

Human Resources for Traceability Implementation

Tools for Establishing Your Implementation Team

April 2020



Contents

- Contents 1**
- Acronyms..... 2**
- Introduction..... 3**
- Key Considerations..... 3**
 - Traceability Vision and Strategy 3
 - Organizational Approach 4
- Notional Organizational Structure..... 6**
- Responsibility and Skillset Overview 7**
 - Core Roles 7
 - Supporting Roles 10
- Annex A. Traceability Project Manager Job Description 16**
- Annex B. Pharmaceutical Traceability Regulatory Specialist Job Description..... 18**
- Annex C. Supply Chain Master Data Management Specialist Job Description..... 20**

Acronyms

AIDC	automatic identification and data capture
API	application programming interface
EPCIS	Electronic Product Code Information Services
EU	European Union
LMIS	logistic management information system
MO	GSI member organization
PMP®	Project Management Professional
PRINCE2®	PRojects IN Controlled Environments
PtD	People that Deliver
RESTful	representational state transfer
SOP	standard operating procedure
USFDA	United States Food and Drug Administration

Introduction

For country programs to begin to develop and operationalize visions for pharmaceutical traceability in local healthcare systems, adequate human resources are required to execute the required tasks accompanying traceability activities and work. The following tools have been designed for country programs and national authorities to adopt and adapt in resourcing in-country traceability implementation strategies:

- Notional organizational diagram
- Primary responsibilities and required skillset for the roles identified in the notional organizational diagram
- Detailed job descriptions for traceability project manager, regulatory specialist, and supply chain master data management specialist roles

These resources have been developed using lessons learned from case studies that documented implementation of global standards, in addition to informational interviews with key stakeholders that have supported pharmaceutical traceability programs in the European Union (EU), United States, and sub-Saharan Africa. The tools have been created specifically to support national governments that are executing pharmaceutical traceability strategies in their health systems.

Key Considerations

The organizational structure employed and the resources utilized for traceability implementation will rely on several factors that are related to the local context and the implementation approach that has been defined. When determining what human resources are required, key factors that government entities should consider will include the below.

Traceability Vision and Strategy

Human resources, including project managers and executive sponsors, will be required to support the development of a pharmaceutical traceability vision and strategy. Once this has been established, the resources required will be determined based on the strategy and scope defined for implementing the vision. For example:

- If the government does not intend to manage their own central repository to store track and trace data, fewer full-time technology focused roles will be required.
- If traceability requirements are being rolled out for only a subset of the products in the health system, fewer industry engagement and compliance resources may be required.
- If product verification is part of the traceability vision, more resources may be required for stakeholder engagement and communication when the model is verified at point-of-use rather than at point-of-dispense.

As such, the roles included in this document should not be considered prescriptive and role requirements should be determined on a case-by-case basis depending on the implementation context and traceability model being employed.

Organizational Approach

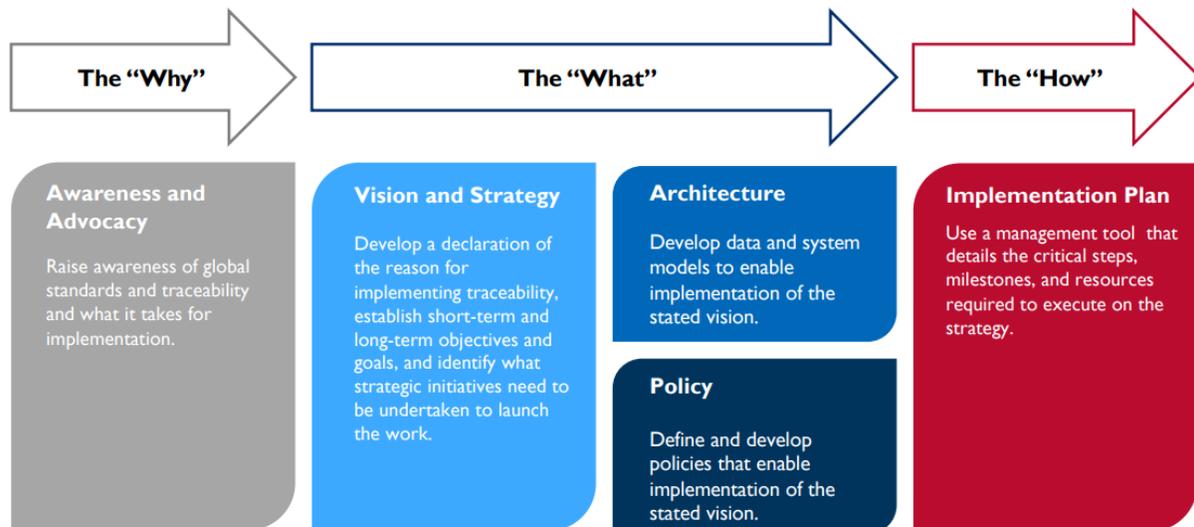
Implementation of a traceability vision requires engagement from a crosscutting group of stakeholders within and outside of the government. It is recommended that an organizational unit be created to support implementation and where this unit sits shall be determined by the implementing government. The work of this unit will likely cut across government agencies, which will require strong support from an executive sponsor with decision-making authority and influence across agencies. Implementation of a traceability system is a multi-year endeavor and it is important to adopt an organizational approach that is able to continue even in the event of changes in political dynamics.

This document provides a number of roles that implementing authorities should consider when implementing pharmaceutical traceability strategies, because implementation requires significant investment in a range of skills sets for an extended period of time. It is recommended that the roles be full-time positions. However, to support decisions in contexts where this may not be possible roles that may, in particular, be considered for outsourcing are italicized and roles that may be incorporated into existing roles are denoted with an asterisk following the role title.

Implementation Stage

Required roles — and determinations about whether these roles should be filled as a percentage of existing positions or as fulltime positions — may vary depending on the point in the implementation lifecycle. The *Traceability Planning Framework* provides a way to systematically organize the implementation stages. Under the Responsibility and Skillset Overview section, recommendations are provided about the points in the *Traceability Planning Framework* at which a role should be in place.

Figure 1: Traceability Planning Framework



Local Labor Market

Countries may elect to use existing resources or recruit new resources to fulfill these roles, which generally require expertise in regulation, supply chain, information technology, data strategy, and GSI standards for healthcare. If resources with expertise in these areas are not readily available in the labor market, outsourcing of the role and/or tasks should be considered. Specifically, technology roles are well positioned to be outsourced to leverage the experience and expertise of vendors with specialized skillsets.

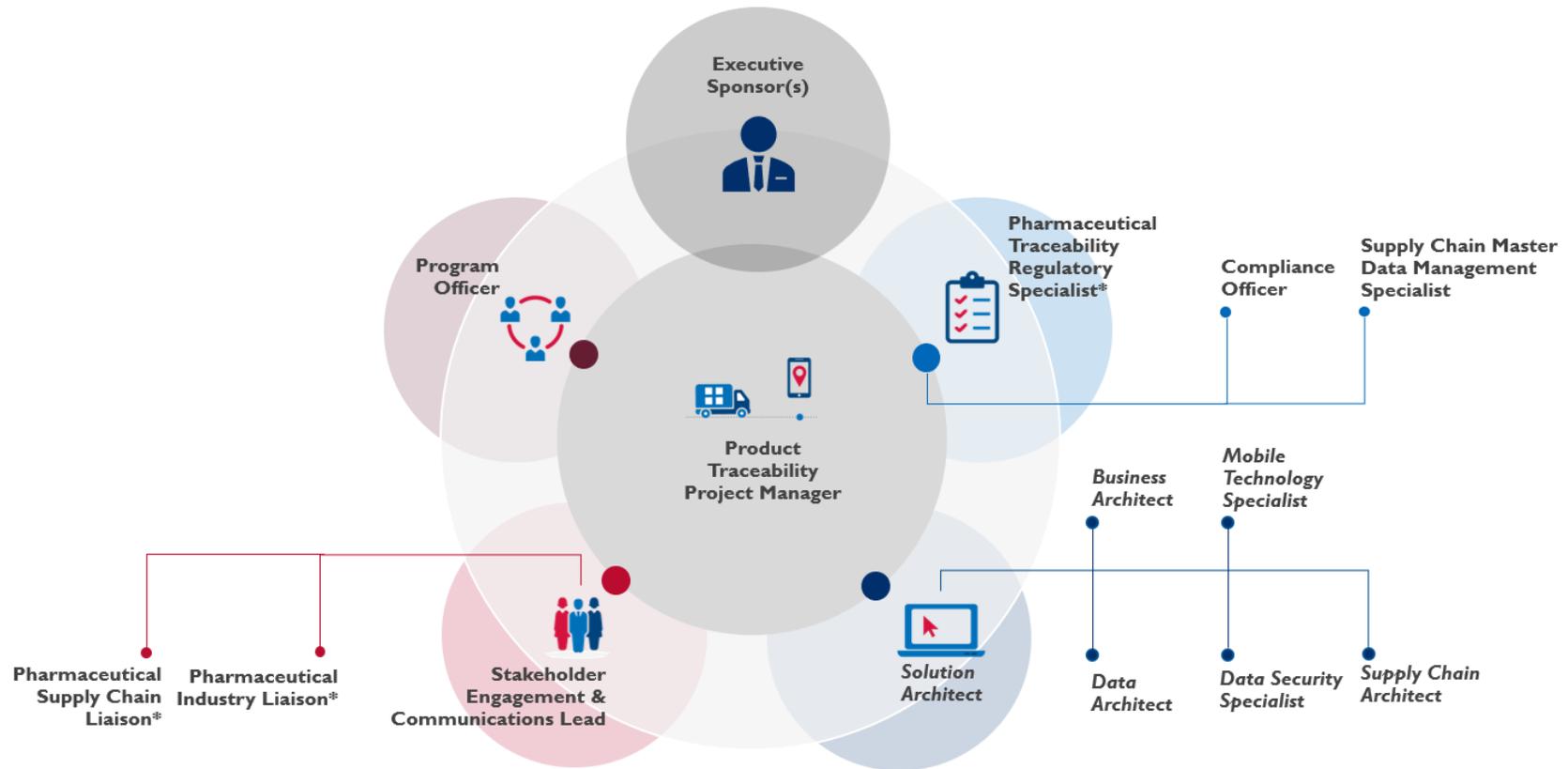
Required vs Desired Skillsets and Experience

Articulated skillsets for these positions have been categorized as “required” and “desired.” Required skillsets are the minimum and mandatory skillsets for performance. Desirable skills are added skillsets with more value. It is likely that a candidate with desired skillsets will have the required skillset for performance for each of the roles. It is important to distinguish those skillsets that are truly required from those that may be desired but can be taught or developed in a reasonable timeframe to fulfill each of the roles.

Presence of a GSI Member Organization

Local GSI member organizations (MOs) are used in some contexts as resources for expertise on standards, education, stakeholder engagement, and consultation on global trends and regulations. In countries or regions where there is no GSI MO, the implementation team may consider contracting with a vendor to provide these services when they require in-depth technical expertise on implementation of GSI standards.

Notional Organizational Structure



How to Interpret This Diagram

This diagram and the following section provide examples of possible roles that national authorities may require when implementing traceability strategies. Determining which roles are needed and the reporting lines associated with these roles should be determined based on the context and the traceability model that has been selected.

Roles denoted in *italics* are particularly suited for outsourcing. An asterisk denotes a role that may be supported as part of existing role in the event a full-time resource cannot be recruited.

Responsibility and Skillset Overview

Core Roles

Role	Primary Responsibilities	Key Skillsets and Training
Executive Sponsor(s)	<p>This should be a part-time role in place at the start of the “vision and strategy” implementation phase that is filled by a senior government official as an extension of the individual’s existing role, with added responsibilities for:</p> <ul style="list-style-type: none"> Defining the overall vision for traceability and data standards implementation Advocating for budget to support resourcing and implementation of initiatives Engaging relevant government entities in implementation Sponsoring a technical working group that will bring together key stakeholders to inform the implementation plan 	<p>An executive sponsor should be identified who possesses the following skillset:</p> <ul style="list-style-type: none"> Demonstrated leadership to support cross-agency collaboration Strong communication skills Ability to influence stakeholders and decision-makers Experience supporting implementation of new legislation Respected by politicians and technocrats Basic knowledge of and experience with implementation of GSI standards in the healthcare sector is an asset
<p>Traceability Project Manager (Full job description included as Annex A)</p>	<p>This role should be in place by the start of vision and strategy implementation phase, with primary responsibility for:</p> <ul style="list-style-type: none"> Leading development of an operational plan for traceability implementation that is consistent with the national traceability vision that links specific goals and strategies with performance indicators Owning execution of traceability implementation plan deliverables including, but not limited to, market assessments, regulation execution, traceability model selection Validating that traceability strategy implementation is in alignment with GSI General Specification requirements and global trends in traceability implementation 	<p>Required</p> <ul style="list-style-type: none"> Experience in implementing supply chain transformation and/or intervention projects Basic understanding of AIDC, GSI Standards in Healthcare, and related concepts <p>Desired</p> <ul style="list-style-type: none"> Degree in supply chain management, project management, information technology, engineering or related field Advanced understanding of health system and/or supply chain processes and roles in the implementation context Experience implementing traceability focused project(s) Expert knowledge in AIDC, GSI Standards in Healthcare, and related concepts

- Coordinating a technical working group that includes representatives from industry and government that will meet monthly to guide implementation
- Soliciting and managing consultants and/or solution providers that may be employed to support execution of the implementation plan
- Producing market assessments of capabilities and compliance as required
- Actively participating in industry groups and conferences to drive development of standards with global impact
- Working knowledge of requirements of local and global traceability regulations, such as USFDA and EU regulations
- Project management certification

Pharmaceutical Traceability Regulatory Specialist*
(Full job description included as Annex B)

This role should be in place by the start of the “policy” phase with primary responsibilities for:

- Participating in forums with industry and other relevant stakeholders to define regulatory objectives and scope for traceability implementation
- Analyzing existing regulations to identify how regulations may support or oppose traceability vision
- Liaising with relevant stakeholders to draft traceability regulations that follow local laws and in alignment with global trends
- Ensuring, in coordination with relevant team members, that relevant market assessments are complete to inform regulation
- Designing framework for regulatory compliance monitoring and enforcement
- Overseeing resources supporting regulatory compliance and enforcement

Required

- Knowledge of regulatory environment and processes
- Proficiency in relevant computer packages that have been identified for use during implementation
- Experience implementing regulation enforcement and compliance systems and processes
- Expert ability to communicate information, including complex concepts, accurately, concisely, and confidently in writing and verbally

Desired

- Degree in law, pharmacy, or other relevant field
- Experience drafting healthcare-focused regulations
- Advanced degree in law or equivalent
- Basic knowledge of and experience with implementation of GSI standards in the healthcare sector
- Ability to anticipate the communication needs and concerns of others and respond to these

Stakeholder Engagement and Communications Lead

This role should be in place by the start of the “vision and strategy” phase with primary responsibilities for:

- Engaging stakeholders impacted by traceability implementation
- Leading markets assessments to identify existing manufacturer capabilities and barcoding practices

Required

- Strong interpersonal skills as well as oral presentation skills
- Basic knowledge of healthcare systems
- Ability to drive collaboration across teams, organizational units, and external stakeholder groups

- Leading supply chain process mapping to ensure regulations and technology solutions support existing value stream
- Creating awareness among stakeholders of new requirements that impact their business practices
- Soliciting input from supply chain stakeholders to inform strategy and implementation
- Training stakeholders on principles of global standards and GSI healthcare standards

- Demonstrated ability to communicate information, including complex concepts, accurately, concisely, and confidently in writing and verbally
- Proficiency in relevant computer packages that have been identified for use during implementation

Desired

- Basic knowledge of and experience with implementation of GSI standards in the healthcare sector
- Ability to actively participate in relevant GSI Standards Development Groups

Solution Architect

This role should be in place by the start of the “architecture” phase and will lead the architecture team with primary responsibilities for:

- Developing the technical architecture to support implementation of traceability
- Conducting information system analyses to identify existing systems and system capabilities for product registration, reporting, and supply chain transactions
- Defining and/or working in consultation with a vendor to select and implement a traceability solution
- Ensuring that solution meets the requirements of the regulation and relevant identification and data exchange standards
- Overseeing design and deployment of the traceability solution during the development lifecycle
- Overseeing solution maintenance post-deployment as appropriate
- Designing data flows with existing information management systems
- Working closely with the supply chain and industry liaisons to define system requirements
- Designing and implementing systems integration

Required

- Ability to document requirements and specifications
- Experiences with software development methodology and release processes
- Experience with full software development lifecycle, including deployment of custom software solutions, and commercial off-the-shelf software solutions
- Advanced understanding and knowledge of AIDC software and associated business processes
- Proven ability to manage development and implementation of project activities
- Demonstrated ability to communicate information, including complex concepts, accurately, concisely, and confidently in writing and verbally

Desired

- Degree in information technology, software engineering, computer science or equivalent
- Basic knowledge of and experience with implementation of GSI standards — especially those for traceability data exchange (e.g., Electronic Product Code Information Services [EPCIS])
- Working knowledge of systems integration technologies, including representational state transfer (RESTful) application programming interface (API)
- Experience integrating business system applications

Program Officer

This role should be in place at the start of the vision and strategy phase with primary responsibilities for:

- Organizing technical working group meetings and leading note taking and reporting
- Supporting traceability team members on administrative and operational tasks as requested
- Assisting the communications teams with training and development of communications materials
- Facilitating travel logistics arrangements for staff and consultants
- Facilitate monitoring and reporting on the team's progress developing and operationalizing the traceability strategy

Required

- Practices effective time management
- Ability to manage multiple tasks simultaneously
- Strong oral and written communication skills
- Demonstrated attention to detail
- Proficiency in relevant computer packages identified for use during implementation

Desired

- Experience developing presentations to communication complex concepts to broad audiences
- Can anticipate the communication needs and concerns of others and respond to these

Supporting Roles

Role	Primary Responsibilities	Key Skillsets and Training
Pharmaceutical Supply Chain Liaison*	<p>This role should be in place in the “vision and strategy” phase with primary responsibilities for:</p> <ul style="list-style-type: none">• Ensuring traceability systems and processes can be adopted into the existing supply chain structure• Engaging with key supply chain stakeholders• Supporting the training of supply chain personnel, including regulatory authority staff and healthcare workers, impacted by traceability regulations and processes <p>Resource Alternatives:</p> <ul style="list-style-type: none">• Use an existing role in the supply chain or an industry representative to serve as a part-time advisor	<p>Required</p> <ul style="list-style-type: none">• Strong understanding of local supply chain processes and stakeholders• Demonstrated ability to communicate information, including complex concepts, accurately, concisely, and confidently in writing and verbally• Ability to drive collaboration across teams, organizational units, and external stakeholder groups to determine traceability vision and implementation strategy <p>Desired</p> <ul style="list-style-type: none">• Direct experience working with visibility and traceability initiatives in the local supply chain context• Basic knowledge of and experience with implementation of GSI standards in the healthcare sector

- Responsibilities can fall under the stakeholder engagement lead and/or the project manager
- Ability to actively participate in relevant GSI Standards Development Groups

Pharmaceutical Industry Liaison*

This role should be in place in the vision and strategy phase with primary responsibilities for:

- Serving as main point of contact for industry
- Performing assessments on market readiness
- Ensuring key industry stakeholders are engaged through implementation process
- Providing technical guidance to industry in how to implement requirements in alignment with regulatory mandates and identified standards
- Staying abreast of best practices with traceability solution implementation

Resource Alternatives:

- GSI member organization
- Responsibilities may be added to the scope of the project manager or stakeholder engagement and communications lead

Required

- Strong communication skills
- Demonstrated ability to communicate information, including complex concepts, accurately, concisely, and confidently in writing and verbally
- Ability to drive collaboration across teams, organizational units, and external stakeholder groups to determine traceability vision and implementation strategy

Desired

- Knowledge of and/or experience working with local, regional, and global industry stakeholders
- Basic knowledge of and experience with implementation of GSI standards in the healthcare sector
- Ability to actively participate in relevant GSI Standards Development Groups

Compliance Officer

This role should be in place upon execution of the implementation plan phase, with primary responsibilities for:

- Monitoring vendor compliance with the regulation
- Implementing regulation compliance processes and systems including post-market surveillance
- Supporting the regulatory lead in responding to stakeholder questions on regulatory requirements
- Liaising with criminal or related enforcement agencies

Resource Alternatives:

- Use existing regulatory compliance resources to support work

Required

- Basic understanding of regulatory systems and processes within the implementation context
- Demonstrated ability to communicate information, including complex concepts, accurately, concisely, and confidently in writing and verbally
- Strong analytics skills

Desired

- Basic knowledge of and experience with implementation of GSI standards in the healthcare sector

Data Architect

This should be in place in the architecture phase with primary responsibilities for:

- Supporting technical lead in development of a technical solution to capture traceability data
- Analyzing structural requirements for new software and applications
- Creating and maintaining logical database models
- Coordinating with the supply chain master data management specialist to identify master product data requirements

Resource Alternatives:

- Outsource to an external organization

Required

- Experience designing and creating a data architecture to support data capture and reporting needs in supply chain
- Experience with leading data warehousing technologies and business intelligence (reporting) platforms such as Tableau
- Experience working with data and system integration technologies

Desired

- Knowledge of and experience with implementation of GSI standards in the healthcare sector
- Experience implementing and supporting business intelligence platforms
- Working knowledge of master data governance protocols in a multi-system environment of shared master data

Supply Chain Architect

This role should be in place by the start of the “architecture” phase and will perform the supply chain architecture work with primary responsibilities for:

- Working closely with the supply chain and industry liaisons to define system requirements
- Designing data flows with existing supply chain information management systems
- Developing the technical architecture to support implementation of traceability
- Conducting information system analyses to identify existing systems and system capabilities for product registration, reporting, and supply chain transactions
- Defining and/or working in consultation with a vendor to select and implement a traceability solution
- Ensuring that solution meets the requirements of the regulation and relevant identification and data exchange standards
- Participating in the design and deployment of the traceability solution during the development lifecycle

Required

- Ability to document requirements and specifications
- Experiences with software development methodology and release processes
- Experience with full software development lifecycle, including deployment of custom software solutions, and commercial off-the-shelf software solutions
- Advanced understanding and knowledge of AIDC software and associated business processes
- Proven ability to manage development and implementation of project activities in distribution and warehousing
- Working knowledge of business to business data exchange technologies
- Demonstrated ability to communicate information, including complex concepts, accurately, concisely, and confidently in writing and verbally

Desired:

- Degree in information technology, software engineering, computer science or equivalent
- Basic knowledge of and experience with implementation of GSI standards — especially those for traceability data

- Performing solution maintenance post-deployment as appropriate
- Designing and implementing systems integration

exchange (e.g., Electronic Product Code Information Services [EPCIS])

- Working knowledge of systems integration technologies, including representational state transfer (RESTful) application programming interface (API)
- Experience integrating business system applications

Business Architect

This role should be placed by the start of the “architecture” phase and will lead the business architecture work with primary responsibilities for:

- Developing the business processes needed to support implementation of traceability
- Working closely with supply chain and industry liaisons to define system functional requirements that drive the implementation of a traceability solution
- Ensuring that solution meets the requirements to support supply chain business processes throughout distribution and warehousing operations
- Engaging system users in business process design and deployment
- Developing standard operation procedures for supply chain operations
- Designing business process flows with existing information management systems

Required

- Ability to document requirements and specifications
- Experiences with software development methodology and release processes
- Experience implementing systems that support supply chain business processes, including forecasting and planning, distribution and warehouse management
- Working knowledge of AIDC software and associated business processes
- Demonstrated ability to communicate information, including complex concepts, accurately, concisely, and confidently in writing and verbally

Desired

- Degree in information technology, software engineering, computer science or equivalent
- Basic knowledge of and experience with implementation of GSI standards — especially those for traceability data exchange (e.g., Electronic Product Code Information Services [EPCIS])
- Experience integrating business system applications

Mobile Technology Specialist

This role should be placed by the start of the “architecture” phase and will lead the integration of mobile technology with primary responsibilities for:

- Developing the technical architecture to support mobile technologies and integration with supply chain information systems
- Conducting information system analyses to identify existing systems and system capabilities for AIDC

Required

- Ability to document requirements and specifications
- Experiences with software development methodology and release processes
- Experience with mobile technology platforms and integration with supply chain information systems
- Experience with full software development lifecycle, including deployment of custom software solutions, and commercial off-the-shelf software solutions

- Defining and/or working in consultation with a vendor to select and implement a mobile technology solution
- Ensuring that solution meets the requirements of the regulation and relevant identification and data exchange standards
- Overseeing design and deployment of the mobile technology solution during the development lifecycle
- Overseeing solution maintenance post-deployment as appropriate
- Working closely with the supply chain and industry liaisons to define system requirements
- Designing and implementing systems integration

- Advanced understanding and knowledge of AIDC software and associated business processes
- Proven ability to manage development and implementation of project activities
- Demonstrated ability to communicate information, including complex concepts, accurately, concisely, and confidently in writing and verbally

Desired

- Degree in information technology, software engineering, computer science or equivalent
- Basic knowledge of and experience with implementation of GSI standards — especially those for traceability data exchange (e.g., Electronic Product Code Information Services [EPCIS])

Data Security Specialist

This role should be in place at the start of the “architecture” phase and will lead data security work with primary responsibilities for:

- Overseeing the inclusion of data security measures in the selected traceability solution
- Identifying data security risks and mitigation strategies
- Documenting data security business requirements and processes
- Define system requirements for data security system capabilities
- Overseeing deployment of data security solutions and processes
- Monitoring solution for data attacks and intrusions
- Monitoring support of data security solutions

Required:

- Experience with managing information security
- Ability to identify vulnerabilities in IT infrastructures
- Ability to document requirements and specifications
- Experience implementing systems that support supply chain business processes, including forecasting and planning, distribution and warehouse management
- Demonstrated ability to communicate information, including complex concepts, accurately, concisely, and confidently in writing and verbally

Desired:

- Degree in information technology, information system security or equivalent
- Experience with system environment management, including data masking
- Basic knowledge of and experience with implementation of GSI standards — especially those for traceability data exchange (e.g., Electronic Product Code Information Services [EPCIS])

Supply Chain Master Data Management Specialist

This role should be in place in the architecture phase with primary responsibilities for:

Required

- Experience managing healthcare product data

(Full job description included as Annex C)

- Managing product master data
- Designing holistic product master data management strategy
- Leading implementation of product master data management program including, but not limited to, implementing processes for data governance, quality, and risk management
- Designing mechanisms and processes for populating product catalogue with supplier/vendor sourced data
- Liaising with business users and information technology team(s) to source, design, enhance, and configure product information management information system
- Training and/or orienting catalogue users and entities providing data to populate the catalogue

Resource Alternatives:

- Outsource role to be a service provide by a vendor
- Utilize the existing role for catalogue management

- Comfort in navigating product information management information technology solutions
- Demonstrates attention to detail to identify the main ideas, detect inconsistencies, and identify missing information in documents

Desired

- Degree in data science, informatics, pharmacy, or equivalent
- Certificate in pharmacy informatics or equivalent training
- Degree in pharmacy
- Knowledge of GSI standards for healthcare
- Experience with or knowledge of the GSI Global Data Synchronization Network
- Exhibits a desire to learn and implement new approaches for data management

Annex A. Traceability Project Manager Job Description

Role Overview

The traceability project manager will be responsible for operationalizing the national authority's traceability vision. This includes leading development of the traceability strategy and subsequently implementing the activities to operationalize this strategy. This role will require an individual with strong leadership and communication skills who has demonstrated these traits in prior implementations of supply chain transformation strategies. The ideal candidate will be local to the implementing context.

Expected Deliverables

- Lead development of an operational plan for traceability implementation that is consistent with the national traceability vision that links specific goals and strategies with performance indicators to be used to measure achievements
- Own execution of traceability implementation plan deliverables including, but not limited to, market assessments, regulation execution, traceability model selection
- Validate that traceability strategy implementation is in alignment with GSI General Specification requirements and global trends in traceability implementation
- Coordinate a technical working group that includes representatives from industry and government that will meet monthly to guide implementation
- Solicit and manage consultants and/or solution vendors that may be employed to support execution of the implementation plan
- Produce market assessments as required
- Actively participate in industry groups and conferences to drive development of standards with global impact

Technical Competencies (knows, understands, and can demonstrate)

- Undertakes inclusive and consultative strategic planning to establish strategic objectives for product traceability
- Demonstrates basic knowledge of data standards, namely GSI standards in healthcare, for product identification, data capture and data exchange
- Answers the questions “Where are we going?” and “How are we going to get there?” and creates a specific and purposeful path to implementation
- Captures the current state of processes and derives the desired future state
- Demonstrates ability to monitor progress and make changes as required
- Selects and applies tools or technological solutions, specifically track and trace solutions for health products
- Communicates decisions and ensures they are incorporated into policies and processes
- Identifies and supports emerging trends and practices related to standards for product identification and data exchange
- Understands that supply chains and logistics are a system of organizations, people, technology, activities, data/information, funds, and other resources involved in moving a product from supplier to customer
- Describes health system and supporting supply chain structure
- Applies lessons learned from prior implementation of traceability initiatives

- Demonstrates knowledge of software development methodology and release processes

Managerial Competencies (knows, understands, and can demonstrate)

- Ability to drive collaboration across teams, organizational units, and external stakeholder groups to determine traceability vision and implementation strategy
- Demonstrates the use of information gathering techniques from stakeholders, analyzing situations and identifying implications to make correct decisions
- Makes strategic decisions in the interest of the government’s goals and makes tough decisions when necessary
- Facilitates meetings for planning and stakeholder engagement
- Understands planning, organizing, and managing resources to bring about the successful completion of projects
- Manages matrixed and cross-functional project team
- Identifies the key issues in a complex situation and gets to the “heart” of the problem quickly
- Communicates information, including complex concepts, accurately, concisely, and confidently in writing and verbally
- Ability to complete deliverables in a timely and complete manner
- Ability to scope and prioritize activities based on impact
- Demonstrates integrity, independent thinking, judgment, and respect for others

Skills/Training

Required

- Experience in implementing supply chain transformation and/or intervention projects
- Basic understanding of AIDC, GSI Standards in Healthcare, and related concepts

Desired

- Degree in supply chain management, project management, information technology, engineering or related field
- Advanced understanding of health system and/or supply chain processes and roles in the implementation context
- Experience implementing traceability focused project(s)
- Expert knowledge in AIDC, GSI Standards in Healthcare, and related concepts
- Working knowledge of requirements of local and global traceability regulations, such as USFDA and EU regulations
- Project management certification (PMP, PRINCE2 or equivalent)

Annex B. Pharmaceutical Traceability Regulatory Specialist Job Description

Role Overview

The traceability regulatory specialist will lead the drafting and publication of regulation that will support the national authority's vision for traceability. This role shall be occupied by an individual with a strong understanding of the national regulatory process in the implementation context. This individual works collectively with other stakeholders to craft regulation in support of the traceability vision that complies with local laws, global trends, and stakeholder constraints.

Expected Deliverables

- Participate in forums with industry and other relevant stakeholders to define regulatory objectives and scope for traceability implementation
- Analyze existing regulations to identify how regulations may support or oppose traceability vision
- Liaise with relevant stakeholders to draft traceability regulation that complies with local laws and aligns with global trends
- Ensure, in coordination with relevant team members, that relevant market assessments are complete to inform regulation
- Design framework for regulatory compliance monitoring and enforcement
- Oversee resources supporting regulatory compliance and enforcement

Technical Competencies (knows, understands, and can demonstrate)

- Describes regulatory environment in implementation context
- Can list steps in the process and describe protocols for developing and publishing regulation
- Demonstrates ability to draft regulatory documentation
- Collaborates with relevant entities to approve and publish regulation
- Demonstrates the use of information gathering techniques from stakeholders, analyzing situations and identifying implications to make correct decisions
- Ability to monitor progress and make changes as required
- Gathers relevant information before making decisions
- Outlines the macro and long-term consequences of decisions
- Describes current and international trends in traceability regulation
- Identifies and articulate risks
- Understands the primary roles in and processes of the national supply chain
- Describes basic principles of pharmaceutical and medical device traceability
- Can review work of colleagues when necessary to identify compliance issues/risks and provide advice or training
- Provides timely and accurate counsel on legal topics

Managerial Competencies (knows, understands, and can demonstrate)

- Ability to drive collaboration across teams, organizational units, and external stakeholder groups

- Can communicate information accurately, concisely, and confidently in writing and verbally
- Ability to build trust, rapport, and credibility with others
- Anticipates the communication needs and concerns of others and respond to these
- Demonstrates integrity, independent thinking, judgment, and respect for others

Skills/Training

Required

- Proficiency in relevant software applications (Microsoft Office, etc.)
- Experience implementing regulation enforcement and compliance systems and processes

Desired

- Degree in law, pharmacy, or other relevant field
- Advanced degree in law or equivalent
- Experience drafting healthcare-focused regulations
- Basic knowledge of and experience with implementation of GSI standards in the healthcare sector

Annex C. Supply Chain Master Data Management Specialist Job Description

Role Overview

The supply chain master data management specialist will be responsible for updating and maintaining a national product catalogue that will serve as a centralized location for product data that can populate information systems and be used in processes throughout the supply chain as part of traceability implementation. The ideal candidate for this position will have expert knowledge of healthcare products, namely pharmaceuticals and medical devices, with a strong understanding of data management principles. The supply chain master data management specialist must have the ability to effectively coordinate between multiple stakeholders who may be either sources or users of product data. The individual in this role must demonstrate an ability to learn and implement innovative data management concepts, especially those focused on implementation of global data standards for product identification and exchange. The individual must have the ability to master navigation of product information management tools. In certain contexts, this position may already exist, though it may be necessary to upskill the existing supply chain master data management specialist to support the maintenance of a product catalogue that can support product identification and data exchange grounded in GSI standards.

Expected Deliverables

- Design holistic product master data management strategy
- Lead implementation of product master data management program including, but not limited to, implementing processes for data governance, quality, and risk management
- Design mechanisms and processes to populate product catalogue with supplier/vendor sourced data
- Liaise with business users and information technology team(s) to source, design, enhance, and configure product information management information system
- Train and/or orient catalogue users and entities providing data to populate the catalogue
- Establish and track key performance indicators for data quality

Technical Competencies (knows, understands, and can demonstrate)

- Demonstrates expert understanding of data management and data science principles
- Can describe data governance roles and processes
- Experience conducting routine data quality assessments to validate completeness and accuracy of product master data
- Ability to develop processes for enhancing, archiving, and retaining product data
- Ability to use analytics tools to monitor the use of product catalogue data
- Ability to manage ad hoc requests by users of the product catalogue data
- Understands how to create and maintain large data sets and complex data structures
- Demonstrates ability to be able to align product catalogue structure global product classification structures
- Knows how to navigate product information management tools
- Can describe current trends in product catalogue systems and content management
- Can identify primary pharmaceutical and medical device attributes used for product identification in product traceability and/or supply chain systems

Managerial Competencies (knows, understands, and can demonstrate)

- Ability to drive collaboration across teams, organizational units, and external stakeholder groups
- Communicates information accurately, concisely, and confidently verbally and in writing
- Pays attention to detail and identifies the main ideas, detects inconsistencies, and identifies missing information in documents
- Implements continues improvement and optimization approaches in catalogue management
- Exhibits high degree of ownership and accountability
- Learns and implements new approaches in data management
- Demonstrated integrity, independent thinking, judgment, and respect for others

Skills/Training

Required

- Experience managing healthcare product data
- Comfort in navigating product information management information technology solutions

Desired

- Degree in data science, informatics, pharmacy or equivalent
- Certificate in pharmacy informatics or equivalent training
- Degree in pharmacy
- Knowledge of GSI standards with specific experience in implementation of solutions using the Global Data Synchronization Network