Promoting the Quality of Medicines Plus (PQM+)

USAID MEDICINES, TECHNOLOGIES, AND PHARMACEUTICAL SERVICES (MTaPS) PROGRAM

Improved Access. Improved Services. Better Health Outcomes.

Pathway to Digitalize Regulatory Information Management Systems for National Medicines Regulatory Authorities in Low- and Middle-Income Countries

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USAID FROM THE AMERICAN PEOPLE

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About the USAID MTaPS Program

Funded by the US Agency for International Development (USAID) and implemented by a team led by Management Sciences for Health, the purpose of the five-year Medicines, Technologies, and Pharmaceutical Services (MTaPS) Program (2018–2023) is to provide pharmaceutical system strengthening assistance for sustained improvements in health system performance and to advance USAID's goals of preventing child and maternal deaths, controlling the HIV/AIDS epidemic, and combating infectious disease threats, as well as expanding essential health coverage. The goal of MTaPS is to help low- and middle-income countries strengthen their pharmaceutical systems to ensure sustainable access to and appropriate use of safe, effective, quality-assured, and affordable essential medicines, vaccines, and other health technologies and pharmaceutical services.

About the USAID PQM+ Program

Promoting the Quality of Medicines Plus (PQM+) is a program operating under a USAID-funded cooperative agreement with the US Pharmacopeial Convention (USP) with a goal to sustainably strengthen medical product quality assurance (QA) systems by providing technical assistance to manufacturers of priority health products and build in-country capacity of medicines regulatory authorities to improve product registration, inspection, and post-marketing surveillance for product quality. PQM+ support also includes accreditation of national drug quality control laboratories per International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) 17025 and/or World Health Organization (WHO) prequalification standards in low- and middle-income countries. PQM+ uses a system strengthening approach to program implementation to enhance sustainability [1]. The program considers the entire system when designing and delivering technical assistance, focusing on the interaction among all health systems functions as they relate to medical product quality assurance [2].

To implement PQM+, USP joined forces with a diversified consortium of four core partners, six field-led extension partners, and eight technical resource partners whose extensive technical expertise can be drawn on to achieve desired results [3].

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Participants represented 17 organizations:

- African Union Development Agency - New Partnership for Africa's Development
- Association of Southeast Asian Nations Secretariat
- Asia Development Bank
- Bill and Melinda Gates Foundation
- Centre for Innovation in Regulatory Science
- Mahidol University
- Management Sciences for Health
- Medicines and Healthcare products Regulatory Agency (United Kingdom)
- School of Pharmacy Muhimbili University, Muhimbili University of Health and Allied Sciences
- The Global Fund to Fight AIDS, Tuberculosis and Malaria
- U3 SystemsWork International
- United States Pharmacopeia
- Université Félix Houphouët-Boigny
- US Agency for International Development (USAID)
- USAID Global Health Supply Chain Program-Procurement and Supply Management project
- World Bank
- World Health Organization

Participants included representatives from 14 national medicines regulatory authorities:

- Bangladesh
- Benin
- Ghana
- Guinea
- Indonesia
- Kenya
- Liberia
- Mali
- Nepal
- Nigeria
- Pakistan
- Rwanda
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CONTENTS

Acronyms and Abbreviations

ADR	adverse drug reaction
API	active pharmaceutical ingredient
ATC	Anatomical Therapeutic Chemical
CAS	Chemical Abstracts Service
CRS	cost-recovery scheme
CTD	common technical document
FHIR	Fast Healthcare Interoperability Standard
GBT	Global Benchmarking Tool
GCP	Good Clinical Practices
GDP	Good Distribution Practices
GLP	Good Laboratory Practices
GMP	Good Manufacturing Practices
GRevP	Good Review Practices
HL7	Health Level Seven
ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
ICSR	Individual Case Safety Reports
ICT	information and communication technology
IDMP	Identification of Medical Products
IEC	International Electrotechnical Commission
IMS	information management system
INN	International Nonproprietary Name
ISO	International Organization for Standardization
IT	information technology
LMICs	low- and middle- income countries
M&E	monitoring and evaluation
MA	marketing authorization
MCS	minimum common standards
MedDRA	Medical Dictionary for Regulatory Activities
ML	maturity level

MTaPS	Medicines, Technologies, and Pharmaceutical Services
NDC	National Drug Code
NMRA	national medicines regulatory authority
PDF	Portable Document Format
PQM+	Promoting the Quality of Medicines Plus
QA	quality assurance
QMS	quality management system
SOP	standard operating procedure
SRS	system requirement specifications
SubID	Substance Identification
US FDA	US Food and Drug Administration
USAID	US Agency for International Development
USP	US Pharmacopeial Convention
WHO	World Health Organization

EXECUTIVE SUMMARY

The US Agency for International Development (USAID) Medicines, Technologies, and Pharmaceutical Services (MTaPS) Program and USAID-funded Promoting the Quality of Medicines Plus (PQM+) Program conducted a series of consultations in 2021 and 2022 aimed at identifying and recommending a set of minimum common standards (MCS) for a regulatory information management system (IMS) that will enable uniform data capture; standardize the data, design, and workflow of digitalized regulatory functions; and facilitate communication among national medicines regulatory authority (NMRA) departments and with stakeholders. These standards should be incorporated into digitalization activities for a regulatory IMS and serve as the basis for harmonizing regulatory processes across NMRAs. The meetings brought together experts in regulatory systems strengthening and IMS representing several low- and middle- income countries (LMICs) and regional and global organizations. The objectives of the consultative process were to:

- Clearly identify the critical gaps and challenges NMRAs and other stakeholders face with a regulatory IMS for the eight regulatory functions outlined in the World Health Organization (WHO) Global Benchmarking Tool (GBT) for evaluation of national regulatory systems[a] [4]
- Use existing IMS and regulatory standards to derive a recommended set of MCS for a regulatory IMS to address identified gaps and challenges, including developing selection criteria for prioritizing which standards to include in the set of recommended standards
- Develop a use case for the MCS and help promote their adoption and use

The consultations spanned a 10-month period and comprised four virtual meetings, supplemented by written feedback and one-on-one and small group sessions, to achieve the stated process objectives. Through this process, a minimum common set of standards for digitalization of a regulatory IMS was identified (figure A).

This document is intended for decision makers at NMRAs in LMICs to guide their adoption of the minimum set of common standards for a regulatory IMS within the broader context of digitalization for a regulatory IMS. The document outlines the steps needed to digitalize a regulatory IMS and highlights key considerations for the process.

The document begins with an overview of the minimum common set of standards for digitalization of a regulatory IMS and the benefits and guiding principles for a digitalized regulatory IMS. Prerequisites for digitalization are presented, including the legal and regulatory framework, quality management system (QMS), human resources, financing mechanisms, and adoption of MCS that should be in place prior to digitalization. Preliminary steps for undertaking digitalization include a rapid feasibility assessment and development of system requirements specifications (SRS), followed by the actual implementation of the digital regulatory IMS. Maintenance and sustainability considerations should be articulated well in

[a] The GBT Revision VI version 1 "comprises eight regulatory functions (Registration and Marketing Authorization, Vigilance, Market Surveillance and Control, Licensing Establishments, Regulatory Inspection, Laboratory Testing, Clinical Trials Oversight, and NRA Lot Release) under the overarching framework of the national regulatory system."

advance of implementation and include written procedures, data quality, monitoring and evaluation (M&E), and political support.

Figure A - Selected minimum common standards for a regulatory IMS

Process Standards	Data Dictionaries and Knowledge Trees	Data Exchange Standards
•Good Laboratory Practices (GLP) •Monographs •ISO 9001:2015 - Quality Management System Procedures •Good Distribution Practices (GDP) •ISO 17025:2017 •Good Practices For Pharmaceutical Quality Control Laboratories •Good Clinical Practices (GCP) •Good Manufacturing Practices (GMP) or ICH Q7 •Good Practices For Pharmaceutical Microbiology Laboratories •Good Review Practices (GRevP) •Good Storage Practices •ICH Q10 •Good Pharmacovigilance Practices	•International Nonproprietary Names (INN) •National Drug Code (NDC) •Anatomical Therapeutic Chemical Index (ATC) •WHODrug Global •The Medical Dictionary for Regulatory Activities (MedDRA) •Chemical Abstracts Service (CAS) registry number •Unique Ingredient Identifier (UNII) •ISO 11240 Units of Measurement (UoM) •ISO 11239 Dosage Form and Route of Administration •ISO 11616 Pharmaceutical Product Identifier (PhPID) •ISO 11238 Substance Identification (SubID) •GS1 Standards •ISO 11615 Medicinal Product Identification (MPID)	•Portable Document Format (PDF) •XML •Common Technical Document (CTD) •E2B - Pharmacovigilance: Individual Case Safety Reports (ICSR) or ISO/HL7 27953-2:2011 •Structured Product Labelling (SPL) •Fast Healthcare Interoperability Standards (FHIR)

BACKGROUND

INTRODUCTION

National medicines regulatory authorities (NMRAs) are increasingly implementing information management systems (IMS) to streamline their regulatory functions to improve efficiency, communication, and transparency and ensure access to quality-assured, safe, and effective medical products. Despite the benefits, adoption of IMS in low- and middle-income countries (LMICs) remains disproportionately low in comparison to high-income countries. Many LMICs rely on paper-based processes or IMS that are underutilized, fragmented, noninteroperable, or mismanaged. The delayed implementation of digital IMS has been attributed to a lack of adequate financial and human resources, a lack of political will, and other factors. Consequently, there is an absence of effective communication among regulatory agencies, a lack of transparency in the regulatory process, information loss, backlogs, and delays in the regulatory approval process.

The lack of interoperable digital IMS in LMICs and the absence of standardized common technical documents (CTDs), documentation, work processes, and timelines limit the use of harmonization actions such as joint assessments and Good Manufacturing Practices (GMP) site inspections. Implementation of regulatory procedures such as reliance and recognition for the registration of medical products requires the deployment of dependable regulatory IMS for efficient information management.

To further harmonization efforts, a set of MCS for regulatory IMS is required to promote interoperability and communication among departments within NMRAs and among NMRAs, stakeholders, and regional and international organizations. The US Agency for International Development (USAID) Medicines, Technologies, and Pharmaceutical Services (MTaPS) Program and Promoting the Quality of Medicines Plus (PQM+) Program initiated a series of consultative meetings with regulatory experts to define a minimum set of applicable common standards for regulatory IMS that would streamline workflows and regulatory processes, ensure uniform data capture, and enable data exchange within and among NMRAs and other stakeholders who support regulatory convergence and harmonization efforts.

MINIMUM COMMON STANDARDS FOR REGULATORY IMS

To further harmonization efforts, a set of MCS for regulatory IMS is required to promote interoperability and communication between international and regional NMRAs. Further, digitalization of regulatory IMS promotes consistency, quality, efficiency, and transparency of regulatory system function within and across NMRAs. The MTaPS and PQM+ programs completed a series of consultative meetings with experts in regulatory system strengthening and IMS representing several LMICs and regional and global organizations and an extensive review of existing literature to define a minimum set of applicable common standards for regulatory IMS.

The following criteria were used to select the minimum set of common standards:

- Relevance—the standard should be critical for at least one of the eight core regulatory functions as defined in the World Health Organization (WHO) Global Benchmarking Tool (GBT) v2.0 [4]
- Feasibility—the extent to which NMRAs' capacity and resources feasibly allow adoption and the anticipated efficiency gains
- Criticality—what would countries gain by applying or lose by not applying a given standard
- Universality—whether a given standard is recommended by WHO and the extent to which it is widely used

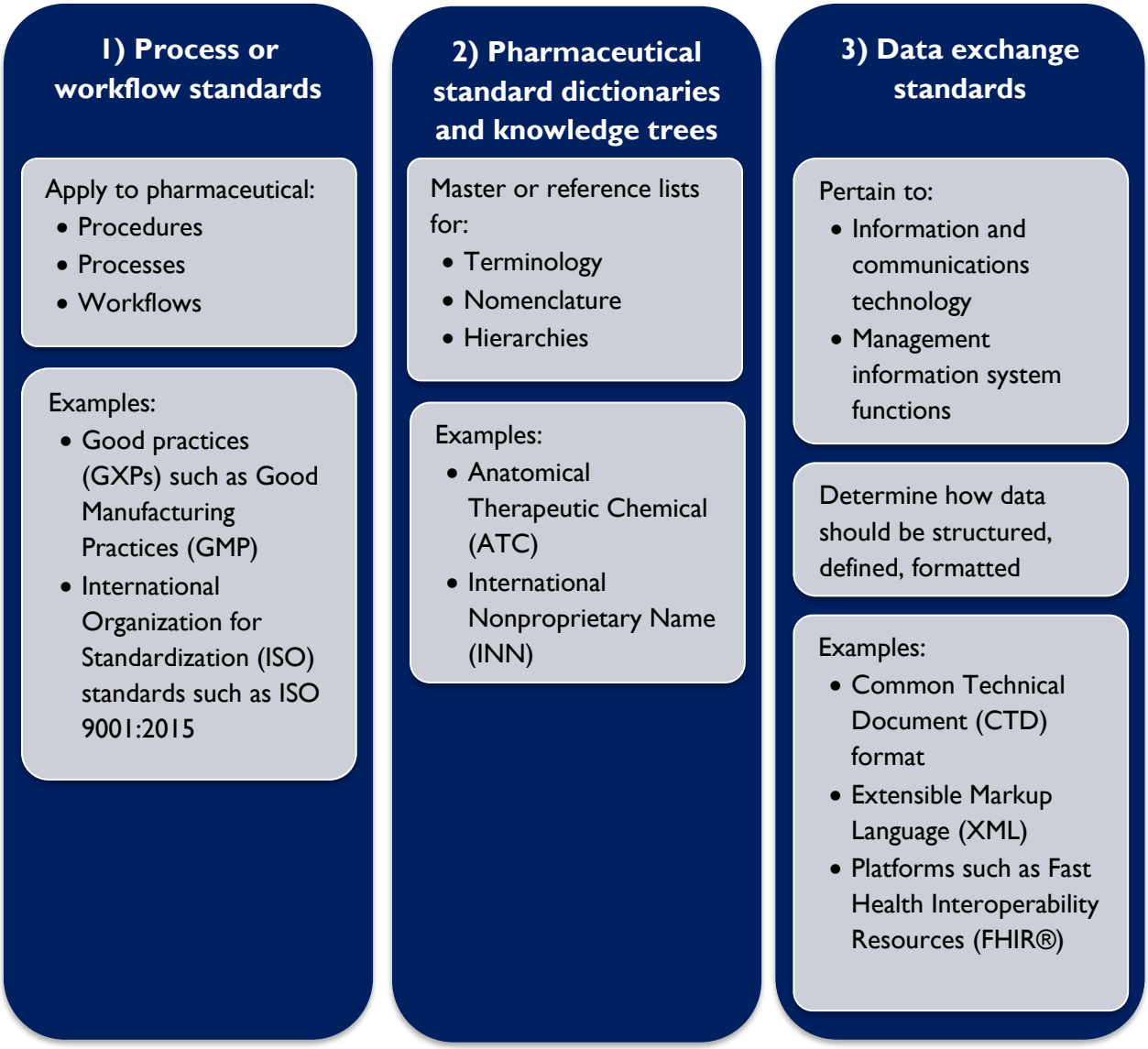
The list of 56 identified standards was circulated to all participants in the consultative process. Participants were asked to evaluate each of the 56 standards on a scale of 1 to 3 for each of the selection criteria. Definitions for each rating are included in table 1. During this selection exercise, relevance was excluded from participant consideration as the 56 identified standards were deemed relevant for inclusion by the MTaPS and PQM+ teams during the literature review process.

Table 1 – Rating definitions by selection criteria

Rating Scale	Feasibility	Criticality	Universality
1	Adopted with greater difficulty, significant technical assistance required	Regulatory performance/processes not impacted without the standard	Not widely used in LMICs
2	Adopted with medium difficulty, marginal technical assistance required	Regulatory performance/processes may be impacted without the standard	The use of the standard is moderately widespread
3	Adopted with minimal, if any, technical assistance	Regulatory performance/processes impacted without the standard	Widely used or recommended by industry or normative bodies

These 56 standards were further divided into three categories:

Figure B - Categories of Standards



The final list of MCS was developed based on analysis of the feedback received from 11 respondents and informed by the MTaPS and PQM+ teams' expertise across regulatory functions.

All of the identified process standards, except for those pertaining specifically to medical devices, were selected for inclusion in the set of MCS. The standards pertaining to medical devices were excluded to align with the WHO GBT v2.0 (medicines and vaccines). Respondents expected that standards for medical devices would be included in a future set of MCS. The remaining process standards are considered prerequisite to digitalizing regulatory IMS or adopting other standards (e.g., data dictionaries, knowledge trees, data exchange). The list of standards recommended for adoption is below, listed in

order from the most to least feasible to adopt (figure C). Table 2 includes a list of the standards as well as a definition of each and external references for more information pertaining to each standard.

Figure C – Selected minimum common standards for regulatory IMS

Process Standards	Data Dictionaries and Knowledge Trees	Data Exchange Standards
•Good Laboratory Practices (GLP) •Monographs •ISO 9001:2015 - Quality Management System Procedures •Good Distribution Practices (GDP) •ISO 17025:2017 •Good Practices For Pharmaceutical Quality Control Laboratories •Good Clinical Practice (GCP) •Good Manufacturing Practices (GMP) or ICH Q7 •Good Practices For Pharmaceutical Microbiology Laboratories •Good Review Practices (GRevP) •Good Storage Practices •ICH Q10 •Good Pharmacovigilance Practices	•International Nonproprietary Names (INN) •National Drug Code (NDC) •Anatomical Therapeutic Chemical Index (ATC) •WHODrug Global •The Medical Dictionary for Regulatory Activities (MedDRA) •Chemical Abstracts Service (CAS) registry number •Unique Ingredient Identifier (UNII) •ISO 11240 Units of Measurement (UoM) •ISO 11239 Dosage Form and Route of Administration •ISO 11616 Pharmaceutical Product Identifier (PhPID) •ISO 11238 Substance Identification (SubID) •GS1 Standards •ISO 11615 Medicinal Product Identification (MPID)	•Portable Document Format (PDF) •XML •Common Technical Document (CTD) •E2B - Pharmacovigilance: Individual Case Safety Reports (ICSR) or ISO/HL7 27953-2:2011 •Structured Product Labelling (SPL) •Fast Healthcare Interoperability Standards (FHIR)

Table 2 – Standards and definitions

Standard	Description
Process Standards	
Good Laboratory Practices (GLP)	A set of principles intended to ensure the quality and integrity of nonclinical laboratory studies that are intended to support research or marketing permits for products regulated by government agencies [5].
Monographs	Pharmacopeial monographs provide an important tool for assurance of the quality of marketed pharmaceutical ingredients and products by testing their quality. They generally cover chemical, biological, and herbal finished pharmaceutical products and their ingredients, which have either been approved by national regulatory authorities or are otherwise legally marketed [6].
ISO 9001:2015 - Quality Management System Procedures	Specifies requirements for a quality management system (QMS) when an organization: • Needs to demonstrate its ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements • Aims to enhance customer satisfaction through the effective application of the system, including processes for improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements [7]
Good Distribution Practices (GDP)	Ensures products are consistently stored, transported, and handled under suitable conditions as required by the marketing authorization (MA) or product specification [8]
ISO/International Electrotechnical Commission (IEC) 17025:2017	Specifies the general requirements for the competence, impartiality, and consistent operation of laboratories. ISO/IEC 17025:2017 is applicable to all organizations performing laboratory activities, including laboratory customers, regulatory authorities, organizations and schemes using peer assessment, accreditation bodies, and others [9].
Good Practices For Pharmaceutical Quality Control Laboratories	This set of Good Practice standards provides guidance on a QMS for analysis of active pharmaceutical ingredients (APIs), excipients, and pharmaceutical products. A QMS and compliance with the Good Practice standards encourage harmonization and cooperation between laboratories and support mutual recognition of quality control laboratory results [8].
Good Clinical Practices (GCP)	GCP is a process that incorporates established ethical and scientific quality standards for the design, conduct, recording, and reporting of clinical research involving the participation of human subjects. Compliance with GCP provides public assurance that the rights, safety, and well-being of research subjects are protected, respected, and consistent with the principles enunciated in the Declaration of Helsinki and other internationally recognized ethical guidelines and ensures the integrity of clinical research data [10].

Standard	Description
Good Manufacturing Practices (GMP) or International Council for Harmonisation (ICH) Q7	A system for ensuring that products are consistently produced and controlled according to quality standards. It is designed to minimize the risks involved in any pharmaceutical production that cannot be eliminated through testing the final product [11].
Good Practices for Pharmaceutical Microbiology Laboratories	Provide guidance on the QMS relating to microbiology laboratories. Pharmaceutical microbiology laboratories may be involved in: • Sterility testing • Detection, isolation, enumeration, and identification of microorganisms (e.g., bacteria, yeast, molds) and testing for bacterial endotoxins in different materials (e.g., starting materials, water), products, surfaces, garments, and the environment • Assay using microorganisms as part of the test system [12]
Good Review Practices (GRevP)	Documented best practices for any aspect related to the process, format, content, and management of a medical product review. The objective of GRevP is to help achieve timeliness, predictability, consistency, transparency, clarity, efficiency, and high quality in both the content and management of reviews [13].
Good Storage Practices	Guidelines that describe the special measures considered appropriate for the storage and transportation of pharmaceuticals. The guidelines are applicable to not only manufacturers of medicinal products but also pharmaceutical importers, contractors and wholesalers, and community and hospital pharmacies [14].
ICH Q10	A guideline for a QMS that applies to manufacturers of pharmaceutical products. The ICH Q10 model incorporates aspects of GMP and ISO standards to develop a pharmaceutical QMS across the product life cycle [15,16].
Good Pharmacovigilance Practices	A set of guidelines for the conduct of pharmacovigilance for MA holders and regulatory agencies. The definition and principles vary across regulatory bodies [17,18].

Standard	Description
Data Dictionaries and Knowledge Trees	
International Nonproprietary Name (INN)	Used globally to identify unique pharmaceutical substances or APIs. Nonproprietary names are also known as generic names and are public property [19].
National Drug Code (NDC)	Drug products are identified and reported to the US Food and Drug Administration (US FDA) as required by US law using a unique, three-segment number called the NDC, which is a universal product identifier for human drugs. The US FDA inputs the full NDC number and the information submitted as part of the listing process into a database known as the Drug Registration and Listing System [20].
Anatomical Therapeutic Chemical (ATC) Index	In the ATC classification system, active substances are divided into different groups according to the organ or system on which they act and their therapeutic, pharmacological, and chemical properties. Drugs are classified in groups at five levels [21].
WHODrug Global	WHODrug Global is the international reference for medicinal product information and is maintained by the Uppsala Monitoring Centre. With its unique drug code hierarchy and extensive coverage, it provides a consistent drug dictionary with exact terminology when coding concomitant medications [22].
The Medical Dictionary for Regulatory Activities (MedDRA)	An extensive medical terminology designed for use in the regulation of medical products with a unique architecture and features that support public health monitoring, data analysis, communication (both electronic and traditional), and data management. This terminology is hierarchical, multiaxial, multilingual, regularly updated, and strictly maintained [23].
Chemical Abstracts Service (CAS) registry number	A unique numeric identifier that designates only one substance and links to the CAS registry entry that contains information about a specific chemical substance [24].
Unique Ingredient Identifier	Alphanumeric identifier linked to a substance's molecular structure or descriptive information and generated by the Global Substance Registration System of the US FDA. It classifies substances as chemical, protein, nucleic acid, polymer, structurally diverse, or mixture [25,26].
ISO 11240 Units of Measurement	Part of the Identification of Medical Products (IDMP) suite of standards developed by ISO. Establishes conventions for using units of measurement, requirements for linkages to international measurement standards, and rules for unit mapping and translation [27].
ISO 11239 Dosage Form and Route of Administration	Part of the IDMP suite of standards developed by ISO. Data elements and structures for unique identification and exchange of regulated information on pharmaceutical dose forms, units of presentation, routes of administration, and packaging [27].

Standard	Description
ISO 11616 Pharmaceutical Product Identifier	Part of the IDMP suite of standards developed by ISO. Used to group similar or identical pharmaceutical products based on substance, product strength, reference strength, and dosage form. Standardizes exchange of pharmaceutical product information based on these data elements [27].
ISO 11238 Substance Identification	Part of the IDMP suite of standards developed by ISO. Defines medical products in terms of their constituent substances. Standardizes exchange of pharmaceutical product information based on these characteristics [27].
GS1 Standards	Provides for the use of unambiguous identification keys to identify goods, services, assets, locations, etc., worldwide. These keys can be represented in data carriers, such as barcodes or EPC/RFID tags, to enable automatic data capture. They may also be used in electronic communications, improving speed and accuracy when sharing master data, transactional data, and visibility event data [28].
ISO 11615 Medicinal Product Identification	Part of the IDMP suite of standards developed by ISO. Used to identify medical products using standard data elements including product name; clinical particulars (e.g., indications, contraindications); substance; dosage form; route of administration; medicinal product packaging; MA; manufacturer) [27].

Standard	Description
Data Exchange Standards	
Portable Document Format (PDF)	A data exchange format used to present and exchange documents reliably—independent of software, hardware, or operating system. The PDF is now an open standard maintained by ISO. PDF documents can contain links and buttons, form fields, audio, video, and business logic. They can be signed electronically, and you can easily view PDF files on Windows or Mac OS [29].
XML	A simple text-based format for representing structured information (e.g., documents, data, configuration, books, transactions, invoices). XML is one of the most widely used formats for sharing structured information between programs, people, and computers and people, both locally and across networks [30].
Common Technical Document (CTD)	A common format for all quality, safety, and efficacy information for application for MA [31].
E2B - Pharmacovigilance: Individual Case Safety Reports (ICSR) or ISO/ Health Level 7 (HL7) 27953-2:2011	A standardized framework for international regulatory reporting and information sharing by providing a common set of data elements and a messaging format for transmission of ICSR for adverse drug reactions (ADRs), adverse events, infections, and incidents that can occur upon the administration of one or more human pharmaceutical products to a patient, regardless of source and destination [32].
Structured Product Labelling	A document markup standard approved by HL7 and adopted by the US FDA as a mechanism for exchanging product and facility information [33].
Fast Healthcare Interoperability Standards (FHIR)	A standard for exchanging health care information electronically. Health care records are increasingly becoming digitized. As patients move around the health care ecosystem, their electronic health records must be available, discoverable, and understandable. Further, to support automated clinical decision support and other machine-based processing, the data must be structured and standardized [34].

The MCS should be incorporated into digitalization activities for a regulatory IMS and serve as the basis for harmonizing regulatory processes across NMRAs. They feed into the SRS that are foundational for the development of regulatory IMS digitalization tools. NMRAs' adoption of the identified common standards would enable the creation of a common language for system design and guide digitalized regulatory IMS development or improvement in LMICs.

Benefits of digitalized regulatory information management systems

Digitalization of a regulatory IMS in NMRAs facilitates transparency and promotes efficiency and expedited delivery of regulatory services. Effective regulatory services contribute significantly to improved pharmaceutical services and health care outcomes.

The implementation of this guidance for digitalization of a regulatory IMS incorporating the set of MCS will:

- Create a common reference for use among regulators, software developers, and policy makers for a regulatory IMS
- Streamline NMRAs' internal operations, such as workflow management, throughout the life cycle of medical products, performance metric tracking, and reporting
- Facilitate convergence and harmonization of regulatory services both within and outside of a defined NMRA
- Enhance the ability of NMRAs to collaborate and share information with one another, including the use of reliance and recognition mechanisms
- Improve communication and enhance evidence-based decision making by NMRAs

Purpose of Guidance

The purpose of this document is to guide regulatory system decision makers and stakeholders in LMICs on the adoption of the identified set of MCS for a regulatory IMS. The document outlines the strategies required to develop a pathway for adoption of the standards and identifies the necessary human, financial, and technical resources for effective regulatory IMS deployment within the context of digitalization.

Principles of Digitalization

Accessible digital technology has been a game changer for international development—leading to major innovations and improvements across sectors, including health. The inclusion of digital tools in routine health system operations can lead to greater efficiency, improved outcomes, and greater connections among the global community. Some digitally enabled programs fail, however, and quite often the reasons for failure are predictable and preventable [35].

To avoid or mitigate such pitfalls, the global community drafted The Principles for Digital Development—nine living guidelines to assist in incorporating best practices into technology-driven systems throughout the project life cycle. First created in 2012 in consultation with organizations such as The Bill and Melinda Gates Foundation, Swedish International Development Agency, United Nations Children's Fund, United Nations Development Program, World Bank, USAID, and WHO, the Principles

incorporate lessons learned and global standards. The principles should provide the basis for the process of digitalizing a regulatory IMS or any digital tool, system, or intervention. The nine principles are: [36]

- Design with the User: User-centered design starts with getting to know the people you are designing for through conversation, observation, and co-creation.
- Understand the Existing Ecosystem: Well-designed initiatives and digital tools consider the particular structures and needs that exist in each country, region, and community.
- Design for Scale: Achieving scale requires adoption beyond an initiative's pilot population and often necessitates securing funding or partners that take the initiative to new communities or regions.
- Build for Sustainability: Building sustainable programs, platforms, and digital tools is essential to maintain user and stakeholder support and maximize long-term impact.
- Be Data Driven: When an initiative is data driven, quality information is available to the right people when they need it, and they use those data to take action.
- Use Open Standards, Open Data, Open Source, and Open Innovation: An open approach to digital development can help to increase collaboration in the digital development community and avoid duplicating work that has already been done.
- Reuse and Improve: Reusing and improving is about taking the work of the global development community further than any organization or program can do alone.
- Address Privacy and Security: Addressing privacy and security in digital development involves careful consideration of which data are collected and how data are acquired, used, stored, and shared.
- Be Collaborative: Being collaborative means sharing information, insights, strategies, and resources across projects, organizations, and sectors, leading to increased efficiency and impact.[b]

PREREQUISITES FOR DIGITALIZATION OF REGULATORY SYSTEMS

Before embarking on the process of digitalization for a regulatory IMS, several key considerations and elements need to be factored into planning. These include the policy and legal landscape; political support; and key infrastructure, including adequate human resources and financing. The SRS should be well developed and based on feasibility assessment findings prior to implementation.

LEGISLATION, REGULATIONS, AND GUIDELINES

One of the reasons for the delayed implementation of a digital regulatory IMS in LMICs has been a lack of political will, which may imply a lack of a legal framework that includes the adoption and implementation of digitalization for a regulatory IMS. Public confidence and trust among regulatory authorities requires effective and efficient regulation built on a sound legal basis. It is because of this that legality is included as part of the nine principles for GRP [38]. WHO emphasizes that a legal framework "should support and empower regulatory authorities to contribute to and benefit from all forms of cooperation," and ideally, this should be stated explicitly in the legal framework [38]. Regarding

[b] For a compendium of lessons learned from implementing the Principles, refer to: From Principle to Practice: Implementing the Principles for Digital Development [37]

digitalization in particular, the legal framework should allow the regulatory authority to implement digitalized systems and enable flexibility and agility over time. WHO defines a regulatory framework as "the collection of laws, regulations, guidelines, guidance documents, and other regulatory instruments through which a government and a regulatory authority control particular aspects of a specific activity," [38]. Legal and regulatory considerations for digitalization should be incorporated into the broader regulatory framework.[c] To identify the degree to which a digital regulatory IMS is included in the relevant legislation, the regulatory authority should carry out a gap analysis. The results of this assessment will aid in setting priorities for updating the existing regulatory framework to ensure the adoption and digitalization of a minimum set of common standards for a regulatory IMS. The laws should also address coordination with other bodies such as the Ministry of Technology; Ministry of Information, Communications, and Technology; or its equivalent to receive support from and align with these institutions' policies when necessary.

The inclusion of a digital regulatory IMS within the regulatory framework will ensure that as technology advances there will be no legal impediments to the use of new systems or technologies within the execution of regulatory activities. This will ensure that harmonization and exchange of information with other regulatory authorities is always an option.

Quality Management System

A QMS is a collection of business processes focused on continuously meeting internal and external customer needs and enhancing client satisfaction. It is aligned with an organization's purpose and strategic direction and encompasses activities by which the organization identifies its objectives and specifies the processes and resources required to achieve desired results. A QMS controls the interdependent processes and resources necessary to deliver value and achieve results for key stakeholders. It enables top-level management to optimize the use of resources considering long- and short-term implications and provides the means to identify ways to address intended and unintended consequences in the provision of goods and services (risk-based thinking) [40,41].

National regulatory authorities should apply a QMS to all business processes, including implementation of a digitalized regulatory IMS to increase efficiency and promote sustainability, improving the availability of safe, high-quality, and effective medical products in the market. The information flowing through a digital regulatory IMS is dynamic and requires a proactive approach to management, allowing users to quickly identify and respond to system malfunction, incorporate new technology and continuous improvement measures, and respond to customer needs. NMRAs should integrate a QMS for a regulatory IMS into their regulatory functions, including the deployment of an electronic document control management system.

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[c] For more information pertaining to regulatory frameworks, please refer to:
WHO Expert Committee on Specifications for Pharmaceutical Preparations: Fifty-fifth report. Annex 11[38]
WHO global model regulatory framework for medical devices including in vitro diagnostic medical devices, documents[39]

ISO 9001 is the international standard that outlines the requirements for a QMS. It consists of eight QMS principles that organizations should adhere to:

- Customer focus
- Leadership
- Engagement of people
- Process approach
- System approach to management
- Continuous improvement
- Fact-based approach to decision making
- Mutually beneficial supplier relationship [42]

It also contains subclauses on the Plan-Do-Check-Act cycle, a four-step process for carrying out continuous improvement:

- Plan: recognize an opportunity and plan a change
- Do: study the change
- Check: analyze the results of the test and identify the lessons learned
- Act: act based on what you learned changing the plan if it did not work or implementing it if it were successful and plan new improvements, beginning the cycle again

An effective QMS is a prerequisite for ISO 9001 certification and attainment of Maturity Level (ML) 3 according to the WHO GBT. The WHO GBT is an evaluation tool designed to analyze various regulatory functions and assign an ML score to the regulatory system, ranging from 1 (certain aspects of regulatory duties) to 4 (advanced system) [4]. ISO 9001:2015 sections 4–10 provide QMS sub indicators for audit, 14 of which have been included in the WHO GBT. NMRAs must fulfill seven GBT sub indicators associated with a QMS to reach ML 4, six QMS sub indicators to obtain ML 3, and one QMS sub indicator to achieve ML 2 [42].

An effective QMS will help to ensure a smooth transition from a paper-based to a digitalized regulatory IMS. Clear and updated standard operating procedures (SOPs) should be in place to serve as a reference for the development of SRS for digitalized systems and tools. The NMRA should implement a QMS in a phased manner that involves awareness creation, orientation of all personnel in the organization on QMS principles and benefits, training of personnel, and performance of internal quality audits that inform continuous improvement efforts.

Incorporating QMS principles in the implementation of a digitalized regulatory IMS can increase overall performance and efficiency. It can reduce waste and promote sustainable development by granting NMRAs greater control over processes and operations and improve harmonization efforts within and between regulators in LMICs.

Political Support

NMRAs require full support and commitment from various government ministries and agencies to operate efficiently. As such, any initiative (including implementation and use of a digital regulatory IMS) also requires government commitment. This will include the Ministries of Information, Communication,

and Technology (ICT); Justice; Finance; Health; customs; and police. Proper collaboration among the various agencies and better communication and coordination are important to gain buy-in for a regulatory IMS. A working group comprising relevant ministries and agencies should be formed to provide guidance and input in the development of a digital regulatory IMS. During the assessment phase, key stakeholders should be identified and engaged throughout the process, ensuring their support of and contributions to the digital regulatory IMS initiative.

HUMAN RESOURCES

From planning a digital regulatory IMS through implementation, integration, and routine use, human resource considerations are critical to success. It is important to consider not only the necessary competencies of existing staff but also what new roles will be needed and what initial technical support is required to plan and implement a digital regulatory IMS given the existing workload within the NMRA. Considerations relating to human resources throughout the stages of implementing a digitalized regulatory IMS include:

1. *Planning* – Implementing a digital regulatory IMS for the first time or upgrading it is a major projects that need to be carefully planned with the full engagement of NMRA staff. External expertise in information technology (IT) project implementation and change management may be required to ensure successful implementation. The success of such projects depends on staff engagement and acceptance of the new system with the understanding that a full change management process needs to be considered in addition to the technical and financial requirements of digital regulatory IMS installation. Do not underestimate the extra workload and time needed for both planning and implementation, plan for extra staff and consultants for the project, and ensure that the overall process is led by senior NMRA staff. The planning process should include detailed consideration of the new competencies required by existing staff as well as of new staff positions that may be required to manage, update, and support the system.

2. *Implementation* – Digital regulatory IMS installation requires careful planning and stepwise implementation, overseen by a senior NMRA staff member. Employment and retraining processes can take significant time and need to be thought through carefully to ensure alignment with the roll out of the system. Workload considerations are very important during this stage, as time is taken away from routine NMRA activities for training and systems testing. Often, parallel processes will be in use for a time before the digital regulatory IMS is fully integrated. As part of the change management process, expect staff resistance and concern, which makes ongoing communication and engagement with staff critical. SOPs, job descriptions, organograms, onboarding, supervision, and staff development systems will need to be updated.

3. *Integration and routine use* – For a digital regulatory IMS to be truly integrated into the day-to-day workflow of an NMRA, the IT system needs to be maintained and updated and the software used appropriately. Access to IT competence from either within the NMRA or through contractual arrangements is required to ensure that IT staff are routinely available for all actions required to maintain and update the software and provide help desk support to users. All staff engaged in process flows supported by a digital regulatory IMS will require competence to use

the system, including data entry, monitoring of process flows, and acting on key performance indicators. At this stage, carefully consider workflow responsibilities and ensure that multiple people are trained and maintain their ability to complete various functions required by the system. This approach builds in redundancy to guard against staff unavailability due to leave and staff turnover. Robust supportive supervision, systematic onboarding of new staff, and continued professional development will help optimize use of the system.[d]

Adequate Financing Mechanisms

There should be adequate and sustainable financing mechanisms derived from fees charged by the NMRA for the services it renders and financing from government, donors, and development partners to cover the costs for the assessment, planning, implementation, infrastructure, monitoring, and evaluation of digital regulatory IMS activities. These include funds for adequate human resources (e.g., management staff, regulatory staff, IT staff, administrative staff); integration of the MCS; software design and development; hardware; server hosting and other IT infrastructure; M&E; and database management, including backup, security, and maintenance. NMRAs cannot rely solely on fees (charged for routine regulatory services) to ensure efficient and enforceable regulation. It is critical that the government provide financial support, at least during the initial phase of operation of the NMRA, until the NMRA becomes financially self-reliant. The following options for sustainable financing could be considered to help the NMRA achieve its organizational goals and ensure sustainability:

- A **cost-recovery scheme** (CRS) can be used for charging fees to incrementally recoup a portion or the entirety of costs incurred to deliver regulatory activities or programs. The CRS should be adopted or introduced in a phase approach over a period of time. For example:
    - Year 1: Conduct desk review/situational analysis; define scope and propose fee structure; socialize or consult key stakeholders, including pharmaceutical and health industries, through a consultative workshop; and develop the CRS document and its implementation plan
    - Years 2–3: Implementation plan execution starting with the main priority functional areas
    - From Year 3: Expand the digitalization of regulatory IMS to pharmacovigilance, followed by laboratory testing and lot release. Consider using phased implementation of incremental fees over time, starting with charging CRS fees of 40% of the estimated cost of the NMRA's operations.
    - By Year 5: Increase this to 60%
    - Years 8–10: Increase this to 80%
- Through **resource mobilization** strategies, NMRAs can engage stakeholders, including government, donors/development partners, community, technical agencies, programs, and nongovernmental organizations, to contribute to achieving the NMRA's financing goals. For

[d] For more information, refer to:
IS/IT systems implementation projects tools and techniques for success, Project Management Institute [43]
How To Implement Change Management When Selecting New Software, Technology Innovation Center [44]
Strategic Training Executive Programme (leadership & change management), People that Deliver [45]

example, a coalition of interested parties could support and build the regulatory and quality assurance systems for medical products' quality, safety, and efficacy to safeguard public health against substandard and falsified products. With this option, resources could cover both financial (e.g., funds, capital, physical infrastructure, cash) and nonfinancial (e.g., staff and their skills and competencies; materials like equipment/instrument, hardware, computers, software, and stationary) that each stakeholder could support based on their nature and scope of assistance. Key steps of resource mobilization include:

- Conducting a situational analysis to determine resource needs
- Developing strategies and plans to identify sources of resources
- Raising awareness among key stakeholders, including government, donors, the development community, technical agencies and programs, and nongovernmental organizations
- Leveraging resources and building partnerships with agencies/program to get buy-in
- Developing the action plan and M&E frameworks
- Implementing the action plan for resource mobilization and conducting M&E

System Requirements Specifications

The actual development of a digitalized regulatory IMS needs to be based on SRS, which should be developed by the software developers and regulatory experts who will ultimately use the system. The SRS describes the clients' needs through workflows, roles and responsibilities, and functionality. The main purpose is to ensure that the developed system meets the clients' requirements. The MCS for a regulatory IMS should be incorporated throughout the document and should guide the selection and definition of the components outlined below. Process standards should be used to define regulatory functions, processes, and user requirements; data dictionaries and knowledge trees provide common language for required software and processes; and data exchange standards should be used to identify appropriate hardware and software and guide the functionality of the regulatory IMS.[e]

A typical SRS includes several sections, which are explained below.

User requirements

This section is adapted from "What Is Role-Based Access Control? Definition, Key Components, and Best Practices" by Chiradeep BasuMallick [47].

Typical users of a regulatory IMS consist of two groups:

- External business clients (e.g., pharmaceutical companies, importers, manufacturers, pharmacy owners, wholesalers, laboratories)
- Internal NMRA staff who review applications from external users and approve or deny various applications (e.g., MA, import licenses)

[e] To facilitate the process of writing the SRS, the international standard template can be used [46]

To ensure that all users have access to the functions they need, a digitalized regulatory IMS should consider several distinct groups of users and define role-based access control within the regulatory IMS according to the need:

- External users (e.g., pharmacy owners, pharmaceutical industry, importers/exports)
- Internal NMRA basic users (e.g., screeners, reviewers, moderators, approvers)
- Internal NMRA system administrators

Role-based access control should build on:

- Users: Typically, an individual or company representative
- Roles: See the three groups above
- Operations (e.g., regulatory IMS system administration)
- Objects: Viewing reports in the regulatory IMS or any other area that does not change the system state
- Permissions (e.g., submit an application for an import permit or review an MA application)
- Sessions: A regulatory IMS must have a log functionality that monitors all the above according to when a given user logs in and what actions they take

Hardware and Software

There are several considerations regarding the choice of hardware and software for regulatory IMS installation/deployment:

1. Choice of hosting: Local laws and regulations must be considered. Some countries' regulations require that hosting be on local premises, which may require hardware procurement with cost implications. Regulatory IMS authorities must comply with local laws and regulations regarding hosting requirements.
    a. Cloud server
        i. Easy to design for scale as cloud solutions typically are elastic
        ii. Eliminates or reduces the hardware maintenance aspect, potentially leading to a more sustainable deployment over time
        iii. Readily accessible with an internet connection
        iv. Server management not a concern
    b. On-premises server
        i. Data are kept within the NMRA's local physical infrastructure
        ii. Requires human and financial resources for server management and maintenance
    c. A hybrid of cloud server and on-premises server
        i. Allows the NMRA to keep confidential information on the premises and use the cloud for advanced data processing
2. Choice of software architecture: The choice of platform architecture is clear from the global initiatives for development and governance regarding digital health (Principles for digital development). The selected solution should be based on open-source components, including the

database and application. It should also be cross platform or at least function on an open-source operating system.

   a. Open-source system
      i. Builds out a community of practice
      ii. Allows for broad collaboration and sharing of new software features
   b. Proprietary system
      i. Requires licenses to use, which can be expensive and difficult to budget for
      ii. Has organizational support

3. Choice of specific hardware: Certain restrictions might be in place from various institutions and stakeholders involved in the process of developing a regulatory IMS (e.g., procurement from specific manufacturers might not be allowed).

Rapid Feasibility Assessment

Prior to adopting and implementing a digitalized regulatory IMS, it is crucial for an NMRA to conduct a feasibility assessment of the national health IT policy and legislation for electronic transmission of information, data governance, and standards. The assessment will also investigate the NMRA's IT infrastructure and its health and regulatory personnel's skills and technical expertise relative to their roles and responsibilities in carrying out key regulatory functions. The assessment should determine which of the MCS have been adopted and implemented by the NMRA and recommend the adoption and implementation of the remaining MCS (figure C and table 2).

Objective of the Assessment

The main objective of the feasibility assessment is to identify strengths, weaknesses, gaps, and challenges the NMRA faces and to inform its decision on the digital regulatory IMS selected. The assessment report will also provide practical recommendations for the gradual adoption and implementation of the digital regulatory IMS by the NMRA.

Methodology

Planning for a Feasibility Assessment

Use the following steps as a guide when designing and executing the feasibility assessment. These steps are taken from *Ensuring the Quality of Medicines in Resource-Limited Countries: An Operational Guide*: [48]

- Set up an assessment team: The planning usually starts with the establishment of an independent assessment team with a defined role and scope of work. The team should consist of a team leader and two experienced professionals—ideally one in health and medicine policy and regulation and the other in ICT. To reduce potential bias during the process while ensuring transparency and avoiding potential conflicts of interest, the assessment should be carried out by a nongovernmental organization (e.g., an academic institution such as university or a private organization). It can also be performed by an international organization.
- It is important that the assessment, including the appointment of the team and its role and scope of work, is approved by the NMRA. This approval should be secured before any activities of the actual assessment begin.

- Secure, where applicable, a financial budget based on the scope of work and time frame described in the assessment.
- Communicate information about the assessment to all agencies, responsible authorities, and interested persons to enlist their support and cooperation. These usually include different units or divisions of the NMRA (e.g., MA, pharmacovigilance, market control) and key players in pharmaceutical services (e.g., importers, wholesalers or distributors, MA holders, manufacturers).

Data Collection Methods and Technique

A predefined questionnaire should be used to guide the assessment team through collection of the data and the information required. Data collection may be carried out using a combination of techniques, including:

- Desk reviews of relevant and accessible (both published and unpublished) technical documents and records from primary and secondary sources, including medicines laws; executive orders; inspection records; guidelines; reports; and economic-, health-, and medicine-related indicators. The review should also cover national health IT policy, legislation for electronic transmission of health and regulatory information, data governance and standards, and the NMRA's IT infrastructure.
- Formal or semiformal discussions and consultations with key officials, including directors or their deputies of divisions within the NMRA, government, and other players as described earlier.

To determine the feasibility of implementing a digitalized regulatory IMS, it is necessary to collect and analyze data regarding the country's health IT policy, legislation for electronic transmission of health and regulatory information, data governance and standards, and Ministry of Health and NMRA IT infrastructure. This can be used to explain the what, how, and why. Annex 1 provides a questionnaire template to guide data collection to help determine whether adopting a digitalized regulatory IMS is appropriate for a particular NMRA. Every effort should be made to obtain the most up-to-date data and information.

The collected data should be analyzed and visualized and presented in a report with clear recommendations. The recommendations section should prioritize the issues and problems to be addressed, which will help ensure the best use of limited resources. Where appropriate, a proposed stepwise process should be described for a phase-basis adoption of a regulatory IMS for the country.

Implementing a Digital Regulatory IMS

Planning the Process

Developing and implementing a digital regulatory IMS is a complex and resource-intensive process. A template (table 3) provides a recommended implementation plan structure and is adapted from the WHO computerized information management system implementation guideline [49].

The implementation plan template gives recommendations on tasks to achieve, including allocating a server/hosting environment; developing, deploying, and configuring against reviewed SOPs; training and data management/reporting; and disaster recovery/maintenance planning for a digital regulatory IMS.

Review and Update Existing Business Processes

Throughout the process of digitalizing a regulatory IMS, it is crucial that all NMRA departments and staff work closely together, with the external users/clients, and with the software developers to define the business processes being digitalized and that a plan is made to ensure that the recommended MCS for a regulatory IMS are incorporated. The underlying regulatory functions and processes, workflows and accompanying procedures/SOPs, documents, and forms should incorporate best practices and be up to date before digitalization begins.

Table 3 – Implementation Plan Template [49]

Step	Description	Start	End	Budget
Duration of the project				
Evaluation of organizational readiness				
1	Appoint the project director and project manager			
2	Perform the assessment for organization readiness			
3	Define the project goals and scope			
4	**Human Resources**: Establish the project management structure			
5	Draft the project milestone and timeline			
6	Conduct a rapid feasibility assessment			
Phase 1 Project Initiation				
7	**Human Resources:** Appoint the project team member(s) according to the established project management structure			
8	Identify options and evaluate their potential risks			
9	Define the project approach			
10	Develop the SRS			
11	Prepare any needed tender documents and system and supplier evaluations up to signing contracts			
12	Identify project framework based on the project scope and the selected solution and update the project milestones and timeline			
13	Establish and approve the project budget			
14	Agree on the project deliverables and timeline			
15	Establish and agree on the communication mechanism within the project			
16	Establish the project document structure			
17	Establish and agree on the project master plan and validation master plan			
Phase 2 System Deployment				
18	Conduct the project implementation kickoff			
19	Develop the regulatory IMS and procure the related IT infrastructure			
20	Install the regulatory IMS, allowing adaptation to the business process			

Step	Description	Start	End	Budget
21	Provide training to the project team on the regulatory IMS and related IT infrastructure			
22	Prepare validation plans according to the validation master plan (including for data migration activities)			
23	Define the data migration strategy			
24	Prepare the validation documents according to each validation plan: - Operational specifications - Functional risk assessment - Test scenarios			
25	Prepare SOPs on using and managing the regulatory IMS			
26	Prepare the training plan			
27	Freeze the regulatory IMS implementation			
28	Train users and ICT managers on the regulatory IMS			
29	Perform the qualification of the regulatory IMS according to the prepared test scenarios			
30	Prepare the rollout process for the regulatory IMS go live			
31	Establish business continuity planning to ensure the availability of the regulatory IMS			
32	Establish the server monitoring and preventive server maintenance plan and disaster recovery plan			
33	Establish the regulatory M&E plan and indicators			
34	Write the validation report			
35	Review the regulatory IMS implementation, including the validation documents			
36	Decide on the date for the regulatory IMS go live			
37	Managing go live with data migration of any relevant previous systems			
38	Go live with regulatory IMS			
Phase 3 Project Closure				
39	Plan resolution of open issues			
40	Evaluate the regulatory IMS project post implementation activities			
41	Write the regulatory IMS project report			
42	Approve the project report and close the project			

DATA MANAGEMENT

Data management includes data storage, security, sharing, governance, architecture, and database and records management. Once a data management strategy is in place, the full potential of data can be used to draw important insights.

A data management strategy should be drafted from well-established best practices and proven strategies and should include both offensive and defensive components as described in the following sections.

The **offensive data management strategy** involves NMRA external client (e.g., pharmaceutical companies, manufacturers) activities, such as MA. The goal is to increase NMRA external client satisfaction. This strategy is used to conduct data analysis and modeling or combine separate data streams into dashboards.

The **defensive data management strategy** focuses on security and compliance. The goal is to align with regulations protecting data and privacy while detecting and preventing fraudulent activity.

An effective data management strategy is built on both offense and defense, in addition to the following strategic elements:

- Identification of data and its meaning, structure, source, and/or location
- Data storage to facilitate access, sharing, and data processing
- Provisions for data packaging to allow reuse and sharing and to add rules and guidelines for data access
- Governance to establish, administer, and communicate the policies and processes in place for data use
- Processing to integrate data across systems to provide a single, unified view

A data management plan should be based on the goals of the system. Both offensive and defensive components and the five core elements of data management should be incorporated into the plan.

Evaluate how data are managed and identify any shortcomings in the existing plan. If there is no plan, create a list of desired features (e.g., real-time access to data, predictive analytics, role-based dashboards). Once you have created the list of desired features, explore data management systems in terms of their alignment with the list. Investing in one will increase data accessibility and consistency.

Ensuring data integrity will help guarantee the completeness, precision, accuracy, and validity of data throughout their life cycle. Ensuring data integrity involves accounting for data life cycle, including any intentional or unintentional use of data. The legal and regulatory requirements for information security management systems are defined by the ISO 27000 set of standards.

According to ISO/IEC 27000: 2018 (E), "integrity is the property of accuracy and completeness," [50].

The US FDA defines data integrity as "the completeness, consistency, and accuracy of data. Complete, consistent, and accurate data should be attributable, legible, contemporaneously recorded, original or a true copy, and accurate," [51].

In the context of the digitalization of a regulatory IMS, data integrity should be enforced by NMRAs to ensure the accuracy and reliability of all data associated with the regulatory processes/procedures and to assess data regarding the safety, quality, and effectiveness of medicines and health products on behalf of the public to ensure that the benefits they provide outweigh any potential risks.

In the process of digitalizing a regulatory IMS, NMRAs will need to answer several questions if they want to implement meaningful and effective strategies to prevent and manage any data integrity risks. While this is not an exhaustive list, below are questions the US FDA recommends considering regarding data governance strategies: [51]

- Are controls in place to ensure that data are complete?
- Are activities documented at the time of performance?
- Are activities attributable to a specific individual?
- Can only authorized individuals make changes to records?
- Is there a record of changes to data?
- Are records reviewed for accuracy, completeness, and compliance with established standards?
- Are data maintained securely from data creation through disposition after the record's retention period?

Ensuring data integrity of a digitalized regulatory IMS requires:

- Ensuring that the data being collected are reliable and that all inputs are checked, validated, and consistent with the data dictionary
- Managing and controlling all user permissions and access
- Monitoring all updates made to the data (e.g., data creation, storage, usage, archival, destruction)
- Having a system to back up and restore data
- Periodically performing and generating audit trails
- Training NMRA staff and other users involved in and responsible for implementing data integrity procedures and users involved in NMRA regulatory processes

TRAINING

Training users on how to use a digital tool is an essential step during the deployment phase of any new or enhanced technology. Training can:

- Allow users to familiarize themselves with the different modules/functionalities of the digital tool
- Help trainers identify some of the difficulties that users are facing and address them early and throughout the process
- Promote the use and benefits of the tool being deployed

A training plan improves buy-in and sets clear deadlines for training and roll out methods. While there is no one-size-fits-all approach when it comes to training on new technology (because there are a lot of factors to consider), the need to define a training plan is the same.[f]

The training plan should communicate the details of the proposed training program to decision makers at NMRAs. The document should outline the objectives of the training program and identify participants. A schedule, strategies for curricula and training material development, methods for implementation, and plans for continuous improvement should also be included in the training plan. Ultimately, execution of the plan should ensure that NMRAs and other stakeholders are properly trained to perform their specific job functions.

Training methods (including format, setting, and contents or scope) will vary depending on the target audience and its specific needs. It is therefore important for the team drafting the training plan and associated materials to determine the most effective format for the NMRA and stakeholder communities and the best approach for delivering the training. We propose the training plan template included in Annex 2 as a starting point. This document was developed by the US Centers for Disease Control and Prevention and can be adapted for training in preparation for the introduction of a new digital tool or system [53]. The template can be used in whole or in part to address specific training needs. The template should be used with the training planning checklist (Annex 3) to ensure that all training planning requirements are satisfied.

The templates can be used to establish a training plan to:

- Focus primarily on activities of greatest importance
- Have a training plan checklist for NMRA staff and other stakeholders [52]
- Streamline the training process
- Put in place a training program that can be evaluated and refined over time

Maintenance and Sustainability

Written Procedures

The following procedures must be developed by the NMRA and be in place to ensure continuity of the digital regulatory IMS service provided to both NMRA internal users and external business clients—the end users. The NMRA MIS team should develop and routinely update these procedures.

- Back-up plan: Will routinely back up the system database. Using the disaster recovery plan described below, the regulatory IMS can be restored in case of disaster (e.g., fire, flooding).
- Disaster recovery plan: Describes how the above back up can be restored. The disaster recovery plan should be tested routinely to ensure it is functional.

[f]For guidance on developing a robust training plan, see: CDC Unified Process Practices Guide – Training Planning.[52]

In addition to these documents, the following standard system documents must be available:

- System administrator manual on how to configure and manage the application
- User guide on effective use of the application
- Training materials, including videos, courses, and documents to assist the user to effectively use the application
- Database description/diagram describing the structure of the database for future development or reporting
- Developer environment description of the software development procedures and processes

This will allow the NMRA to refer to the source code and apply changes as needed to update the system, assuming that the needed IT capacity is available to do this.

CHECKING QUALITY OF DATA

It is important to ensure the quality of data sets. Data maintenance, such as rebuilding database indices, is an ongoing process. The deletion of irrelevant data creates index fragmentation, which causes data gaps and slows access. Effective data management will help keep data clean and usable.[g]

MONITORING AND EVALUATION

The regulatory authority should implement an M&E system to monitor and evaluate the implementation and use of the digital regulatory IMS and its utility in improving regulatory performance.

M&E of implementation

The manager of the digital regulatory IMS should track and report to decision makers the status and results of the system's planning and implementation phases and use of the digital regulatory IMS. M&E of regulatory IMS implementation and use will:

- Promote accountability and facilitate timely implementation
- Help guide roll-out of modules for additional regulatory functions and/or new functionality in the digital regulatory IMS
- Maximize use of the digital regulatory IMS
- Generate data that can be used to ensure sustainable support for the digital regulatory IMS

To monitor performance in implementing the digital regulatory IMS, the NMRA should track the dates on which each planning and implementation activity was completed, specifically the dates for addressing each of the prerequisites (i.e., legislation, QMS, HR, financing, SRS, user requirements, hardware and software, rapid feasibility assessment) and each step in the implementation plan. Regular review of performance in implementing the roll-out will help the NMRA stay on track with the initial

[g] Please refer to: Discrete Desk Review of Data Quality Implementation Guide, Module 2, developed by the WHO for more information on data management best practices, including data privacy, storage, and archiving.[54]

implementation, make any necessary course corrections, and ensure smoother implementation of new modules if the system is being introduced in stages.

M&E of utility of digital regulatory IMS

Sustained support for the digital regulatory IMS will depend on the system's demonstrated ability to help improve regulatory performance. M&E of the digital regulatory IMS should capture its effect on regulatory performance, including documenting how the system helped:

- Facilitate communications and data sharing with regulated entities
- Reduce data loss
- Reduce backlogs and turnaround times in regulatory activities
- Support consistent, evidence-based regulatory actions
- Facilitate data and information sharing with other regulators (table 4)

Table 4 - Important outcomes, methods and illustrative indicators for tracking outcomes

Outcomes	Examples of indicators
Improved efficiency and quality of regulatory processes (e.g., reductions in data loss, errors, backlogs, turnaround times)	• Regulatory activity performance metric tracking (e.g., time to find information, time to complete a regulatory activity, speed of enforcement action) • Workflow management (e.g., number of nonautomated hand offs, number of data inputs that require manual aggregation or calculation) • Reporting (e.g., lag time to issue a report, number of errors in reports, gaps in reports)
Consistent, transparent, and evidence-based regulatory actions	• Statistics on regulatory decisions (e.g., trends in number and nature of regulatory decisions, approvals, or rejections based on staff person, regulated entity, nonconformity/violation, and application type)
Improved communications and data and information sharing with regulated entities and other regulators	• Number of entities (in country and externally) with which data are exchanged electronically • Number of electronic exchanges of data • Number of regulatory actions that benefited from electronic exchange of data • User feedback on access to information on regulatory outcomes

The NMRA should review data on these outcomes over time to understand trends. These outcome data will help make the case for continued support of a digital regulatory IMS. NMRA leadership should carefully review outcome data to inform decisions about how to improve its performance in ensuring medical product quality in the country. For example, outliers in decisions by staff or related to specific entities may identify the need for better staff training or supervision or for more consistent treatment of entities. Review of performance metrics may motivate the NMRA to emphasize new approaches (e.g., reliance) that show benefit. Review of performance in exchanging data may indicate unused potential for data sharing that will improve the quality of medicines in the country and regionally or globally.

CONCLUSION

Digitalizing a regulatory IMS in LMICs is no easy feat—there are context-driven considerations and planning steps that must be taken for implementation, including the size of the system, the composition of external clients, the complexity of existing data streams and systems, and the availability of human and financial resources. The adoption of the minimum common set of standards for a regulatory IMS should be a prerequisite for digitalization, as the set of standards aims to promote regulatory harmonization based on international best practices across regulatory functions. The process to adopt these standards and digitalize a regulatory IMS must be tailored to each country and address the specific needs of NMRAs. This document serves as a pathway to guide that process. Following a gap assessment to determine whether digitalization is feasible and appropriate, the critical steps for digitalization of a regulatory IMS include designing an intervention plan, developing an action plan, mobilizing needed resources, and implementing the action plan. M&E is key to ensuring that all aspects of this process are on track, allowing for continuous improvement throughout.

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ANNEX I – RAPID ASSESSMENT QUESTIONNAIRE

This questionnaire serves as a guide to obtaining general information and specific data for informing the decision making of an NMRA to adopt or not to adopt a digitalized regulatory IMS. Every effort should be made to obtain the most up-to-date data and information. This section is adapted from *Ensuring the Quality of Medicines in Resource-Limited Countries: An Operational Guide* [48].

1. Background Information (BI) (Indicate the year the data were collected)

BI.1: Country information:

a. Area (in square kilometers)_____
b. Administrative divisions (number of provinces, states, districts)_____

_____

BI.2: Demographic and socioeconomic data:

2. Total population _____
3. Life expectancy (male/female)_____
4. Literacy rate_____
5. Gross domestic product per capita (year)_____

BI.3: Health and health system data. Indicate the year for which the data apply: _____

6. Infant mortality rate (per 1,000 live births) _____
7. Maternal mortality rate (per 100,000) _____
8. Total government health expenditure _____
9. Total value of international aid for health sector _____
10. Total number of health facilities, both public and private (provide data in table below)

Health Facilities	Government/Public	Private
Central/major hospitals		
Provincial or state		
District		
Health center		

BI.4: Pharmaceutical-sector data. Indicate the year for which the data apply: _____

11. Total government expenditure on medicines _____
12. Per capita expenditure on medicines _____
13. Total value of domestic production _____
14. Total value of imports of finished products _____
15. Total value of imports of APIs _____
16. Total value of exports of finished products _____
17. Total value of exports of APIs _____

BI.5: Country health and pharmaceutical human resources:

Description		Year
Type and number of health professional training schools		
	Medical	
	Pharmacy	
	Other (e.g., dentistry, nursing)	
	Total number of medical doctors	
	Total number of pharmacists	
	Total number of nurses	

BI.6: Country pharmaceutical sector status (specify year):

No. of establishments	Government	Private	Other	Year
Pharmaceutical manufacturing plants				
For APIs				
For finished dosage forms				
For packaging finished dosage forms				
Research-based pharmaceutical industry				
Generic (incl. branded) pharmaceutical product manufacturers				
Pharmaceutical importers				
Pharmaceutical exporters				
Pharmaceutical wholesaler or distributors				
Retail pharmacy outlets				

BI.7: Evolution of medicines laws and regulations:

18. Existence of a medicines law: ☐yes ☐No If yes, provide answers to questions 19 and 20 below.
19. The year when the medicines law or regulation was first introduced: _____
20. Which of the following aspects of medicines quality, safety, and efficacy are covered by present medicines law(s) or regulations:

- Product registration/MA ☐Yes ☐No
- Pharmaceutical establishment licensing ☐Yes ☐No
- Control of importation ☐Yes ☐No
- Control of exportation ☐Yes ☐No
- Regulatory inspection ☐Yes ☐No
- Quality monitoring and ADR/ADE surveillance ☐Yes ☐No
- Control of drug promotion and advertising ☐Yes ☐No
- Quality control and testing ☐Yes ☐No
- Clinical trials oversight ☐Yes ☐No
- Lot release ☐Yes ☐No
- Other (specify) _____

21. Existence of national medicines policy: ☐Yes ☐No

If yes, indicate the year of its promulgation or introduction: _____

22. When was the NMRA was established?_____

Provide its organizational structure or organogram as an annex to this document

_____

BI.8: Annual government budget (specify in local currency) allocations for an NMRA's operation and function:

a. Current year: _____

b. Has the government budget increased over the last three years?

☐Yes ☐No

If yes, provide approximate figures in the following table:

Year	Government budget figure in local currency
Current year	
Last year	
The year before	

If no, provide reasons (e.g., introduction of cost-recovery scheme or charge of fees for services):

_____

_____

_____

2. Pre-Marketing Quality, Safety, and Efficacy Assessment for Registration/ Marketing Authorization (MA)

MA.1: Existence of medical product assessment/evaluation unit/division for registration/MA within the NMRA: ☐Yes ☐No

If yes, which of the following aspects do the unit/division assess:

☐ Quality ☐ Safety ☐ Efficacy ☐ Cost-effectiveness ☐ Other (please specify):_____

MA.2: Current number of officers/evaluators responsible for routine products (medicines, biological and vaccines, blood products, and medical devices) evaluation for registration within the NMRA:_____

MA.3: In addition to the NMRA staff persons in this unit/division, is there a medical products evaluation (or advisory) committee consisting of appointed members from relevant disciplines whose role is to make decision on product registration? ☐Yes ☐No

If yes, check the appropriate boxes below:

☐ Clinician(s) from a major teaching hospital.

☐ Pharmacologist(s) from teaching institution or major hospital

☐ General or community practitioner(s)

☐ Community pharmacist(s)

☐ Manufacturing or GMP expert(s)

☐ Pediatrician(s)

☐ Representative(s) from consumer associations

☐ Other (specify)_____

MA.4: Existence of processes and standard operating procedures (SOPs) for product registration/MA: ☐Yes ☐No

If yes, check the appropriate boxes below:

☐ Receiving the dossier

☐ Screening the dossier for completeness

☐ Paying fee(s)

☐ Triaging the dossier

☐ Evaluation and review

☐ Issuance of R/MA certificate

☐ Renewal

☐ Post-R/MA variation

☐ R/MA certificate suspension and revocation

☐ Other (specify)_____

MA.5: What key information is required for the registration/MA? Check all that apply:

☐ Complete information about the applicant

☐ Manufacturer information

☐ Complete product information

☐ Complete batch manufacturing record

☐ Packaging material

☐ Labeling detailed information

☐ Product registration status certificate in producing country

☐ Stability study data

☐ Bioavailability/bioequivalence data

☐ Clinical trials data

☐ Product samples and certificate of analysis

☐ Information required as per the common technical document (ICH or WHO)

MA.6: What dossier format does the NMRA require applicants to use?

☐ Common technical document (CTD)

☐ Other (specify) _____

MA.7: Do the same requirements apply for both branded/innovative and generic pharmaceutical preparations? ☐Yes ☐No If no, explain what requirements are different:

_____

_____

_____

MA.8: How much does it cost the applicant to apply, renew, or change the application for a medicine product for human use registration?

Description	local currency
Application for registration of new branded/innovative product	
Application for registration of a generic product	
Application for change of application/variation	
Application for renewal	

MA.9: Is there a specific budget for R/MA function? ☐Yes ☐No

If yes, please specify sources:

☐ Government: _____local currency (year: _____)

☐ Fees charged from services:_____(year: _____)

MA.10: Does the NMRA charge fees for registration/MA? ☐Yes ☐No

If yes, provide more information in the table below:

Type of application/product type	Approx. fees charged (local currency)	Remarks
Investigational new drug		
New (innovator) drug		
Generic product		
Over the counter		
Biological and vaccine		
Fast track		
Emergency use authorization		
Other (specify)		

MA.11: Number of MA applications received by the NMRA in the last three years:

Description	Number		
	Year	Year	Year
Total number of applications received			
- Applications for registration of new branded/innovative product			
- Applications for registration of a generic product			
- Applications for renewal			
- Applications for change of application/variation			

MA.12: Number of registration/MA certificates issued, renewed, suspended, or revoked in the last three years:

Description	Year	Year	Year
Total number issued			
Total number renewed			
Total number suspended			
Total number revoked			
Total number under consideration/investigation			
Total number not yet evaluated (backlog)			

MA.13: Total number of pharmaceutical product preparations for human use officially registered in the country by the NMRA:

Last year	Current year	Next year estimate

MA.14: Total number of MA holders registered by the NMRA:

Last year	Current year	Next year estimate

MA.15: Estimated total number of unregistered pharmaceutical product preparations for human use available in the market: _____(year) _____

MA.16: Does the country allow the import of unregistered pharmaceutical products?

☐Yes ☐No

If yes, please briefly explain under what circumstances (e.g., donated medicines, emergency use): _____

MA.17: Registration validation is for: ☐ <2 years ☐ 2 years ☐ 3 years ☐ 4 years

☐ 5 years☐ > 5 years

MA.18: Lead time (i.e., average time span between application submission/receipt and date of issuance of the registration certificate, if successful) for registering a pharmaceutical product.

For generic products:

☐ < 6 months ☐ 6–12 months ☐ 1–2 years ☐ > 2 years

For innovative (or investigational) new drug products:

☐ < 6 months ☐ 6–12 months ☐ 1–3 years ☐ > 3 years

For biological or vaccines:

☐ < 6 months ☐ 6–12 months ☐ 1–3 years ☐ > 3 years

For use in emergency situation (emergency use authorization)

☐ < 6 months ☐ 6–12 months ☐ 1–2 years ☐ > 2 years

MA.19: Existence of fast-track registration system: ☐Yes ☐No

If yes, indicate conditions or requirements for a product to be eligible for fast-track registration:

MA.20: Are guidelines or instructions on medical product registration/MA available and freely accessible: ☐Yes ☐No

If yes, they are available:

☐ Online (specify URL address):

_____

☐ In hard copy only

MA.21: Does the NMRA adopt or adapt bilateral and/or regional reliance and harmonization arrangements or other mechanisms in its product evaluation for registration/MA?

☐Yes ☐No

If yes, check all that apply:

☐ Reliance on neighboring NMRAs

☐ Participate in regional harmonization/reliance

☐ Participate in collaborative registration procedures

☐ Use reference regulatory authorities

☐ Participate in joint assessment group

☐ Other (specify)_____

_____

MA.22: Current registration/MA system:

☐ Manual (or with MS Excel spreadsheet)

☐ Computer-assisted standalone; specify the software being used: _____

_____

☐ Internet interface application; specify the software being used:_____

_____

MA.23: Main constraints faced in carrying out robust licensing system. Check all that apply:

☐ Financial constraints – low government budget

☐ Limited numbers of qualified inspectors

☐ Lack of continuing education/training

☐ Lack of SOPs or guidelines

☐ Limited access to relevant regulatory IMS for marketing authorization

☐ Lack of software application on regulatory IMS

☐ Other (specify)_____

_____

3. Licensing of Persons and/or Pharmaceutical Establishments (LI)

LI.1: Existence of unit/team in charge of issuing, variation, suspension, and revocation of license for persons or pharmaceutical establishments: ☐Yes ☐No

LI.2: Current number of officers/professionals responsible for routine licensing:_____

Their professional qualifications: _____

_____

LI.3: Is the NMRA the only agency that issues licenses for persons or pharmaceutical establishments in the country? ☐Yes ☐No

If no, please specify if the provincial or state authority that also issues licenses for those establishments operating at provincial/state level:

_____

_____

LI.4: Existence of process and standard operating procedures (SOPs) for licensing of persons or pharmaceutical establishments: ☐Yes ☐No

If yes, provide titles of the key SOPs: _____

_____

_____

LI.5: What key professional qualifications are required to obtain a license to engage in or operate the following pharmaceutical activities?

Practice/activity	Professional requirements
Manufacturing	
Importing/exporting	
Wholesale selling	
Retail selling/pharmacy	

LI.6: For retail pharmacy outlets, what are the key regulatory requirements to be met for license approval? Check all that apply:

☐ Specified location (e.g., based on population needs)

☐ Specified list of medicines to provide for sale

☐ Completion of certified pharmacy or dispensing training program

☐ Other (specify)_____

LI.7: Number applications from **manufacturers** received by NMRA in the last three years for LI:

Description	Year	Year	Year
Total number of applications received			
- New licensing			
- Renewal			
- Change of application/variation			

LI.8: Number of **manufacturer**/producer licenses issued, renewed, suspended, revoked, or not yet assessed in the last three years:

Description	Year	Year	Year
Total number issued (new)			
Total # renewed			
Total # suspended			
Total # revoked			
Total # under consideration/investigation			
Total # not yet assessed (backlog)			

LI.9: Is prequalified inspection for GMP compliance of the manufacturing site a precondition for licensing of a manufacturing plant? ☐Yes ☐No

L.10: Number of **wholesaler/distributor/importer** and **exporter** applications for LI received by NMRA in the last three years:

Description	Year	Year	Year
Total number of applications received			
- New licensing			
- Renewal			
- Change of application/variation			

LI.11: Number of **wholesaler/distributor/importer** and **exporter** applications for LI issued, renewed, suspended, or revoked, or not yet assessed by NMRA in the last three years:

Description	Year	Year	Year
Total number issued (new)			
Total # renewed			
Total # suspended			
Total # revoked			
Total # under consideration/investigation			
Total # not yet assessed (backlog)			

LI.12: What are the main requirements and qualifications to be met for license approval of a pharmaceutical **wholesaler or distributor**?

☐ In compliance with regulatory requirements (e.g., based on outcomes of the inspection)

☐ Specified location

☐ Professional qualification (e.g., pharmacist as technical manager)

☐ Adequate facility with proper air ventilation and air conditioning

☐ Appropriate storage areas (e.g., cold, cool, and room temperature rooms)

☐ At least 80% of the transport means are in good working condition

☐ Other (specify)_____

LI.13: Number of **retailed pharmacy** (of all categories, if different) applications for LI received by the NMRA in the last three years:

Description	Year	Year	Year
Total number of applications received			
- New licensing			
- Renewal			
- Change of application/variation			

LI.14: Number of **retailed pharmacy** (of all categories, if different) applications for LI issued, renewed, suspended, revoked, or not yet assessed by the NMRA in the last three years:

Description	Year	Year	Year
Total number issued (new)			
Total # renewed			
Total # suspended			
Total # revoked			
Total # under consideration/investigation			
Total # not yet assessed (backlog)			

LI.15: Estimated total number of illegal (or unlicensed) pharmaceutical establishments that are engaged in the manufacture, import, export, or retail sale of pharmaceutical products in the country in the last three years.

Description	Year	Year	Year
Manufacturer/producer			
Importer/exporter			
Wholesaler/distributor			
Retail pharmacy outlet			

LI.16: License validation applied to the following establishments:

Description	< 2 years	2 years	3 years	4 years	5 years	> 5 years
Manufacturer/producer						
Importer/exporter						
Wholesaler/distributor						
Retail pharmacy outlet						

LI.17: Lead time (i.e., average time span between application submission and date of issuance of the license) for a license of a retail pharmacy:

☐ < 6 months ☐ 6–12 months ☐ 1–2 years ☐ > 2 years

LI.18: Are guidelines or instructions on retail pharmacy licensing available and freely accessible? ☐Yes ☐No

If yes, are they available:

☐ Online (specify URL)

_____

☐ In hard copy only

LI.19: Does the NMRA charge fees for service to an applicant for a license to operate a pharmaceutical establishment? ☐Yes ☐No

If yes, provide more information in table below:

Type of license	Approx. fees charged local currency	Remarks
Manufacturing		
Importing/exporting		
Wholesaling/distributing		
Retail pharmacy		

LI.20: In addition to the NMRA staff persons in charge of licensing, is there an advisory or expert committee comprising appointed members from relevant agencies whose role is to make decisions on licensing?

☐Yes ☐No

If yes, check the appropriate boxes below:

☐ Local (provincial or state) authority

☐ Professional association

☐ Other (specify) _____

_____

LI.21: What are the main constraints faced in carrying out robust licensing system? Check all that apply:

☐ Financial constraints – low government budget

☐ Limited number of qualified inspectors

☐ Lack of continuing education/training

☐ Lack of SOP or guidelines

☐ Limited access to relevant regulatory IMS for licensing

☐ Lack of software applications on regulatory IMS

☐ Other (specify)_____

_____

4. Regulatory Inspection (RI) (GMP and Pharmaceutical Supply / Distribution Chains)

RI.1: Existence of provisions in the drug law/regulations defining the powers and status of GMP inspectors: ☐Yes ☐No

RI.2: Existence of a **GMP and GDP inspectorate**: ☐Yes ☐No

If yes, provide additional information in the table below on the **number**:

Description	Last year	Current year	Plan for next year
GMP inspector			
Pharmaceutical distribution chain inspector			
Same inspector performs both GMP and distribution chain			
Other (e.g., investigational)			

RI.3: Relationship of GMP inspector(s) to the unit/division in charge of licensing of manufacturers and product registration unit/division:

_____

_____

RI.4: Existence of national GMP guidelines: ☐Yes ☐No

If yes, name and year of introduction _____

_____ (year_____)

If no, what GMP guidelines (e.g., WHO) are officially accepted for use in the country?

_____

RI.5: Existence of manuals or standard operating procedures (SOPs) for GMP inspectors:

☐Yes ☐No

If yes, name and date of publication: _____

_____(year_____)

RI.6: Status of application of GMP guidelines/standards for manufacturing plants to comply:

☐ Voluntary

☐ Compulsory (required by law) _____

RI.7: Information on current GMP inspection-related activities:

No. of plants and type of inspection	Last year	Current year	Plan for next year
Total no. of manufacturing plants in the country			
Of which:			
- As routine			
- For renewal of license			
- For investigation/for cause			
- As follow-up			
Other (specify)			

RI.8: Information on number of GMP inspections carried out by the NMRA:

No. of inspections	Last year	Current year	Plan for next year
Total no. of inspections carried out			
Of which:			
- As routine			
- For renewal of license			
- For investigation/for cause			
- As follow-up			
- Other (specify)			

RI.9: Number of administrative and regulatory measures taken against GMP non-compliant manufacturing plants:

Measures taken:	Last year	Current year	Plan for next year
Written notice of warning			
Fine			
License suspended			
License revoked			
Production suspended			
Other (specify)			

RI.10: Existence of strategy or plan to increase number of manufacturing plants to comply with national/international GMP standards: ☐Yes ☐No

If yes, indicate target number by year:

Status	Last year	Current year	Plan for next year
Target plan to increase			
Actual manufacturing plants increased			

RI.11: Existence of inspection services of the **pharmaceutical supply/distribution chain:**
☐Yes ☐No

If yes, provide additional information below:

No. of establishments inspected	Last year	Current year	Plan for next year
Total			
Of which:			
- Importers			
- Distributors/wholesalers			
- Retail outlets			
- Other (specify)			

RI.12: Information on number of inspections carried out by the NMRA on the **pharmaceutical supply/distribution chain:**

No. of inspections	Last year	Current year	Plan for next year
Total no. of inspections carried out			
Of which:			
- As routine			
- For renewal of license			
- For investigation/for cause			
- As follow-up			
- Other (specify)			

RI.13: Number of administrative and regulatory measures taken against establishments non-compliant to **GSDP:**

Measures taken	Last year	Current year	Plan for next year
Written notice of warning			
Fine			
License suspended			
License revoked			
Other (specify)			

RI.14: Existence of strategy or plan to increase number of establishments complying with national/international GSDP standards: ☐Yes ☐No

If yes, indicate target number by year:

Status	Last year	Current year	Plan for next year
Target plan to increase			
Actual increase			

RI.15: Does the NMRA charge fees for inspection services for both GMP and distribution chain?
☐Yes ☐No

If yes, indicate approximate fees charge for the type of inspection:

Type of inspection	Fee charges applied, in local currency		
	Per hour	Per day	Per plant facility
GMP			
Distribution chain			

RI.16: Main constraints faced in carrying out inspection services. Check all that apply:

☐ Financial constraints – low government budget

☐ Limited number of qualified inspectors

☐ Lack of continuing education/training

☐ Lack of SOP or guidelines

☐ Limited access to relevant regulatory IMS for inspection

☐ Lack of regulatory IMS software applications

☐ Other (specify)_____

_____

5. Post-Marketing Surveillance (PMS) and Market Control (MC)

MC.1: Existence of post-marketing surveillance and control unit/division within the NMRA:

☐Yes ☐No

If the post-marketing surveillance and control unit exists, which of the following do they conduct surveillance for (select all that apply):

☐ Quality ☐ Safety ☐ Efficacy

MC.2: Current number of officers responsible for PMS/MC of health products (medicines, biological and vaccines, blood products, and medical devices) within the NMRA:_____

MC.3: In addition to the NMRA staff persons in this unit/division, are there any other stakeholders involved in the PMS/MC in the form of technical working groups or committees?
☐Yes ☐No

If yes, check the appropriate boxes below:

☐ Health program

☐ Central medical store

☐ Customs

☐ National and provincial QC laboratory

☐ Manufacturers association

☐ Police

☐ Representative(s) from consumer associations

☐ Other (specify)_____

MC.4: Existence of process and standard operating procedures (SOPs) or guidelines for PMS/MC:

☐Yes ☐No

If yes, check the appropriate boxes below:

☐ Technical working group

☐ National guidelines for PMS/MC

☐ PMS protocol (sampling and testing)

☐ Reporting and results dissemination

☐ Regulatory enforcement action

☐ Other (specify)_____

MC.5: Does the country deploy a conventional or risk-based approach to PMS?

☐ Conventional

☐ Risk-based

MC.6: Are medicines and vaccine samples collected either by the inspector(s) or the PMS sample collectors during inspections and/or PMS? ☐Yes ☐No

If yes, provide information below:

Samples collected and tested last year in connection with	# of samples collected	# of samples tested	Average % of poor-quality medicines documented in the last PMS round
Manufacturers			
Importers/wholesalers/distributors			
Retail pharmacy outlets			
Total			

MC.7: Number of administrative and/or regulatory measures taken against practices related to producing and/or selling poor-quality products in the last two years:

Measures taken	Year	Year
Written notice of warning to the violator(s)		
Products in stock seized/confiscated		
Fines		
License suspended		
License revoked		
Product recall		
Withdrawal by the manufacturer/distributor		
Other (specify)		

MC.8: Existence of product quality and safety surveillance, including adverse drug reactions, and events reporting mechanism or system: ☐Yes ☐No

MC.9: Existence of product recall mechanism or system: ☐Yes ☐No

MC.10: Existence of strategy or plan to expand PMS/MC nationwide: ☐Yes ☐No

If yes, provide additional information in the table below:

Status	Last year	Current year	Plan for next year
Current geographical coverage % of country territory			
Target plan to increase coverage in %			
Current product class(es) of PMS coverage			
Target plan to increase coverage to other medicines (describe)			

MC.11: What are PMS data on product quality used for? Check all that apply:

☐ Revising laws, rules, and regulations on medical products

☐ Policy change on regulating and controlling medical products

☐ Improve PMS guidelines and protocols (sampling and testing)

☐ Reporting and results dissemination for awareness raising, including WHO Rapid Alert System

☐ Regulatory enforcement action

☐ Other (specify)_____

MC.12: Does the NMRA participate in the WHO Member State Mechanism on Substandard and Falsified Medical Products and report SF cases to the WHO Rapid Alert System?

☐Yes ☐No

If yes, provide information in the table below:

	Last year	Current year	Plan for next year
Number of cases reported			

MC.13: Does the Government invest in PMS/MC programs? ☐Yes ☐No

If yes, provide information in the table below:

	Last year	Current year	Plan for next year
Government budget local currency			

MC.14: Main constraints faced in carrying out PMS/MC services. Check all that apply:

☐ Financial constraints – low government budget

☐ Limited number of qualified inspectors

☐ Lack of continuing education/training

☐ Lack of SOPs or guidelines

☐ Limited access to relevant regulatory IMS for inspection

☐ Lack of regulatory IMS software applications

☐ Other (specify)_____

_____

6. Laboratory Access and Testing (LT)

LT.1: Existence of a national medicines quality control laboratory (NMQCL):

☐Yes ☐No

If yes, provide the following information:

- Number and name of each unit or division of the lab: _____

1.
2.
3.
4.
5.
6.
7.
8.

LT.2: Professional qualifications and **number** of people working at NMQCL (provide year when data/information is collected _____):

Qualification	Pharmacy/pharmaceutical sciences	Chemistry	Other (specify)
Postgraduate			
Graduate			
Technician			
Other (specify)			

LT.3: Types of tests or assays the laboratory can perform for pharmaceutical products:

☐ Identification of APIs

☐ Hardness (for solid form)

☐ Loss on drying

☐ Melting range

☐ Residue on ignition

☐ Disintegration

☐ Dissolution

☐ Assay for content of API(s)

☐ Sterility

☐ Pyrogen

☐ Bacterial endotoxin

☐ Impurities (ordinary impurities)

☐ Water content

☐ Heavy metals

☐ Other (specify)

LT.4: Existence of a national pharmacopoeia: ☐Yes ☐No

If yes, provide name, year first published, and current edition:

_____

LT.5: Pharmacopeias officially accepted for use in the country:

- _____
- _____
- _____
- _____
- _____
- _____

LT.6: Estimated maximum number of samples (including APIs and finished products) the lab is able to test per year: _____

LT.7: Number of tests (with report of results) that were performed using pharmacopeial procedures by the lab:

Total no. samples tested	Last year	Current year	Est. next year
APIs			
Finished pharm products			

LT.8: Specify the five most common medicines groups (e.g., antibiotic, antipyretic, anti-inflammatory, antimalarial) that the lab has tested in last year

- _____
- _____
- _____
- _____
- _____

LT.9: Sources that have sent medicines samples and requests for tests (e.g., inspection unit of NMRA):

- _____
- _____
- _____
- _____

LT.10: Purposes for quality testing of medicines samples in the last two years:

Purpose	#/year	#/year
Registration		
Quality monitoring		
Request from other NMRAs or labs		
Request from individuals		
Investigation for regulatory action		
Other (specify)		

LT.11: Does the lab charge fees for testing services? ☐Yes ☐No

If yes, indicate the average fees the lab charges for the following tests using pharmacopeial procedures:

Test	Fee (local currency)/test	Remarks
Organoleptic		
Identification		
Assay		
Dissolution (solid dosage)		
Sterility (injectable)		
Impurities		

LT.12: Total annual budget for lab operation, including staff salaries:

_____ local currency (year_____)

LT.13: Total annual budget for lab equipment/instrument maintenance:

_____ local currency (year_____)

LT.14: Major sources of budget for lab operations/activities:

☐ Government

☐ Fees for services

☐ Donations, including grants and foreign assistance

LT.15: Has the lab received any financial or in-kind support from any international agencies since its establishment? ☐Yes ☐No

If yes, indicate name of the agency(ies):

- _____
- _____
- _____
- _____
- _____

LT.16: Main constraints the NQCL faces in its operation and performing various tests/assays. Check all that apply:

☐ Financial constraints – low government budget

☐ Limited number of qualified professionals

☐ Lack of continuing education/training

☐ Limited number of adequate lab equipment/instrument

☐ Lack of certain reference standards/substances

☐ Lack of pharmacopeial specifications or methods

☐ Lack of certain reagents, solvents, or other consumables

☐ Other (specify) _____

_____

LT.17: Laboratory management regarding some aspects of Good Laboratory Practices, Quality Management System, and international standards of practices. Check all that apply:

☐ Existence of a quality policy manual

☐ Existence of a Quality Management System (QMS)

☐ Existence of standard operating procedures (SOPs)

☐ Existence and use of lab equipment logbook

☐ Existence (in written document) of safety rules and measures applied

☐ Existence and use of appropriate PPE (e.g., lab clothes, gloves, goggles)

☐ Existence and use of appropriate and separate storage room for reference substances, toxic and poisonous materials, and inflammable chemicals

☐ Compliance with GLP

☐ ISO/IEC 17025 ☐ ISO/IEC 17047 ☐ ISO 13458 ☐ Other (specify) _____

_____

LT.18: Has the lab participated in any international or regional assessment for professional and technical competency? ☐Yes ☐No

If yes, describe the event and year:

_____

_____

LT.19: Has the lab ever been requested to test a certain product's quality by an international agency or neighboring countries? ☐Yes ☐No

If yes, describe the event and year: _____

_____

LT.20: Does the NQCL use any information management system? ☐Yes ☐No

If yes, specify the IMS the lab uses and year of introduction: _____

_____

7. Data Standards and Minimum Common Standards (DS and NCS) for Regulatory Information Management System

DS.1: What communication mechanism is the NMRA using for sharing information internally? Check that all apply:

☐ Manually (i.e., handwritten in printed template)

☐ Semi-manual and electronic

☐ Fully electronic through broadband/intranet with share-drive across the agency

☐ Other (specify) _____

DS.2: What categories of common standards does the NMRA use to consistently and effectively exchange regulatory information of its activities with other NMRAs and their regional networks? Check all that apply:

☐ Process standards that are prerequisites for standardizing regulatory functions (e.g., Good Regulatory Practices, Good Reliance Practices, GMP, GRevP, GDP, ISO standards)

☐ Pharmaceutical standard dictionaries and knowledge trees that are reference lists for terminology, nomenclature, and hierarchies (e.g., Anatomical Therapeutic Chemical (ATC), International Nonproprietary Name (INN), Data Standards for Identification of Medicinal Products (IDMP), Unique Ingredient Identifier, National Drug Code (NDC), Chemical Abstract Service (CAS) registry number, Global Standard 1 (Global System of Supply Chain Standards)

☐ Data exchange standards that determine how data should be structured, defined, and formatted to share across computer systems (e.g., Structured Product Labelling and Portable Document Format (PDF) and platforms such as Fast Health Interoperability Resources (FHIR®) that define a common standard for health systems data exchange, Common Technical Document (CTD), Clinical Data Acquisition Standards Harmonization (CDASH))

☐ Other (specify) _____

DS.3: What Common Minimum Standards does the NMRA plan to deploy in the future (short-, medium-, and long-term) to be able to communicate and exchange its regulatory information in

view of harmonizing with the regional and international effort in regulatory IMS and moving toward a digitalization platform of its key regulatory functions (e.g., R/MA, RI, LI, MC, LT)

☐ Short-term (6–12 months): _____

☐ Medium-term (13 months–2 years): _____

☐ Long-term (>2 years): _____

8. Information and Communication Technology (ICT)

Q. N#	Questions	Remarks	Concise response
ICT.1:	How is the NMRA currently managing whole or part(s) of the above-mentioned functions and activities? (manual, semi-automated, automated)	Any of the given options	
ICT.2:	How many proficient IT staff does the NMRA have?	Total proficient IT staff	
ICT.3:	Is the NMRA currently using any installed server? Detailed specification of the server, if applicable.		
ICT.4:	Is the NMRA office connected via a local area network (LAN) or wide area network (WAN), or is no network installed?	Any of the given options	
ICT.5:	How many desktop and laptop computers are there in the NMRA (PC, laptop, workstation). Please also mention the specifications of similar computers.		
ICT.6:	Details of Internet being used in NMRA	Connection type, bandwidth	

Q. N#	Questions	Remarks	Concise response
ICT.7:	Is any switch, router, firewall or data center established in the NMRA? Please provide details	Data center details	
ICT.8:	Are you using any software to support performing routine activities in the NMRA? Details of the software application.		
ICT.9:	Do you have any human capital development plan in place?		
ICT.10:	Do you conduct trainings for staff to improve staff skillsets? If yes, specify the frequency of training:		
ICT.11:	Does the NMRA have an IT department? Please share the hierarchy of the same along-with the expertise and skill set of each staff member of the department.		
ICT.12:	How do applicants interact with the NMRA for submissions of applications and to communicate during the process for any clarifications?		
ICT.13:	What power backup options are available in the NMRA premises?		
ICT.14:	How many NMRA locations are there in the country?		
ICT.15:	How does the NMRA collect the fee against various services provided to applicants?		
ICT.16:	Tentative timeline to grant a license to a manufacturer?		

Q. N#	Questions	Remarks	Concise response
ICT.17:	Tentative timelines to grant a Market Authorization/Registration to a manufacturer?		
ICT.18:	Tentative time spent by an officer to complete the task on each approval process (marketing authorization, licensing, etc.)?		
ICT.19:	How many printers and scanners are there in the NMRA? Details of each is required.	Make, model, network enabled	
ICT.20:	Is there any pharmaceutical manufacturers association or other mechanism for quick information sharing?	Awareness of ICT benefits	
ICT.21:	How does the NMRA share information among its divisions and among stakeholders outside the organization?	Communication system	

[1] The names of the law might vary from one country to another (e.g., drug law, pharmaceutical management law)

ANNEX 2 – REGULATORY IMS TRAINING PLAN

This document was developed by the US Centers for Disease Control and Prevention and can be adapted for training in preparation for the introduction of a new digital tool or system [53].

<Regulatory IMS PROJECT NAME>

TRAINING PLAN

Version *<1.0>*

<mm/dd/yyyy>

VERSION HISTORY

[Provide information on how the development and distribution of the training plan will be controlled and tracked. Use the table below to provide the version number, the author implementing the version, the date of the version, the name of the person approving the version, the date that the particular version was approved, and a brief description of the reason for creating the revised version.]

Version Number	Implemented By	Revision Date	Approved By	Approval Date	Description of Change
1.0	*<Author name>*	*<mm/dd/yy>*	*<Project Manager name>*	*<mm/dd/yy>*	*<description of change>*

Notes to the Author

[This document is a template of a training plan document for a project. The template includes instructions to the author, boilerplate text, and fields that should be replaced with the values specific to the project.

- Blue italicized text enclosed in square brackets ([text]) provides instructions to the document author or describes the intent, assumptions, and context for content included in this document.
- Blue italicized text enclosed in angle brackets (<text>) indicates a field that should be replaced with information specific to a particular project.
- Text and tables in black are provided as boilerplate examples of wording and formats that may be used or modified as appropriate to a specific project. These are offered only as suggestions to assist in developing project documents; they are not mandatory formats.

When using this template, the following steps are recommended:

1. Replace all text enclosed in angle brackets (e.g., <Project Name>) with the correct field document values. These angle brackets appear in both the body of the document and in headers and footers. To customize fields in Microsoft Word (which display a gray background when selected) select File->Properties->Summary and fill in the appropriate fields within the Summary and Custom tabs.

After clicking OK to close the dialog box, update all fields throughout the document by selecting Edit>Select All (or Ctrl-A) and pressing F9. Or you can update each field individually by clicking on it and pressing F9.

These actions must be done separately for any fields contained with the document's header and footer.

2. Modify boilerplate text as appropriate for the specific project.
3. To add any new sections to the document, ensure that the appropriate header and body text styles are maintained. Styles used for the section headings are Heading 1, Heading 2 and Heading 3. The style used for boilerplate text is Body Text.
4. To update the table of contents, right-click on it, select "Update field", and choose the option "Update entire table".
5. Before submission of the first draft of this document, delete this instruction section "Notes to the Author" and all instructions to the author throughout the document.

Table of Contents

1.0 INTRODUCTION

[This section of the training plan provides a management summary of the entire plan. There is no need to provide information in this section if the descriptions provided in the subsequent sections are sufficient.]

1.1 BACKGROUND AND SCOPE

[This subsection of the training plan provides a brief description of the project from a management perspective. It identifies the system, its purpose, and its intended users. This subsection also provides a high-level summary of the training plan and its scope.]

1.2 POINTS OF CONTACT

[This subsection of the training plan provides the organization name (code) and title of key points of contact for system development. It includes such points of contact as the project manager, program manager, QA manager, security manager, training manager/coordinator, and training representative, as appropriate.]

[Add additional lines as needed. If the applicable team members are listed in the project management plan, reference the appropriate section within this document.]

Role	Name	Contact Number
Business Sponsor		
Program Manager		
Project Manager		
QA Manager		
Configuration Manager		
NRA ISSO		
Training Manager/Coordinator		
Training Representatives		

1.3 Document Organization

[This subsection of the training plan describes the document's organization.]

1.4 Security

[This subsection of the training plan, if applicable, provides a brief discussion of the system's security controls and the need for security and protection of sensitive data.]

1.5 Glossary

[This subsection of the training plan contains a glossary of all terms and abbreviations used in the plan. If it is several pages in length, it may be placed as an appendix. A reference can be made to the OPDIV-specific glossaries.]

2.0 Instructional Analysis

2.1 Needs and Skills Analysis

[This subsection of the training plan describes the target audiences for activities to be developed. Target audiences may include technical professionals, user professionals, data entry clerks, clerical staff, NMRA and non-NMRA staff, and other stakeholders. Described the tasks that must be taught to meet objectives successfully and the skills that must be learned to accomplish those tasks. A matrix may be used to provide this information. Also in this subsection, the training needs for each target audience are discussed. If appropriate, this subsection should discuss needs and activities in terms of staff location groupings, such headquarters and field offices.]

2.2 Development Approach

[This subsection of the training plan discusses the approach used to develop the activity curriculum and to ensure quality training products. This description includes the methodology used to analyze training requirements in terms of performance objectives and to develop activity objectives that ensure appropriate instruction for each target group. The topics or subjects on which the training must be conducted should be listed or identified.]

2.3 Issues and Recommendations

[This subsection of the training plan includes any current and foreseeable issues surrounding training. Recommendations for resolving each issue and constraints and limitations should also be listed. Review and update the risk management plan with any new risk information uncovered during the development of this plan.]

3.0 Instructional Methods

3.1 Training Methodology

[This subsection of the training plan describes the training methods to be used in the proposed activities; these methods should relate to the needs and skills identified in Section 2.3, Needs and Skills Analysis, and should consider such factors as activity objectives, the target audience for a particular activity, media characteristics, training criteria, and costs. The materials for the chosen training approach, such as activity outlines, audiovisual aids, instructor and trainee guides, trainee workbooks, examinations, and reference manuals, should be listed or discussed in this subsection. Sample formats of materials can be included in an appendix, if desired.]

3.2 Training Database

[This subsection of the training plan, if applicable, identifies and discusses the training database and how it will be used during computer systems training. It discusses the simulated production data related to various training scenarios and cases developed for instructional purposes. This subsection also explains how the training database will be developed. If this subsection is not applicable to the system involved, indicate "Not applicable."]

3.3 Testing and Evaluation

[This subsection of the training plan describes methods used to establish and maintain quality assurance over the curriculum development process. This description should include methods used to test and evaluate training effectiveness, evaluate trainee progress and performance, and apply feedback to modify or enhance the activity materials and structure.

One source of feedback could be an activity, a module-specific activity, or an instructor evaluation form. This form should gather trainee reactions on the following topics: scope and relevance of activity or module, appropriateness of objectives, usefulness of assignments and materials, effectiveness of activity training materials, stronger and weaker features of the activity, adequacy of the facilities, timing or length of the activity or module, effectiveness of the instructor(s), and participant suggestions and comments.]

4.0 Training Resources

4.1 Activity Administration

[This subsection of the training plan describes the methods used to administer the training program, including procedures for training enrollment, trainee release, reporting of academic progress, activity completion and certification, monitoring of the training program, training records management, and security, as required.]

4.2 Resources and Facilities

[This subsection of the training plan describes the resources required by both instructors and trainees for the training, including classroom, training, and laboratory facilities; equipment such as an overhead projector, projection screen, flipchart or visual aids panel with markers, and computer and printer workstations; and materials such as memo pads and pencils, diskettes, viewgraphs, and slides. Information contained in this subsection can be generic in nature and can apply to all activities. Specific activity information and special needs may be itemized here as well or, if many different activities are involved, in Section 5, Training Curriculum.]

4.3 Schedules

[This subsection of the training plan presents a schedule for implementing the training strategy and indicating responsible parties. Include key tasks to be completed, such as when to set up training facilities and schedule participants; other activities essential to training; and dates on which those tasks and activities must be finished. This subsection provides an overview of tasks; deliverables, such as approach and evaluation forms; scheduled versus actual milestones; and estimated efforts, such as the work plan. In the final version of the regulatory IMS training plan, actual activity schedules by location should be included.]

4.4 Future Training

[This subsection of the regulatory IMS training plan discusses scheduled training modifications and improvements. This information can include periodic updating of activity contents, planned modifications to training environments, retraining of employees, and other predicted changes. Indicate procedures for requesting and developing additional training.]

5.0 Training Materials List

5.1 Purpose and Scope

The purpose of this document is to assist the project manager and project team in managing the training materials produced by the project as part of the <regulatory IMS Release Name>. Training materials can include seminars, presentations, workbooks, and self-study tutorials associated with a regulatory IMS version release.

The training plan template, located in the <NRA Document Repository>, provides the framework for determining how the training materials will be identified, developed, and delivered. This should be a living document that is updated frequently to reflect new or changing training material information.

Although both the training plan and training material templates can be used by NMRAs of any size, they are intended to be used mainly by larger, more complex, and more critical NMRAs.

5.2 Training Materials List

[Populate the table below with the applicable information when the training material is being developed or delivered. Add or remove any columns as necessary.]

Explanation of the table fields:

- Document Name: Provide the name of the document
- Version Number: Provide the version of the document being distributed (this information may already be in the document name)
- Document Format: Provide the format the document is saved or delivered as. This could be a:
    - Word document
    - PowerPoint presentation
    - Computer-based training (CBT) application
- Date Delivered: Provide the date the training was provided, or the documents were distributed.
- Intended Audience: Identify the target group that the document was created for. This could include:
    - Executive management
    - General users
    - Power or super users
    - Technical support staff
- Storage Location: Identify the location where the master documents are stored. For electronic documents, provide the network location. For printed documents, provide a physical location.

regulatory IMS Training Materials List for <regulatory IMS Project or Release Name>

Document Name	Version Number	Document Format	Date Delivered	Intended Audience	Storage Location

6.0 TRAINING CURRICULUM

[This section of the training plan provides descriptions of the components that make up each activity. If many activities or modules are described, place these descriptions in an appendix. A subsection should be created for each activity.

Each activity may comprise one or more modules. An activity description should be developed for each module. At a minimum, each activity description should include the activity/module name; the length of time the activity/module will take; the expected class size (minimum, maximum, optimal); the target audience; activity objectives; module content/syllabus; specific training resources required, such as devices, aids, equipment, materials, and media to be used; and any special trainee prerequisites. The activity description could also include information on instructor-to-trainee ratio, total number of trainees to be trained, estimated number of classes, location of classes, and testing methods.

Include an explanation to the following questions:

- *After the training is completed, what will happen to the training activity materials, trainee information, and other materials?*
- *Who will own, manage and maintain the training materials in the future?*
- *How will training materials be used in the future to train new staff?*
- *How will training materials be used in the future for refresher training?*

APPENDIX A: Training Plan Approval

The undersigned acknowledge that they have reviewed the ***<regulatory IMS Project Name>*** **training plan** and agree with the information presented within this document. Changes to this **training plan** will be coordinated with, and approved by, the undersigned or their designated representatives.

Signature: _____ Date: _____

Print Name: _____

Title: _____

Role: Project Manager

APPENDIX B: REFERENCES

[Insert the name, version number, description, and physical location of any documents referenced in this document. Add rows to the table as necessary.]

The following table summarizes the documents referenced in this document.

Document Name	Description	Location
<Document Name and Version Number>	*<Document description>*	*<URL to eRoom where document is located>*

APPENDIX C: KEY TERMS

The following table provides definitions and explanations for terms and acronyms relevant to the content presented within this document.

Term	Definition
[Insert Term]	*<Provide definition of term and acronyms used in this document.>*

ANNEX 3 – REGULATORY IMS TRAINING PLAN CHECKLIST

[52]

Regulatory IMS Training Plan Checklist

PURPOSE

The purpose of this document is to provide a quick checklist for use by the project manager to ensure that all appropriate activities related to training planning have been addressed.

ACTIVITIES CHECKLIST

This section provides a checklist of activities to ensure proper preparation, use, and post-completion review and continued use of this template.

Checklist	
Has a training plan been created?	
Have training requirements been identified and prioritized?	
Have training program outcomes been identified?	
Has the training audience been identified?	
Have the topics/information that the audience needs to be trained on been identified?	
Has a time and location for the training been scheduled?	
Has the best approach and most appropriate method of training been identified?	
Has a training program been defined?	
Have training resources been allocated to support the training effort?	
Have training materials been developed/acquired?	
Has a training strategy been developed?	
Has a schedule for training development and implementation been constructed?	
Has a training environment been identified?	
Has the training staff been trained on the curriculum they will be instructing?	
Have appropriate facilities been established that are adequate to perform training?	
Have regulatory requirements been met (e.g., records management, privacy)?	