International Conference on Clinical PET-CT and Molecular Imaging (IPET2015)

IAEA-CN-232-180P

Quality Assurance and Quality Management System in Radiopharmaceuticals Production at the Uruguayan Centre for Molecular Imaging

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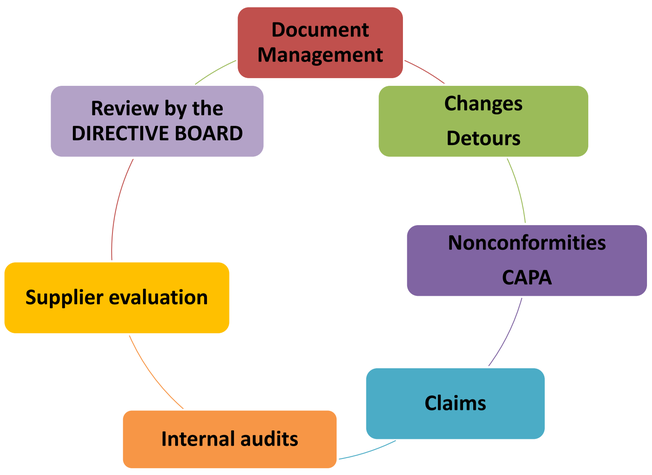
The Uruguayan Centre for Molecular Imaging started on 2010. The goal in the clinical area is to perform molecular imaging studies of oncological, neurological and cardiovascular diseases. For this purpose 13 radiopharmaceuticals of ^{18}F, ^{11}C, ^{15}O, ^{13}N and ^{68}Ga are produced on routine basis.

View of building

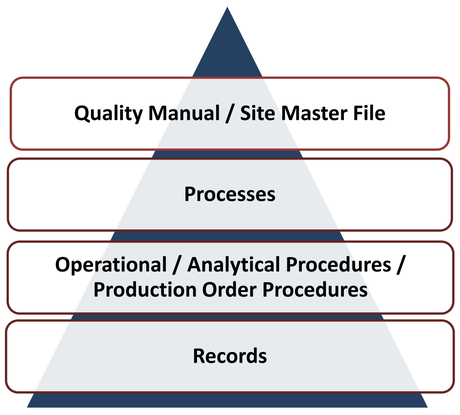
^{18}F	FDG
	FLT
	FMISO
	Fluorine
^{11}C	Choline
	Methionine
	PIB
	Deuterodeprenyl
^{15}O	Water
^{13}N	Ammonia
^{68}Ga	DOTATATE
	Gallgas
	PSMA

Quality and safety are considered priorities in our facility. Radiopharmaceuticals are manufactured according to the guidelines of Good Manufacturing Practices (GMP), which require the manufacturing and testing of products in a specified and controlled manner ensuring the application of validated processes and procedures. While the GMP guidelines are the basis for manufacturing radiopharmaceuticals, the management of quality in the finished product and integration of the internal policies and procedures of the organization have been achieved through a well-defined and executed quality management system (QMS).

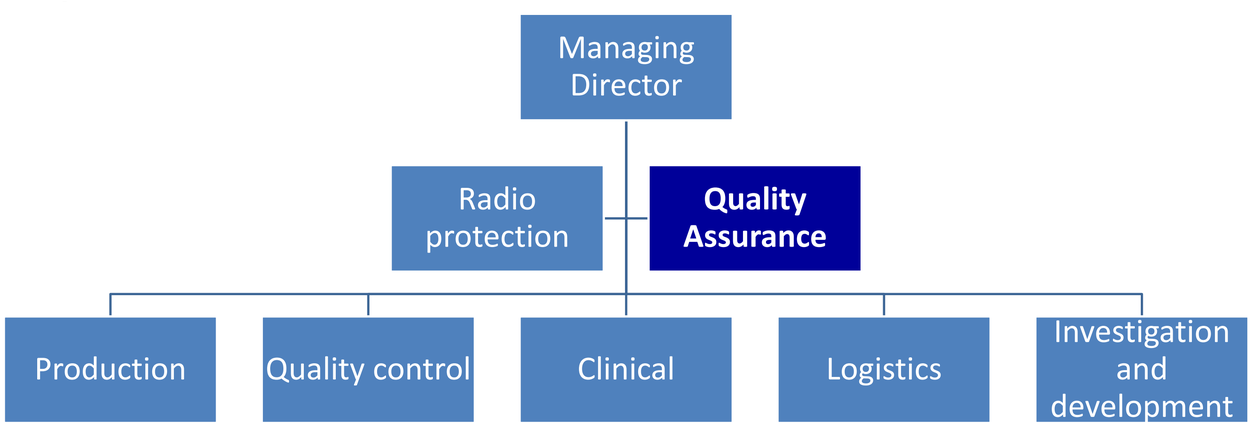
Tools for Quality Assurance



Documentary pyramid



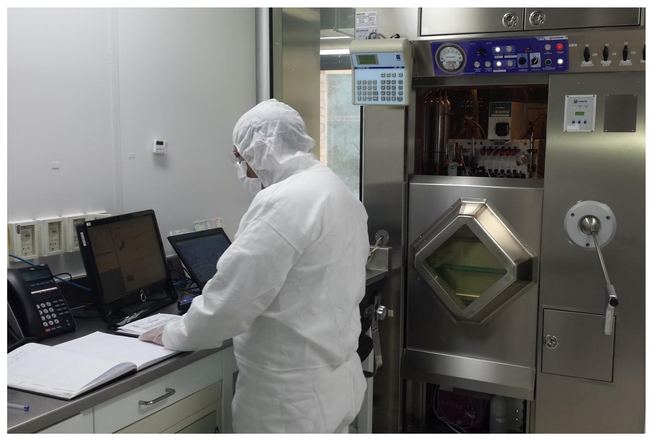
This system applied and supervised by the Quality Committee of CUDIM, integrated by representatives of each working area and leaded by an external responsible.



Quality Committee

Coordinator: Responsible for quality
Secretary: Representative of the Production area
Representative of the Production area
Representative of the Clinical area
Representative of the Logistics area
Representative of the Pharmaceutical Research and Development area
Representative of the Biomedical Research and Development area

Good documentation is one of the key issues to a good quality assurance program and consequently the following documents have been created and are used as a tool of the GMP system.



View of the production area

View of Quality Control Laboratory

Documents in the CUDIM quality management system

- Site Master File (SMF), including information about the quality management policies and all the activities of CUDIM
- Manuals (Radioprotection Manual, Emergency Manual)
- Standard operation procedures (SOP) for production and QC of each radiopharmaceutical
- Instructives describing how to work and maintain each equipment used for this purposes
- Completed batch reports
- Reports of working conditions (environmental, equipment's, staff)
- A validation plan is also being developed, including how production, quality control and staff management is performed. So this includes products, equipment and process validation

Staff training in CUDIM

Another key point of the QMS is to have highly educated personnel, that has also been provided with specific training and to implement a continuous education program. These standards have been achieved in part through IAEA cooperation that provided fellowships and expert missions.

Conclusion

As a result of the Quality Management System established in CUDIM more than 11.000 studies have been performed in last 4 years using high quality and safety radiopharmaceuticals.

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