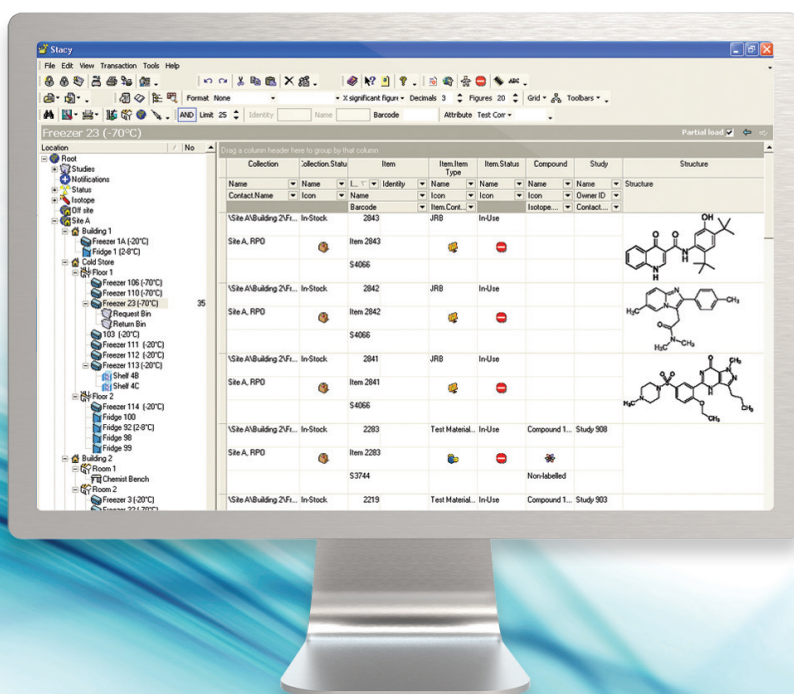




# Stacy™

Sample Tracking and Radioisotope Inventory Software



# Radioisotope Stock Control and Sample Tracking

Stacy™ is 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.

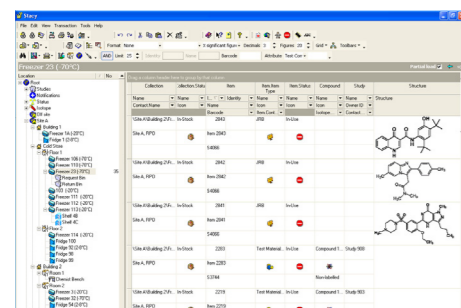
Stacy™ provides a host of features for tracking the flow of compounds and samples through a facility, or just keeping track of where items are stored, including full chain of custody records and 21 CFR Part 11 compliance. These include:

- 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.

## Key Features

### 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 be found via their name, particular attributes or bar-code.

### 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.

### 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.



### 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 unauthorised 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.



## Service and Support

Users of our systems can benefit from our comprehensive, fully inclusive service and support.

We can give reassurance that if things go wrong or you need expert advice, help is only an e-mail or phone call away.



## Validation Services

Our Validation Service enables you to implement and get maximum value from your investments as soon as possible.

We work as a partner with your Quality Manager, System Manager and users to provide a tailored Validation Plan, suited to your needs. Our Validation Specialists have years of experience in GLP system validation, detailed knowledge of our systems, together with other industry standard systems to help you meet company and regulatory requirements.



## Training

LabLogic can provide a variety of training courses and workshops to help you get the most out of your instruments and software.

All training is performed by our expert Product and Support Specialists who have many years experience in the development and use of the instruments and software.

Certificates can be provided to complement your internal GLP training records.

## Related Products



### Europe & Worldwide

#### LabLogic Systems Limited

Paradigm House, 3 Melbourne Avenue  
Broomhill, Sheffield, S10 2QJ, UK

E-mail: [solutions@lablogic.com](mailto:solutions@lablogic.com)

Tel: +44 (0)114 266 7267

Fax: +44 (0)114 266 3944

Web: [www.lablogic.com](http://www.lablogic.com)



Certificate No: 1535  
ISO 9001



### USA & Canada

#### LabLogic Systems, Inc.

East Pointe Park, 1040 East Brandon Blvd.  
Brandon, FL 33511-5509, USA

E-mail: [solutions@lablogic.com](mailto:solutions@lablogic.com)

Tel: +1-813-626-6848

Fax: +1-813-620-3708

Web: [www.lablogic.com](http://www.lablogic.com)



Certificate No: 10926  
ISO 9001



EXPERIENCE & EXPERTISE