PETra™

PET LIMS Software

LabLogic

EXPERIENCE & EXPERTISE

www.lablogic.com

A purpose built Laboratory Information Management System, successfully implemented in PET facilities around the world.

PETra is a true **PET** Laboratory Information Management System (LIMS), designed specifically for use within PET production facilities, in order to improve efficiency and compliance.

Since its introduction to the market PETra has quickly become an industry favourite following **successful installations** in some of the world's most prestigious and regulated PET facilities including;

- Mallinckrodt Institute of Radiology (Washington University, St Louis, USA)
- King's College London (London, UK)
- University of Oxford (Oxford, UK)
- Memorial Sloan Kettering Cancer Research Center (New York, USA)
- A multi-site deployment at Triad Isotopes (USA)
- Plus many more...

Improved Efficiency

By managing data electronically, PETra significantly improves workflow efficiency in the following areas;

- Pre-production checks.
- Direct capture from equipment, thus eliminating transcription errors.
- Dose Requirements; storing site, customer and dose information in one manageable place.
- Barcode driven inventory management, providing you with up to date stock levels and allowing use of accepted raw material only.
- Quality Management System; SOP, CAPA, Deviation, Change Control, OOS and Trending.
- Instrument Maintenance / Calibration; ensuring equipment is maintained in accordance with your SOPs.
- Labels and shipping documents.
- Notifications for efficient communications and reminders of any tasks.
- Training / User Records.
- Audit Trail.
- Sub-batches / Drug Stability Testing.
- Security Access in accordance with regulatory requirements.
- Electronic signatures; no more missing manual signatures.

Improved Compliance

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

User access is managed via a unique login ID that is linked to users' training and skill set. Electronic signatures and audit trails are configurable and in line with the FDA 21 CFR part 11 requirements in sections 11.50 and 11.10, respectively. These functionalities ensure that you don't miss signatures where required and that retrieving audit trails for review is the effort of a few mouse clicks.

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

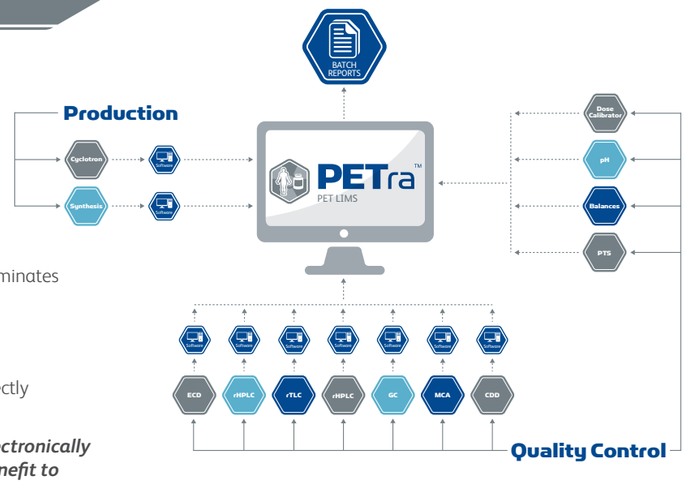
See page 6 for more features of the regulatory compliance module.

"LabLogic understand the regulatory requirements within PET. Their experience of working within highly regulated environments combined with their knowledge of compliance within PET is second to none. The PETra system is certainly ahead of the game."

Jacek Koziorowski, Chief Radiochemist, Linköping, Sweden

Direct Data Capture

During the various phases of PET production, facilities have to manage data from a range of equipment and software packages, resulting in multiple outputs and reports. What's unique about PETra, is that it captures data directly from equipment used in the process.



Eliminates Transcription Errors

As a result of direct data capture, PETra completely eliminates manual transcription and the likelihood of any errors.

Interfaces to all Equipment

PETra captures data from all the equipment either directly or by interfacing to the respective software.

"PETra collects and stores all the relevant data electronically throughout the process. That in itself is a huge benefit to us, it's now simple to retrieve information for regulatory inspections or any other purpose."

Sally Schwartz, Professor of Radiology, Washington University School of Medicine

Standardised Production

Multi-site facilities can standardise production of their radiopharmaceuticals with PETra.

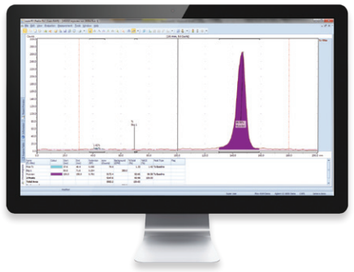
Each site can be configured to ensure the same processes are being routinely carried out, removing inconsistencies.

"The implementation of PETra has strengthened our Quality System by exposing inconsistencies and requiring greater standardisation of existing processes."

Jose Zayas, Director of Compliance, Triad Isotopes

A modular system aimed at improving workflow efficiency whilst ensuring regulatory compliance.

PETra is modular system which can be configured to suit the needs of any PET production facility. It is designed to improve efficiency whilst maintaining regulatory compliance at all stages of the PET production workflow.



Production

PETra interfaces to all the leading Cyclotron systems and integrates the key information directly into the batch report. Beam current, LOB, EOB, etc., – all directly transferred into the batch report at the touch of a button.

With the Synthesis process, PETra integrates key data directly from the manufacturers' system, no manual transcription, no data errors.

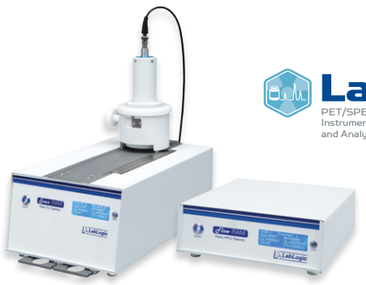
Quality Control

PETra **captures data directly** from **all** QC instrumentation used within PET production, bringing it directly into the batch report.

As some QC tests are done manually PETra allows for **manual data entry** with a full audit trail.

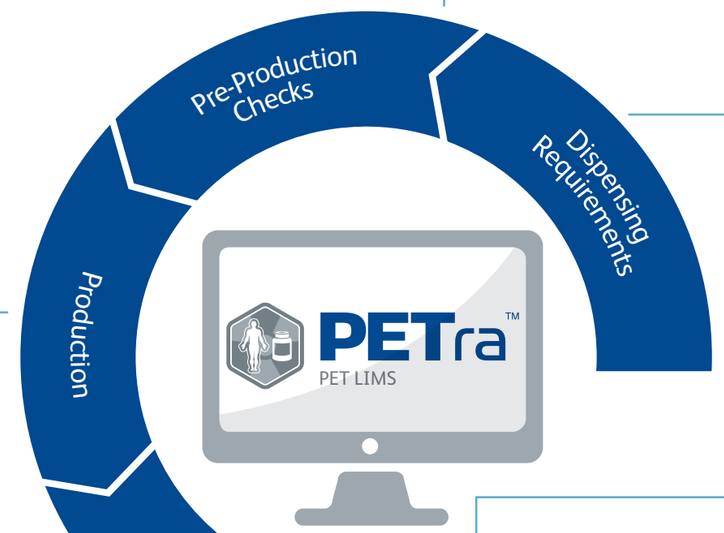
For customers wanting to streamline control of their radiochromatography equipment, we have a dedicated single point of control software package called **'Laura for PET.'**

Also see page 11 for further information on **QC solutions.**



Laura for PET™
PET/SPECT Radiochromatography Instrument Control, Data Collection and Analysis Software

QC Solutions
The Complete PET Quality Control Service

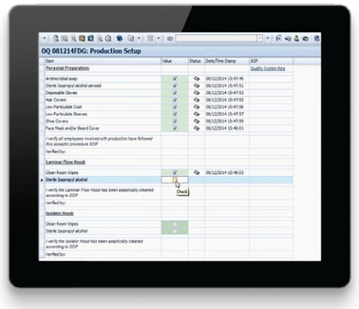


Pre-Production Checks

Often Pre-Production checks are done by completing printed check sheets where errors can occur.

In PETra there are logical **step-by-step prompts** ensuring pre-production checks fall in line with your SOPs.

PETra can also be installed on a tablet which can be carried around the facility.



Dispensing Requirements

Dispensing requirements can be entered manually, collected from on-line data systems or from bespoke in-house systems.

Using that information PETra then **automatically calculates** the required activity.

Requested Dose	Corrected Dose	Activity to Dispense	Dispensed Dose
452.00	660.21 @ 15:00	787.15 @ 14:32	50.93

Customer and Site information can also be maintained within PETra.

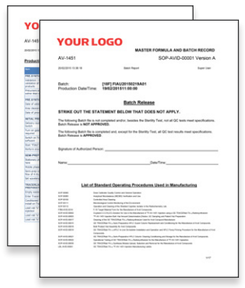
Product Release

Throughout the whole production and QC process, PETra provides a simple and logical way of reviewing batch progress. This information is available to review from any workstation allowing technicians and quality personnel maximum visibility.

Once all the required test have been completed successfully, the responsible person can electronically sign off the release.

Batch Reports

All data is consolidated in a single, central repository. This can be printed to a user defined batch report.



Additional Modules

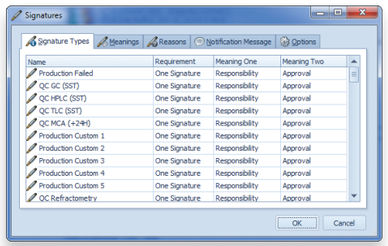
Turn to page 6 - 9 for more information on PETra's additional modules.

Regulatory Compliance

Regulatory compliance is an essential feature of PETra, built to meet GMP, Pharmacopeia and FDA 21 CFR part 212 / 11 requirements.

Electronic Signatures

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 a requirement for two signatures (the second signature normally being approval of the first for peer review).

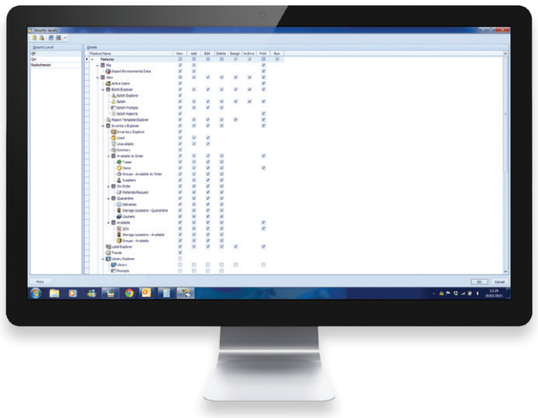


This is in line with the FDA 21 CFR part 11 requirements in section 11.50, "Signed electronic records shall contain information associated with the signing that clearly indicates all of the following:

- The printed name of the signer.
- The date and time when the signature was executed.
- The meaning (such as review, approval, responsibility, or authorship) associated with the signature."

Audit Trail

PETra provides auditing facilities so that data can be checked and validated as described in FDA 21 CFR part 11 Section 11.10 paragraph (b): "The ability to generate accurate and complete copies of records in both human readable and electronic form suitable for inspection, review, and copying by the agency." PETra provides system level control for auditing and all auditing should be enabled for FDA 21 CFR Part 11 compliance. Whenever a change is made to the data, PETra adds that change to the audit trail. The reason for any change is requested (or selection from a user pre-defined list), and the previous value, new value, operator and the date/time is recorded.



User Settings

Quickly and simply configure user settings for access, training and statistics.

Access Levels

Hierarchial levels of access can be configured within PETra.

User Groups

Users groups can be created so that relevant notifications are sent to appropriate users.

Training Records

Personnel training records can be maintained within PETra and access rights within the system linked to their training and qualifications.

Quality Management

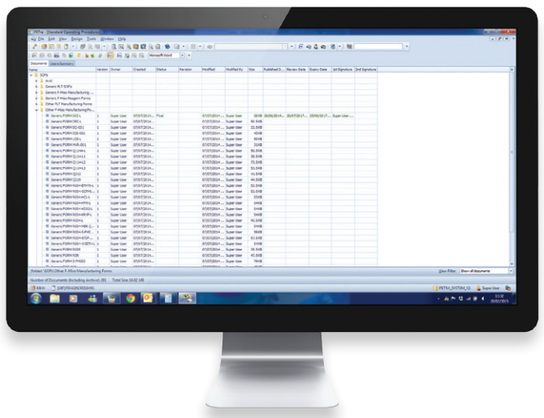
The quality management module in PETra, ensures every action is completed following predefined processes. Documentation is therefore easily and securely accessed throughout the system and completely eliminates the need for a paper chase.

SOP

- Provides an easy and intuitive way of managing SOPs.
- Operators are able to view all the SOPs on-line and alongside the applicable section.
- Reminders can be set so that the Responsible Person is notified of when an SOP is due for review etc.

Document Management

- The Document Management facility is an information portal for all types of documents, not just those subject to formal change control.
- Providing the benefit of a closed and fully auditable system.



Out Of Specification (OOS)

- Provides electronic management of the investigation of a result outside the parameters.
- The findings are maintained within PETra, can be reported at any time and progressed to CAPA, if applicable.

Corrective Action and Preventive Action (CAPA)

- This module is designed to solve problems quickly, minimise the impact of discrepancies and reduce the chance of re-occurrence.
- CAPA process in PETra ensure corrections, cause analysis and preventive actions are all recorded effectively.

Deviations

- Electronically manages any deviation from the established procedures using pre-defined forms.
- Allows for efficient and consistent data capture along with immediate corrective action.

Change Control

- Allows users to control changes to manufacturing processes.
- Changes can be drafted, reviewed and accepted by authorised users.

Notifications

- Notifications in PETra improve communication to users throughout the facility.
- They can be sent directly to a user or group, automatically generated in relation to an event or scheduled in the system.
- Notifications are very flexible and can be used for a variety of reasons including reminding people of certain tasks, communicating group messages and operational alerts.

Trending

- Any function can be analysed over time, this may be to look for variations in instrument performance or any other parameter such as synthesis yields.

Instrument Management

Information on each piece of equipment from which PETra captures data, is automatically registered within PETra. A range of tools are provided in order to help manage the instrumentation.

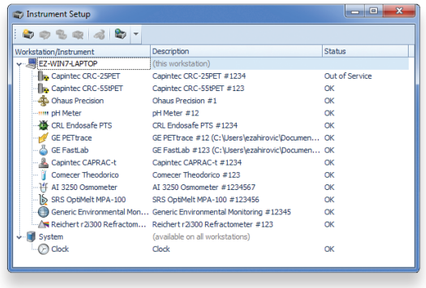
Instrument Maintenance

PETra is capable of storing and managing all instrument maintenance records.

Notifications can be set up to remind responsible people for regular checks.

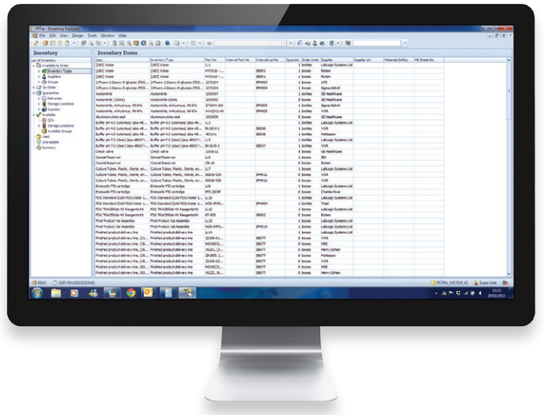
Records for each piece of equipment can be fully maintained based upon a number of key parameters, namely; Supplier, Instrument Name, Instrument Type, and Frequency of the required maintenance or tests.

The frequency may be defined as manually, week days, weekly, monthly, quarterly, annually or biannually and notifications set up accordingly.



Inventory Management

Synthesis of any radiopharmaceutical generally requires multiple raw materials. This PETra module enables you to keep track of your entire inventory along with the respective QC data electronically.



Stock Control

This powerful module provides for full chain-of-custody management of all inventory. This includes options for dealing with the ordering of items, receipt, quarantine (including on-line collection of relevant QC data) and monitoring and prompting of expired items. During production preparation items can be simply scanned into the batch using barcodes and the records are automatically checked and updated to ensure complete traceability and compliance. Add to this powerful search/find functionality, first in first out rules, user defined re-order levels and an inventory overview section, PETra really does provide a comprehensive solution to deal with all your inventory management needs.

Labels & Barcodes

To ensure compliance and traceability each product, raw material etc. is required to have an eligible label on it. The PETra Label Designer provides for configurations of various labels including; Syringe, Final Product Vial, Lead Pig, Shipping Document and Inventory labels. Each label can be customised to contain images and company logos. All labels can be created with the additional option of using barcodes to make the tracking simpler. Alternatively, suppliers own barcodes can be used.

Sometimes, it is necessary to make up 'kits' that contain numerous raw materials, the tracking of this can sometimes be challenging. However, by implementing PETra you will be able to automatically track the components and automatically generate a tracking barcode.

"Most importantly though PETra allows us to control our inventory, produce and test our PET drugs whilst compiling all the necessary information into an appropriate report. The benefit of doing this and having PETra collect data automatically from a range of equipment, is that it significantly reduces the likelihood of human error."

Sally Schwartz, Professor of Radiology, Washington University School of Medicine

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

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

Deployment Plan

The managed LabLogic deployment plan provides users a clear understanding as to what is happening and when.

Everything from client preparation, installation, training, validation and system reviews are detailed.

Installation

A comprehensive installation service is provided, using our team of PETra software developers and product specialists.

Our team is happy to work with a range of departments to ensure the system is installed correctly.

The whole installation processes is managed using tried and tested processes to ensure a trouble-free experience.

Training

LabLogic offer comprehensive user training for PETra, leaving users confident in their ability to use the system effectively.

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.

Method Configuration

As with any LIMS, it is paramount to get the system configured correctly in the first place for your particular needs. LabLogic's customers can vouch for the level of detail that LabLogic pays to this invaluable service.

Testimonials

Triad Isotopes
patient focused. community driven.

"Triad's PET manufacturing facilities are committed to providing our customers with the highest level of safety and compliance, our investment in PETra demonstrates our commitment to the highest standards of manufacturing quality.

We feel confident that this is a forward-thinking investment that positions Triad to meet and exceed the needs of our industry and our pharmaceutical partners. In the future, we anticipate this technology becoming the guiding standard for PET manufacturers, and are pleased to be on the forefront of that evolution.

The commitment from LabLogic to ensure that the system is installed successfully and configured to meet our needs has been tremendous. We look forward to working with LabLogic again on future technological enhancements."

Kerry Gillespie, President, Triad Isotopes, Inc.

"We feel they are a great group to work with. They have ensured PETra is configured to suit our needs – following various requests – and they have worked diligently alongside us to establish the preparation of the Dilute FDG batch which is required for the initial delivery to the clinic."

Sally Schwartz, Professor of Radiology,
Washington University School of Medicine

QC Solution

Are you installing a new PET QC lab? LabLogic offers off-the-shelf solutions that address whatever requirements you may have.

We ensure your lab is fit for purpose and the implementation of which is hassle free. This is with the added benefit of market leading solutions that are backed by global warranty.

Full Project Management

Our team of experienced staff will fully project manage the whole process using tried and tested methods. Having installed QC labs in many of the world's leading facilities, you can trust us, we know what it takes deliver a successful deployment.

Cost and time efficiency

Having one company supply all the equipment within the QC laboratory offers many benefits, none more so than significant cost and time savings.

QC Solutions
The Complete PET Quality Control Service

Optimise your workflow and compliance

At LabLogic we understand the need for efficient workflow processes and regulatory compliance. To help with this, we design lab layouts and utilise proven solutions to help you achieve these fundamental goals.

On the product front, the Laura for PET radiochromatography package offers a single point of control software for all related instruments. Another example is our innovative Scan-RAM; a system that is available in various configurations. One of these is radio-TLC and radio-HPLC in one system that saves you space and money.

Service and Support

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

We provide complete service and support for all of our customers to 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 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

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.

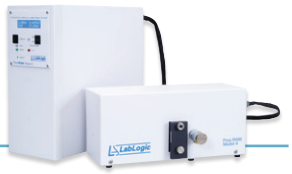
Certificates can be provided to complement your internal GLP training records.

Related Products

Scan-RAM™
PET/SPECT radio-TLC Scanner

Flow-RAM™
PET/SPECT radio-HPLC Detector

Posi-RAM™
PET Metabolite radio-HPLC Detector



Hidex AMG
Automatic Gamma Counter

SPECTra™
Radiopharmacy LIMS Software

Laura for PET™
PET/SPECT Radiochromatography Instrument Control, Data Collection and Analysis Software

QC Solutions
The Complete PET Quality Control Service

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Certificate No: 1535
ISO 9001

INVESTORS IN PEOPLE

Certificate No: 10926
ISO 9001

LabLogic
EXPERIENCE & EXPERTISE

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