

QC-CUBICLE

V2

INTEGRATED QUALITY CONTROL LAB FOR RADIO-PHARMACEUTICALS

A FULLY INTEGRATED AND MODULAR
QC SOLUTION ON 1,4M² LAB SPACE



- COMPACT
- FOLLOWING FDA & EU PHARMACOPOEIA QC STANDARDS
- REDUCES TIME FROM INSTALLATION TO ACCREDITATION
- PAPERLESS DOCUMENTATION FOR DATA SECURITY AND REDUCING HUMAN ERROR

The QC-Cubicle is an all-in-one solution for the Quality Control of radio-isotope labelled radiopharmaceuticals. The basic system incorporates all the hardware needed for Quality Control tests of radio-pharmaceuticals according to the European Pharmacopoeia. It can be easily tailored to your present or future tracers.

It has been designed to save space and to permit optimally efficient workflows. The complete QC system, including local shielding, can be fitted into 1,4m² lab space.

In addition to the high-end hardware, the QC-Cubicle comes with extensive software and service package enabling the setup of a complete QC lab in a very short time.

Hardware



The QC-Cubicle is modular and can be adapted to your personal needs and regional legislation. The core system contains all the hardware needed for the Quality Control of radiopharmaceuticals according to the European pharmacopeia or the FDA regulations.

We propose different extension modules, for the preparation of the samples and for additional tracers. The additional tracer modules allow for the integration of additional bench space, room for a second HPLC and additional storage capacity.



Radiation protection and environmental control



One aim of the QC-Cubicle is to increase the safety of the users. To reach this goal we have increased the radiation protection with specific shielding and an improved environmental control. Additional lead shielding on sensitive parts and some small handling tools reduce the risk of irradiation during the QC and the sample preparation.

The extraction of GC gases and the use of a hydrogen generator decrease the risk of using hydrogen and of radioactive gas evacuation during the QC. The inbuilt shielded waste systems offer an optimal waste management and user protection.

To ensure that your QC can be done even in case of a power failure, the QC is secured for 20 minutes by the built-in UPS battery pack.

Additional sample preparation module

The sample preparation module has been designed to optimize the workflow whilst increasing radiation protection for the user. It comes with built-in waste containers and a shielded storage compartment for the daily production and decontamination.



The module is delivered with some special sample holders, small shielding and working tools to facilitate the work and to minimize the hands-on time. The automatic door opener for the waste makes the work smooth and easy.



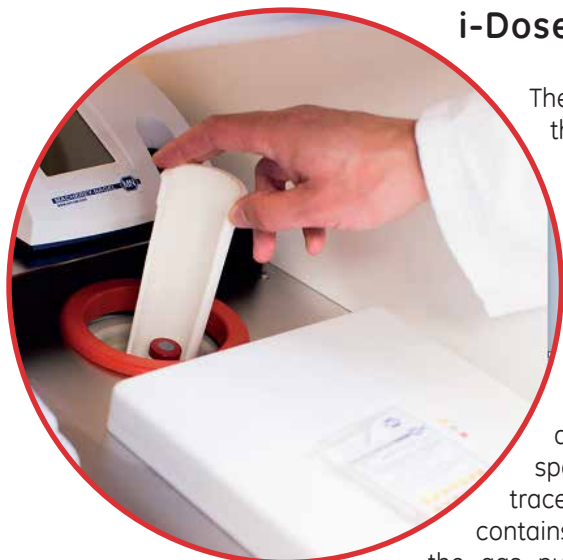
Instruments

GC with Flame Ionization Detector (FID) + Injector

The GC has been designed and configured for the residual solvent control. The small size, the automatic sample injector for up to 12 samples and the adapted column allow highest quality and easy standardization. The GC is optional and can be taken out if not required by local regulations.



i-Dose



The ionization chamber is designed for the fast and accurate determination of the activity or volume activity of radiopharmaceuticals. It is controlled with our Gina X software and calibrated for the PET nuclides (e.g. ^{18}F , ^{65}Ga). It is embedded in a large lead shielding to reduce background noise.

RADIO HPLC

The HPLC is especially designed to achieve best performance in minimum space for the quality control of radio tracers according to the pharmacopeia. It contains all the hardware you need, including the gas purge, manual injector, degasser, pump, column heating, radio detector and product specific detector.

We propose different HPLC configurations adapted to a special tracer as, for example ^{18}F -FDG, ^{68}Ga -PSMA or NH_3 .



CCD Camera

For a good digital recording of the kryptofix and other visual tests, we deliver the QC-Cubicle with a CCD camera.



Osmometer

The Semi-Micro Osmometer enables freezing point depression to be measured and determines the total osmolality of aqueous liquids. In our QC-Cubicle, the system is fully controlled by software and all data can be digitally transferred to the server. The system is delivered with a corresponding calibration buffer. As with the GC, the osmometer is optional and can be omitted if not required.



Multi Channel Analyzer (MCA)

Our non-cooled fast MCA comes with a $3\times 3\text{NaI}$ crystal, a 5 cm low radiation lead shielding and a sample holder. High-end electronics enable the system to perform fast spectrum analysis of radiopharmaceuticals. The system is delivered with a software package for the instrument control and data analysis.

H2 Generator

To avoid any potential problems with hydrogen supply or quality, the Cubicle is equipped with an integrated low maintenance hydrogen generator, installed in its own compartment and with air extraction to increase safety.



TLC Scanner



The integrated miniGITA single TLC scanner has been designed for optimal space-saving without decreasing the sample size. It can be used with TLC plates up to 20 cm. The standard PET detector has been designed for PET applications to ensure excellent sensitivity, a high resolution and minimal background interferences. We propose different detector probes like a SPECT or an alpha probe which can easily be exchanged by the customer. The System will recognize the probe and ensure a digital registration according to the GMP rules.

Besides the various probes we propose also different collimators, which can also be exchanged by the user. Collimators or source holders are also automatically recognized by the system.

Nexgen PTS system

The Nexgen PTS system utilizes FDA Licensed LAL Cartridges for sensitive and rapid endotoxin detection. It is a rapid point-of-use test system that provides quantitative test results in less than 15 minutes with only 2 simple steps.

Easy pH

The QC-Cubicle contains an automatic pH-strip reader.

The system allows rapid testing and high precision, eliminating the subjectivities of visual reading. The measurement results are automatically transferred to the central server and the digital analysis certificate.

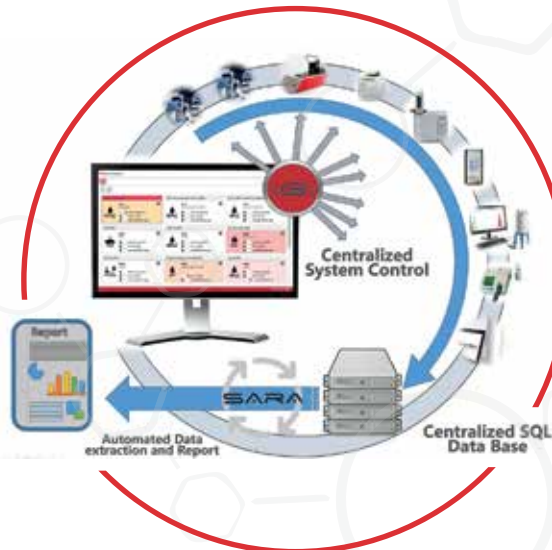


QC-reference sources

Our QC-reference sources pack contains four different radio-active reference sources. It covers all your needs for the calibration and validation of your QC-cubicle. It contains a ^{137}Cs Gamma reference standard; a multi-point gamma source, an ionization chamber reference standard and a beta standard source.*

IT & Software

The QC-Cubicle high-end hardware is completed with an extensive software and service package which will help you to set up the new lab in a very short time. This will enable you to fulfill highest GxP standards with optimal data transfer, documentation and storage. To fit your local regulations as well as your personal needs, we deliver two different LIMS solutions.



GINA CDS

Gina CDS is the Centralized Data Solution based on our Gina X software. The centralized solution is based on a SQL database. The client/server architecture facilitates the easy centralization of all data on the in built server and an access to the instruments and data from your office. With the GINA X CDS platform, you can control and analyse the data from the radio-HPLC's, the TLC, the GC, the MCA, and the i-Dose with an intuitive single User Interface. This User Interface renders additional interfaces unnecessary. Gina X will also handle the automatic data transfer and verification of the endotoxin, pH and the osmometer. Other instruments can be integrated upon request.



* Customers need a user authorization from the local authorities before we can deliver the sources



SARA

SARA is the basic LIMS solution. It is focused on essential information for the analysis certificate and designed for high simplicity, ease-of-use and fast handling. SARA helps you to save time, ensure easy data transfer, allow safe data storing and simplifies the data visualization. Handle the relevant data transfer from the cyclotron, the dispenser, the synthesis unit and all QC equipment by a simple mouse click. Simply generate QC analysis certificates on a single page containing all data from the QC and synthesis instruments required for the release of the product. Bar codes will help you to introduce data, trace samples and minimize the risk of human errors.

BIOTRAX

BioTrax QMS was created to provide your facility with an easily accessible, comprehensive database and an efficient system for inventory tracking and batch record maintenance.

It's covering the data management needs of the Pharmacist, the Cyclotron Engineer, the Radiochemist, the Technician, the production manager and the administrator.

Biotrax QMS providing you with a streamline and paperless approach to manage your facility's inventory, manufacturing and delivery needs.



Data security and compliancy

To comply with GMP and 21 CFR Part 11 regulations, each operation is recorded and archived for subsequent audits and reviews. The process data, raw data and application-specific setup information are stored in the protected SQL database to increase the data protection. Filters and search tools allow simple identification of who, when, why, how?

Services

The QC-Cubicle is delivered with an extensive service package to support the customer, both with the set-up of the facility and their daily routine work. Depending on the customer's needs, we can extend the service pack with additional training and service contracts.

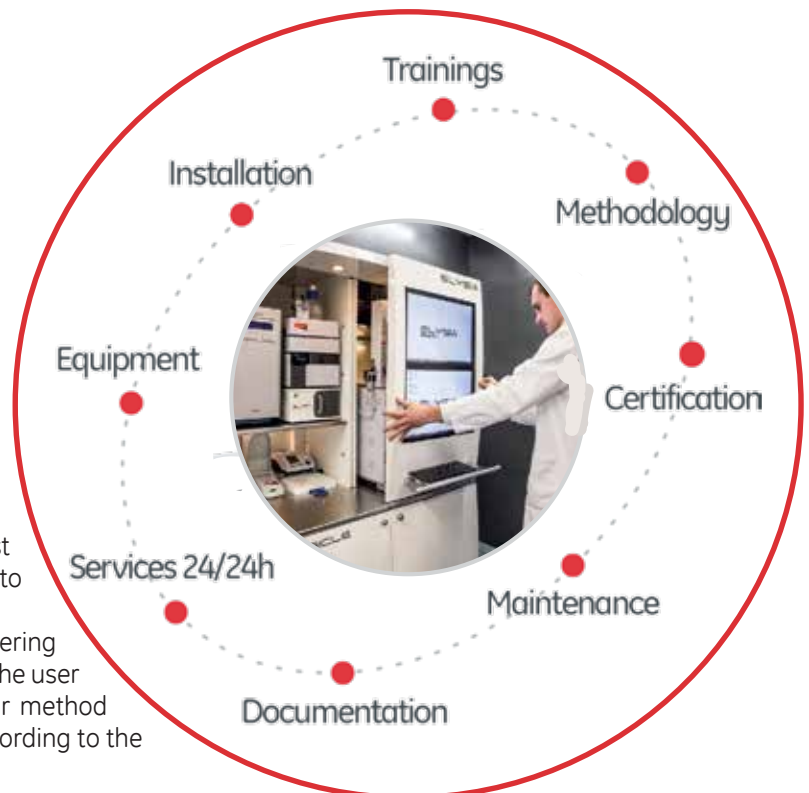
Each system undergoes an extensive factory acceptance test as well as an installation test according to Elysia test procedures and guidelines to ensure a high-end quality standard.

The standard package includes on-site training, covering the basic hardware and software functions, offering the user an optimal use of the different QC instruments. Our method training is dedicated to the QC of FDG or Gallium according to the pharmacopoeia.

Other tracer QC trainings are available upon request.

QC methods include the following tests: determination of pH, turbidity, radioactive concentration, radiochemical purity, radionuclide purity, specific activity, residual solvents and pyrogens.

The sterility determination and other methods are not included in the standard pack but are available upon request. IQ/OQ-service of the entire QC-Cubicle, with separated IQ/OQ modules of each QC instrument, is performed by trained and certified Elysia-raytest technicians. Advanced and customized application trainings are also available upon request.



Technical specifications

Radio HPLC for FDG	<ul style="list-style-type: none">• Manual injector, degasser, gas purge, solvent container, isocratic pump, active seal wash, thermostatic column, Pulse Amperometric Detector, Radioflow monitor• Columns for FDG• Pre-column and analytical column
Radio HPLC for ⁶⁸Ga	<ul style="list-style-type: none">• Manual injector, degasser, solvent container, quaternary pump, active seal wash, thermostatic column, UV Detector, radio flow monitor• Columns for ⁶⁸Ga• Pre-column and analytical column
GC	Gas chromatograph, Split/Split less Injector, FID, Fast residual solvent GC column. Automatic Liquid Sampler for GC and Hydrogen generator
TLC for PET	TLC scanner
pH-meter	Laboratory pH-measuring device
LAL test	LAL test system, suitable for the Charles River cartridges
Dose calibrator	i-Dose ionization chamber with lead shielding
Osmometer	Semi micro Osmometer
Camera	CCD camera
Multi Channel Analyzer	Multi-channel analyzer for gamma spectroscopy, 3x3" scintillation detector and lead shielding
Printers & bar code reader	Laser printer, label printer, bar code reader
Radiation protection	Additional lead shielding on sensitive parts to reduce the irradiation risk and background interference during the QC
Gas extraction	Extraction of Hydrogen and gases
Waste control	Lead-shielded waste container with optional overflow control
FDG-QC starter kit	<p>Our QC starter kit contains nearly all consumables you need to set up the QC method of your choice and to make the first run. The kit is very helpful for the installation and training.</p> <p>Besides some chemicals (like 2-chloro-2-deoxy-d-glucose, glucose, 2-fluoro-deoxy-glucose, 2-fluoro-2-deoxy-mannose; 1,2,3,4-tetra-O-acetyl-beta -D-glucopyranose...), it also contains some consumables and small material needed for the kryptofix test and the TLC (kryptofix, DC plates, development chamber, Micropipette...).</p>

Physical specifications

Dimensions	W146 x D93 x H192 cm
Weight	+/- 850 kg (fully equipped)



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