Debra™

Metabolism LIMS Software

www.lablogic.com

LabLogic

EXPERIENCE & EXPERTISE

The world's leading metabolism Laboratory Information Management System

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 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.

Improved efficiency

By managing data electronically, Debra significantly improves workflow efficiency in the following areas:

- Direct capture from equipment, thus eliminating transcription errors.
- 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 radiochromatography and Seescan WBA software.
- Automatic calculation of results.
- Audit Trail.
- Security Access in accordance with regulatory requirements.
- Electronic signatures; no more missing manual signatures.

Improved compliance

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

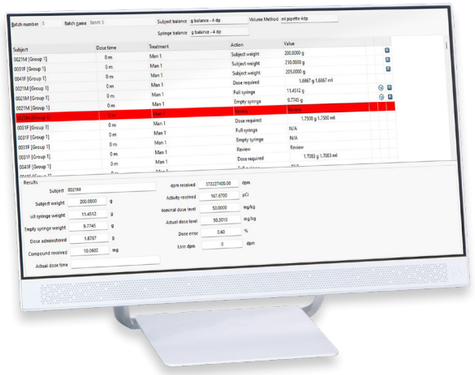
- User access is managed via a unique login ID and password that is linked to users' training and skill set.
- Electronic signatures and audit trails are fully configurable and in line with the FDA 21 CFR part 11 requirements.
- Debra has full auditing capabilities to ensure that any changes are fully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

LabLogic have decades of experience creating systems within highly regulated environments. We are confident that our systems will improve compliance within your facility.

Direct data capture

To achieve the goals of productivity and GLP confidence, Debra avoids transcription errors by capturing raw data either directly from the instrument or via sample result data files from analytical instrumentation systems.

- 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.

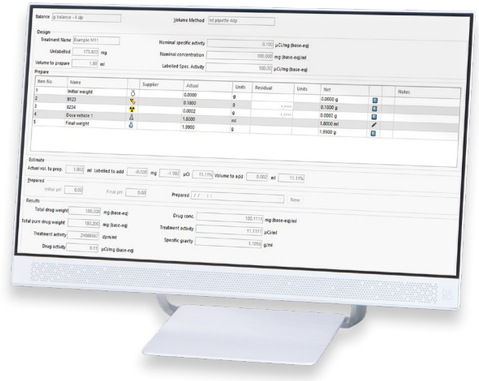


Dosing

- Automatically perform dose calculations based on treatment data and nominal dose rate.
- Design dosing schedule ahead of time.
- Directly capture subject and dose weights either separately or as a single process.
- Allows multi-dose studies.
- Capture the actual time of dosing to calculate real-time sampling for PK studies.
- Immediate calculation of compound and activity administered.

Treatment

- Design, prepare and analyse dose preparations, dose vehicles and stock solutions.
- Manually enter existing treatment data or interactively create new treatments.
- Automatically calculate dose compound requirements accounting for compound properties.
- Directly capture preparation weights and analysis data.
- Automatically calculate treatment concentration and specific activity.



Sampling

- Eliminate transcription errors; no manual entry or data checking required.
- Directly capture weight data from balances.
- Interface with LSCs to import dpm data.
- Design and print sample labels.
- Create scheduled or barcoded batches for data capture.
- Automatic detection of manual data entry, with full audit trail.
- Immediately generate reports following data capture.

Protocol

- Create simple or complex protocols to suit your needs.
- Easily add subjects and apply naming masks.
- Group subjects by species, sex, dose level, dose rate.
- Configure single or multi dosing schedules per project, group or subject.
- Easily configure sampling schedules.
- Assign users to the study based on their access rights.

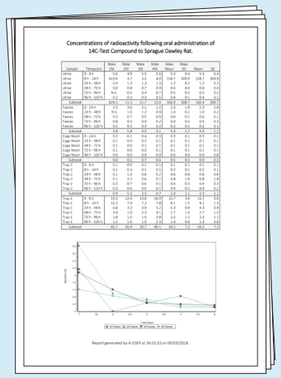
Pooling

- Pool samples across subjects or timepoints to create new samples for analysis.
- Specify percentage of original sample to split, or use a fixed amount.
- Automatically specify samples to be pooled based on dose recovery.
- Optionally capture pooled sample data, or use calculated values.

Reports

Go from raw data to final results in minutes. A wide range of reports is available, covering all functional areas of the system.

- Raw data reports.
- Summary tables for final recovery and concentration reporting.
- Instant graphical data to track sample recovery and concentration.
- Tissue grouping.
- Configurable decimal and significant figures.
- Statistical analysis.
- Normalisation of data.
- LOD and LOQ reporting rules.
- Include/exclude subjects, tissues and timepoints.



Analysis

- Direct link to our industry standard radiochromatography software, Laura.
- Create HPLC batches within Debra ready to run your analyses in Laura.
- View chromatography data in Debra for each sample; calculate and report metabolite concentrations and dose recovery.
- Link security between the two systems.

Laura™
Radiochromatography Data Collection and Analysis Software

Calculations

Calculate recoveries and concentrations taking into account parameters such as:

- Multi-dose settings.
- Variability rules.
- LOD / LOQ settings.
- Tolerances.
- Normalisation settings.

Regulatory Compliance

Regulatory Compliance is an essential feature of Debra, built to meet GLP, and 21 CFR part 11 requirements.

Electronic Signatures

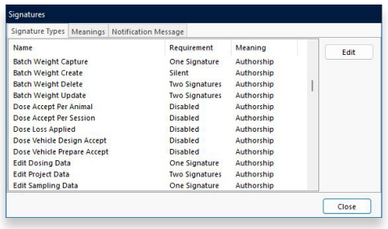
- Fully configurable for all tasks.
- Options for:

  Single signatures.

  Double signatures for peer approval.

  Silent signatures where no action is required by the user to apply the signature.

  Disabled signatures.

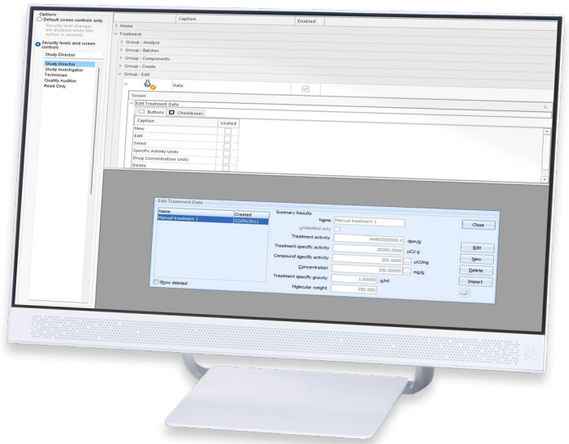


Debra's electronic signatures are in line with regulatory guidance to ensure that relevant details are captured:

- Printed name of the signer.
- Date and time that the signature was executed.
- The meaning associated with the signature (e.g. authorship, review, approval etc).

Audit Trail

- Debra provides full auditing facilities. This ensures that changes to date are tracked with reference to the new and previous value, the operator and date / time.



User Settings

- Quickly and simply configure user access and rights.

Access Levels

- Configure hierarchical levels of access.

Screen Controls

- Fully configure access to every control within Debra based on access level.

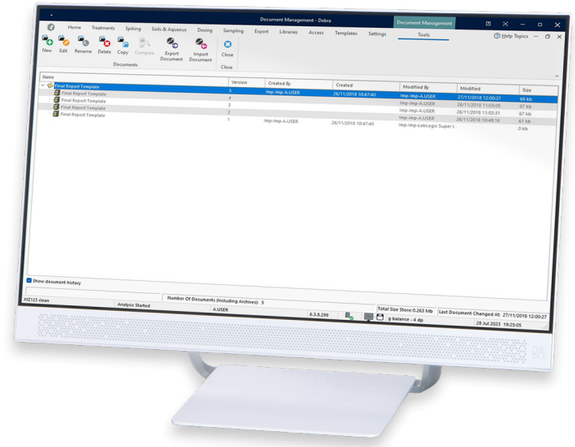
Labelling

- Generate project specific labels based on data entered into the system with just a few clicks.
- Highly configurable user-defined formats.
- Predefined label formats can be created to cover the corporate standard.
- Barcoded labels allow the user to take advantage of barcoding options for data collection to speed up processes within the laboratory and reduce the risk of user error.

Document Management System

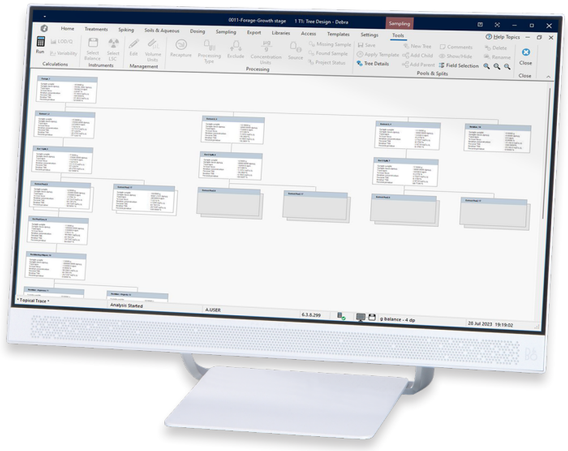
Debra's reporting package provides convenience and flexibility. Using the comprehensive range of reports in conjunction with the Document Management System to allow management of your reports in a secure environment.

- Save and track reports within the database.
- Seamlessly integrate tables, graphs and text into final reports through an automated link to Microsoft® Word.
- Quickly and accurately create final reports using standard templates linked to study-specific information.
- Record document history, highlighting changes between versions of the document.
- Define columns, print order, assign macros, add free text, size the table and its position and even specify the decimal precision of the data.



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.
- View all calculations.
- Can be used for any sample in any study, or as a stand-alone study.



Trace™
Metabolism Residue Extraction Software

Study Types

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

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.

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.
- Adsorption / Desorption extraction trees.

Topical Application

- Specify application area (ha / m^2 / cm^2).
- Specify dose rate per area.
- Specify default areas.

WBA

- 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.

A full range of services are available from LabLogic to maximise investments in Debra

At LabLogic we do not underestimate the need for a comprehensive set of services to ensure successful implementation of Debra. 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.

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.

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 system. Our Debra team include ex-scientists and users of Debra who can relate directly to any problems or questions that you may have.

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.

Bespoke Development

Debra's direction has always been dictated by the customer's needs – all functionality in the system 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.

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 who have many 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 instrument 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.

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EXPERIENCE & EXPERTISE

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ISO 9001

INVESTORS IN PEOPLE
We invest in people Gold

Certificate No: 10926
ISO 9001

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