LabLogic

stacy™ 2

Radioisotope Stock Control and Sample Tracking...

Stacy™ by LabLogic Systems Limited provides a host of features for tracking the flow of compounds and samples through a facility, or just keeping track of where items are stored, including full chain of custody records and 21 CFR Part 11 compliance.

Stacy™ provides real time information on the status and location of all items including detailed history and disposal records.

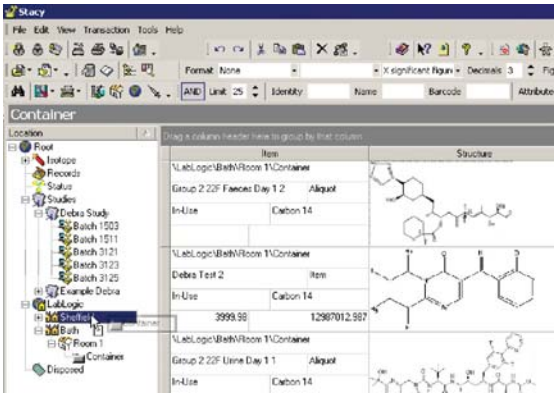
Stacy™ includes the following features:

- User-definable item types, locations and transactions
- Full security module with user defined access levels
- Direct Interface to Debra™ ADME LIMS
- Moveable containers
- Simple searching for items
- Comprehensive user defined reports
- Barcode and label creation and recognition
- Easy personalisation to adapt to your facility and procedures
- Instant observance of holding, accumulation and disposal limits
- Full GLP compliant edit with comprehensive audit trail
- 21 CFR Part 11 compliance
- Validation Service available

A totally interactive compound management and sample tracking system with direct links to the Debra™ ADME LIMS database allowing automatic sample registration and full tracking throughout the sample life-cycle.

User-Definable Location Tree

Physical locations are completely user defined and can be general, such as a building or specific as in a particular section of a box. The number and type of locations that can be created are limitless allowing the system manager to map the entire company structure.



Items can also be placed in user-defined containers so that many items can be moved simultaneously without having to be individually selected first. Once created, items and containers can be selected and moved around the tree by the 'drag and drop' method.

Not only are items grouped by physical location, but also via certain common attributes, such as Isotope, Debra™ Study and Batch or Status. When an item is added to the system, it will be automatically located as an item relevant to the attribute in the tree.

Definable Item Types

As well as being able to automatically pick up and track samples generated by the Debra™ ADME LIMS, Stacy™ will also track any other item within an organisation, including assets or employee records. Item types can be defined with complete control over the entry fields and type of data required for identification. Multiple items can be added together via an Excel™ spreadsheet.

Item Searching

Items can be located quickly in your system using the simple search tools that are part of the Stacy™ experience. Items can found via their name, particular attributes or bar-code.

Bar-code Creation, Printing and Reading

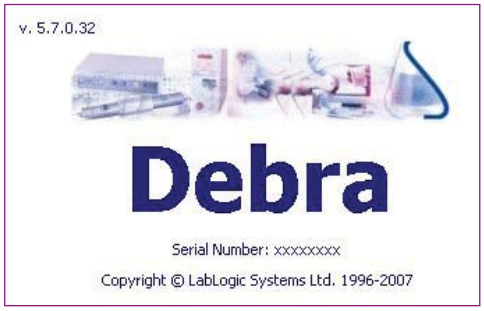
The bar-coding options within Stacy™ allow the user to create, print and read a wide variety of industry standard bar-code formats. Labels can be user-defined within the system to not only identify the individual samples but also to identify and record location and container information. The label type, dimensions and content are defined by the user, making it a flexible and powerful tool. Pre-defined label formats can be set to cover the corporate standard. Scanning labels allows Stacy™ to rapidly facilitate sample registration or sample location

Radio-isotope Stock Control System

Stacy™ allows for the tracking and disposal of radioactive samples. The system allows for automatic creation of disposal records when transferring active samples to waste, disposal or accumulation sites. When combined with the Debra™ interface this provides complete inventory control from initial compound receipt through study usage to final disposal. Entry of the Site Radioactivity Holding and Disposal licences allows Stacy™ to track the amount of activity held against those limits and warn if they are being approached.

Direct Interface to Debra™ ADME LIMS

For clients using the Debra™ ADME LIMS, Stacy™ provides automated integration with the Oracle® study and sample database to allow direct registration of all study samples to the tracking database. All study critical information with regard to the samples is held to allow complete control and monitoring throughout the study and sample life-cycle. Comprehensive grouping and display filtering techniques allow for sample batches to be easily created and moved at the click of the mouse. Stacy™ also reads Debra™ labels to enable easy selection of samples, aliquots etc. for movement or disposal.



Reporting

Of major importance is the retrieval of the information stored in Stacy™. The reporting package provides exceptional convenience and flexibility. Stacy™ comes with many reports built in to show the history of items and locations. All reports can also be edited or created by users to suit your needs.

Security

Stacy™ has a comprehensive and flexible security structure, which is used to control access to menu items, transactions and locations. Stacy™ is able to guard against unauthorized access to data, so is ideal for use in a regulatory environment. Security is assigned on a user-by-user basis; controlled by your system administrator and can be configured to the strength of your requirements. System and sample-level security roles can be assigned to users to ensure that only those individuals who have the appropriate rights assigned to them can perform their necessary functions. Stacy™ can also use Windows authorisation.

Regulatory and FDA 21 CFR Part 11 Compliance

Stacy™ is designed to fully support GLP and associated regulatory requirements and specifications for both laboratory operations and laboratory software design. This includes functionality to meet with the FDA 21 CFR Part 11 ruling for electronic signatures and electronic records. The system allows for System Manager control of signature points on key events. Each area of the application that could require a signature is configurable. Administrators can disable the signatures, set a silent signature which doesn't require any action on the users' part, set a single signature or 2 signatures (the second signature normally being approval of the first). Signed electronic records contain information associated with the signing that clearly indicates the following:

- The printed name of the signer
- The date and time when the signature was executed

Quality Assurance

Certificate No:1535/97

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Quality of service and product is of paramount importance to LabLogic and this is reflected in our systems. Our continued efforts in this area have resulted in ISO 9001 accreditation for:

Design, development and supply of laboratory information management systems, scientific applications software with ongoing maintenance support, including the supply of instrumentation systems for pharmaceutical, agrochemical and contract research organisations.

Validation Services

LabLogic's Validation Services can provide you with a range of options to help validate either system upgrades or newly installed systems.

At LabLogic, we believe that nobody knows and understands our systems and the needs of the drug metabolism laboratory better than we do, which is why we have put together our Validation Service to enable you to implement and get maximum value from your investment as quickly as possible.

By purchasing this service, our Validation Specialists will provide on-site consultancy and advice for your Company throughout the Project Life Cycle and will provide a tailored Validation Plan suited for your needs to meet your Company's corporate standards. We work in partnership with your System Manager and users; involving them in the actual running of the test scripts, so that the users learn more about their own system before it is implemented.

Clients

Some of the many clients LabLogic are proud to be associated with:

..... Abbott Laboratories, AstraZeneca, Boehringer Ingelheim, DuPont, GlaxoSmithKline, Johnson & Johnson, Novartis, Pfizer, Roche, Sanofi Aventis, Wyeth Ayerst, Aptuit, BioDynamics, Charles River Laboratories, Covance, HLS, MDS, RTI International...

For more information or a detailed on-site demonstration please contact:

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Stacy™2

Specifications

Client

Hardware

minimum Pentium III at 500 MHz
(preferred Pentium IV at 1 GHz or higher)
minimum SVGA 800x600, 16 colours
mouse or other pointing device
printer (or access to a network printer)

Operating system

Microsoft® Windows 2000 Professional with 256Mb (512Mb preferred)
Microsoft® Windows XP Professional with 512Mb (1024Mb preferred)

Oracle® software

SQL*Net 9 and Required Support Files with Oracle® 9.2 (or later).

Storage

~30Mb for a local client installation
~200Mb free required after installation

Installation

It is possible to store the Stacy™ executable program and online help either locally or on a network fileserver. Issues to consider in order to make this decision include the fact that storing the executable on a central server will ease updating the software and also the client installation process. Conversely, storing the executable locally will reduce network traffic and improve the performance of the software.

Server

Hardware, operating system and Oracle® software

Due to the nature of Oracle® and the client/server architecture of , the server platform is largely immaterial. Stacy™ requires an Oracle® server. Full stop. Currently, Stacy™ supports the following Oracle® server version.

- Oracle® Server 9.2 and later (including Oracle® 10).

Example Platforms

- Quad 250MHz Sun server
- Dual 2.8GHz Pentium Xeon Windows 2000 Server
- 3 GHz Xeon Centos 4 server running as a virtual machine

Storage

- Default initial sizing of the database at install-time is 600Mb.