Level 3 – Senior Professional
Behavioral competencies per level *At each career level, personnel should be able to:*	• Detect adverse events for marketed drugs/vaccines/biological products. • Understand the principles of GVP. • Demonstrate systems' thinking and approaches and understand how this impacts safety monitoring and vice versa. • Understand risk management including risk identification, risk assessment, risk mitigation, and tools associated with the pharmacovigilance system. • Understand the quality system that resides within the PV system. • Demonstrate global and national regulatory requirements governing PV activities. • Participate in audits and inspection activities with experts. • Follow record management procedures and best practices. • Compile complete and high-quality data on adverse events for further evaluation.	• Apply GVP while designing policies and processes. • Develop clear job descriptions and roles for PV staff. • Develop process manuals for PV centers. • Monitor staff workload to ensure adequate staff to manage the PV system. • Design procedures and tools for detection, management, and reporting of ADRs/AEFIs by healthcare professionals. • Carry out timely investigations of cases and establish causality assessment • Communicate safety results appropriately. • Communicate risk from vaccines and biological products to the healthcare workers and public and highlight products of public health concern, like those with potential for abuse. • Organize the PV system to capture quality planning, quality adherence, quality control, quality assurance, and quality improvement. • Organize and document the training records for various members. • Continuously update the risk to benefit ratio for the drug product or vaccine.	• Design PV awareness/sensitization campaigns for the public. • Support hiring of staff members with appropriate training and expertise. • Ensure that PV centers are appropriately staffed with relevant experts. • Organize rigorous training of incoming staff members in all organizational policies and procedures. • Build scientific evidence based on safety by identifying trends and anomalies based on the presented scientific problems to reduce the risk or anticipate problems. • Develop and incorporate risk communication in public health campaigns for vaccines. • Approve clear roles and responsibilities codified in job descriptions, to maintain the PV system. • Achieve the goal of the PV system, including complying with all legal requirements, preventing patients from being harmed by adverse events, and contributing to the overall protection of patients. • Formulate system and procedure aligned with international standards and principles of pharmacovigilance.

Domain	4-Role-based Competencies		
Activity	**(7-4-III) Establish country-wide system for pharmacovigilance**		
Career Progression	Level 1 – Early Career Professional	Level 2 – Mid Career Professional	Level 3 – Senior Professional
		• Design a record management system to retain all information related to the operation of the PV. • Organize a monitoring and compliance system with ongoing audits and inspections. • Design detailed policies and procedures to comply with regulatory guidance on PV, including application of knowledge from local, national, and global regulatory requirements governing PV activities.	• Design appropriate resources to ensure GVP are achieved and sustained. • Develop a robust system that complies with the requirements of all applicable rules and regulations for PV. • Recommend improvement areas for the immunization programs.

Domain	4-Role-based Competencies		
Activity	**(7-4-IV) Take regulatory actions and communicate product status with stakeholders**		
Career Progression	Level 1 – Early Career Professional	Level 2 – Mid Career Professional	Level 3 – Senior Professional
Behavioral competencies per level *At each career level, personnel should be able to:*	• Explain to consumers where they can find additional information (i.e., NRA's website, consulting with pharmacist) for vaccines or biologics on possible side effects or other issues, such as recalls. • File proper documentation for recalled products. • Draft technical reports for simpler applications or cases. • Prepare general documentation on various issues such as communication to stakeholders, and product recalls. • Demonstrate knowledge of relevant laws, regulations, and guidelines for regulatory decisions. • Explain good regulatory practices in managing regulatory actions. • Participate in audits of PV systems when needed. • Assist in data compilation to include in inspection reports. • Draft and write inspection and audit reports. • Illustrate relevant, clear, and accurate safety communication to the appropriate audience, i.e., healthcare professional versus the public. • Classify risk information and risk-to-benefit ratio per product. • Demonstrate necessary regulations for	• Categorize the validated risks as per appropriate classification based upon their severity. • Develop procedures for informing patients if their prescription medication, vaccines, or biological products are on a recall list. • Implement procedures for updating the community on the website or public notice boards on product recalls/market actions in progress. • Integrate information from multiple sources to inform recommendations and decision making. • Write comprehensive, clear, and coherent technical reports on product issues and recalls. • Apply relevant laws, regulations and guidelines on regulatory decision making. • Review recall reports and evaluates the proposed CAPA. • Organize internal and external PV systems inspections and write inspection report. • Identify and record noncompliance in PV system. • Evaluate CAPA plans. • Provide training to sponsors and industry members on GVP.	• Assess appropriate policies to manage a product recall. • Monitor public communication systems associated with recall or product safety. • Perform critical review of reports that fall within one's discipline or specialty. • Appraise that regulatory decisions are made in accordance with the appropriate laws, regulations, and guidelines. • Deduce if sound regulatory processes are utilized in the decision to recall products based on defects or ADRs. • Facilitate the involvement of level I and II regulatory in assessing the effectiveness of the recall activity. • Evaluate the effectiveness and completeness of the recall. • Report the reason/cause to WHO Program for International Drug Monitoring. • Evaluate the results of industry, sponsors, and stakeholders' audits. • Design and appraise risk communication plans for healthcare workers and the public. • Develop and document QMS, including quality plans, quality manuals, and quality records. • Develop and implement risk-based

Domain	4-Role-based Competencies		
Activity	**(7-4-IV) Take regulatory actions and communicate product status with stakeholders**		
Career Progression	Level 1 – Early Career Professional	Level 2 – Mid Career Professional	Level 3 – Senior Professional
	communication of safety issues for biologicals and vaccines. • Strong understanding of, and commitment to, the QMS and the associated activities. • Interpret changes in regulatory landscape related to PV. • Understand the global safety regulations for vaccines and biologics. • Demonstrate the application of electronic tools and systems for managing ADR, product quality defects, medication errors, and AEFI reporting.	• Examine corrective action based on audit findings. • Review direct healthcare professional/provider communication for a drug, vaccine, or biological related issue. • Review manuscripts for publication of ADRs/AEFIs or a series of events in a scientific journal. • Review patient information leaflets for distribution by health care professionals for drug, vaccine or biological related problems in appropriate language and format suitable for multi-lingual and diverse literacy levels. • Participate in design and implementation of vaccine public campaigns to be used as appropriate channel for vaccine safety communication. • Contribute to the development and update of guidelines on GVP. • Detect early warning signs that impact safety profile of vaccines and biologics • Identify knowledge gaps in safety regulations for vaccines/biologics. • Organize ongoing review on the adequacy of adverse event reporting systems.	PV audit plans. • Ensure that internal GVP policies and procedures are updated. • Continuously assess PV system for improving effectiveness. • Develop strategies for collection of PV intelligence. • Implement changes in regulatory requirements that may impact vaccines and biologics. • Critique systematic literature reviews of the potential risk of drugs, vaccines, and biologics. • Communicate changes in regulatory landscape to inform regulatory strengthening/policy change. • Design relevant training/education program for PV staff. • Evaluate the utility of mobile applications for adverse drug reporting.