**Radiation Safety** 

# Services

Equipment, Software, Training and Validation Services





www.lablogic.com

# Minimise downtime and maximise reliability

At LabLogic, we understand the need for outstanding services to allow customers to use our products quickly and easily, minimising downtime and maximising reliability.

Our team of product specialists, engineers and software developers provide unrivalled experience and expertise in the delivery of a complete range of after sales services.

If you need expert advice or assistance, help is only an e-mail or phone call away.

## Equipment

#### Service Contract

Our all-inclusive service contracts offer ultimate peace of mind. We pro-actively schedule preventative maintenance (PM) visits and will take care of all repairs at no additional cost.

As well as providing contracts for LabLogic equipment, we can also simplify your service needs by supplying cover for related third party equipment in your laboratory.

Description	Included
Unlimited call outs	Yes
Unlimited repairs	Yes
Unlimited parts	Yes
Unlimited labour/expenses	Yes
Priority response	Yes
Performance verification following repairs	Yes
Full engineer report	Yes
Remote technical support	Yes
Annual preventative maintenance	Yes
Pro-active PM scheduling	Yes
Routine PM parts	Yes
Full PM report	Yes
Refresher user training	Yes
Discounts on accessories and upgrades	Yes
Annual operational re-qualification	Optional
Full re-qualification documentation	Optional

#### Preventative Maintenance / Qualification

An annual preventative maintenance visit is the best way to keep your instrument running problem free, to specification and in many cases to ensure regulatory compliance.

LabLogic can provide a maintenance service and qualification on all of our equipment, as well as many third party systems that work in conjunction with LabLogic products. A full report is provided for your records.

#### Repairs

If you have a problem or fault with your instrument, our engineers will to diagnose and repair the fault.

We also have fully equipped service centres where instruments can also be repaired, serviced and calibrated by our qualified personnel.

If you are on a service contract, there's no need to worry – it is all included.

#### **Third Party Service**

LabLogic provide a full range of services and contracts on associated third party equipment.

As an official Agilent Value Added Reseller, LabLogic's engineers are formally trained in Agilent HPLC/GC troubleshooting, repair and maintenance, and also have experience in servicing other major brands of HPLC.

# Software

#### Support Contract

A support contract gives you the ultimate technical support capabilities, with immediate answers to any questions you may have. It future-proofs your investment by providing free and discounted upgrades, as well as priority implementation of new feature requests.

Description	Included
Unlimited technical support	Yes
Priority response	Yes
Free upgrades within version	Yes
Discounted upgrades to new versions	Yes
Full access to software release notes	Yes
Suggested validation of software changes	Yes
Software development requests	Yes
Discounted training options	Yes
ESCROW agreement	Yes

#### Software Development

Customers on a support contract can directly influence the development of the software. We are able to prioritise requests for change from customers with a support contract; we work with you to add new functionality and build the system around your needs.

#### **Technical Support**

Our team includes experienced help-desk professionals who can offer support by telephone and e-mail, as well as remote online assistance.

All issues are logged within our support database with a unique tracking number, enabling regular feedback on the status of your enquiry.

You will have unique access to the developers who write the software, our Quality Assurance personnel who can advise on validation requirements, as well as industry specialists, who are renowned for their knowledge of our products and their applications.

#### Free Upgrades

Customers on a support contract are entitled to free releases within a specified major version (e.g. Laura 5, Debra 6). Each release is accompanied with detailed software release note documentation, enabling customers to track changes and identify the benefits of implementation of the new release, as well as getting guidance on appropriate validation and testing of the change.

Future-proof your software; upgrades to new major versions are available at a significantly reduced cost to customers on a support contract.

Access is given to the customer support area of the LabLogic website via a unique login, where product documentation and new releases may be downloaded.

Customers on a contract also have ESCROW agreements for source code access and regulatory authority inspection.



# Training

Add value to your investment with a range of training options available from LabLogic.

Our fully certified training courses are delivered by product specialists and are available as off-the-shelf or bespoke packages to suit your needs.

Training delivery can include a variety of methods and materials including:

- Interactive classroom presentations.
- One-on-one training.
- Laboratory hands-on demonstrations.
- Group exercises and practice.
- Proficiency tests.
- Training guides.
- Training videos.
- Webinars.
- Pre-configured training laptops.
- Off-site training options.

#### **Introductory Training**

Every installation that we perform is accompanied by a product familiarisation training session. This takes users through the basic functions of the system to ensure they are able to start using it quickly and effectively.

#### New User / Refresher Training

We recognise that as staff changes occur, system knowledge is often either lost, forgotten or diluted. This can result in inefficiencies, or the system not being used to its full potential. To avoid this, we recommend regular refresher training, both for existing users and also for new users who are unfamiliar with the system.

If customers' systems have been upgraded since the initial introductory training, refresher training can also incorporate details on new features and functionality.

#### System Manager Training

All systems require an on-site system owner or manager who is responsible for configuration and ongoing maintenance. We will provide assistance and training during initial setup of the system, including security setup, user management, library and settings configuration and regulatory compliance.

#### **Regulatory Compliance**

LabLogic has many years experience in implementing software and hardware solutions into regulated environments. We are experts in GLP and GMP and can provide guidance on how to use your products and systems in a compliant manner.



# **Qualification / Validation**

Get your systems implemented quickly and with minimum effort using LabLogic's range of validation services.

As focused industry specialists, our validation specialists incorporate years of experience in GLP/GMP system validation, detailed knowledge of our systems, together with other industry standard systems to help you meet company and regulatory requirements.

Many highly regulated environments require software and instruments to be qualified with respect to installation (IQ), operational (OQ) and performance (PQ).

#### Installation/Operational Qualification

All installations performed by LabLogic, whether software or hardware, can include an IQ/OQ service. LabLogic has tried and tested qualification scripts for all products, saving our customers valuable time and effort.

Our team of engineers and specialists have many years experience in successfully performing qualifications in numerous facilities around the world. Use of these services has proven to be the quickest and easiest way for many customers to get their systems installed, qualified and in use.

Depending on the regulatory guidelines being worked to, regular requalification of systems may be required. LabLogic can provide this service, which is often available at a discounted rate as part of a service/support contract.

#### Performance Qualification

LabLogic can streamline the PQ process; we will work with you to understand your procedures and create suitable documentation for your systems.

#### **Bespoke Services**

LabLogic can provide expert guidance with bespoke qualification / validation services to meet the individual customer needs. We work as a partner with your Quality Manager, System Manager and users to provide a tailored validation plan suited to your needs.

# PET QC Solution

Are you installing a new PET QC lab? LabLogic offers off-the-shelf and bespoke 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 to know what it takes to deliver a successful deployment.

#### Cost and time efficiency

Having one company supply all the equipment within the QC laboratory offers many benefits, including significant cost and time savings.

#### Optimise your workflow and compliance

At LabLogic we understand the need for efficient workflow processes and regulatory compliance. We optimise your lab layouts using compliant instrumentation and software to help you achieve these fundamental goals.

On the product front, Laura for PET, radiochromatography software offers a single point of control for key QC instruments.

Our innovative Scan-RAM system is available as a standalone radio-TLC scanner, or as a dual-functioning radio-TLC and radio-HPLC system, optimising your workflow and saving you time, space and money.

#### 1. Plan

At the planning stage, LabLogic offer comprehensive, in depth consultation service to ensure the lab will be equipped as required.

#### 2. Procure

Once the list of equipment needed is agreed, LabLogic will take full control of the procurement process.

As a leading manufacturer of PET QC equipment, with links to all other major manufacturers, this process is made significantly quicker and more cost effective.

#### 3. Design

With the equipment sourced, LabLogic will optimise the design of your laboratory with ergonomics, efficiency and safety in mind.

We can work closely with designers and architects to ensure that utilities, technical gases and network points are located to meet the optimised instrument arrangement.

#### 4. Deploy

LabLogic understand that just supplying the correct equipment is not enough. We therefore create and execute a detailed deployment phase, including all the necessary services:

- 1. Planning & Preparation for on-site activities.
- 2. Shipping, Installation & Testing.
- 3. Validation & Training.
- 4. System Review and Handover.

# EXPERIENCE & EXPERTISE

# **Radiopharmacy GMP**

LabLogic recognises that GMP compliance is no straightforward task, it requires a good understanding of GMP principles, document requirements and their application in a radiopharmacy setting.

Our range of consultancy and training services, as well as tried and tested document templates have been created to make the implementation of GMP smoother in your facility.

Services can be tailored to suit the needs of organisations of all sizes, whether you need assistance through the whole process or simply help in specific areas.

#### Consultancy

LabLogic's consultancy services can be tailored to suit the needs of your organisation. Popular GMP consultancy services include:

**GMP Review:** Prior to a regulatory audit, LabLogic can offer an independent assessment of your facility's GMP compliance.

**QC Lab Design**: Based on your schematics or architectural drawings, we use our extensive knowledge of QC requirements to define the optimal arrangement of the laboratory equipment within the space available.

**Process Validation:** Our experts can help you prepare for a successful Process Validation (PV), by ensuring that the essential pre-requisite operations have been planned and are in place.

	LabLogic	Site Master File
	SITE MASTER FILE 1 SCOPE OF DOCUMENT	
	2 REFERENCES	
	3 GENERAL STE AND COMPANY INFORMATION     1. Bird Information on the company	4 4 4 t on the site 5 5 5 6 6 6
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#### Documentation

LabLogic can help tackle the mountain of paperwork required when implementing GMP. We have valuable experience of completing these documents across numerous facilities, with tried and tested document that are templates ready to go.

Specific areas in which can help include:

- Site Master File (SMF).
- Validation Master Plan (VMP).
- Quality Assurance Procedures.
- Manufacturing Procedures and Batch Records.
- IQ / OQ / PQ.

#### Training

#### **Basic GMP Training**

A knowledge and appreciation of GMP is essential for staff at all levels in order to meet the demands of manufacturing and testing a radiopharmaceutical product. LabLogic offers flexible and structured GMP training to prepare staff for working within this demanding but essential regulatory environment.

#### Advanced GMP Training

We offer flexible and structured courses for individuals and small groups in order to develop an in depth understanding of what is required to prepare for a regulatory audit.

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