OpenRIMS. Use cases

The Open Regulatory Information Management System (OpenRIMS) is a free open-source ready-to-use software that drives digitalized business processes. OpenRIMS is a successor to a set of proprietary, narrow specialized solutions implemented in the previous decade.

The predecessors of OpenRIMS are serving medicines regulatory agencies, local retailer networks, management companies, and the pharmaceutical and engineering industries. Below, are examples of real proven use cases. You can use these examples to learn and tailor your needs.

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# Medicines regulatory Agency

## Certificates

A certificate is an official document attesting the truth of the facts stated. Examples are a Marketing Authorization Certificate or any other fact-grounded allowance to run activities defined in the legislation.

A Business should apply for the Certificate Authority for a certificate. The Certification Authority considers the application and issues the certificate when the facts are confirmed. The Certification Authority can ask the Applicant for additional data, require improvements, and assign the audit.

As time passes, a Business can make allowed changes in the facts certified. The Business should apply the Certification Authority for major modification. The minor ones require notification.

The Certification Authority can revoke or suspend a certificate when the facts are no longer confirmed. Facts in the certificate are the subject of the inspection audit.

A certificate is valid until the defined date or event. The certificate can be extended by the Certification Authority.

A Business can apply to terminate the certificate. The termination often requires additional actions from the Business.

A Certificate Authority may process thousands of certification applications annually. Data visualization tools are necessary to control internal processes and to publish certificate data as legislation requires.

ISO IDMP Standards provide a framework for the identification of medicinal products. ISO 15378, ISO 14001, ISO 17025, and Good Manufacturing Practices (GMP) are vital for the Pharmaceutical Industry.

## Clinical Trial Protocols

A Clinical Trial Protocol is a comprehensive document that describes the background, rationale objectives, design, methodology, statistical considerations, and organization of a clinical trial. It serves as a blueprint for conducting the research.

A Principal Initiator submits the Application Letter and Protocol Components to the Clinical Trial Office of the National Regulatory. The approval process consists of screening, reviewing by Clinical Trial experts, meeting with the Clinical Trial experts, and approval or disapproval. During this process, the National Regulatory can ask for additional information from the Principal Initiator.

Before the research finishes, the Principal Initiator can amend the Clinical Trial Protocol. The Principal Initiator should send a notification letter to the National Regulatory for a minor amendment. The major amendments should be approved using the initial approval process described above.

A Clinical Trial Protocol is valid until the defined date. The expired Clinical Trial Protocol means revoked. When the research doesn't start in time, the National Regulatory can revoke the Clinical Trial Protocol.

The Principal Initiator can terminate the Clinical Protocol at any time without the approval of the National Regulatory. The National Regulatory doesn’t recognize the research results for terminated protocols.

The ISO 14155:2020 standard outlines the guidelines for the clinical investigation of medical devices for human subjects, focusing on good clinical practice (GCP). Data visualization tools are necessary to control internal processes.

# Local Retailer Network

## Standard Form contracts (Offers)

Standard Form Contracts are pre-written legal agreements where one party (Offeror) sets the terms, which the other party (Offeree) must accept without negotiation. Standard Contracts are prevalent in industries where contracts are frequently used and require minimal customization for each transaction. Typical customizations include the contract’s date, number, and specifications.

The Offeror provides the Offer Form. The Offer Form enables the Offeree to fill out the customization data and apply for the Standard Contract.

The Offeror considers the Standard Contract application from the Offeree. The Offeror can approve the application, ask for additional actions, or disagree with it. The typical consideration process consists of registration, internal approvals, and contract implementation.

The Offeror can run an audit of the Offeree. In the contract implementation stage, an Offeror assigns the Standard Contract responsible person.

For the Standard Contract, the Offeror can modify conditions, cancel, or extend the duration.

A Local Retailer Network may manage thousands of Standard Contracts with suppliers. Data visualization tools are necessary to control internal processes. Standards are internal.

# Industrial Management Company

## Enterprise Contracts Repository

The Enterprise Contracts Repository unifies treaty management. The centralized storage provides convenient and controlled access to drafts, valid contracts, and archives.

The Initiator applies for a Contract Draft to a Lawyer. The application contains internal classifiers and contract documents attached.

The Lawyer reviews the application and submits it to the Member of the Board.

The Lawyer or the Member of the Board can ask for additional data or return the application to the Initiator.

When the Member of the Board approves the application, the Initiator applies for finalization to the Secretary's Office.

For the returned application, the Initiator remedies defects, and applies for a Contract Draft to a Lawyer again.

The Secretary's Office finalizes the contract, and the Contract Monitoring workflow will be scheduled. The typical schedule is weekly or bi-weekly. The scheduled Contract Monitoring allows for collecting files and text notes or applying for the archive.

The Initiator can initiate amendments to a valid contract. Any amendment can be applied for a draft until the Signer approves it.

For existing contracts and in special cases it is possible to apply for contract registration by bypassing the draft.

An Industrial Management Company may manage thousands of contracts at once. The Contract Repository requires rich information views and analytical reports created using the data visualization tool. Standards are internal.

## Logistic Information Management

An Industrial Management Company collects customers’ orders, converts them into production orders, and manages production and shipping.

The Sales Manager applies for production to the Production Manager using the Production Order form. The Production Order form includes data from a Customer Order and internal classifiers. The Production Manager proposes a way to fulfill the production order – goods from storage, a regular production plan for the next quarter, or accelerated production. This proposal should be submitted to the Sales Manager.

The Sales Manager finalizes the proposal. After the finalization, the Production or Shipping will be scheduled for the Production Manager. Rejecting a Customer Goods Order is also possible.

The Production Manager applies for production to the Shop Principal or applies for shipping to the Storage Principal.

The Production Workflow collects production data. The Shipping Workflow runs on the first shipping, collects shipping data, and will be finalized after all goods are shipped.

The Customer Order, Production, and Shipping workflows collect all necessary information. The amendments do not apply to this process.

An Industrial Management Company may manage thousands of customers’ orders annually. Logistic Management requires rich information views and analytical reports created using the data visualization tool. Standards are internal.

# Pharmaceutical and engineering industries

## Protocols management

Protocol is a system of rules about the correct way to act. Examples are Quality Policies, Standard Operating Procedures, Job Descriptions, Factory Standards, Process Charts, Job Cards, and User Manuals.

The protocol's lifecycle processes are creation, consideration, approval, implementation, amendment, scheduled reviews, and withdrawal. These processes are internal in an organization. A typical protocol is a member of a hierarchical structure of protocols.

A large plant or factory manages hundreds of thousands of protocols.

Protocol Management ensures the availability of all valid protocols from a workplace and the unavailability of outdated protocols. It will be nice to use the data visualization tool to manage this. Protocol Management is included in the Quality Management System ISO 9000 family, and ISO 9001.

## Change management

Change Management refers to the structured approach to transitioning organizations from a current state to a desired future state. It involves managing the human, organizational, and operational aspects of change to minimize resistance and maximize the effectiveness of the change initiative.

Anyone can submit a Change Request to the Manager for approval. The Manager submits the request to the Quality Management Department or implements minor changes on one's own.

The Quality Management Department prepares the Change Request for consideration and submits it to the selected experts. The Experts should review the change proposed. During the review, each expert adds action plan items related to the area of expertise.

The Quality Management Department compiles and implements the action plan. All who are concerned should be notified. The execution of the Action Plan is outside the Change Management. The validation of action plan outcomes is the function of Change Management.

A large plant or factory may manage hundreds of change requests annually.

The visualization of the Change Requests along with the respective action plan items is appreciated. Change Management is included in the Quality Management System ISO 9000 family, and ISO 9001.

## Nonconformity Management

Nonconformity Management involves identifying, documenting, evaluating, and addressing instances where products, processes, or systems fail to meet specified requirements.

Anyone can submit the Nonconformity Form to the Manager. The Manager may resolve this locally or delegate it to the Quality Management Department.

The nonconformity resolution consists of corrective actions, preventive actions, and audits. The actions are executed outside the Nonconformity Management. The validation of action outcomes is the function of Nonconformity Management. The Nonconformity Form with the actions and audit data should be visualized.

A large plant or factory may manage hundreds of Nonconformity applications annually. However, a business office or a government agency uses them rarely. Most of the nonconformities are resolved locally. Nonconformity Management is included in the Quality Management System ISO 9000 family, and ISO 9001.

## Office Records Management

Office records refer to documents and correspondence created, received, and stored within a business environment. Examples are incoming and outgoing correspondence, office memos, certificates of unserviceability, and reports.

An office record contains facts. The management of these records is crucial for organizational efficiency and compliance. It involves systematic practices for handling information throughout its lifecycle. The records lifecycle processes are creation, distribution, use, maintenance, preservation, and disposal. Implementation of these processes depends on the record’s type, internal rules, and legislation.

The annual amount of office records for large factories, business offices, or government agencies is thousands. The data visualization tool visualizes office journals. The ISO 15489-1: 2001 standard contains good practices of the Office Records Management.