



# Solutions for Drug Metabolism and eFate Studies

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



**LabLogic**

EXPERIENCE & EXPERTISE

LabLogic provide a range products for Drug Metabolism and eFate Studies. From individual instruments to dedicated LIMS software – plus validation, qualification, service, and training – we have the experience and expertise to provide a custom solution for your laboratory.

Software

Debra™	4 - 5
Laura™	6 - 7

Instruments

Beta-RAM™	8 - 9
Logi-CHROM™	10 - 11
Hidex 600 SLe	12 - 13
Hidex 600 OX	12 - 13
Hidex AMG	12 - 13

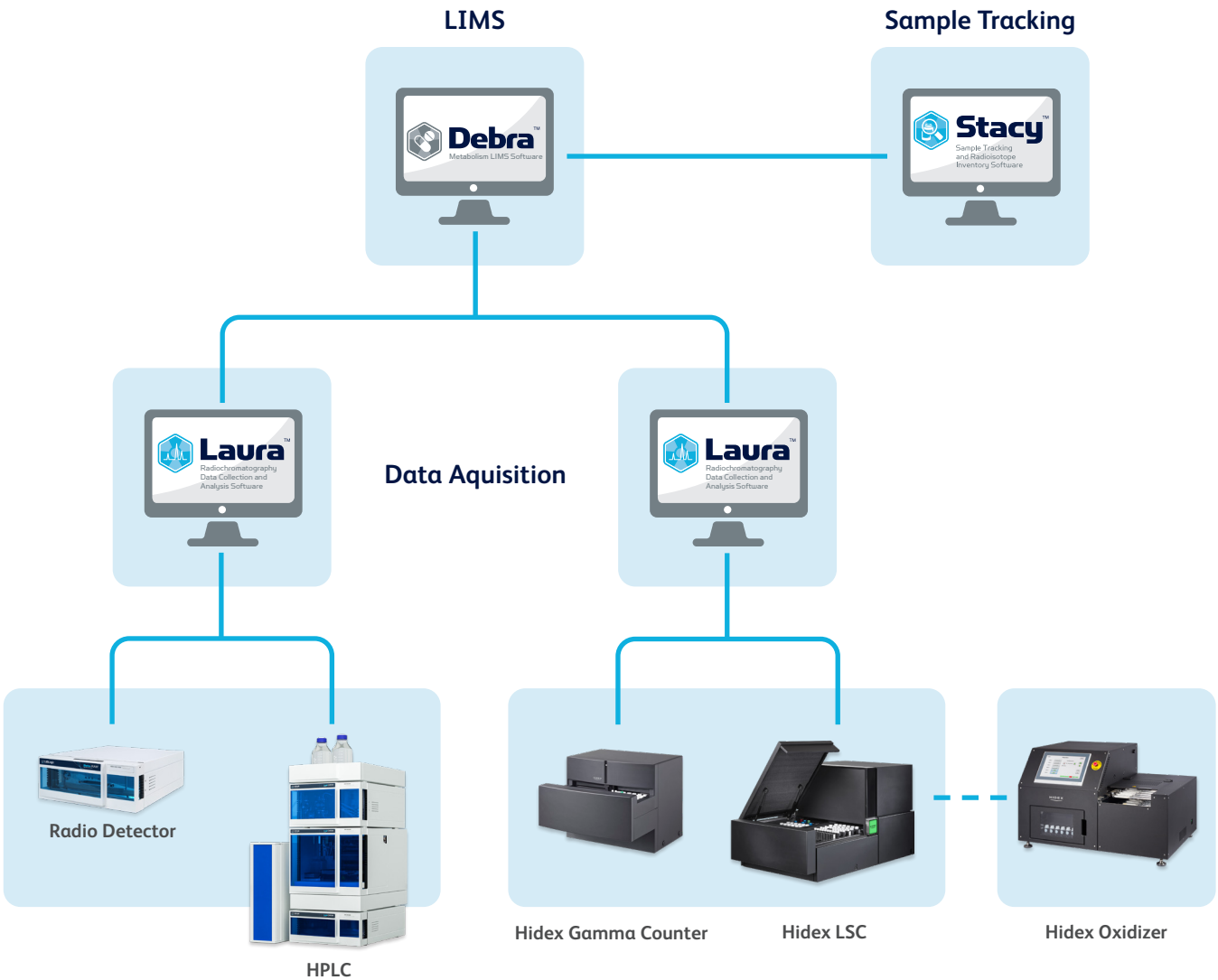
Sample Tracking Software

Stacy™	14
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Services

Quality Assurance	15
Validation	15
Support	15
Training	15
Custom Development	15

LabLogic products are unique in their seamless integration to one another. Data integrity is maintained throughout the process.



Debra™

Debra is a purpose built LIMS designed specifically to manage the entire life cycle of a range of drug and environmental metabolism studies within a FDA/GLP regulated environment.

Continuous development over 30 years has resulted in a system that is the industry standard in its field and is used by many of the world's leading Pharmaceutical, Agrochemical and Contract Research Organisations.

Whatever the scope of your study, Debra allows you to take complete control of the process, improving efficiency, whilst meeting the requirements of regulatory compliance at every step.

Direct Data Capture

- Direct capture from equipment, thus eliminating transcription errors.
- No transcription necessary.
- Seamless communication to and from the instrument.
- A wide variety of models and versions of balances, LSC's and WBA are handled with instrument specific interfaces.

Improved Efficiency

- Easy to use batch worksheets to organise data capture.
- Automatic calculations of dosing requirements.
- Immediate generation of raw data and summary reports.
- Easy label generation for all samples.
- Direct links with the industry standard Laura system for radiochromatography and LSC analysis.
- Automatic calculation of results.

Regulatory Compliance

Debra is a closed system that ensure compliance with regulatory demands.

- User access is managed via a unique login ID and password that is linked to users' training and skill set.
- Electronic signatures and audit trails are fully configurable and in line with the FDA 21 CFR part 11 requirements.
- Debra has full auditing capabilities to ensure that any changes are fully tracked and easily reportable.

Extraction Trees

- Isolate metabolites and residues.
- Further analyse or characterise existing samples.
- Create on-the-fly extraction pathways, displayed as a tree structure, adding extracts and samples as you go.
- Pool and concentrate samples, monitoring recovery and concentration at each stage.
- View and report all extraction data.
- Extraction trees can optionally be created as a stand-alone study.
- Can be used for any sample in any study, or as a stand-alone study.
- View all calculations.

Study Types

Debra allows the user to undertake a range of study types including ADME, Environmental Metabolism, Protein Binding and Topical Application.



ADME

- ADME study types include: mass balance, tissue distribution, blood : plasma ratio, pharmacokinetics.
- Easily configure complex protocols.
  - Multiple dose routes, species, dose rates.
  - Define sampling schedules.
- Design prepare and analyse dose solutions and dose vehicles.
- Create and perform dilutions on stock solutions.
- Interactively weigh subjects and administer dose.
- Capture sampling data directly from balances and LSCs.
- Full reporting at all stages with automatic generation of final summary tables.



Environmental Metabolism

- Perform rate of degradation studies including:
  - Aerobic soil / anaerobic soil.
  - Aqueous sediment.
  - Adsorption / Desorption.
- Define soils with water holding capacity details.
- Determine soil moisture content.
- Calculation of target equivalent dry weight of dispensed soil.
- Maintain moisture content.
- Dose rate calculations from field rates.
- Quickly apply known dose amount to all flasks.



Protein Binding

- Multiple assay types available:
  - Ultrafiltration.
  - Equilibrium Dialysis.
  - Blood Cell Partitioning.
- Set up studies with single or multiple species.
- Select multiple concentrations and number of replicates.
- Options to perform non-specific binding and time to equilibrium assays prior to the main study.
- Define spiking schedule and analyse the spiked samples.
- Create serial dilutions of stock solutions.
- Free/bound and other associated calculations automatically performed and reported.



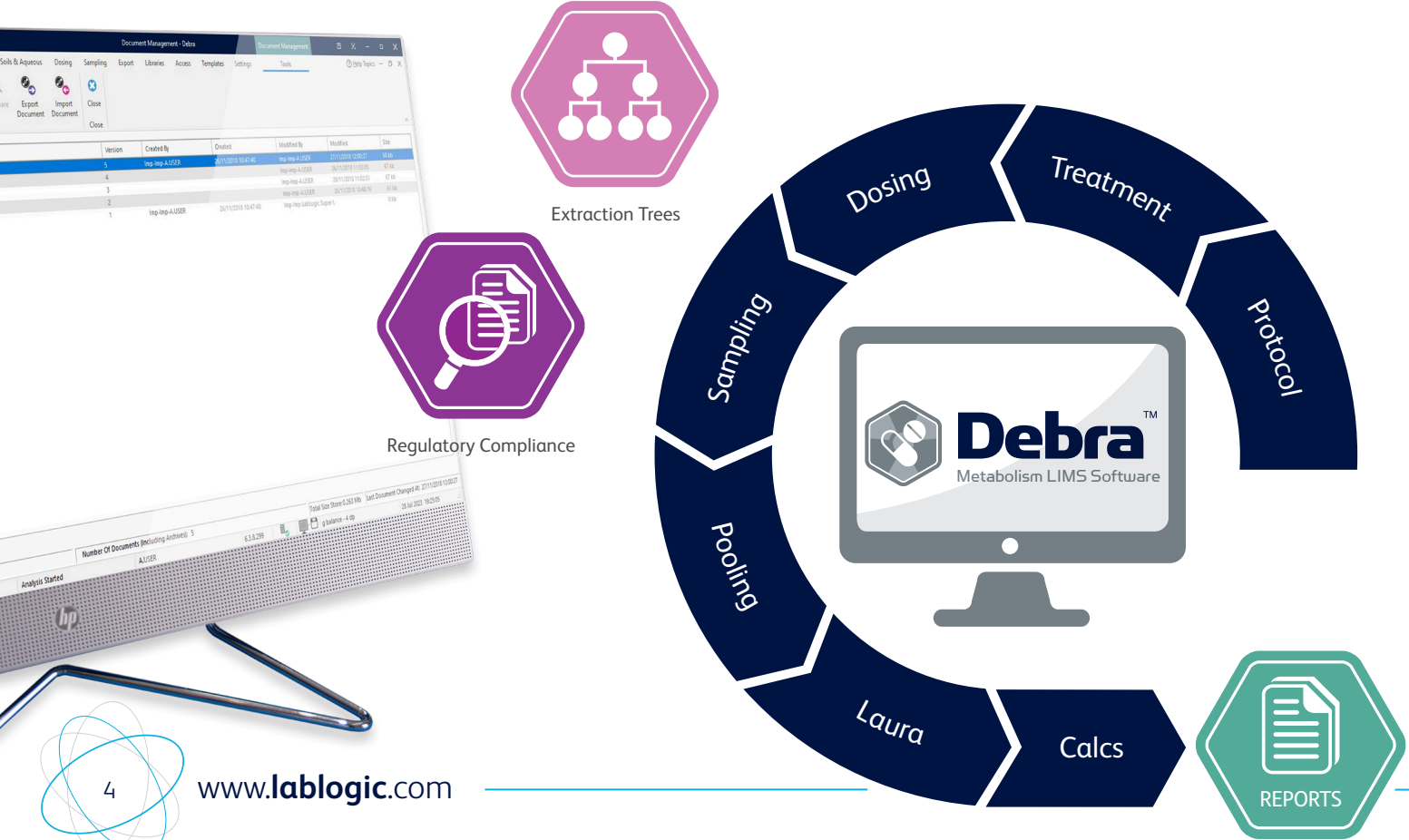
Topical Application

- Specify application area (ha / m² / cm²).
- Specify dose rate per area.
- Specify default areas.



QWBA

- Direct links to Seescan WBA software.
- Use Debra's core features to facilitate QWBA studies.
- Create batch worksheets to import WBA data from a variety of sources.
- Perform QWBA work as part of a larger ADME study or as a discrete project.
- Use Debra's reporting tools for consistent and seamless reporting in a secure environment.





# Software

## Laura™

Laura™ is the ideal software package whether the work involves metabolite profiling, quality control, compound purification or any other chromatography task. Laura™ offers a Single Point of Control of both the radio-detector and HPLC system, as well as LSC/Gamma counters, in a GxP environment.

It offers users the facility to create and edit methods, set up sample runs and view data collection across the network, in real time and without being confined to the bench-top PC.

Laura™ provides connectivity to a wide range of instruments. As well as LabLogic's Beta-RAM™ for radioactivity detection, Laura™ connects to and controls HPLCs and LSCs.

### Regulatory Compliance

Laura™ is designed to fully support GLP and associated regulatory compliance. This includes support for FDA 21 CFR part 11. Totally configurable to meet all requirements, Laura™ features audit trail, flexible security settings, multi-level access and e-signatures.

### Electronic Signatures

Laura™ supports the use of electronic signatures and the system can be configured to suit the user sites requirements for electronic data.

### Audit Trail

Laura™ has a fully featured audit trail that can again be configured to suit the requirements of the user site. Response from the user can be a simple as choosing from a pre-defined list of standard audit reasons or require a unique response depending on the situation and site rules.

### Access Levels

Laura™ features multi-level access control and the system can be configured to have as many levels of access as the user site requires. Menu items are then restricted according to the security level of the individual logged in.

### Security Settings

Laura™ can be configured to suit your particular site requirements for security. User names and passwords can be controlled relative to the site requirements as can inactivity time outs and all other functions required for a secure system.

### Data Integrity

Regulatory compliance is an essential feature of Laura™, built to meet GLP/GMP, MHRA and FDA 21 CFR part 212 / 11 requirements. Featuring configurable audit trail, electronic signatures, secure data storage in a database environment and multi-level security Laura Radiopharma™ can be configured to meet regulatory requirements for data integrity.

Seamless direct links with the industry standard Debra LIMS system.

### Signal to Noise Calculation

Whether you work to USP or EP, Laura™ has the option to calculate signal to noise in line with both requirements.

### Half-Life Correction

### Automatic pass-fail criteria

Eliminate subjectivity, save time, and trust in your results.

### Nuclide ID

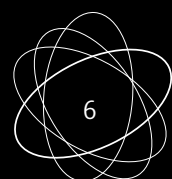
Laura Radiopharma™ can identify radionuclides by analysing samples at specific time points and using the built in half-life calculation.

### Automatic Peak Finder

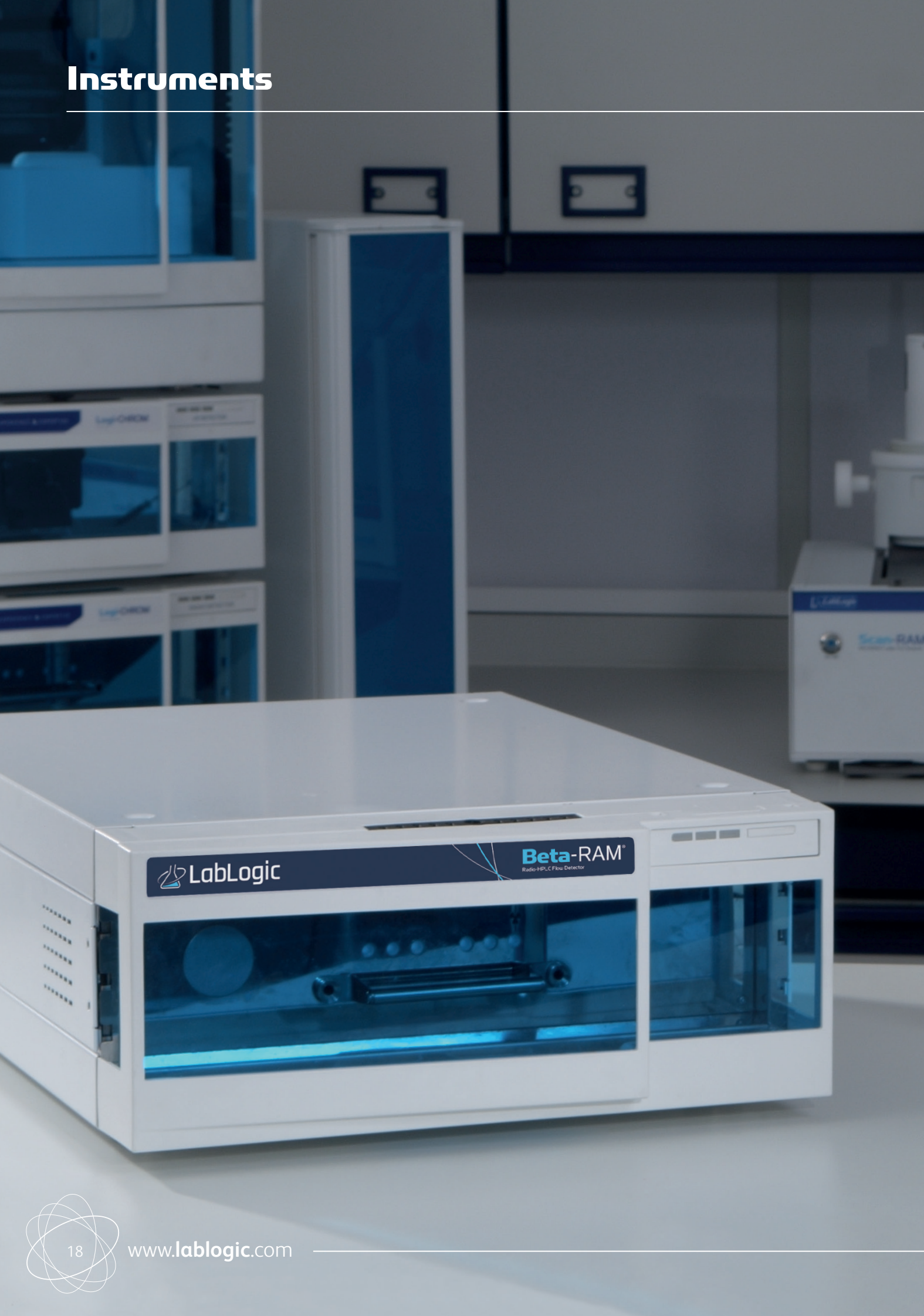
Speed up analysis with our peak finder, improving accuracy, efficiency, and consistent results across different samples.

### Reporting

Fully configurable to meet needs of Radiochemists.







## Beta-RAM™

The world's leading radio flow detector for HPLC offers unrivalled sensitivity, resolution and versatility.

With over 30 years of development and used by thousands of researchers worldwide, the Beta-RAM™ radio flow detector for HPLC coupled with the industry standard Laura radiochromatography software, leads the way for radiochromatographers. The all-new Model 6 has impressive features which improve the Beta-RAM's performance and the efficiency of the radiochromatographer, including:

### Patented IRIS Technology

IRIS technology allows users to optimise sensitivity and resolution by making a range of cell volumes available dynamically. Unlike traditional radio flow detectors for HPLC, which rely on a fixed flow cell volume, the IRIS technology gives a wide range of cell volumes without the need to change the flow cell.



### NEW Integrated Liquid Manifold

The compact and integrated liquid manifold handles the liquid distribution and mixing with scintillation cocktail. The manifold is designed to reduce dead volume to the minimum, ensuring excellent peak shape and resolution.

### Integrated into the Logi-CHROM™ HPLC Series

Alongside the Logi-CHROM™ HPLC series, the Beta-RAM™ 6 is the first flow detector for radio-HPLC to be fully integrated into a HPLC stack.

### Industry standard software

The Beta-RAM™ is controlled by LabLogic's Laura™ software, which has been recognised as the industry standard radiochromatography software package for over 30 years. It features connectivity to the world's leading HPLC systems and impressive data analysis.





# Logi-CHROM™ HPLC

## The Logi-CHROM™ HPLC Series

Logi-CHROM™ HPLC modules, are a new addition to LabLogic's radiochromatography range. Compact, cost effective and fully integrated within Laura software, Logi-CHROM™ is available as a standard HPLC or UHPLC.

### Versatility and reliability

The new Logi-CHROM™ instruments are designed to meet your everyday challenges with versatility and reliability. These systems are flexible in many ways, offering a range of materials, flow rates and complexity levels. Logi-CHROM™ accomplishes your demanding analytical tasks with a selection of detectors, pumps, and columns.

### Single point of control









Integration with LabLogic's Laura™ radiochromatography software ensures data integrity and regulatory compliance; all parameters can only be changed within the software, with a full audit trail recorded.

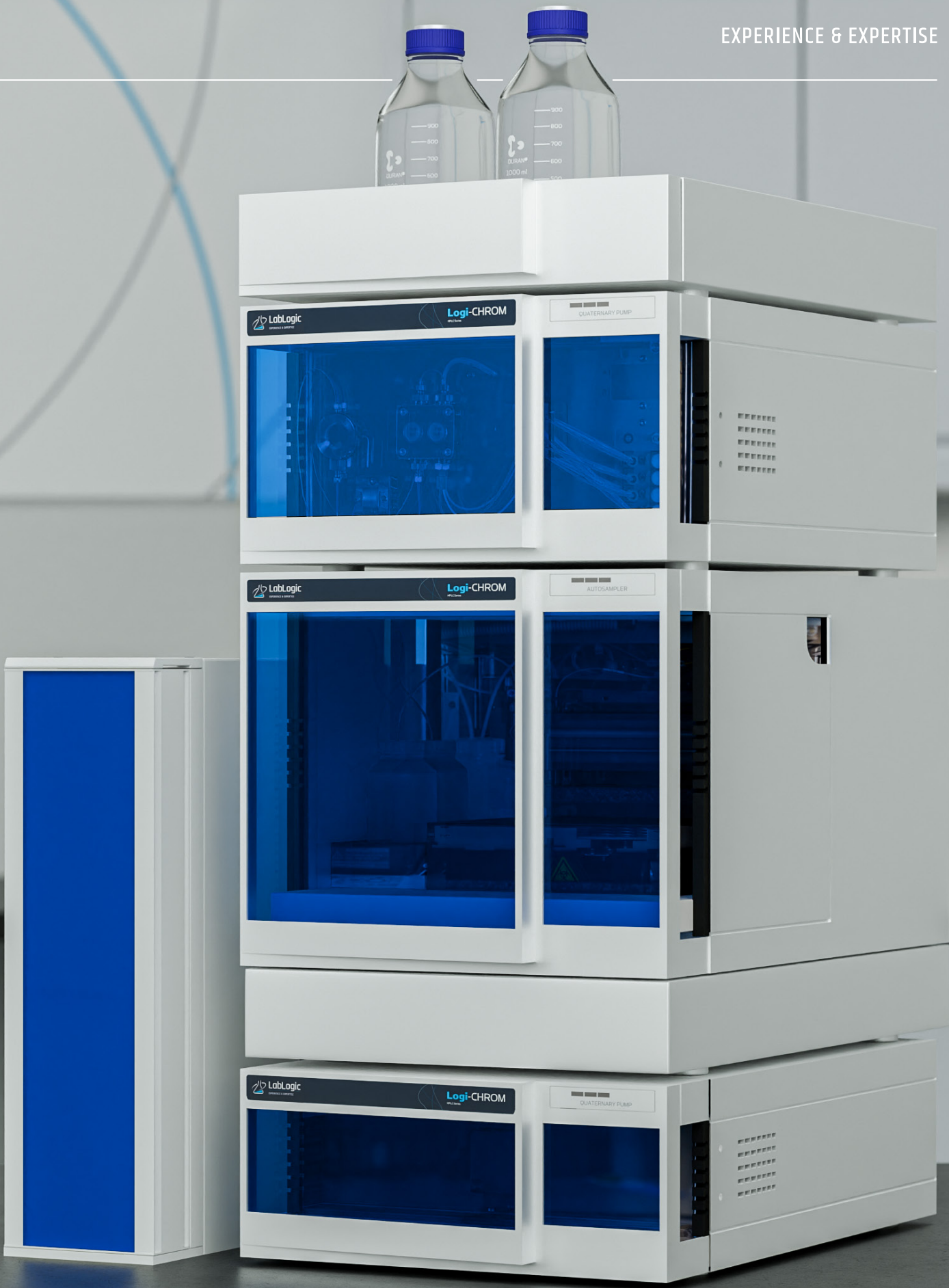
Control and monitor your Logi-CHROM™ system and process your data within Laura™, the industry-standard radiochromatography system used in thousands of laboratories worldwide.

## Third party HPLC Manufacturers

Laura™ interfaces to equipment from the following manufacturers:

**Agilent Technologies**  
Channel Partner







## Hidex 600 SLe

Designed to meet the needs of laboratories processing large quantities of samples, the Hidex 600 SLe is a high throughput automatic TDCR liquid scintillation counter.

### Compliance

The Hidex 600 SLe can be used in a 21 CFR part 11 compliant manner thanks to Laura™ software. The 600 SLe can now be validated to ensure accuracy and reliability. Time-stamped audit trails are generated automatically and cannot be modified, making it easier to track end-user activity. Also in line with 21 CFR regulations, each end-user will have a unique, secure ID login and password.

### Proven technology

The Hidex 600 SLe uses the robust and unique triple-to-double coincidence ratio (TDCR) counting technology from the successful 300 SL series. Coupled with added sample capacity for over 500 small vials (or 210 large vials), the 600 SLe can process samples at a rate which will satisfy even the most demanding production schedule.

The instrument's software allows the user to work with an unlimited number of methods and apply them to a sample using a simple ID or barcode number. Samples are loaded in racks and as they automatically pass through the system, the instrument can scan an identification label on the vial and apply the required method accordingly.

### Optional Features

The Hidex 600 SLe is available with all the options of the standard model, such as low level PMT detectors, cooling unit, and internal Eu-152 reference source.



## Hidex 600 OX Sample Oxidizer

The Hidex 600 OX Oxidizer is a fully computer controlled automated catalytic combustion unit for the preparation of samples such as soil, concrete, faeces, tissue, cellulose, paint, adipose, crude oil, blood, plant material, bones, and concrete from decommissioned nuclear power plants.

The system uses industrial standard logic and mass flow controllers to manage the sample combustion process. An organic sample is combusted into carbon dioxide and water vapour at a high temperature of 900°C. The carbon dioxide is absorbed directly into the liquid scintillation cocktail and the vial is ready for instant <sup>14</sup>C liquid scintillation counting (LSC). In a tritium application, water vapour is condensed into a vial containing cocktail for tritium LSV measurement.



## Hidex AMG

The Hidex AMG gamma counter is specifically designed to meet the needs of modern laboratories. The instrument delivers effortless workflow and provides results quickly and efficiently.

### Exceptional performance

An optimal lead shield design and a single 3" NaI well-type detector provide superb counting efficiency, low backgrounds and minimal interference from samples on the conveyor.

### Compliance

The Hidex AMG can be used in a 21 CFR part 11 compliant manner thanks to LabLogic's Laura™ radiochromatography software. The AMG can now be validated to ensure accuracy and reliability. Time-stamped audit trails are generated automatically and cannot be modified, making it easier to track end-user activity. Also in line with 21 CFR regulations, each end-user will have a unique, secure ID login and password.





# Stacy Sample Tracking and Radioisotope Stock Control System

Stacy provides a host of features for tracking the flow of compounds and samples through a facility, or just for keeping a track of where they are stored with a full chain of custody report.

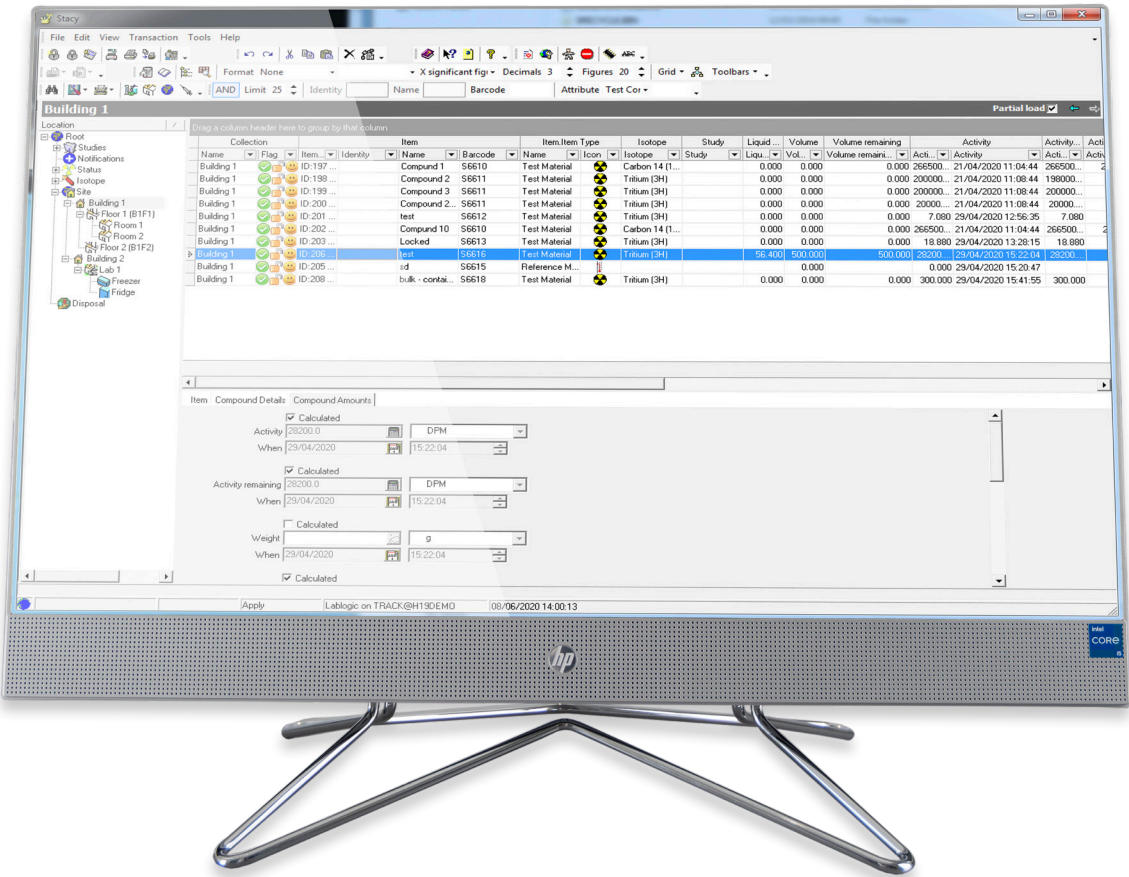
Stacy is designed to simplify the essential record-keeping for ordering, receipt, issue and disposal of such items.

## Sample Tracking

Stacy will track any sample type within an organisation. Sample types can be defined with complete control over the entry fields and type of data required to identify the individual items. Entry of details can be via spreadsheet, file import or via bar-code reader

Features include:

- User-Definable Location Tree.
- Radio-isotope Stock Control System.
- GLP compliance including support for FDA 21 CFR Part 11.
- Comprehensive security features.
- Direct link to Debra LIMS to track all samples generated in studies.
- Flexible reporting.



# A full range of services are available from LabLogic to maximize your investment

At LabLogic we do not underestimate the need for a comprehensive set of services to ensure successful implementation of your products. Years of experience and unrivalled expertise in providing these services, are what make our systems so successful.

## Quality Assurance

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 scientific instrumentation, laboratory information management systems (LIMS) and applications software with on-going maintenance support, including, installation, validation and training of systems for pharmaceutical, agrochemical, nuclear medicine and contract research organisations.

## Support

Supporting our systems and products has always been our priority and what our reputation has been built on. Our support team are experienced in not only deciphering coding problems, but also in the use of the systems. Our team include ex-scientists and users who can relate directly to any problems or questions that you may have.

## Validation

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 incorporate years of experience in GLP system validation, detailed knowledge of our systems, together with other industry standard systems to help you meet your company's requirements.

## Training

We can provide tailored training to suit your needs, from one-on-one sessions to full classroom based training. This can also be split between systems managers training and user training to enable each group of people to get the most out of the system.

## Custom Development

Development direction has always been dictated by the customer's needs – all functionality in our systems has been as a result of a customer request.

LabLogic will work closely with you to understand your processes. We have product and industry specialists with experience in many types of metabolism studies who can work with you to ensure successful and timely implementation of your functionality.







Visit our website



Download the brochure



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Certificate No: 1535  
ISO 9001

**INVESTORS IN PEOPLE**  
We invest in people Gold

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