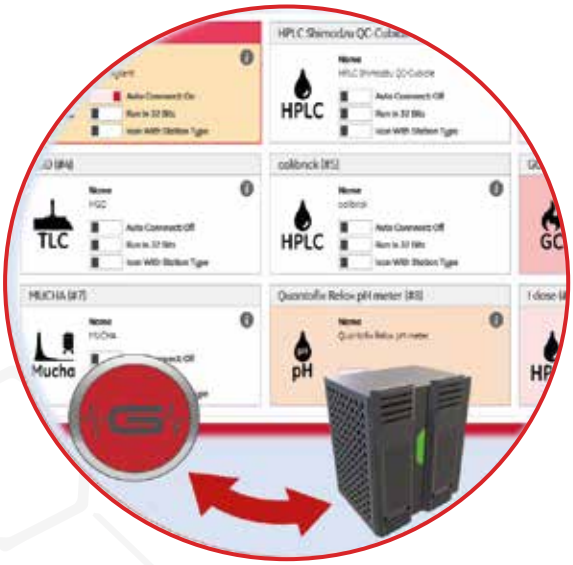
GINA X

CENTRALIZED DATA SOLUTION

Central control and analysis software for radiopharmacy quality control

- COVERS ALL RELEVANT QC INSTRUMENTS
- EASY AND INTUITIVE
- SPECIFIC FEATURES FOR RADIOACTIVE SIGNALS
- DESIGNED FOR GMP AND 21 CFR PART 11 USE



GINA X is a data acquisition and evaluation software for different analytical instruments used during quality control of radiopharmaceuticals. Simply collect all data from typical Quality Control steps like radiochemical purity, residuals measurement, pH, endotoxin, or radio-isotopic purity. Data from radio chromatography (HPLC & TLC), GC, MCA, LAL and dose calibration are commonly needed to confirm that the products are fully compliant to pharmacopeia or FDA regulations and standards. GINA X and SARA will lead you through the entire workflow, from single measurement to signature of the QC analysis certificate. Integrated methods and automatic data transfer have an important role in documenting the whole process to comply with the SOP in a GMP environment.

GINA X is the heart of the QC laboratory, offering a single software platform to control all your QC instruments with a single interface. With the GINA X CDS platform, you are able to control and analyse the radio-HPLC, all Elysia radio detectors, TLC systems, the GC, our multichannel analyser and dose calibrator from a single user interface. This intuitive central user interface renders additional interfaces unnecessary. Automatic data transfer and verification of other QC instruments like endotoxin, pH, osmometry or others is also possible.

The centralized solution is based on a SQL database. The client/server architecture allows an easy centralization and access to the instruments and data from different PC's. With all data stored in the central SQL database, it is easy to secure the data integrity and be fully GMP and CFR 21 part 11 compliant.

ELYSIA RAYTEST

GINA X is the latest evolution of our GINA Star software, bringing the software to the modern client/server architecture. With an SQL database as the heart of the GINA X CDS environment, it offers powerful data storage and data integrity.
Laboratory information and management systems start with the digital management of a few relevant laboratory data such as measurements and can be extended to a large digital network and data collection, covering every action and step in a production or an R&D process. GINA X and SARA are the first important steps into a LIMS.

GINA X offers a modern graphical user interface which has been optimized for intuitive operation and allows both standard/keyboard/mouse or touch screen control. All instruments of the QC lab are controlled by the single GINA X software, which offers a single look & feel, greatly reducing the training time of the operators on the different instruments.

It also helps to avoid multiple logins and confusion where data is stored, allowing the operators to switch from one instrument to the next in the QC sequence.

Easily switching between different languages is another strong point for the customer experience.
GINA X covers the digital data acquisition, instrument control and evaluation of the data and comes with different algorithms to serve the different instruments connected to GINA X.

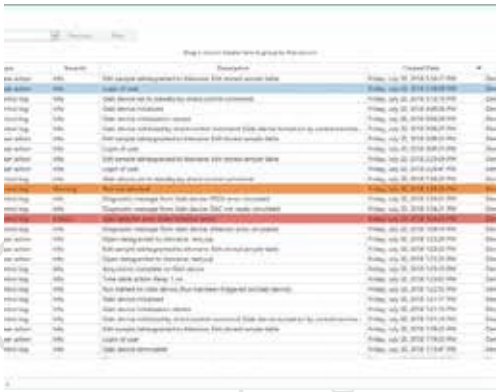
Chromatography, spectroscopy, activity and half-life determination, multiple trace chromatography (DAD) but also pH and endotoxin measurements are all integrated in the same software.

The chromatography software is a universal solution for many commercially available chromatography systems, combining control of the HPLC/GC systems and analysis of the chromatograms. GINA X controls nearly the full range of Agilent and Shimadzu HPLC and other HPLC and GC brands.

GINA X controls all Elysia radiodetection instruments and seamlessly integrates them with the associated non-radioactive traces and data. The portfolio of controlled instruments increases constantly, and the list of validated instruments is available on our web page.

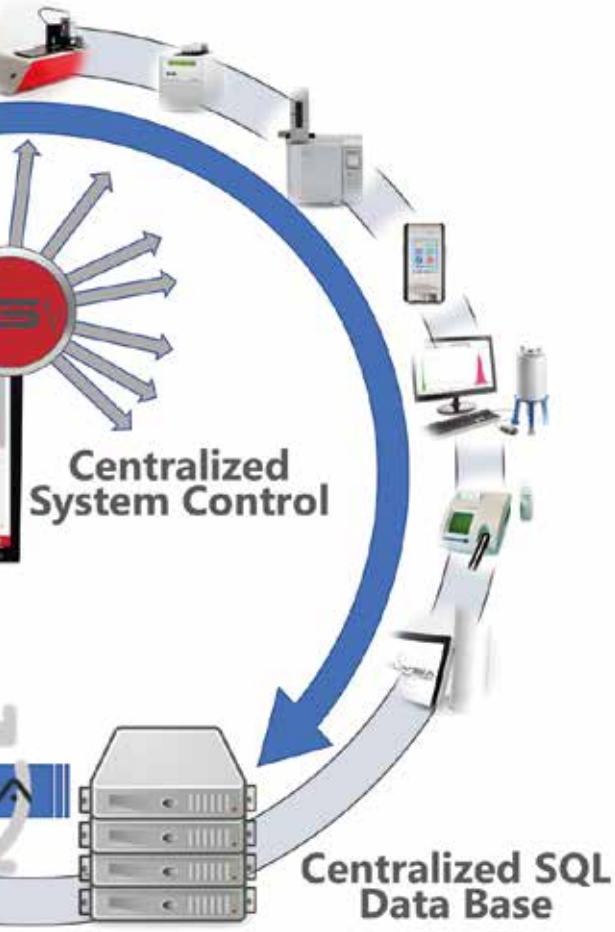
You can simply upgrade your GINA Star to GINA X as older GINA data sets can still be used for evaluations.

GMP & CFR 21 Part 11



The access module requires the users to log in individually with a username and password. This allows management of the different rights for each user and is also the basis for a full audit trail.
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. Special check sums and name tags allow to link data sets, measurements and instruments and prevent data manipulation.
Filters and search tools allow simple identification of who, when, why, how?.

Database structure



The GINA X data base structure will make you daily life easier. No need to search on different PCs for one data set, simply create methods on one system and share them with all the devices from your network. Increase your data safety with automated disaster recover backups without the need of complicated short and long term data backup of each individual station. Consistent time stamps and audit trail func tions on all devices will enable faster, simpler and stress less audits.
The central data base can be set up according to your personal preferences with a single access setup or a multiple access setup.

GINA X Software Modules

GINA X is a modular software with optional software modules for specific features or instruments. The basic licence contains the evaluation module and can simply be upgraded by all other modules. Some of these modules can also be combined to improve redundancy or even optimize QC protocols. For example, the TLC scanner is traditionally used for TLC chromatography, but adding the spectroscopy and half-life module to the same instrument will also allow to measure a gamma spectrum and perform a half-life determination.

Half-life module

Delivered with our iDOSE dose calibrator and optional on spectroscopy or TLC chains, this software option allows the automatic determination of half-life during an activity or spectrum acquisition.

Radio detector control module

This extension is needed to use GINA X to control one of the Elysia-Raytest radio flow detectors (GABI Star, GABI Nova, RAMONA, POMO...). It allows to control the detectors, provide a full digital signal transfer, and give access to advanced instrument settings.
With a suitable probe and the optional gamma spectrum module, you can also acquire and analyse a gamma spectrum.

Radio TLC control module

Offers the full control of our different miniGITA TLC scanners and associated probes.
Automatic detection of collimators, scan hight, probe model, scan time determination by peak hight levels allowing the best LOD achievements under full GMP conditions.

LC control module

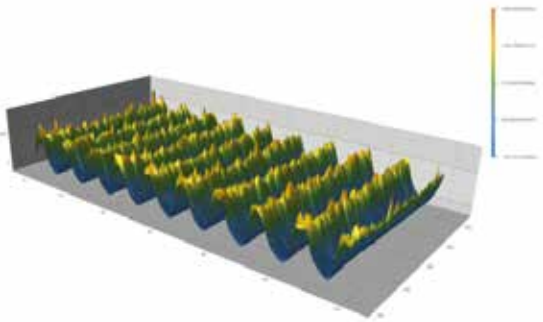
We propose LC control modules for different HPLC brands such as Agilent or Shimadzu. Each LC module will give you the control of nearly the entire LC range of a specific brand, including pump, autosampler, column oven, detector (UV, RID, DAD...) and fraction collector control.

GC control module

We propose LC control modules for different HPLC brands such as Agilent or Shimadzu. Each LC module will give you the control of nearly the entire LC range of a specific brand, including pump, autosampler, column oven, detector (UV, RID, DAD...) and fraction collector control.

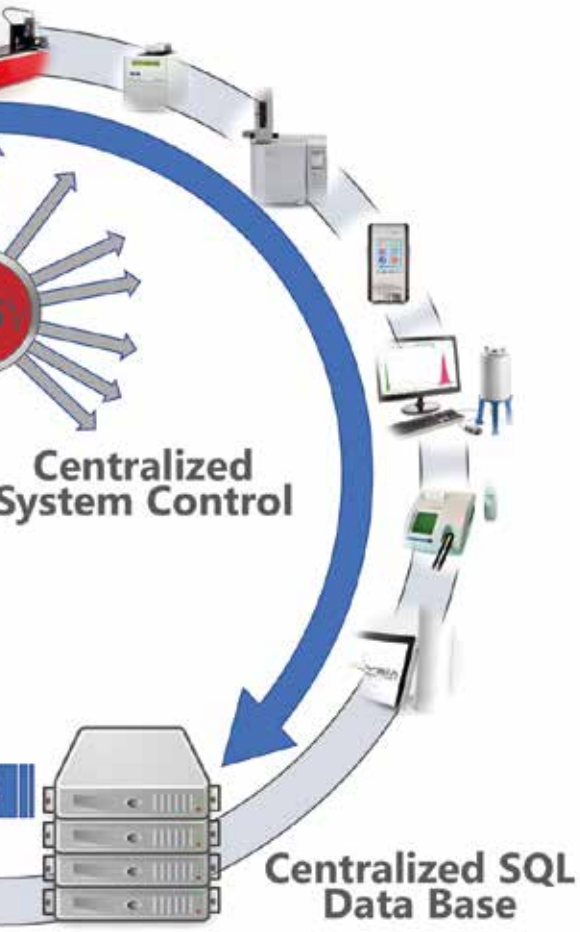
Diode array module

This module is needed for the data acquisition from a diode array detector. It allows to show the complete data set from the DAD measurement in a 3D graph. Simply track your mouse over the 3D spectrum to find the regions of interest. The software will show you in a 2D window the corresponding spectrum and chromatograph.



Access control module

The access control module will give you access to the full audit trail and the extended search functions. Beside the audit trail, it will also give you access to the full user mana gement. Simply create different users, define user levels and rights for each user level spectrum and chromato-graph.

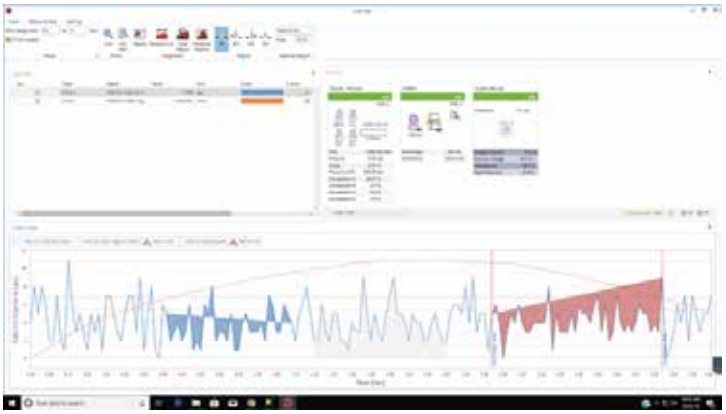


MCA or Spectroscopy module

This module is needed to control our Multi-Channel Analyzer (MUCHA). The module allows to control the system settings, data acquisition and spectrum evaluation.

Evaluation module

The basic evaluation module is used to evaluate older GINA Star data sets or to evaluate data sets generated with instruments controlled by GINA X. It allows to use and work with GINA measurement files without the need of a connected Elysia-Raytest detector. It has all the features needed for the evaluation of a data file from a GC or a radio-HPLC, such as automatic peak detection, half-life time correction, background subtraction or automatic report generation.



SARA or Smart Automatic Report Analysis module

This is a powerful tool for automating your reports, per batch. SARA will verify, validate, and highlight a set of parameters according to your personal settings in an automatic report. Digital signatures and archiving functions are some of the features of SARA.

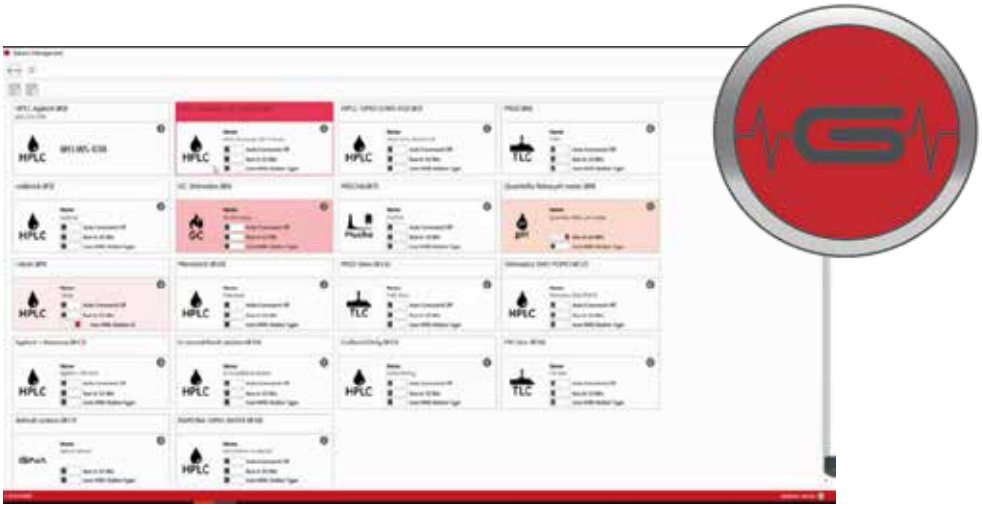
QC Cubicle

As GINA X will bring all your instruments together in a user-friendly software, Elysia also offers a solution to integrate all your hardware into a compact and optimized cabinet. Our QC-Cubicle offers a full radio-pharmaceutical QC lab in just over 1 m^2 floorspace. A clever combination of the different instruments, optimizing lead shielding for MCA, dose calibrator and waste containers, and even a TLC scanner integrated in the cabinet hardware, it offers a great ergonomic workplace. A built-in GINA X server and large screens offer a true all-in-one lab experience.

Technical specifications

(Some features are only available with the optional module).

- Client/Server configuration
- SQL database data storage
- Automatic peak detection and integration
- Dead time correction
- Half-life time correction
- Basic spectrum analysis
- Advanced radio signal background subtraction
- Multi-language (French, German, English…)
- GxP features
- User management (access and level control)
- Audit trail
- Electronic signature
- GC, LC, MCA, Dose calibrator and TLC control



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