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**CONSULTANCY FOR IMPLEMENTATION OF ELECTRONIC COMMON TECHNICAL DOCUMENT (eCTD) SYSTEM**

CONSULTANCY FOR DEVELOPMENT OF THE INTEGRATED REGULATORY INFORMATION MANAGEMENT SYSTEM (IRIMS) FOR THE RWANDA FOOD & DRUGS AUTHORITY (RWANDA FDA)

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# Background Information

In today's rapidly evolving regulatory landscape, agencies such as the Rwanda Food and Drugs Authority (FDA) bear the critical responsibility of ensuring the safety, quality, and efficacy of products and services within their jurisdiction. Recognizing the pivotal role of efficient regulatory systems, the Rwanda FDA is poised to embark on a transformative journey towards modernization and enhanced regulatory efficacy.

This document serves as an introduction to the concept of implementing an Electronic Common Technical Document (eCTD) system within the Rwanda FDA. The eCTD system represents a cutting-edge solution designed to revolutionize regulatory operations, streamline processes, and elevate overall organizational performance.

Similar to the objectives driving the adoption of modernized solutions, the introduction of an eCTD system aims to address key challenges faced by regulatory agencies, including the Rwanda FDA. By transitioning to a digital platform for regulatory submissions, the agency endeavors to enhance transparency, responsiveness, and effectiveness in regulatory operations, all while adhering to stringent regulatory requirements.

The implementation of an eCTD system promises a multitude of benefits for the Rwanda FDA. These benefits include streamlined document management processes, automation of compliance checks, expedited product approvals, improved inspection management, enhanced incident response capabilities, comprehensive employee development initiatives, and data-driven decision-making facilitated by robust reporting and analytics capabilities.

As with any transformative initiative, the primary goal of introducing an eCTD system is to enhance the regulatory agency's overall performance, streamline internal processes, and strengthen compliance with regulatory requirements. By embracing modern technology and standardized processes, the Rwanda FDA aims to improve decision-making, data management, and collaboration across departments, ultimately advancing its mission to safeguard public health and ensure the highest standards of product safety and efficacy.

In the subsequent sections of this concept note, we will delve deeper into the specific requirements, functionalities, and implementation methodologies pertinent to the adoption of an eCTD system within the Rwanda FDA, elucidating how this transformative initiative will propel the agency towards greater efficiency, effectiveness, and regulatory excellence.

## Purpose:

The purpose of this document is to delineate the user requirements for the development and implementation of an Electronic Common Technical Document (eCTD) system within the Rwanda Food and Drugs Authority (FDA). The eCTD system aims to revolutionize the submission of regulatory documents, offering a standardized format for the preparation, submission, and review of regulatory submissions.

By transitioning to an eCTD system, the Rwanda FDA seeks to modernize its regulatory processes, enhance efficiency, and ensure compliance with global regulatory standards. The eCTD system will streamline the preparation and management of regulatory submissions, facilitating seamless communication and collaboration within the organization and with external stakeholders.

Through the implementation of an eCTD system, the Rwanda FDA aims to achieve the following objectives:

1. Standardization: Establish a standardized format for the submission of regulatory documents, ensuring consistency and compatibility with global regulatory requirements.
2. Efficiency: Streamline document preparation, review, and submission processes, reducing administrative burden and accelerating regulatory approvals.
3. Compliance: Ensure adherence to regulatory guidelines and standards, minimizing the risk of submission errors and rejections.
4. Collaboration: Facilitate seamless communication and collaboration among internal departments and external stakeholders involved in the regulatory submission process.
5. Transparency: Enhance transparency and traceability of regulatory submissions, enabling stakeholders to track the status and progress of submissions in real-time.
6. Accessibility: Provide a user-friendly platform for accessing, reviewing, and managing regulatory documents, improving accessibility and usability for all stakeholders involved.

Overall, the eCTD system will serve as a cornerstone in the modernization efforts of the Rwanda FDA, empowering the agency to effectively regulate products and services within its jurisdiction while upholding the highest standards of safety, quality, and efficacy.

## Scope:

The implementation of the Electronic Common Technical Document (eCTD) system will encompass the following functional areas:

* Document Control & Management:

The eCTD system will provide robust tools for the creation, management, and version control of regulatory documents. It will enable users to organize, review, and archive documents in compliance with regulatory requirements.

* Submission Preparation:

Users will be able to prepare and assemble regulatory submissions in the eCTD format, organizing documents into the appropriate sections and sequences according to regulatory guidelines. The system will facilitate the compilation and validation of submissions for regulatory approval.

* Submission Lifecycle Management:

The eCTD system will track the lifecycle of regulatory submissions from creation to approval, providing real-time status updates and notifications to stakeholders. It will support workflow automation to streamline review, approval, and publishing processes.

* Collaboration and Review:

Collaboration features will be integrated into the eCTD system, enabling stakeholders to securely share, review, and annotate documents within the platform. It will support collaborative review processes, ensuring comprehensive feedback and comment resolution.

* Regulatory Authority Interaction:

The eCTD system will facilitate electronic submission to regulatory authorities through standardized formats and interfaces. It will integrate with regulatory agency systems for submission tracking, validation, and receipt acknowledgment, ensuring compliance with regulatory requirements.

* Security and Compliance:

The eCTD system will adhere to stringent security standards and encryption protocols to protect sensitive regulatory information. It will ensure compliance with regulatory requirements, including data integrity, electronic signature, and audit trail provisions.

* Performance and Scalability:

The eCTD system will be designed for high performance and scalability to accommodate increasing volumes of submissions and users. Performance metrics will be monitored and optimized to ensure optimal system performance under varying load conditions.

* User Interface and Experience:

The eCTD system will feature an intuitive, user-friendly interface accessible to users with diverse technical backgrounds. Training resources and user support will be provided to assist users in navigating the system and leveraging advanced features effectively.

* Reporting and Analytics:

The eCTD system will offer robust reporting and analytics capabilities, allowing users to generate various reports on regulatory submissions and performance metrics. Ad-hoc report generation and data export will be supported for enhanced data analysis.

* Integration:

The eCTD system will integrate with existing systems and databases within the Rwanda FDA, ensuring data consistency and interoperability. APIs will be available for potential future integrations with external systems and regulatory platforms.

Overall, the scope of the eCTD system encompasses the entire lifecycle of regulatory submissions, from document creation to approval, while ensuring compliance, security, and efficiency in regulatory operations.

## Integration to the iRIMS solution

The integration of the eCTD system will encompass various core functions and processes within the Rwanda Food and Drugs Authority (FDA), ensuring seamless interoperability and data exchange with existing systems. The integration points will include, but not be limited to:

* Product Registration and Authorization:

The eCTD system will integrate with the product registration and authorization database to facilitate the submission of regulatory documents for new product applications and updates. It will ensure that submission data is accurately transferred to the registration system for processing and approval.

* Pharmacovigilance and Adverse Event Reporting:

Integration with the pharmacovigilance system will enable the automatic submission of adverse event reports and safety updates in the eCTD format. This integration will streamline the reporting process and ensure timely dissemination of safety information to regulatory authorities.

* Good Manufacturing Practices (GMP) Inspections:

The eCTD system will integrate with the GMP inspection management system to facilitate the submission of inspection reports and compliance documentation. It will enable inspectors to capture and document inspection findings directly within the eCTD platform for regulatory review.

* Market Surveillance and Compliance Monitoring:

Integration with the market surveillance and compliance monitoring system will enable the submission of surveillance reports and compliance data in the eCTD format. This integration will facilitate regulatory oversight and enforcement actions based on real-time market data.

* Regulatory Audits and Assessments:

The eCTD system will integrate with the regulatory audit and assessment management system to streamline the submission of audit reports and regulatory assessments. It will ensure that audit findings and compliance status are accurately reflected in regulatory submissions for review and action.

* Quality Control and Laboratory Testing:

Integration with the quality control and laboratory testing system will enable the submission of testing protocols, results, and quality assurance documentation in the eCTD format. This integration will ensure that product quality data is seamlessly incorporated into regulatory submissions for review and approval.

* Training and Competency Management:

The eCTD system will integrate with the training and competency management system to track and document employee training records and competencies related to regulatory submissions. This integration will ensure that personnel involved in the submission process are adequately trained and qualified.

# User Requirements:

The system specifications have been categorized into two aspects

* **Functional Requirement:** What the system does, this outlines the functionalities and features as defined by the terms of references and elaborated by the user and technical stories.
* **Non-functional requirement**. How well the system performs under defined parameters.

## Functional Specifications

### Document Management:

The eCTD system shall enable the creation, organization, and management of regulatory documents in compliance with the eCTD format.

It shall support document versioning, metadata management, and template-based authoring to streamline document preparation processes.

Users should be able to securely access, review, and annotate documents within the system, facilitating collaborative document authoring and review.

### Submission Preparation:

The system shall facilitate the assembly and compilation of regulatory submissions in the eCTD format, ensuring adherence to regulatory guidelines and requirements.

Automated validation checks shall be performed to ensure submission integrity and compliance with formatting standards, reducing the risk of submission errors and rejections.

### Submission Lifecycle Management:

The eCTD system shall track the lifecycle of regulatory submissions from creation to approval, providing real-time status updates and notifications to stakeholders.

Workflow automation capabilities shall be implemented to streamline review, approval, and publishing processes, minimizing turnaround times and enhancing submission efficiency.

### Collaboration and Review:

Collaboration features shall be integrated into the eCTD system, enabling stakeholders to securely share, review, and annotate documents within the platform.

It shall support collaborative review processes, ensuring comprehensive feedback and comment resolution among stakeholders involved in the submission process.

### Regulatory Authority Interaction:

The system shall facilitate electronic submission to regulatory authorities through standardized formats and interfaces, such as the FDA’s Electronic Submission Gateway (ESG).

Integration with regulatory agency systems for submission tracking, validation, and receipt acknowledgment shall be established to ensure compliance with regulatory requirements.

## Non-functional Requirement

### Security and Compliance:

The eCTD system shall adhere to stringent security standards and encryption protocols to protect sensitive regulatory information from unauthorized access, modification, or disclosure.

Compliance with regulatory requirements, including data integrity, electronic signature, and audit trail provisions, shall be ensured to maintain the trust and credibility of electronic submissions.

### Performance and Scalability:

The system shall be designed for high performance and scalability to accommodate increasing volumes of submissions, users, and regulatory requirements.

Performance metrics, such as response time, throughput, and system availability, shall be monitored and optimized to ensure optimal system performance under varying load conditions.

### User Interface and Experience:

The user interface of the eCTD system shall be intuitive, user-friendly, and accessible to users with diverse technical backgrounds and skill levels.

Training resources, user guides, and online support shall be provided to assist users in navigating the system, troubleshooting issues, and leveraging advanced features effectively.

# Implementation Methodology

The implementation of the eCTD system will be guided by a structured methodology that combines elements of prototyping for continual improvement and agile methodology to ensure iterative development and deployment of system functionalities. The implementation plan will adhere to a defined lifecycle and work plan, encompassing gap analysis, customization, training, and rollout phases, with the objective of achieving full implementation within a timeframe of 6 months.

## Hybrid Implementation Approach:

The eCTD implementation will adopt a hybrid approach, integrating prototyping for continual improvement and agile methodology to facilitate iterative development and deployment. This approach will allow for the progressive release and deployment of specific system features throughout the project lifecycle, enabling stakeholders to provide feedback and incorporate changes incrementally.

## Iterative Development and Deployment:

The agile methodology will drive the iterative and incremental review of specific user and system requirements, allowing for customization and rollout of functionality in successive releases. This iterative approach will enable stakeholders to actively participate in the development process, providing feedback and validation at each stage to ensure alignment with their needs and expectations.

## Phased Deployment:

An implementation plan will be devised to outline the phased deployment of the eCTD system across different regulatory functions within the Rwanda FDA. The deployment phases will be structured to prioritize critical functionalities and regulatory processes, ensuring a smooth transition to the new system while minimizing disruption to ongoing operations.

## Key Components of Implementation:

Gap Analysis: A comprehensive gap analysis will be conducted to identify existing processes, systems, and functionalities that need to be addressed by the eCTD system. This analysis will serve as the foundation for defining system requirements and customization needs.

* Customization: The eCTD system will be customized to align with the specific needs and requirements of the Rwanda FDA, incorporating feedback from stakeholders and addressing identified gaps in functionality. Customization efforts will focus on enhancing usability, functionality, and integration with existing systems.
* Training: Training sessions will be conducted to familiarize users with the eCTD system, its features, and functionalities. Training programs will be tailored to the roles and responsibilities of different user groups within the Rwanda FDA, ensuring comprehensive user adoption and proficiency.
* Testing: Rigorous testing will be conducted to validate the functionality, performance, and reliability of the eCTD system. Testing activities will include unit testing, integration testing, user acceptance testing, and performance testing to identify and address any issues or discrepancies prior to deployment.
* Rollout: The phased rollout of the eCTD system will be carefully managed to minimize disruption to regulatory operations. Rollout activities will be coordinated with stakeholders, and support mechanisms will be put in place to address any issues or challenges encountered during the transition.

# Conclusion

The implementation methodology for the eCTD system will prioritize collaboration, flexibility, and stakeholder engagement to ensure the successful deployment and adoption of the system within the Rwanda FDA. By leveraging a hybrid approach that integrates prototyping and agile methodologies, the implementation process will be agile, responsive, and tailored to the specific needs and requirements of the regulatory agency.