QUALITY CONTROL APPLICATION TRAINING

5 DAYS ONSITE 18F-FDG QUALITY CONTROL TRAINING

Training is focussed on quality control of 18F-FDG and includes practical exercises at the customer's radiochemistry laboratory, using installed Elysia-Raytest equipment.

- 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 CUSTOMER'S RADIOCHEMISTRY LABORATORY

Quality Control Application Training is conducted at customer's site directly after installation of the instrumentation. The training commences with the theoretical part on 18F-FDG quality control and how to comply with regulatory requirements. The second part of the training takes place in the QC laboratory where reagents and standard solutions, needed for 18F-FDG QC, will be prepared. These solutions are then applied during analysis required to release 18F-FDG. Attendees will discover the critical performance of those analytical methods requiring monitoring (calibration, baseline stability, suitability test etc.) as well as QC work-flow.

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PROPOSED TRAINING PROGRAM

Day 1: Introduction and General Overview

- General overview: Quality Control for F18-FDG
- Detailed examination of the tests based on the regulatory relevant documents (monograph, guidelines...)
- Required analysis and linked specifications, instruments needed for these analysis and options available to perform the test. For each test : necessary reagents, materials, standard preparation will be discussed during the laboratory practice

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

- Instruments presentation (general overview, presentation of the HPLCs and of the different modules (detectors, specificity, etc.), Presentation of GC and radio-HPLC system
- Part of basic system set-up, how to prepare systems to analyse alternative compounds (multi-PET HPLC)
- Software operation (methods for 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 the efficiency curve, data analysis for 18F-FDG
- Further instruments
  - Activimeter
  - pH Meter
  - Osmometer
  - Endotoxin test

For each test/instrument :

- Short review of the Elysia basic Quality Control instrument training, software and acquisition program, data analysis
- Practical lab analysis on a sample/standard related to 18F-FDG

Day 5: Summary and review of all the analysis

- Review and discussions of analysis performed
- Analysis of an unknown sample of 18F-FDG
- Analysis of a 18F-FDG batch

Requirements for trainees

- Chemical education (bachelor or master degree in pharmaceuticals, chemistry or physics)
- Good level in both written and spoken English.
- Max. 5 trainees per session

Site requirements

The following materials have to be available the first day of the training:

- Elysia-Raytest QC starter kit
- 5L of water HPLC grade
- Attendees should have followed the basic Quality Control equipement training
- Suitable calibration source for ionization chamber, gamma spectrometer, TLC-scanner and radiodetectors
- Cold 18F-FDG sample and „hot" 18F-FDG samples for the second part of the training (day 3 to 5).



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