SPECTra™

Radiopharmacy LIMS Software

www.**lablogic**.com

LabLogic

EXPERIENCE & EXPERTISE

A purpose-built laboratory information system

SPECTra is a true Radiopharmacy Laboratory Information Management System (LIMS), designed specifically to improve efficiency and compliance.

SPECTra is based on our market leading PET LIMS system called PETra. Since its introduction to the market PETra has quickly become the industry standard following **successful installations** in some of the world's most prestigious and regulated PET facilities including;

Optimised workflow efficiency

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

- Customer orders with consolidated invoicing information.
- Pre-production checks and worksheets.
- 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

SPECTra 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.

Direct data capture

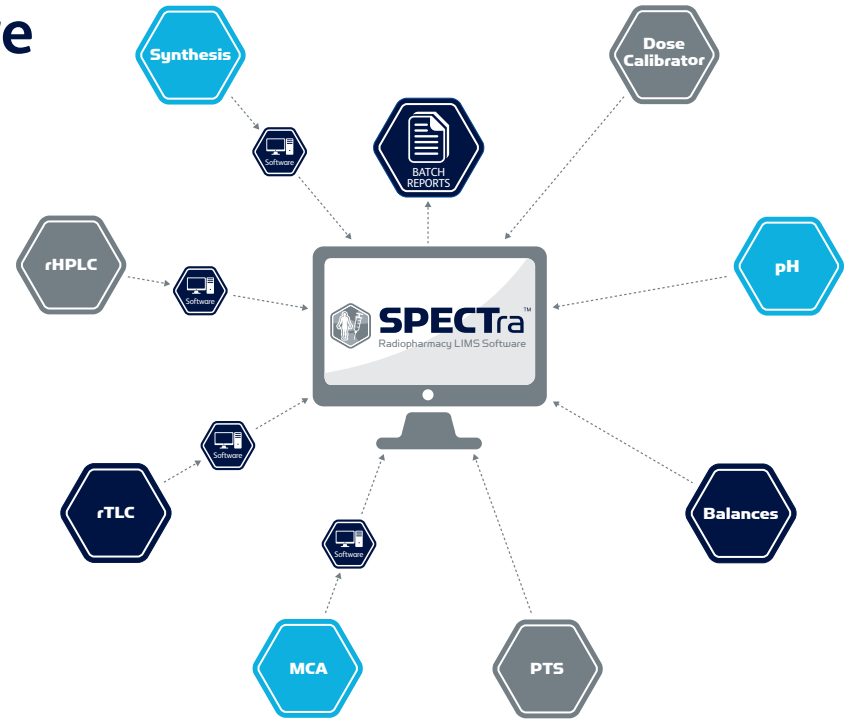
During the various phases of the workflow, facilities have to manage data from a range of equipment and software packages, resulting in multiple outputs and reports. What's unique about SPECTra, is that it captures data directly from equipment used in the process.

Eliminates Transcription Errors

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

Interfaces to all Equipment

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



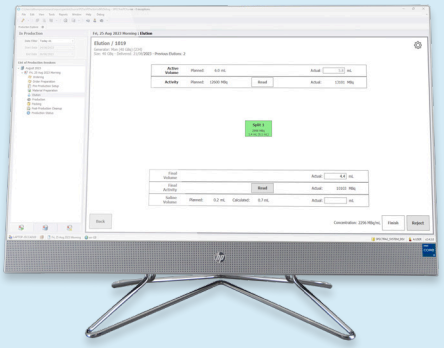
Standardised production

Multi-site facilities can standardise production of their radiopharmaceuticals with SPECTra. Each site can be configured to ensure the same processes are being routinely carried out, removing inconsistencies.

Implementing SPECTra enables LabLogic experts, alongside end user QA, to review and challenge current practices, building improvements and industry best practice into existing processes.

A modular system that improves workflow efficiency whilst ensuring regulatory compliance

SPECTra is a modular system which can be configured to suit the needs of any Radiopharmacy. It is designed to improve efficiency whilst maintaining regulatory compliance at all stages of the SPECT production workflow.



Production

SPECTra's allows you to **select the generators** you want to elute for a particular session.

Activity measurements are captured directly from the Dose Calibrator and logged against server date/time.

Calibrator daily checks are recorded directly in SPECTra – results can be reviewed in the **Trending Module**.

Activity dilutions/vial split's are calculated automatically – saving on operator time and avoiding errors in manual calculations.

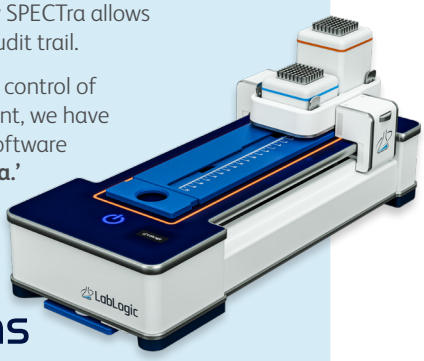
Quality Control

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

As some QC tests are done manually SPECTra 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 Radiopharma.'**

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



QC Solutions
The Complete PET Quality Control Service

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

Dispensing

Individual patient doses will be automatically calculated in-line with each customer's predefined criteria.

Direct data capture with Dose Calibrator and Balance ensure final product activity and volume are within an acceptable limit.

Product and transportation labels/documents are automatically generated and available for printing.

Regulatory Compliance

Quality Management

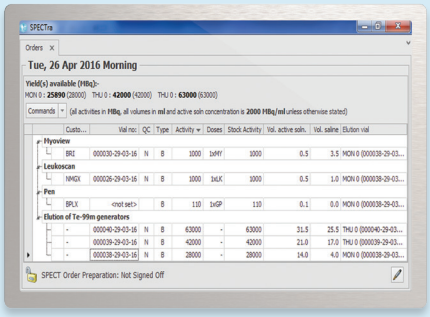
Accour

Preparation

SPECTra **automatically calculates** the required activity for a production session.

Worksheets are **automatically generated** to ensure your production session fulfils all orders efficiently.

The barcode driven **Inventory Management Module** ensures materials are available and are in date ahead of each production session.



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Orders

ECTra™
y LIMS Software

Orders

Both internal and external orders can be taken manually, with a full audit trail, or automatically via SPECTra's **On-line Ordering Module.**

Customer information including delivery addresses, unique pricing details and customised product information can be stored in the customer explorer section to ensure efficient data management.

The **Invoicing Module** seamlessly integrates with customer orders so they are tracked automatically and can be generated in just a few mouse click's.

Release

BATCH REPORTS

Product Release

Throughout the whole production and QC process, SPECTra 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 tests have been completed successfully, the responsible person can electronically sign off the release.

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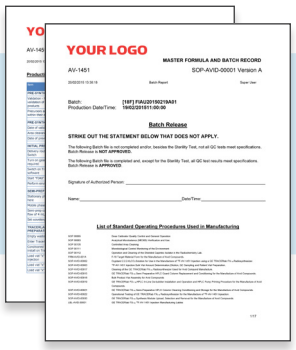
Instrument Management

Inventory Management

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 SPECTra's additional modules.

Regulatory Compliance

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

Electronic Signatures

- A signature can be required in any area of the system.
- All signatures are fully configurable.
- Administrators can disable the signatures, set a silent signature or require a single and double signature.
- Compliant with FDA 21 CFR part 11 requirements in section 11.50.

Audit Trail

- SPECTra provides auditing facilities so that data can be checked and validated as described in FDA 21 CFR part 11 Section 11.10 paragraph (b).
- Whenever a change is made to the data, SPECTra adds that change to the audit trail. The reason for any change is selected – the previous value, new value, operator and the date/time is recorded.

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 SPECTra.

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 SPECTra and access rights within the system linked to their training and qualifications.

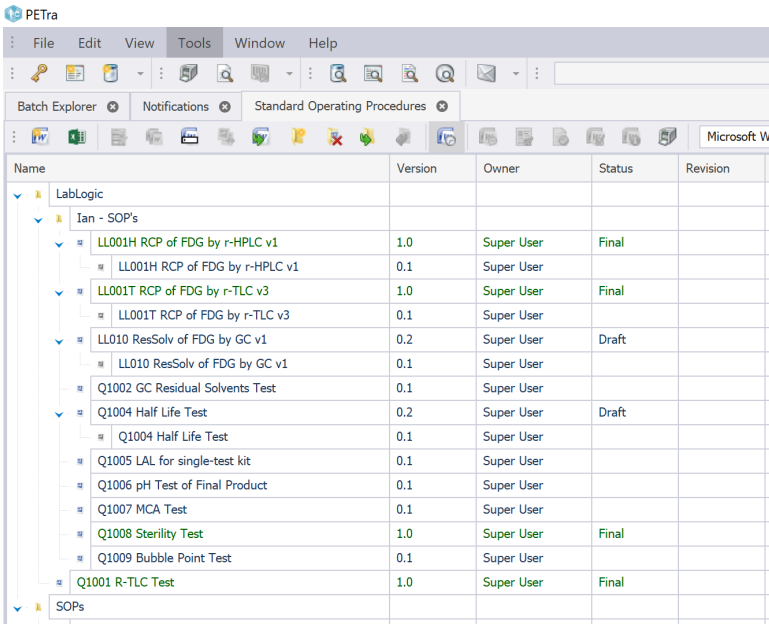
Signatures

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 in SPECTra 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 Module

- 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 Module

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

Out of Specification (OOS) Module

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

Change Control (CC) Module

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

Deviation Module

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

Corrective Action and Preventive Action (CAPA) Module

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

Notifications

- Notifications in SPECTra 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 Module

- 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.

Accounting

Automatically generate customer invoices, eliminating transcription errors and saving a considerable amount of time.

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.

Online Ordering

- Customers can place orders via the online ordering module using a predetermined product list, with customer specific pricing.
- Orders are automatically integrated into SPECTra's production worksheets. Giving real time updates on upcoming orders.
- Eliminates the need for manually processing customer orders, removing transcription errors and further streamlining the process.

Instrument Management

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

Instrument Maintenance

- Stores and manages 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 such as supplier, instrument name, instrument type etc.
- The frequency may be defined as manual, 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 SPECTra module enables you to keep track of your entire inventory along with the respective QC data electronically.

Labels & Barcodes

- Ensure compliance and traceability of each product and raw material.
- The Label Designer can produce 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.
- SPECTra can create, or use suppliers own barcodes, to simplify tracking.
- Automatically track components and generate barcodes for 'kits' of raw materials.

Stock Control

- Provides full chain-of-custody management of all inventory.
- Can deal with the ordering of items, receipt, quarantine, monitoring and prompting of expired items.
- Items can be simply scanned into the batch using the barcode feature. Records are then automatically checked and updated to ensure complete traceability and compliance.
- Powerful search/find functionality, for quick and easy access.
- First in first out rules, ensure continuous stock rotation.
- User defined re-order levels, help maintain a satisfactory level of stock.
- Inventory overview section for easy monitoring of stock.

Radioactivity Stock and Waste Management Module

- Half life decay calculations in SPECTra ensure efficient monitoring of radioactive materials.
- SPECTra allows for traceability of radioactive waste.


Shipper:

PET Center - 29 Acacia Road, London, England
(333) 333-3333 Fax: (333) 333-3333

BILL OF LADING
HAZARDOUS MATERIALS
RADIOACTIVE MATERIAL

Consignee:
Customer 1
Newark

Carrier:
Business Delivery Systems
(555) 555-5555
Ctrl. #
Driver:
Bill of Lading #

Radio-Nuclide	Chemical Form	Physical State	Type Label Radioactive	Activity MBq	Activity (mCi)	Wipe Test (dpm/cm2)	Max. Surface Rad. Level (mRem/hr)	Transp. Index*	Package/ Case #
F-18	Inorganic Salt	Liquid	Yellow-II	555	15				

Number of packages:
Deliver By:
Parking details:

To be filled by the consignee
Returned packages: _____ Delivery time: _____
Consignee signature

Wipe Counter: Capintec CAPRAC-R s/n
TI survey meter: Ludlum 14C s/n
Surface survey meter: Ludlum 14C s/n

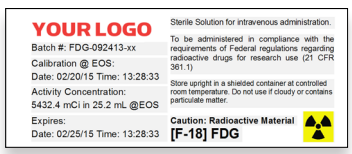
*maximum radiation level at 1m in mSv/hr multiplied by 100 (equivalent to mRem/hr)

This form is "SHIPPER'S DECLARATION OF DANGEROUS GOODS" for ground movements of RAM.
This is to certify that the above named materials are properly classified, described, packaged, marked and labeled, and they are in proper condition for transportation according to the applicable regulations of the department of Transportation.

In case of EMERGENCY, contact
(555) 555-5555

Shipper's signature

LL Shipping v1.0



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

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

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.

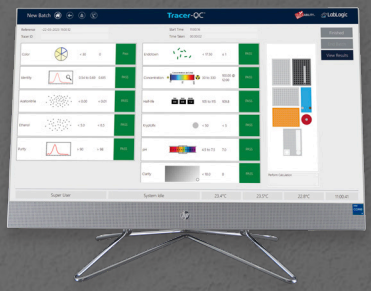
Optimise your workflow and compliance

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.



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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LabLogic
EXPERIENCE & EXPERTISE

Certificate No: 1535
ISO 9001

INVESTORS IN PEOPLE
We invest in people Gold

Certificate No: 10926
ISO 9001

Version 1.4 March 2024