PETra™

PET LIMS Software

www.**lablogic**.com

LabLogic
EXPERIENCE & EXPERTISE

A purpose-built, batch-driven LIMS, 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 workflow 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.

An investment in the future

Regarding any investment, it is prudent to look at Return on Investment (ROI). In the case of PETra, we have engaged with the PETra community to try and understand what the ROI is and this is how it was derived;

Quantifiable benefits

- Resources.
- QMS / batch record / inventory / trending management and associated costs based on salaries.
- Record storage costs.

Non-Quantifiable Benefits

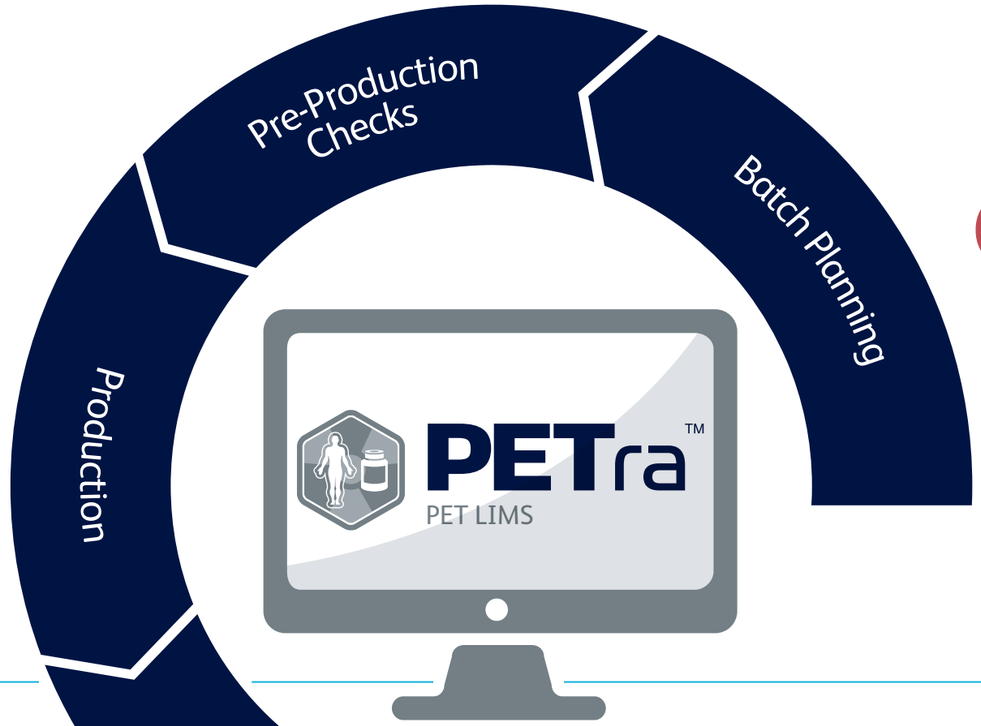
It is difficult to place a direct monetary value on the reduced risk of incorrect processing, batch record keeping and enhanced facility operations management as these are often intangible benefits.

Value Enhancement

Implementation of PETra will lead to the following value enhancements;

- Improved regulatory compliance.
- Elimination of transcription errors.
- Improved Trending functionalities.
- Improved facility operation and management.
- Improved storage and retrieval of all relevant documentation.
- Improved resource utilisation.
- Improved administrative and operational effectiveness.
- Smoother annual visits by the regulatory authorities.

Based on the above, it is estimated that ROI is anywhere between 2 - 4 years.



What our customers say

"Our decision to use an electronic LIMS instead of a paper-based system was made very early in the process. Some of my colleagues have worked with paper-based systems before, and they strongly believed that an electronic LIMS would be much more reliable than a "home-made" paper-based system, easier to validate and less prone to operator error."

"All this has proven true over the course of the PETra implementation. PETra was, and is, the most developed and complete PET LIMS on the market."

Vera Gjervan, Physicist, St. Olavs Hospital HF / Trondheim University Hospital

"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

"We chose to move to a LIMS system to simplify the work carried out in our labs using paper-based processes, which took up a lot of time and resources. Moving from a traditional paper-based system to a LIMS allows less room for miscommunication and human error with administrative paperwork."

"The more we use PETra, the easier everything is in the labs. Using PETra means we can focus on critical drug development work, rather than chasing paper."

"I am really happy with the support I receive from LabLogic. I know my suggestions are taken seriously with the support team and they have been implemented in new releases."

Paul Saliba, Quality Assurance / Production Chemist, Karolinska University Hospital

"We conducted thorough market research on other PET LIMS providers, as well as LabLogic. That included visiting an existing PETra user site and attending a LabLogic PETra User Group. As a result, it was clear to us that PETra was by far the most developed product on the market, and would be something we could not only implement but learn from."

Neanke Bouwman, Hospital Pharmacist Leiden University Medical Center

Optimised workflow efficiency

PETra significantly improves operational efficiency by managing data electronically.

- Pre-production checks can be configured in preparation for batch production.
- Configurable design of batch Production, QC and Product Release processes (through Product Method Explorer) ensure logical organisation of batch or sub-batch manufacturing records.
- Multiple-user log-ins allow for batch tasks to be performed and recorded in parallel.
- Trending of batch parameters over time enables further process optimisation, by ensuring that key areas receive the required additional focus.

Standardised Production

- PETra can be configured for multi-site facilities to ensure the same processes are being routinely carried out, removing inconsistencies.

Electronic Data Management

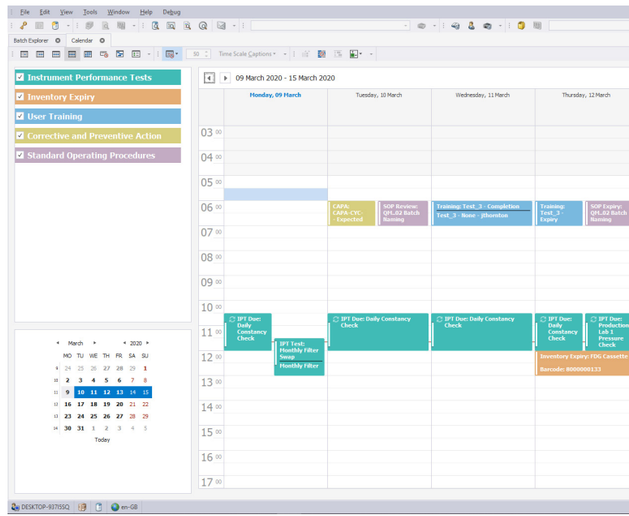
- Electronic signatures means reduced paperwork and prevents missing manual signatures.
- Barcode-driven recording of inventory improves accuracy and saves time.

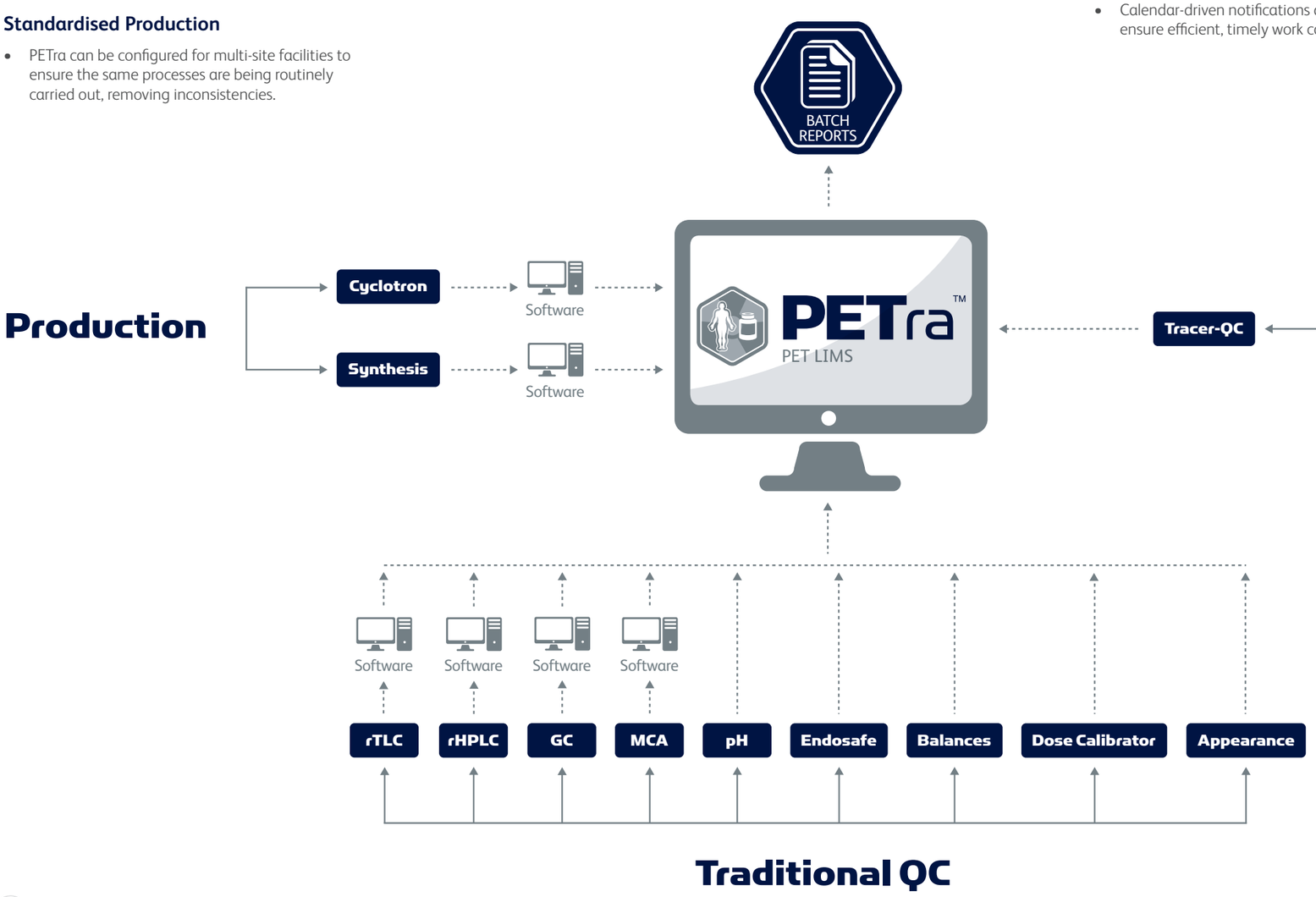
Eliminates Transcription Errors

- Direct capture of data from equipment, saves time and eliminates transcription errors.

Calendar View

- Calendar-driven notifications and task-driven reminders ensure efficient, timely work completion.





"PETra is developed with our type of production and workflow in mind. It is so clear that GMP and data integrity has been a central focus all the way during the development of PETra."

"The automatic and built-in audit trail makes the whole workflow and quality system very transparent and traceable. Functions such as automatic OOS generation and connecting deviations to batches also contribute to this."

Vera Gjervan, Physicist, St. Olavs Hospital HF / Trondheim University Hospital

Dashboards

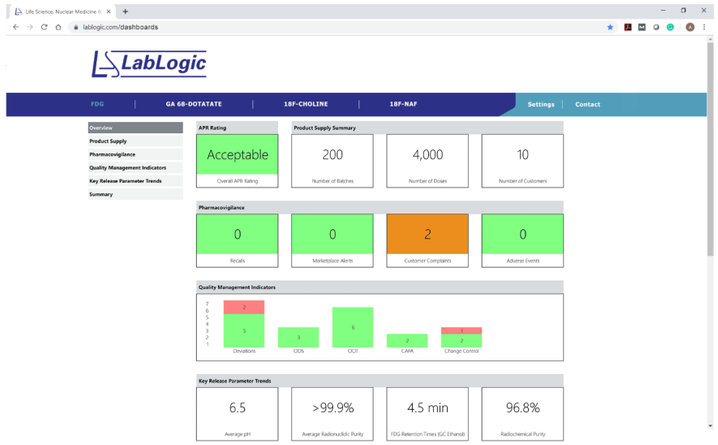
Dashboards are a way of simply and dynamically representing key performance indicators or other relevant data.

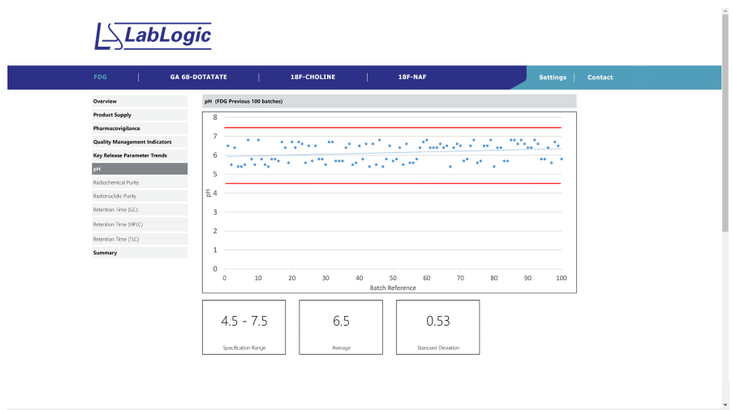
Interactive User Experience

- Data is more visually appealing, with graphs, charts and key metrics.
- Dashboards can be configured to provide users with a simple overview, allowing trends to be quickly identified and actioned.

Support for Key Reporting (e.g. Annual Product Review)

- Data and graphics from dashboards can be easily organised per radiotracer.
- Directly supports key reporting such as Annual Product Reviews, Pharmacovigilance reporting and Product Recalls.





Unrivalled regulatory compliance

PETra is specifically designed with regulatory compliance in mind. LabLogic has decades of experience of creating systems within highly regulated environments. We are confident that our systems will improve compliance within your facility.

Data Integrity

- PETra is designed to comply with ALCOA+ principles and following the latest ISPE / EMA Data Integrity guidance.
- PETra can securely capture data from all equipment and software involved in the manufacture and testing of a radiopharmaceutical product.
- As a result of direct data capture, PETra completely eliminates manual transcription, reducing the likelihood of data entry errors.
- Original data and/or true copies are permanently retained in the secure PETra database, where they can be accurately retrieved (at any future time).

User Access and Auditing Features

- User access is managed via a unique login ID and password for every user.
- User access to specific PETra modules and functionality can be directly linked to users' GMP training and certified functional skill set.
- Electronic signatures and audit trails are configurable, enabling compliance with both Eudralex Volume 4 GMP, Annex 11 and with US FDA 21 CFR part 11 requirements.
- Audit trails allow tracking of all GMP actions via a time/date/User ID stamp. Audit retrieval and review is a simple process, requiring the effort of just a few mouse clicks.

Materials and Instrument Compliance

- Barcode-driven inventory management (including live status of stock items) ensures use of only approved/released materials in your GMP process.
- Instrument Maintenance / Calibration schedules – ensure equipment is maintained in accordance with your SOPs and that only compliant instruments are used for capturing batch data.

A modular system to suit the needs of your PET production facility

Production

- PETra interfaces to all leading cyclotron systems and integrates the key cyclotron run-data directly into the batch report at the touch of a button.
- For sites with Gallium-68 generators PETra keeps track of each generator's status and available activity for use in batch planning.
- PETra also integrates key synthesis data directly from the synthesis module report.

Pre-Production Checks

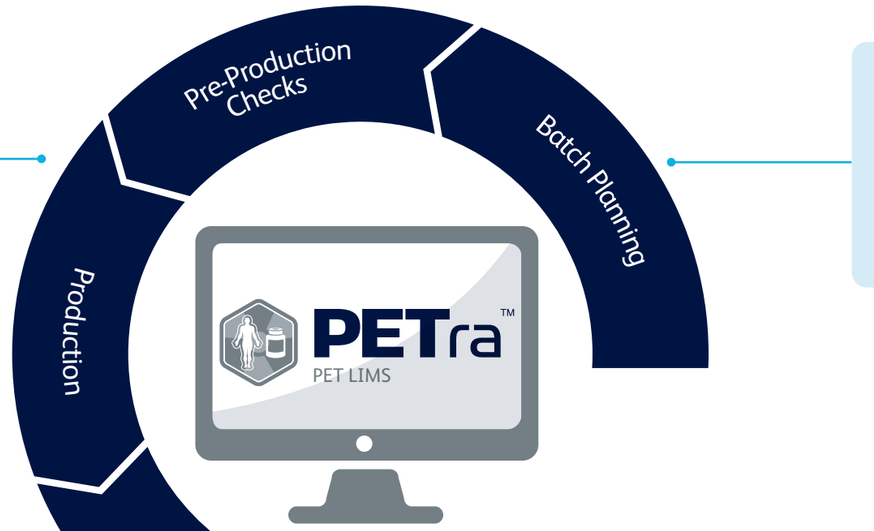
- PETra batch explorer allows daily checks to be easily performed and electronically reported prior to each day's production.
- Logical **step-by-step prompts** ensure pre-production checks follow your established procedures.

Batch Planning

- PETra includes a number of features to allow effective planning of batch manufacture.
- Features such as **Batch Planning Tool** and **Orchestration Module** enable online orders to be converted into detailed dose planning.
- Reports from various dispensing modules can be imported into the PETra batch report and the results checked against the original plan.

Traditional QC

- PETra **reports results electronically** from QC instruments, either via direct live data capture or by importing reports generated by the QC instrument.
- Where QC tests are performed 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.'**
- LabLogic's **'QC Solutions'** service provides a comprehensive package for the supply, qualification and training of most PET QC instruments (see page 18).



Batch Reports

- All data is consolidated in a single, secure database.
- Completed batch reports can be printed or saved in pdf format.

Automated QC

- PETra is fully compatible with Tracer-QC.
- Tracer-QC is an automated solution for PET/SPECT radiotracer quality control that utilises only an optical plate reader, a pipetting robot and single-use consumable kits for release testing of PET/SPECT radiotracers.

✓ **1 Sample**
✓ **1 Analytical instrument**
✓ **All QC release tests**
✓ **1 Traceable and objective report**

Product Release

- Throughout the whole manufacturing and QC process PETra provides a simple and logical way of reviewing batch progress.
- The live status of a batch is available to view from any workstation.
- When all production steps and QC tests have been completed the product can be released for patient injection by the Responsible Qualified Person (QP), using a password-protected electronic signature.

Additional Modules

Turn to page 10 - 13 for more information on PETra's additional modules.

Regulatory Compliance

Regulatory Compliance is a key feature of PETra, evident throughout the user experience and in the underlying functional design.

Electronic Signatures

- Electronic signatures are linked to a user's security profile.
- Single or second signatures are possible for any process or task.
- 'Silent' signatures allow smooth workflow, whilst ensuring actions are fully audited.
- Auditing meets GMP Annex 11 and FDA 21 CFR Part 11 requirements for recording name, date/time and reasons for an electronic signature.

Audit Trail

- Meets FDA 21 CFR, Part 11 auditing requirements to generate accurate and complete copies of records to allow regulatory body review.
- PETra audit trail can report all changes made to system configuration or to data values, including:
  - previous value and new value.
  - operator involved, along with date/time of the change.
  - reason for change.

User Settings

- Quickly and simply configure user and system 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.

Signatures

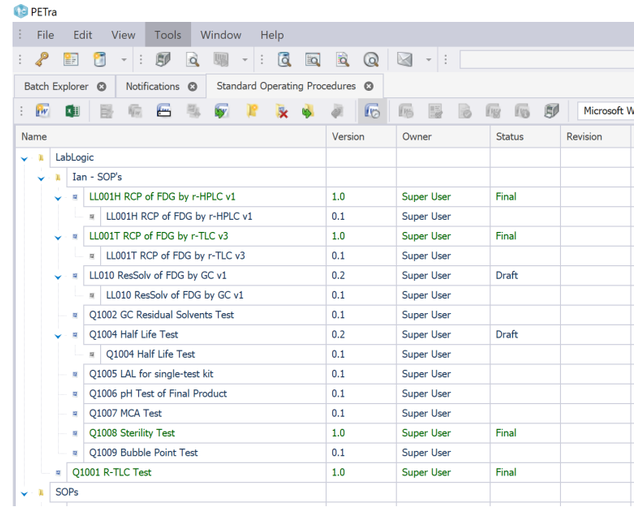
Signature Types | Meanings | Reasons | Notification Message | Options

Name	Requirement	Meaning One	Meaning Two
Production Failed	One Signature	Reject	Reject
QC GC (SST)	Two Signatures	Signing as Author	Approval given
QC HPLC (SST)	One Signature	Reviewed, no comments	Approval given
QC TLC (SST)	Two Signatures	Reviewed with comments	Approval given
QC MCA (+24H)	One Signature	Signing as Author	Approval
Production Custom 1	Silent	Reviewed, no comments	Reviewed, no comments
Production Custom 2	Two Signatures	Signing as Author	Approval given
Production Custom 3	Two Signatures	Signing as Author	Approval given
Production Custom 4	Silent	Reviewed, no comments	Reviewed, no comments

Quality Management

The QMS module in PETra, ensures that every task can be completed in accordance with your company's controlled procedures and in compliance with the applicable GMP regulations.0

Controlled documentation can be easily and securely accessed throughout the PETra application, completely eliminating the need for a paper chase.



SOP Module

- Provides an easy and intuitive way of managing SOPs.
- Operators are able to view the latest version of any SOP within the relevant section of the PETra application.
- Reminders can be set to notify the responsible person/group of when an SOP is due for review.

Document Management Module

- The Document Management facility is an information portal for storing and accessing all types and formats of documents, not just those documents which are subject to formal version-control.

Out of Specification (OOS) Module

- Provides electronic management of OOS investigations.
- OOS reports can be generated automatically during execution of a batch and can be retrieved at any time or progressed to a CAPA, if applicable.

Change Control (CC) Module

- Allows users to document controlled changes to GMP-relevant processes.
- Proposed CCs can be drafted, reviewed and authorised and their progress easily tracked through to completion.

Deviation Module

- Using pre-defined template forms this module allows the recording of any incident where a deviation from an established procedure has occurred.
- Allows for efficient and consistent reporting, including recording and auditing of any immediate actions/decisions taken following the deviation.

Corrective Action and Preventive Action (CAPA) Module

- This module is designed to document the progression of CAPAs quickly, in order to help improve process quality and thus prevent reoccurrence of common issues.
- The logical CAPA process in PETra ensures that the necessary stages of a CAPA are effectively documented from planning, through execution and reporting and allows supporting documentation to be appended.

Notifications

- Notifications in PETra drive communication between users or group of users within the system.
- They can be automatically generated in response to a new or scheduled event, such as operational alerts, or can be used to communicate group messages or used to send reminders of important upcoming tasks, such as maintenance or calibration.

Trending Module

- In PETra's Trending Module any parameter or variable can be analysed over a specified period of time, or over a series of batches, to identify performance trends, e.g. synthesis yield, pH value, radionuclidic purity, etc.

Instrument Management

Information on each instrument 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 stores key data relating to all instruments with which it interfaces.
- The instrument ID and status is traceable to all relevant data captured in the batch record.
- The instrument management module – with it is clear calendar-style overview – helps prompt users when instruments require maintenance, recalibration or requalification.

Inventory Management

Production and testing of radiopharmaceutical requires multiple raw materials. The barcode-driven inventory management module enables key stock and consumable material status to be electronically tracked.

Labels & Barcodes

- Barcode can be assigned automatically in PETra or existing item barcodes can be retained.
- Various label types can be customised in the PETra Label Designer to include, for example, barcodes, logos, dates and other batch-specific information.

Stock Control

- This powerful module provides comprehensive and fully traceable chain-of-custody management of all your inventory.
- The status of inventory items is traceable through each logical stage of the process:
  - Ordering of materials.
  - Receipt of materials into quarantine.
  - Release/approval of materials for use (availability) in the GMP process.
  - Use of materials in specific production batches.
  - Historical traceability in case of product recall or investigation.
- Inventory stock levels can be efficiently controlled in PETra, via automatically generated notifications, linked to pre-defined reorder levels.
- Logical first-in first-out rules and first-use expiry updates ensure that PETra provides a comprehensive inventory management tool for your business.

Radioactivity Stock and Waste Management Module

- Allows monitoring of the type and total amount of radioactivity held on site.
- Current and future radioactivity amounts are automatically checked against site radioactive licences.

"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

Orders

PETra can use inputs from the online dose ordering module along with details of manufactured and delivered doses to automatically generate customer invoices.

Online Ordering

- Customers can place orders via the online ordering module.
- Orders can be restricted to customer-specific products, with the ability to apply customer-specific pricing.
- Online-generated orders can be sent to the orchestration module (for a multi-site operation) or directly to the Production Planning Tool for individual sites.

Production Planning Tool

- The production planning tool allows detailed planning of radiopharmaceutical production batches on a single site.
- The module takes as its input orders for individual or multiple doses received:
  - directly from customers.
  - from an on-line ordering system.
  - from a centralised Orchestration Module.
- The module allows the production planner to:
  - confirm that the required orders can be produced with the available site resources (personnel, materials cyclotron/ synthesis modules, time & delivery constraints, etc.)
  - create an efficient production plan, meeting the ordered dosing schedule.
  - if necessary, communicate with a central orchestration planning module (see below) to formally accept/reject a request for production.

Invoice Data Management

- Seamless integration with the 'Customer Explorer' and online ordering feature where unique prices and rules are allocated to each customer and their available products.
- Quickly and simply generate consolidated invoicing data, which can be sent to the accounts department or directly onto the customer.
- User Access Levels ensure only the relevant people have visibility of customer pricing details.

Single Site Operation

Orchestration Module

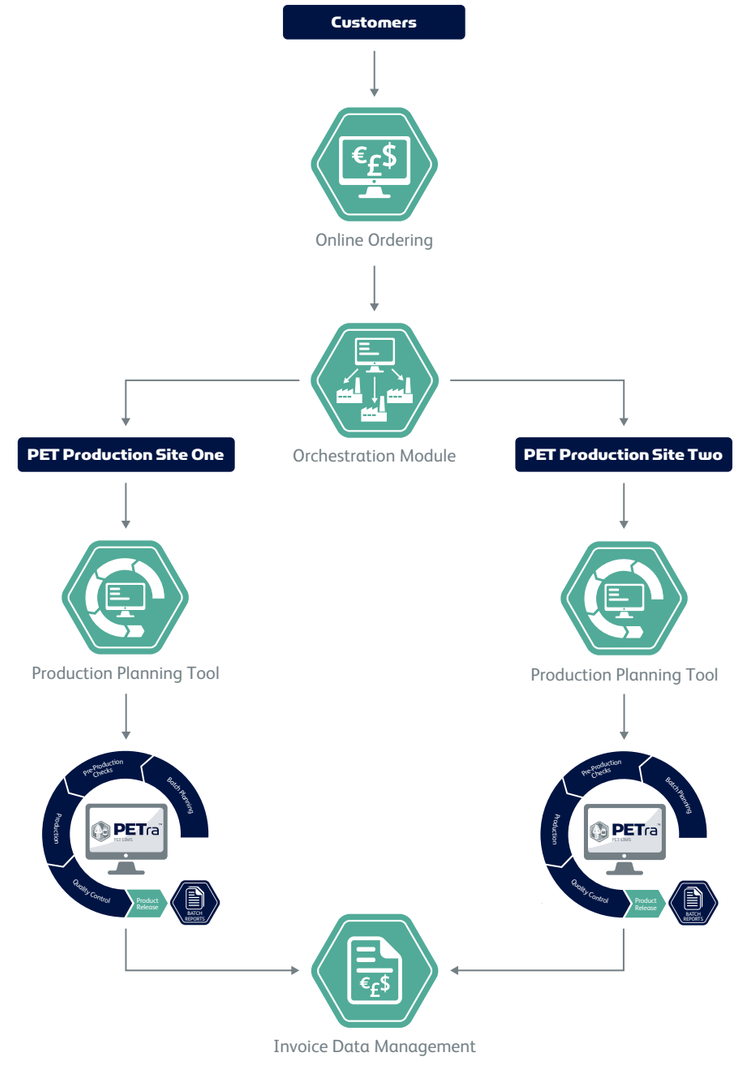
PETra's orchestration module allows a multi-site organisation to optimise the production of radiopharmaceutical doses amongst its available manufacturing sites, for any given day.

Orders for multiple customers received via a central on-line dose ordering system are input to the orchestration module.

The orchestration module allows the central planning function to allocate the optimum production site for each set of doses, based on a number of factors, including:

- manufacturing site availability / suitability.
- efficiency of pooling/transporting doses.
- requirement to provide late or unplanned (back-up) orders.
- requirement to meet other constraints, such as transit times or using specific transport methods.

Multiple Site Operation



Managed deployment plan

LabLogic understand the need for a comprehensive set of complementary services to ensure successful implementation of PETra. Our experience and unrivalled expertise in providing these over many years, is 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, qualification and system reviews are detailed.

Client Preparations

- Equipment List
- Equipment installed and networked
- BMS installed and working
- Access to all equipment and data files
- Master Batch Record
- Inventory details for the product on which the (MBR) is based

1 Kick-off and Tests

- Kick-off meeting
- Testing

2 Installation and Training

- Review configuration
- Configure and check instruments and PC set up
- 2 PETra installed
- Training
- Guided run x 2 and on 2 separate days

3 Validation

- Review changes
- PQ discussion
- Training review
- IQOQ
- Guided run x 1

4 System Review

- Feedback
- Additional training requirements
- 1 day (1 man day)

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 offers comprehensive user and advanced user training for PETra.

- Training can be performed on-site during software installation or online, via teleconferencing / screen-sharing applications.
- Training is always structured and hands-on. LabLogic specialists present the key functionalities of PETra, after which trainees complete example exercises from a structured workbook.
- LabLogic provides formal certification of completion of training and provides follow-up telephone support, as required from our PETra application specialists.
- Trained users can be confident in their ability to use and configure their system effectively, knowing that further support is always available.

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.

Maximise your investment in PETra

PETra Qualification

LabLogic's qualification services enable you to obtain maximum value and benefit from your PETra investment, within a minimal timeframe.

We work closely with your Quality Systems manager to provide a tailored PETra qualification solution, suited to your compliance needs and ready to present at your next regulatory inspection.

Our Installation Qualification (IQ) and Operational Qualification (OQ) protocols ensure you have a comprehensive, compliant series of documents.

PQ/PV Services

When requested, our additional Performance Qualification (PQ) and Process Validation (PV) consultancy services are offered with your specific process or test application in mind. We can provide advice, protocols and report templates to help you generate the specific PQ/PV data required for your Marketing Authorisation application.

PETra Advisory Committee

At LabLogic we recognise that talking about new developments and enhancements can open up innovative discussions, especially when new developments can be visualised. To enable this, LabLogic provides a platform via PETra User Group Meetings. Another, more recent platform is with the PETra Advisory Committee, where we plan to provide mock-ups of enhancements to review on a regular basis.

This is an important step forward in the development of PETra and will propel PETra developments which are, as with all our solutions, customer driven.

PETra™ PET LIMS Software Advisory Committee

"The LabLogic team have been great. They own the issue, communicate quickly and thoroughly, and resolve issues at an impressive speed. Overall, we are extremely pleased with PETra and the service from LabLogic. They really stand out compared to other hospital software providers."

Neanke Bouwman, Hospital Pharmacist
Leiden University Medical Center

Installing a new PET QC lab?

LabLogic offers off-the-shelf and customised traditional QC solutions which address whatever requirements you may have. We ensure your lab is fit for purpose, with hassle-free implementation, using 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.

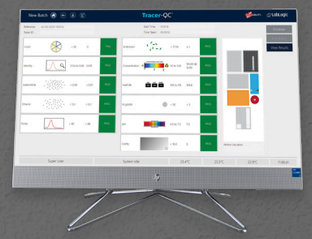
Optimise your workflow and compliance

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.

Automated QC

LabLogic and Trace-Ability have invested significantly into an automated QC solution, Tracer-QC. We recognise it is 'bottle-neck' in terms of staff and skills, so we are delighted to have the FDA recognise this and back the project. FDA Tracer -QC validation was successfully completed in May 2019.



SPECTra™

An order driven LIMS for Radiopharmacies

In PETra, each product method is specific to a product that is dependent on Cyclotron, Synthesis and many QC tests. Therefore, each product method focuses on one particularRadiopharmaceutical – the batch', thus making PETra a 'Batch Driven' solution.

Conversely, in SPECT Radiopharmacies, the production and QC is much simpler 'shake and bake/compounding' chemistry and in each production session the Radiopharmacists are typically making several different products.

As they are making them up in different ways – sometimes multidose vials, sometimes patient syringes – for patients or for other satellite hospitals – the workflow in SPECTra makes it an order driven solution.

The below diagram is intended to illustrate the differences between PETra and SPECTra as well as highlight functional similarities.

PETra™ PET LIMS Software

- Batch driven.
- Cyclotron Interface/s.
- Synthesiser Interface/s.
- Extensive QC Interface/s.

PETra™ PET LIMS Software + **SPECTra™** Radiopharmacy LIMS Software

- Central repository for all data.
- Comprehensive QMS.
- Electronic Inventory.
- Direct Data Capture.
- Produces a single Batch Report.
- Improves efficiency.
- Improves compliance.

SPECTra™ Radiopharmacy LIMS Software

- Order driven.
- Generator Elution.
- Touchscreen Interface for Clean Room.
- Dose Dispensing.
- Automated Consignments / Print Shipping Labels.
- Radioactive Stock / Waste Management.

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.

Visit our website

Download the brochure

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LabLogic
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ISO 9001

INVESTORS IN PEOPLE
We invest in people Gold

Certificate No: 10926
ISO 9001

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