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Bika Open Source LIMS. Top level functional specification Inventory and Supply Chain Management

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1 Purpose of this document

Tab

This document is used to establish the scope of the project and a common understanding for coders in the 2015 Google Summer of Code to build their proposals around.

1.1 Document Convention

Note the page is written in the present tense describing the requirement as if it is there already. Also see the <u>GSoC \cdot Inventory Management Module</u> wiki page. Lower priority items are designated as **Phase II.**

2 Background

While <u>Bika LIMS</u> already has the basics for Product and Sample References management, as well as some simple Supply Order functionality, this module has been neglected for too long.

In most cases the inventory management of lab products and reagents are managed by an external application as ERP, using Bika's JSON API. A native Bika module will add better lab customised functionality, suitable for resource limited settings too, yet sophisticated enough to deal with best of breed requirements.

3 Database Considerations

3.1 **Product Categories**

These Product types are managed as inventory items:

ReagentsPrinter consumables - Ink, labelsReference SamplesLab coats, safety glasses, shoesSampling KitsFirst aid kit, fire extinguishersAnalysis KitsCleaning materialsKit componentsCanteen;-)Sample containers - bottles, filters, zip-locks, etc.

3.2 Products. Inventory Items

At the bottom of the DB pyramid lives Products, the individual entities the system manages. Products often arrive in Batches, and this is resolved via a Product Batch DB container.

Product attributes include but are not limited to:

Title	Storage Location
Description	Hazard Rating
Lab ID	Toxicity
Supplier Catalogue Id	Health Effects
Supplier	Storage Conditions
Quantity	Date Disposed
Ordered by	Disposal SOP
Date Ordered	First Aid SOP
Date Received	Spill-Handling Procedures
Date Opened	MSDS. Material Safety Data Sheets
Expiry Date	Relevant Images
CAS Number	PDF and other Attachments

4 Workflow and Functionality

4.1 Suppliers and Purchase Orders

Ordering of Products are integrated with Bika's current Suppliers structure. Authorised users create purchase orders (PO) in the UI, with status Pending. Orders are printed or emailed, followed by transitions to e.g. Dispatched, Received, Stored.

Courier details and links to online tracking in the Order online is a must have.

Phase II

Approved suppliers and their contracts Vendor catalogue integration

4.2 Receipt and storage. Labeling

When a new inventory Shipment arrives, lab clerks check it in against pending orders, print barcodes labels, capture data such as expiration date, batch and item IDs. Vendor supplied labelling scanned in tracked to each individual container.

The LIMS updates the stock levels of the items stored at their allocated locations.

Phase II

Incomplete orders

Returned orders

4.3 Storage management

This function is shared with biobanking's Sample inventory management, which can go quite a distance...

When the lab clerk receives Product Shipments, they are stored at barcoded storage locations managed at hierarchical addresses, e.g.

a Product is stored

- in a container (optional)
- at a shelf position
- in a fridge or cabinet
- in a room.

Storage conditions for the location, e.g. 4 $^\circ\text{C},$ must match that of its the item's specification.

The storage locations are searchable for available and adjoining space.

Phase II

2D Graphical presentation of freezer shelves with shelf positions linked to the items stored, and available positions indicated.

Consolidation and optimisation of storage locations – 'de-fragmentation' of storage space.

4.4 IM. Inventory Management

Tracking and maintaining sustainable inventory levels, monitor batches or individual Products:

4.4.1 Dynamic Record keeping

The quantities of reagent used in analysis, e.g. titration volumes or usage reports produced by instruments, are used to maintain reagent stock levels, allowing for spillage.

Labs might also want to capture location of use, user and cost centre.

Other items, e.g. glass ware pieces are scanning out per unit, and the Inventory automatically updated.

4.4.2 Low stock level alerts

Each item is set up with a minimum 'Re-ordering level' at which a replenish alert is raised for lab clerks and lab managers.

Reordering levels are calculated as:

Re-order level = max rate of consumption x max lead time

The alert, be it by email or on-line, offers and easy hyper-linked re-order workflow.

4.4.3 Expiry alerts

Most reagents and reference material have expiry dates. A similar alert as for re-ordering is raised, based on configurable period before expiry.

These expired are immediately cancelled on expiry and not offered in LIMS look-ups for selection.

4.4.4 Inventory QC. Defective Batches

On the worksheets and and ARs where results are captured, the reagents' batch numbers are captured too. Through their standard QC procedures, the lab might find that some reagent batches are defective and will decommission them.

These defective batches are immediately taken out of stock, and not offered in LIMS look-ups for selection any further and alerts raised to all analysts and lab managers.

All analysis results that involved a defective batch of reagents go into quarantine for retesting. Verified and Published results are invalidated as per standard Bika invalidation workflow.

If the decommissioning of the defect products or batches, results in minimum stock levels being breached, the replenishment alert and workflow kick off.

4.4.5 Physical stock taking

For maintaining accurate stock levels, the LIMS offers:

- Printable stock taking sheets, including barcodes for the inventory items and their expected storage locations
- A layout optimised for data capturing on tablets through barcode scanning

Data captured during stock taking are used to adjust inventory levels, and a reconciliation report of these adjustments made available.

Phase II

Employ some of the popular statistical stock taking formulas & methods, e.g. Random selection as well as ABC & VED analysis etc.

4.4.6 Phase II. Disposal

Empty and expired reagents are disposed of as per SOP maintained in the system.

4.4.7 Phase II. Stock loss alerts

Loss detection and reporting.

4.5 Reporting

Most of all Bika Inventory management offers real-time inventory data of inventory stock levels, keeping track of where inventory items are and how much of it is available.

The UI allows these numbers to be mined and displayed by authorised users, from where they may print, email or export the data as per standard Bika practice.

The LIMS generates reports listing inventory items by location, vendor, name, catalogue number and custom fields,

Others report Amount of reagent used for a selected period, Expenses forecast, How long stocks will cover lab requirement, Inventory valuation, Future demand estimates, etc.

Phase II

The inventory data could be used to create regulations related reports, e.g. regarding hazardous air pollutant (HAP) and volatile organic compound (VOC) usage data.

5 Regulations

Good Laboratory Practice (GLP) and Food and Drug Administration (FDA) Guidelines, including 21 CFR Part 11 requirements prescribe are adhered to: audit trails for every data change including the date/time stamp, what was modified, and user name are captured.

Phase II

Bika's Plone versioned document management is used to manage audits, preventative and corrective actions

6 Document management

Bika's document management includes version control and is used to develop Inventory SOPs that are hyper-linked to the items in the DB.