



STARLIMS BIOREPOSITORY SOLUTION

A comprehensive knowledge management system
for biorepositories



STARLIMS Biorepository Solution

Effective Storage Utilisation

Decision support for effective storage utilisation, which includes tools to plan and track the capacity in each storage location, consolidate inventory within a location, and proactively remind personnel to perform periodic physical inventory reconciliation.

Specimen Placement and Removal

Intuitive screens with barcode scan fields and graphical tools that clearly delineate the specific position of a specimen within a container, and the container within another container or a storage location. This serves to guide placement and removal and to streamline all specimen handling procedures.

Specimen Usage and Movement

By tracking the individuals responsible for each specimen and its respective storage location, user-configurable approval workflows allow the biorepository to enforce the appropriate business logic for approval of specimen usage or movement. STARLIMS tracks a specimen's home location and the due date for its return and it enables researchers to reserve specimens for a specified time interval.

Chain of Custody with Electronic Signatures

Using electronic signatures allows chronological tracking of the entire history of each specimen. This ranges from initial electronic manifest login and/or accessioning to final disposal. STARLIMS offers functions including pooling, aliquoting, freeze-thaw tracking, quantity adjustment, shipping, and disposal management, ensuring that the full genealogy and history of the specimens are maintained.

Flexible Web-based Query Capabilities

Powerful and flexible query tools enable researchers to identify and locate specimens of interest for clinical research purposes. Queries can be conducted from across the globe using STARLIMS' intuitive graphic interface, flexible query templates, and a standard Web browser.

Flexible Specimen Metadata Options

STARLIMS' flexible biorepository metadata templates makes it easy to add or modify specimen metadata attributes. The biobank can quickly add a new specimen attribute and then researchers can immediately use that attribute in their biobank queries.

Convenient Aliquot Ordering and Test Assignment

Specimen aliquots or tests can be ordered for an individual specimen or a group of specimens by biobank personnel or external researchers. STARLIMS' powerful laboratory testing

workflow tools manage all specimen preparation and testing including extraction and quality testing of molecular components (such as RNA and DNA).

Billing

STARLIMS manages client specific pricing and invoicing related to completed tasks such as specimen shipping, processing and/or testing in addition to periodic charges for storage and handling.

Patient Manager

STARLIMS' Patient Manager provides the flexibility to track demographic, clinical, and lifestyle information about donors to support medical research efforts. The Patient Manager also provides a convenient tool to view historical test results, attached files, and special notes.

Comprehensive Consent Management

Patient consent information is managed to a level of detail that ensures all human biological specimens are handled per IRB and regulatory requirements and in accordance with donor preferences.

Timely Identification and Resolution of Discrepancies

STARLIMS' tight integration with Clinical Study Management enables timely identification and resolution of discrepancies between specimen/donor attributes (arrival condition, container, transit time, etc.) and clinical study requirements.

Powerful Interoperability Tools

STARLIMS provides automated import of E-manifest, test requests, and test result files; powerful interfacing tools including interfacing to automated specimen handling systems and analytical instruments; and system-to-system communications via web services, file (text, CSV, HL7, ASCII, etc.) transfer, and direct database communications.





STARLIMS enables biorepositories to promote scientific collaboration, maximise the value of their specimens and meet stringent regulations.

Biorepositories are looking for sophisticated data management solutions—largely as a response to the exponential growth in the volume of biological samples, growing use of molecular methods by medical researchers to characterise the samples, and increasingly stringent regulations. STARLIMS Biorepository solution meets these needs by combining extensive sample management tools with the comprehensive capabilities of an advanced laboratory information management system (LIMS).

Leveraging more than 25 years of enterprise-level laboratory automation experience, STARLIMS has developed an exceptionally flexible solution platform to archive, trace, and manage scientific and laboratory information in a wide variety of formats. Going beyond specimen storage management, STARLIMS also manages clinical studies, laboratory testing workflows, donor data, legal consent data and more. All of this information can be made available to any authorised user through a Web-based platform designed for rapid global deployment.

STARLIMS Biorepository solution is designed for biotechnology companies, academic and medical institutions, pharmaceutical labs and contract research organisations. STARLIMS solutions have been implemented by pharmaceutical, clinical, biotechnology, government, and academic laboratories worldwide.

Decision Support for Effective Logistics Management

STARLIMS offers a solution suite which provides all the decision support tools biorepositories need to help them maximise the efficiency of their operations. This includes flexible configurable workflows for a wide range of lab processes—from specimen collection; reception; testing and processing; through storage location management; to querying and referral. Lab managers and research staff are presented with real-time data that facilitates inventory management, storage management, specimen usage and movement, specimen placement and removal, test assignment, and much more.

Comprehensive Data Management for Full Regulatory Compliance

STARLIMS solution provides a complete chain of custody with electronic signatures covering every step in every workflow. Furthermore, STARLIMS provides the biorepository with the flexibility to capture and manage new specimen and donor attributes as needed to address research needs and changing local requirements. This enables biorepositories and their clients to meet increasingly stringent regulatory and legal requirements relating to the use of human and other tissues.

Flexible Workflow Management Tools

STARLIMS solution comes with multiple ready-made workflow tools and wizards developed specifically for biorepositories. A rich GUI based on intuitive drag & drop functions makes it possible to easily and conveniently fine-tune the STARLIMS solution to meet the needs of any lab. The STARLIMS solution guides analysts through defined steps and makes appropriate recommendations based on entered data, calculated data, or a resource reference. STARLIMS can model existing procedures and business logic within an automated system.

Ensuring Full Regulatory Compliance

STARLIMS solution facilitates compliance with a wide range of different laws and regulatory standards including: 21 CFR Part 11, ICH, GxP, HIPAA, CAP, CLIA, and ISO 17025, with features including:

- Comprehensive audit trail
- Consent management
- Chain of custody and e-signatures
- Lab audit manager
- Analyst training and certification
- Instrument and reagent management
- QA/QC with Levey-Jennings plots/Westgard Rules
- Document/SOP management
- Advanced security

Web-based Solutions for Global Deployment and Effective Collaboration

STARLIMS solution was built from the ground up as an entirely Web-based solution, leveraging XML, the .NET framework and other advanced Internet technologies. Multilingual solutions available for global deployment, STARLIMS is accessible through a standard browser with no need for client-side downloads. In addition, the inherent flexibility of the system means that changes to business needs and laboratory practices can be supported and implemented without losing existing functionality or data.

STARLIMS' intuitive user interface simplifies both user training and implementation in new sites or new parts of the organisation. The Web-based interface also makes it possible to submit specimens, request results online, and track specimens anywhere within the enterprise—providing outreach capabilities to third parties and customers, and dramatically reducing transcription errors and queries to lab personnel.



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