GMP Services

Consultancy, Training and Documentation
for Radiopharmaceutical Production

LabLogic
EXPERIENCE & EXPERTISE

www.lablogic.com

GMP compliance with help from the experts

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. So whatever your requirements, just contact LabLogic we will be happy to discuss them with you.

Consultancy

GMP Review

Prior to a regulatory audit, LabLogic can offer an independent assessment of your facility's GMP compliance. The review will assess your site's readiness for inspection by the regulatory authorities.

The extent of the review will cover 2-3 days of inspection, followed by a feedback summary report. Key areas of inspection will include:

- All key documentation within the Pharmaceutical Quality System (VMP, SMF, PV, QRM, QC & QA procedures, batch records, etc.)
- Manufacturing process workflow.
- Product testing (QC) and release procedure.
- Environmental Monitoring and sterility assurance.

Process Validation

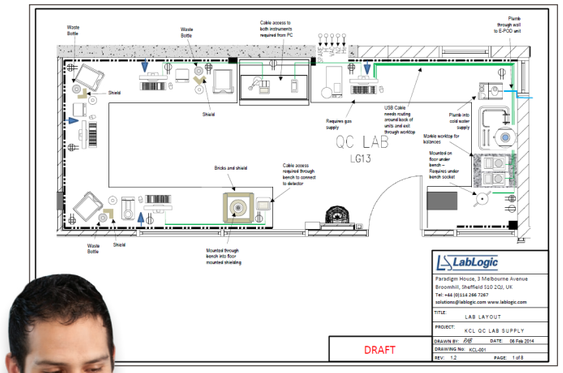
Our experts can help you prepare for a successful Process Validation (PV), by ensuring that the essential pre-requisite operations have been planned and are in place.

All aspects of PV required for supporting a Marketing Authorisation application are covered in the service, including PV processing runs, stability studies and aseptic process validation (APV, media fills).

Media fills are a key part of the overall PV exercise and we offer a bespoke service, including protocol development and training in APV techniques.

QC Lab Design

LabLogic have been consulted to help design numerous radiopharmacy QC labs around the world. 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.



Documentation

Site Master File (SMF)

Your Site Master File (SMF) should describe all GMP-related activities on your site. Lablogic can assist you in completing this important regulatory document.

Validation Master Plan (VMP)

GMP requires that all validation activities should be planned with a Life Cycle approach in mind.

We can ensure that the scope of your validation activities are comprehensively detailed and planned, using the most up to date Risk Management and life cycle principles.

Working from our tried and tested planning template, LabLogic will work with you to define and plan the following VMP components.

- Scope of facilities and processes to be qualified.
- Key roles and responsibilities.
- List of protocols.
- Key test acceptance criteria.
- Time-line planning for Qualification and Process Validation activities.
- Ongoing Process Verification.

Quality Assurance Procedures

All manufacturers of radiopharmaceuticals are required to implement and maintain a comprehensive Pharmaceutical Quality System (PQS). This system, should include a series of version controlled Quality Assurance Procedures (QA SOPs).

The GMP requirements for the key QA SOPs are embedded in LabLogic's PETra (PET LIMS) Quality Management module. These include:

- Change Control.
- CAPA.
- Deviations.
- Out of Specification.

LabLogic also offers support for development of other customised QA SOPs.

Manufacturing Procedures and Batch Records

For LabLogic's PETra PET LIMS customers we offer help with development and customisation of local manufacturing procedures and processes.

As part of the configuration of the PETra system, we naturally gather important information about the manufacturing process in order to create the batch record for each product/molecule.

This detail can be developed as operating procedures and can be stand alone or embedded directly into the batch records.

IQ / OQ / PQ

LabLogic offers installation, operational and performance qualification on all equipment supplied. We have tried and tested qualification scripts for all products, saving our customers valuable time and effort.

Our team of engineers and GMP 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.

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.

We can offer on-site, classroom or web-based training covering the following topics:

- The importance of GMP.
- Awareness of the key areas and structure of GMP.
- Understanding the application of GMP within your radiopharmacy.
- Planning and preparation for working in a GMP environment.

Advanced GMP Training

LabLogic is renowned for supplying and manufacturing QC equipment, software and LIMS for radiopharmacies worldwide. We can therefore offer advanced training in relation to these areas of expertise.

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.

Before the opening of a new facility, it is extremely useful for staff to gain hands on experience. LabLogic can arrange training at one of our existing customers sites, providing an insight into using similar equipment within an active, GMP-compliant radiopharmacy.

We can offer on-site, classroom or web-based training covering the following topics:

- PET LIMS GMP.
- Quality Control GMP/GLP.

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