

QUALITY CONTROL TECHNICAL TRAINING

5 DAY RADIOPHARMACEUTICAL QUALITY CONTROL TRAINING
OF CUSTOMER STAFF AT THE ELYSIA-RAYTEST TRAINING LAB

Training is focussed on quality control of tracer ^{18}F -FDG and includes practical exercises in our radiochemistry laboratory.

- 18F-FDG QUALITY CONTROL TRAINING TO EUROPEAN PHARMACOPOEIA STANDARDS
- DIRECT HANDS-ON INSTRUMENT TRAINING WITH PREPARATION OF SUITABLE STANDARDS AND REAGENTS
- THEORETICAL TUTORIAL ON QUALITY CONTROL OF RADIOPHARMACEUTICALS
- PRACTICAL TRAINING AND EXERCISES IN THE ELYSIA RADIOCHEMISTRY LABORATORY



Quality control technical training is typically organized at Elysia-Raytest headquarters in Liège, Belgium. Training commences with theoretical instruction on quality control of ^{18}F -FDG and compliance with regulatory requirements. Furthermore training takes place in the radiochemistry laboratory where reagents and standard solution needed for the ^{18}F -FDG QC will be prepared with the attendees. These solutions are then used during the analysis needed to release ^{18}F -FDG. Attendees discover the critical performance of the analytical methods that must be monitored (calibration, baseline stability, suitability test...) as well as QC work-flow. This training also offers the opportunity to apply and utilise the hardware and software required to carry out the analysis.

PROPOSED TRAINING PROGRAM

Day 1: Welcome and General Overview

- Welcoming and Introduction tour
 - Facility visit
 - History of Elysia-raytest
- General overview: Quality Control for F18-FDG
- Detailed discussion of the tests based on the regulatory relevant documents (monograph, guidelines etc.)
- Required analysis and linked specifications, instruments needed for these analysis and options available to perform the test. For each test : needed reagents, materials, standard preparation will be discussed during the laboratory practice.
- Overview of laboratory equipment

Day 2 & 3: Chromatographic analysis (HPLC, radio-TLC and GC) training based on 18F-FDG

- Instruments presentation (general overview, presentation of HPLC instruments and of the different modules (detectors, specificity, etc.), Presentation of GC and radio-HPLC system
- Quick system set-up, how to prepare systems to analyse alternative compounds (multi-PET HPLC)
- Software operation (18F-FDG preparation, system-baseline monitoring, calibration file management, run analysis, critical points for radiopharmaceuticals)
- Practical lab exercise (18F-FDG) : system preparation, injection of a standard, injection of a QC sample, preparation of the report (preparation of template files), how to analyse data

Day 4: Non-chromatographic measure

- Radionuclide Purity and identity with a multichannel analyser :
Instrument set-up (parameters, configuration), recording a spectrum, system calibration, importance of efficiency curve, data analysis for 18F-FDG
- Further instruments
 - Activimeter
 - pH Meter
 - Osmometer
 - Endotoxin test

For each test/instrument :

- Presentation of the hardware components, software and acquisition programs, data analysis
- Practical lab analysis on a sample/standard related to 18F-FDG

Day 5: Summary and review of all analysis

- Review and discussions of analysis performed
- Analysis of an unknown sample of 18F-FDG, a radioactive sample will be analysed during training, the exact day for this "hot" analysis will depend on the production calendar.

Requirements for trainees

- Chemical education (bachelor or master degree in pharmaceuticals, chemistry or physics)
- Good level in both written and spoken English.
- Max. 3 trainees per session

Comments

The above standard 5 days agenda is given as an example. Depending on the customer's experience and laboratory configuration, the agenda can be adapted.

Elysia-Raytest recommends to plan this training a few weeks before the QC laboratory installation at the customer's site. This allows attendees to anticipate installation by preparing some SOP's, to have a better understanding of the site requirements or accessories needed (source, standard, etc.).

Included : pick-up at airport and hotel.

Excluded : travel expenses, hotel and food for the attendees.

