



An ELN and Data Management System

Designed by Bioanalytical Scientists for
Bioanalytical Laboratories



“Labnotes
implementation is
expected to give us
a 3 yr net benefit of
4 million dollars”

CHAD BRISCOE, DIRECTOR OF BIOANALYSIS,
MDS PHARMA SERVICES



Labnotes is more than just an ELN...

Designed by bioanalytical scientists to enhance productivity and streamline workflows in the lab, Labnotes is both a powerful data management system and ELN. Labnotes was created to work 'out-of-the-box' to replicate existing paper worksheets and is suitable for use in tightly regulated GLP-compliant laboratories.

Who are we?

Labnotes utilises a highly successful and intuitive platform, LabsForm, created by Terrington Data Management. Our team of programming experts have extensive experience in perfecting software which sets new standards for the pharmaceutical, manufacturing, chemical, petrochemical, gas and oil industries. We're proud to include some of the world's most respected companies as our clients, including:

- Shell
- BP Chemicals
- Eli Lilly
- Celerion

Terrington Data Management worked with a team of highly skilled and experienced bioanalysts to design a network of templates and forms – creating the product Labnotes. Stringent specifications were set to ensure the software was flexible, enhanced laboratory productivity and data traceability while satisfying 21 CFR Part 11 criteria. We have since installed, validated and supported Labnotes at client sites globally to help ensure a smooth transition from paper to the electronic format.

We are driven by making sure our products contribute significantly to your success.

Why use an ELN?

More and more companies are making the transition to ELN's to enhance their data management. Every laboratory has different requirements and each ELN varies in form and function. All are intended to help improve your workflow. Labnotes goes one step further bringing additional data management features to the ELN platform and its flexibility ensures that it is suitable for your requirements both now and in the future.

Some of the key differentiators of Labnotes include:

- Advanced data capture capabilities
- Enhanced data integrity
- Streamlined workflow
- Exception reporting
- Improved productivity and efficiency
- Easy data access, sharing and collaboration (across divisions and sites)
- Integration with equipment and other applications
- Robust archiving
- Elevated compliance levels
- Detailed audit trails
- Fully customisable to fit perfectly within your laboratory
- Archives to digitally signed .xml for security and as a human readable format.





What are the features and benefits of Labnotes?

Features

- Reduction in paper
- Fully searchable data using an Oracle™ database (Microsoft SQL server also supported)
- Enhanced productivity
- SOP's and procedures can be embedded into a studies interface
- Labels with barcodes can be created and printed within Labnotes
- Calculations and thresholds embedded for calibrations
- Calculations for calibrations are dynamic and immediately visible
- Reagent location, usage and expiry is fully traceable
- Scheduling feature, for example for calibration or PM procedures
- Clear highlighting of any un-calibrated equipment
- Workflow emailing
- Web interface available
- Electronic signatures 21 CFR Part 11 compliant

Benefits

- Reduces storage requirements and associated costs
- Easier and more detailed audit trails at the click of a button
- Reduce the time taken to run routine procedures, for example the time to calibrate a pipette can be reduced by 66%
- Minimises room for error, streamlines the project
- Eliminates risk of transcription errors
- Eliminates the risk of calculation errors
- Prevents the un-authorised use of expired reagents or equipment
- Ensures routine or time-critical procedures are performed
- Allows remote access across multiple sites, aids harmonisation of procedures, no downtime required for any upgrades



What does Labnotes look like?



Using the web view you see all your groups or Apps; equipment, methods, studies, etc. Assets and forms are colour-coded. Asset details can be viewed - the asset illustrated is a balance asset.

The balance is out of calibration. To calibrate the balance you need perform a new form completion. The form automatically brings in information from associated assets - in this case the check weights and the balance asset.

Before you complete the form a pop-up box will warn you if you have selected an out-of-date asset; you must give a reason for use. In this case the reason is 'calibration'. Once completed the form generates a new expiry date.

On saving the form an automatic 'work flow' email can be generated to send to users permitted to approve the new completion



Folder Tree | Go to | Search | Administration

All Equipment

| Equipment Type | Manufacturer | Model | Equipment ID | Service Company | Expiry Date |
|----------------------|--------------|----------------|--------------|-----------------|-------------|
| Automatic analyte | Baird | Baird CS-15UL | PFT31a | Anachem | 28 Sep 2011 |
| Automatic analyte | Baird | Baird CS-15UL | PFT31 | | 28 Sep 2011 |
| Automatic analyte | Baird | Baird K202 | PFT32 | | 19 Oct 2012 |
| FGP | Glaxo | Microan K25 | SPK01 | | 08 Sep 2011 |
| Mass spectrometer | MDI Sciex | Sciex API 4000 | TQ900 | | 25 Jul 2012 |
| Mass spectrometer | MDI Sciex | Sciex API 5500 | TQ900 | | 31 Jan 2010 |
| Autogravim | Shimadzu | SH 204C | LCK49 | | 22 Jul 2011 |
| HFCC Spray Pump | Agilent | G7102A | LCF40 | | 12 Oct 2011 |
| Centrifuge | Sigma | 4010 | CEN10 | | 27 Sep 2011 |
| Fiber Luminol/iodine | Siak | Center set | FUMC1 | | 30 Aug 2011 |
| Water bath | Grant | SUB20 | WB471 | | 10 Aug 2011 |
| Thermometer | Barnon | Nivitas | TR996 | | 05 Jan 2012 |
| fridge | Labcoil | RLP900040 | FRD00 | | 30 Aug 2012 |
| Balance | Mettler | NL43679 | BALC0 | | 19 Jan 2012 |
| Balance | Mettler | NL43679 | BALC0 | | 30 Sep 2012 |
| Balance | Mettler | NL43679 | BALC0 | | 18 Dec 2012 |
| Buik | Buik | S123 | PFT11 | | 13 Oct 2012 |
| Pipette | Forapipette | F315676 | PFT02 | | 16 Aug 2011 |
| PE Scale | MDI Pharma | AP13000 | TQ900 | | 28 Oct 2011 |
| UV Spectrophotometer | 1 | 1 | SPK02 | | 13 Oct 2011 |
| Buik | 1 | Forapipette | PFT12 | | 24 Sep 2011 |
| Balance | Sartorius | BL100 | | | 24 Sep 2011 |
| Turbid | | | | | |
| Turbid | | | | | |
| Turbid | | | | | |
| Nitrogen Evaporator | | | | | |
| Nitrogen Evaporator | | | | | |
| PI Bath | | | | | |

In Labnotes you can quickly search for any properties associated with any group. In the case illustrated all the equipment can be searched for 'out of calibration' using the calendar filter. The information can also be used to generate schedules for individuals or teams of users

Schedules in Equipment

Filter by Schedule Group: All

| Form Name # | Folder | Description | Start Date | End Date |
|---|------------------------------|------------------------|-------------|-------------|
| FRM003 EQP Packed/Dispensed 10.00000 Manual | Forapipette(PFT31) | pipette calibration | 15 Jun 2012 | Open Ended |
| FRM003 EQP Bal Cal D Eq Top Pan- Manual | Balances/BALC01 | balance calibration | 15 Jun 2012 | Open Ended |
| FRM003 EQP Bal Cal D Eq Top Pan- Manual | Balances/BALC01 | PM | 15 Jun 2012 | Open Ended |
| FRM003 EQP Bal Cal D Eq Top Pan- Manual | Balances/BALC01 | BALC01 Calibration | 14 Jun 2010 | Open Ended |
| FRM003 EQP Bal Cal D Eq Top Pan- Manual | Balances/BALC01 | CALC01 calibration | 11 Jun 2012 | 11 Jun 2012 |
| FRM003 Equipment Maintenance | General Lab Equipment/CENT01 | certifcate maintenance | 28 Jun 2012 | Open Ended |

Routine procedures, such as stock solution preparation, are made simple as information is brought in from associated assets. In this case the analytical standard (in green). Calculations are built into the form, eliminating error and speeding-up form completion. All forms require an electronic signature - Labnotes is FDA 21 CFR part 11 compliant.

Stock Solution Preparation Manual
ASS003 Version 04

Compound Name: Aspirin AS ID Number: AS/YBS/00198
 Lot No: AS4346 Correction Factor: 0.936
 Expiry Date: 05 Nov 2012 Amount of AS (mg): 1000.0

Analytical Standards received as solutions
 Solution Conc (µg/mL) Volume per vial (mL)
 Solvent No of vials

Analytical Method Number: M/YBS/456
 Stock Solution ID: AS/YBS/00198/00251
 Preparation Vessel: Polypropylene scintillation vial(s)
 Balance ID: BALC02
 Tare Weight (g): 0.00000 Actual Wt. (g): 0.05000
 Analytical Standard Weight (g): 0.05000
 Required Stock Concentration (µg/mL): 1000.0
 Solvent/Reagent: Water
 Reagent ID (if required)
 Volume (mL): 46.800
 Pipette IDs: PIP102
 Storage Vessel: Polypropylene scintillation vial(s)
 Storage Location: FRD001
 Storage Condition: +4°C
 Preparation Date: 06 Jul 2012
 Storage period: 3 Month(s)
 Stock Expiry Date: 06 Oct 2012
 Approx. spillage amount (g): 0.00010
 Amount of AS remaining (mg): 949.9

Stock Solution Prepared By: Administrator (06 Jul 2012 1
 Preparation Details Checked By: Administrator (06 Jul 2012 1

Enter electronic signature to save form -- W...

Username Administrator
 Password
 Submit Cancel

Folder Tree | Go to | Search | Administration

Aspirin AS/YBS/00198/00251

| Created Date | User Name | Comment | Field Name | Old Value | New Value | Comments |
|----------------------|---------------|---|-----------------------|-----------|-----------|----------------------|
| 06 Jul 2012 14:58:08 | Administrator | Form initialization automatically updated Asset, Analytical Standards and Stock Solution/AS/YBS/00198 | | | | |
| 06 Jul 2012 14:58:07 | Administrator | Save New Asset Completion | | | | |
| 06 Jul 2012 15:54:23 | Administrator | Data Internal Linked from asset: Analytical Standards and Stock Solution/AS/YBS/00198 | | | | |
| 06 Jul 2012 15:54:07 | Administrator | Data Internal Linked from asset: 195320195320 Study Asset/1954498 Raw Material/Analytical Standards and Stock Solution/1954498 Asset Stock Solution Preparation | | | | |
| 06 Jul 2012 15:54:07 | Administrator | Updated field value | Storage Period Number | 10 | 3 | new asset completion |
| 06 Jul 2012 15:54:06 | Administrator | Data Internal Linked from asset: Equipment/Balances/BALC02 | | | | |
| 06 Jul 2012 15:53:36 | Administrator | Save New Asset Completion | | | | |

All completions are fully audit trailed. Any exception i.e. use of an out-of-date standard is logged. An archiving tool enables data to be stored as a digitally signed .xml which can be viewed without the requirement for Labnotes to be present.

What else can you expect from Labnotes and Terrington?

Labnotes was created using series of powerful tools and modules. Although Labnotes comes with a selection of ready-built templates and forms the underlying software provides you, the user, with the ability to modify the forms and settings to suit requirements, create new applications, control the security and user settings. Modules & tools include:

Form Generator

An intuitive tool enabling you to modify existing templates or design your own at the click of a button. Minimal levels of IT skills are required to create forms in-house which can be used immediately by your team.

Security Centre

This module allows you to manage Users and their access to the various applications through the use of Roles, User Groups and Program Privileges. It also allows you to configure other settings such as minimum password length and re-use of old user names.

Terrington's Services

At Terrington we works closely with all our clients and our data management expertise can be used to enhance existing features of Labnotes or create entirely new modules to suit your needs. This ensures that by investing in Labnotes you are protecting yourselves against any future changes in your requirements, better positioning your laboratory within a rapidly evolving industry.

Asset Management

Incorporated into all aspects of Labnotes is the ability to link one asset to another asset. This combined with our work flow management system, further streamlines and secures your processes. For example you must give justification before using un-approved or expired reagents, or un-calibrated equipment.

App Centre

This console manages access to, and the creation of, Labnotes Apps. In Labnotes an App can be a study/project, methods, set of equipment – any group of work in the lab. Users can be given access to an App on a per-App basis helping to control and manage work flow in the Lab.

Terrington Data Management is dedicated to supplying high quality products and services to our clients. As such, we have been assessed and certified as meeting the requirements of ISO 9001:2008 (including TickIT for Software Development).



Additionally, we take care to ensure the security of any information we hold. As such, we have been assessed and certified as meeting the requirements of ISO 27001:2005 for Information Security Management. ISO 27001 is designed to ensure the selection of adequate and proportionate security controls that protect information assets and give confidence to our clients.





Getting started with Labnotes

Labnotes is available via a client based server and our highly trained software engineers are experienced in installing software in a wide range of tightly regulated environments, either remotely or on-site. Terrington also offers a fully managed Software as a Service (SaaS) solution for all our Labnotes clients. Cloud computing is one perceived to be the fastest growing in the IT sector, with the general consensus being that SaaS will overtake traditional I.T. provision by 2015. So why are businesses choosing to take to the Cloud?

High availability and uptime - Users can access their software and data from anywhere around the world, where they have access to the internet, and at any time.

Maintenance and upgrades - Businesses can be confident that all users are working to the same version and standards whilst problems can be dealt with promptly by experienced and knowledgeable software engineers.

Financial benefits - The service is subscription based so the cost of licenses, support and upgrades are covered by quarterly charges rather than upfront payment, thereby spreading cashflows and freeing-up capital..

Efficiency - In addition to the financial benefits, SaaS deployments also save businesses their most valuable asset, time, as companies can validate and roll out quicker and without the expense of buying new equipment or internal I.T. resource that can be better utilised elsewhere.

Security and data integrity - All of your data is held in a central secure data centre which is backed up to ensure the availability and integrity of that data. We only use approved data centres that offer the latest in data protection security.



“I was surprised it was so compatible with our processes right out of the box”

SENIOR SCIENTIST, CRO

Training

We're committed to providing all our clients with comprehensive, hands-on training for Labnotes. Our trainers are experienced professional scientists themselves who have an appreciation and understanding of your business practices and workflows.

Advanced on-site training will be given to administrator level to ensure you have the highest working knowledge of Labnotes and can set up new users, new templates and new processes yourselves.

We will have worked closely with you right from our first contact to understand what you need most from an ELN. This relationship will help us to customise our training so that it's specific to your laboratory and workflows, and helps to give you a head start.

Training modules will cover the key functions, allowing you to get the most from Labnotes:

- Basic navigation and basic Labnotes principles
- Create users with embedded authorisation levels
- Form generation
- Data capture
- Workflow and data management
- Scheduling
- Searching, audit trails and archiving

Implementation within a GLP environment

Validation is a critical step when implementing Labnotes into a GLP environment. Our experienced team of scientists are also on hand to provide as much support as you may need when it comes to validation of Labnotes. If you wish to run the Installation Qualification (IQ) and Operational Qualification (OQ) phases of your validation yourselves then we can provide you with validation scripts, helping to save you the time and effort in creating them yourselves. If you want to fast-track implementation even further, then our qualified team of scientists can validate the installation and functionality of Labnotes for you on-site in order to comply with 21 CFR Part 11 requirements.

Labnotes is a powerful data management package which will enable you to optimise your processes and take your compliance to new levels. Labnotes is proven to increase efficiencies across compliant and non-compliant laboratories, and can even be tailored to suit your workflow.





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Just scan to visit LabsForm.com

We take pride in our open approach to all aspects of the software. So please feel free to ask us any questions you have about Labnotes or LabsForm. We would be very happy to discuss your requirements in detail, arrange a demonstration for you or an in-depth workshop in your laboratory. Similarly, if you require a quotation please don't hesitate to ask. We will clearly outline all considerations to ensure there are no hidden extras at a later date.

We'd like to thank you for taking the time to read this brochure and look forward to hearing from you again.