

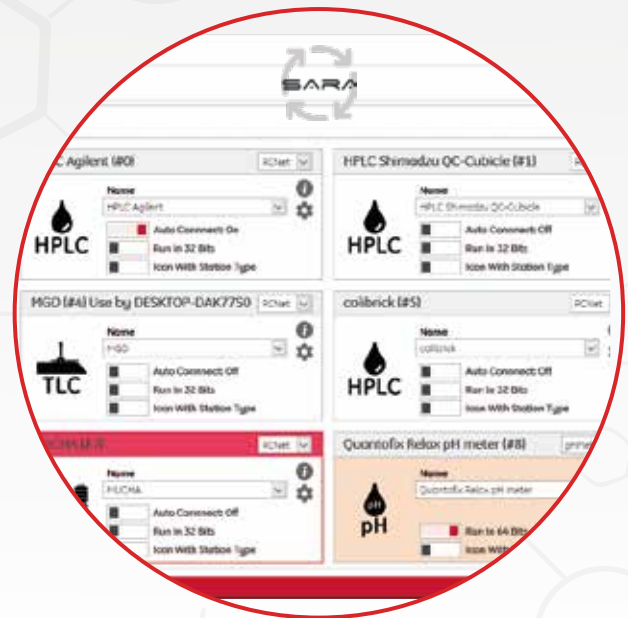


SMART AUTOMATIC REPORT ANALYSIS

ANALYSIS CERTIFICATE GENERATOR FOR RADIO TRACERS

AUTOMATED CENTRALIZED DATA RECORDING AND REPORTING OF ALL QUALITY CONTROL DATA FOR PRODUCTION BATCHES

- AUTOMATED RECORDING OF ALL QC RELEVANT DATA
- USER FRIENDLY
- SECURE DATA BACKUP
- GMP AND 21 CFR PART 11 COMPLIANT



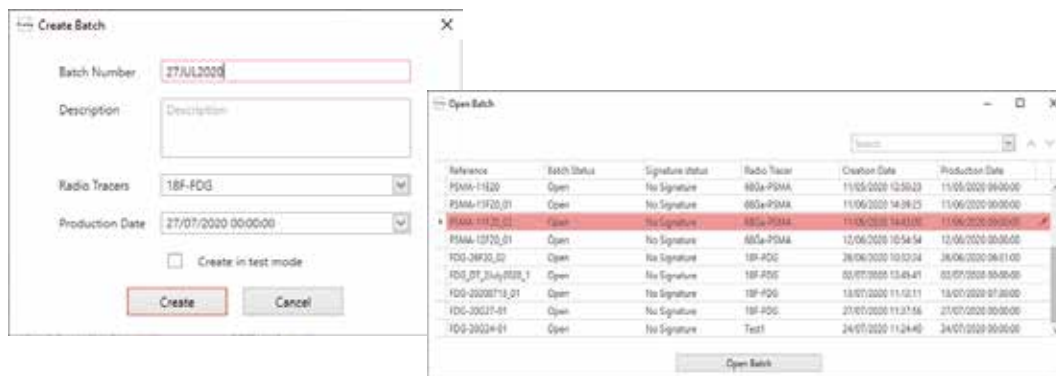
SARA is a central data recording and reporting system for all quality control data for production batches. Authorities require complete documentation of radio-pharmaceutical production, covering raw materials, production process, quality control and aseptic processing.

For quality control, Elysia-raytest has developed a fully automated solution for the digital data transfer and reporting of all relevant data.

In combination with GINA X and a centralized SQL database, SARA is the easiest-to-use LIMS solution on the market.

Batch entry

Once SARA has been configured, no further intervention on the part of the user is necessary.

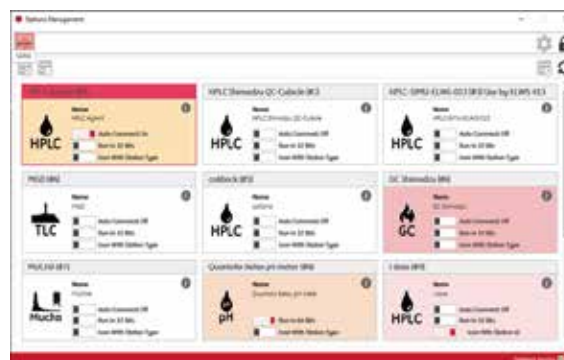


Instrument control

SARA is embedded into GINA X. From here you can launch QC instruments, set methods and integration methods. Use different instruments in parallel and decide whether you want to run your system directly in the lab or if you want to follow the run from your home office.

Simply control or generate automatic summary of relevant data from the following systems:

- GINA X controlled radio-HPLC
- GINA X controlled radio-TLC
- GINA X controlled GC
- GINA X controlled Multi Channel Analyzers
- pH-Meter (compatible types available on request)
- Osmolality (compatible types available on request)
- PTS endotoxin system from Charles River
- Dose calibrator (compatible types available on request)
- Manual input of data from QC results possible (labeled)

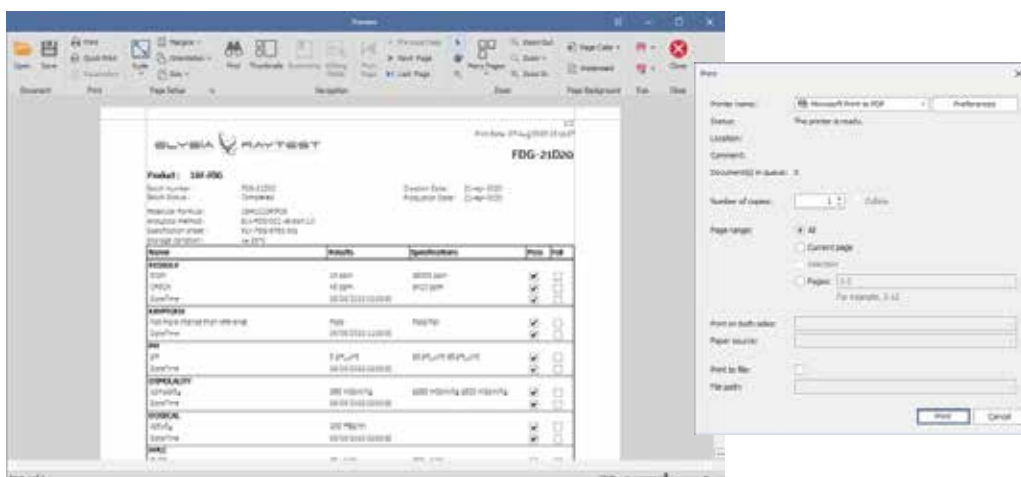


Reporting

Reports in SARA can be configured to reflect user requirements; report templates are built using simple dropdown menus directly linked to the methods setup in GINA X.

Just select the relevant measurement values, instrument data, time points or user information you want to record in your report.

For each data point you can set a minimum and a maximum value to be compliant with local regulations. The report will highlight whether the measured data is inside or outside the specifications, and if all required tests have been performed. The generation of reports can be triggered automatically and sent to multiple destinations including printers or email.



SARA produces analysis certificates containing all required data for production and quality control on a single page.

SARA is fully integrated into our GINA X software. The entire workflow uses a single user interface. All quality control instruments and steps, going from a simple pH reader up to an advanced Radio-HPLC, are controlled with the same software.



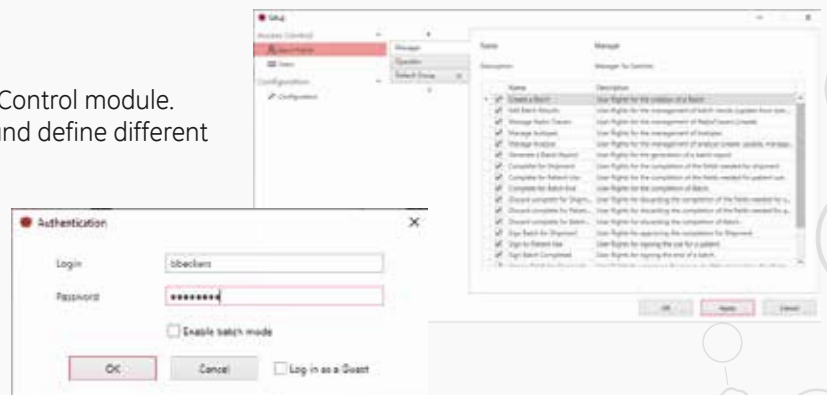
All data, covering raw data, chromatograms, instruments settings, methods and data evaluation are securely stored in one database. The open SARA structure also allows the exchange of data with other databases for simple integration of SARA into existing LIMS structures (compatible models available upon request).

The analysis report can be configured by the customer and can be fully adapted to local regulations. Data generated in a quality control run will be automatically - and without the need of a user intervention - be stored in the centralized database.

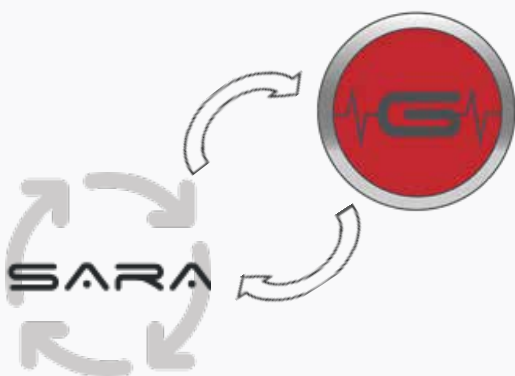
The report generator will look for all data selected by the user and indicate whether the values are within the predetermined specifications.

User management

SARA and GINA X have an optional User Access Control module. If this module is enabled, you can create users and define different user rights and user access levels for each user. The password and security settings ensure electronic signatures and high data safety. The advanced audit trail will enable you to supervise all actions from all users.



Data transfer



Sample and batch registration can be done either manually or automatically. SARA will use a centralized GINA database. All instruments controlled with GINA X and connected to the centralized database will save the raw data, instrument settings, methods, and evaluation directly into the database without a user intervention.

Data transfer is fully digital and secured without the need for work with the four eyes principle.

Besides the direct instrument data, it is also possible to configure fields for manual data entry or to use an import tool to automatically import data from digital reports from instruments that are not controlled with GINA X.

Audit trail

SARA has an advanced audit trail. Simply track who, what, when and why. User access, user activities and data points are logged. An advanced search function exists to sort actions, entries or warnings, to retrieve specific information you are looking for, and get an easy and comprehensive overview of your last actions.

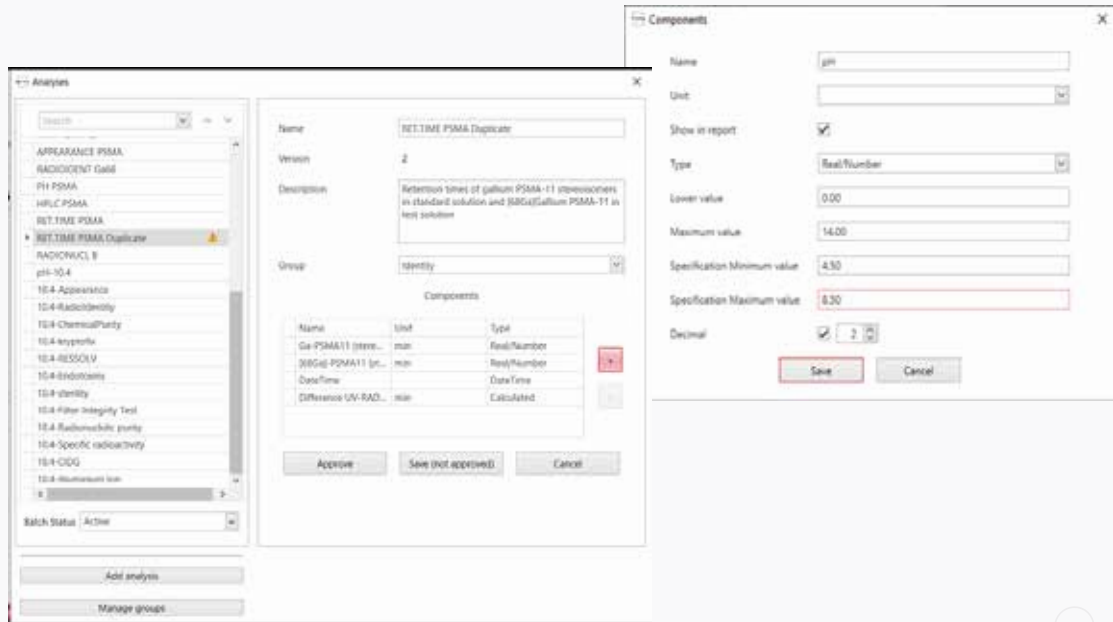
act	username	description	timestamp	status
act	admin	User access management for database: SQL stored sample table	Monday, July 02, 2018 13:47:17 PM	Done
act	admin	Logout of user	Monday, July 02, 2018 13:48:04 PM	Done
act	admin	SQL device will be installed by direct connect command	Monday, July 02, 2018 13:48:04 PM	Done
act	admin	SQL device uninstalled	Monday, July 02, 2018 13:48:04 PM	Done
act	admin	SQL device uninstalled (forced)	Monday, July 02, 2018 13:48:04 PM	Done
act	admin	SQL device uninstalled by direct connect command (SQL device forced on by system console)	Monday, July 02, 2018 13:48:04 PM	Done
act	admin	SQL device uninstalled by database: SQL device uninstalled	Monday, July 02, 2018 13:48:04 PM	Done
act	admin	Logout of user	Monday, July 02, 2018 13:48:04 PM	Done
act	admin	SQL device management for database: SQL stored sample table	Monday, July 02, 2018 13:48:04 PM	Done
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Compliance with regulations

SARA and GINA X support GxP requirements and offer comprehensive functionality to facilitate compliance with standards such as "21 CFR Part 11", GAMP and ISO 17025.

A wide variety of standard functionalities is available to help meet regulatory and security requirements and support standard operating procedures, including:

- Full control of data review and approval
- Password checks
- Extensive versioning management and tracing
- Ability to configure secure electronic signatures



LIMS validation and Compliance Services

Elysia's professional validation and compliance specialists combine laboratory expertise with a deep understanding of regulatory requirements to help companies in regulated industries address issues with LIMS validation and "21 CFR Part 11" compliance. Services include validation consulting, IQ/OQ and training.

Data security

All SARA and GINA X data is directly stored into the GINA SQL database. This SQL database has a high data protection and can't be deleted or copied, as is the case of file-based solutions.

The database is password protected and user-right customisable. Individual datasets are also protected and use versioning and audit trail entries protection to avoid data manipulation.



Email:
Website:
Headquarters:

info@elysia-raytest.com
www.elysia-raytest.com
Elysia s.a.
rue du Sart-Tilman 375
4031 Angleur - Belgium
Tel +32 (0)4 243 43 50
Elysia-raytest GmbH
Benzstraße 4
75334 Straubenhardt - Germany
Tel. +49 (0)7082 92 55 0

Production: