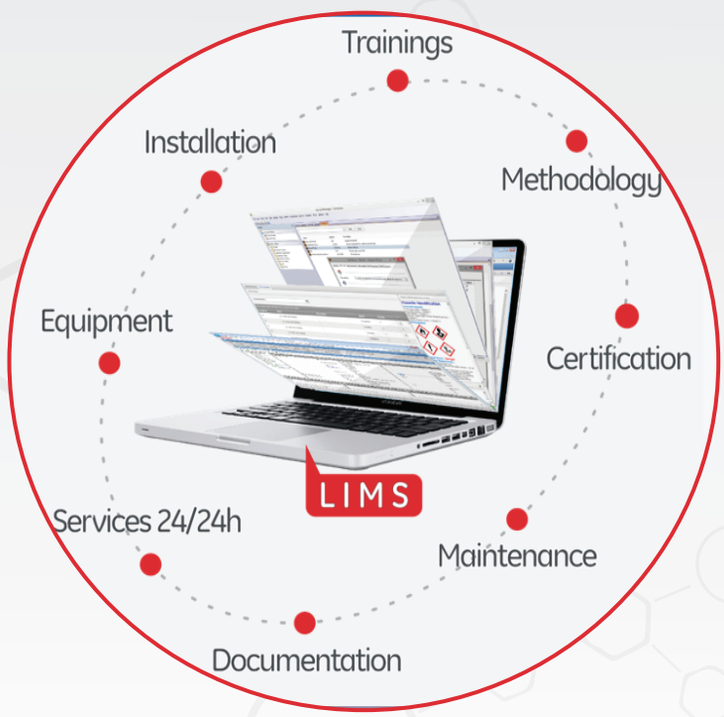
ARGUS-RPS

LABORATORY INFORMATION MANAGEMENT SYSTEM AND LABORATORY EXECUTION SYSTEM FOR RADIOPHARMACEUTICAL AND MEDICAL LABORATORIES.

COMPREHENSIVE SOLUTION DESIGNED FOR AND ADAPTED TO PAPERLESS RADIOPHARMACEUTICAL LAB.

- LABORATORY INFORMATION MANAGEMENT SYSTEM (LIMS)
- LABORATORY EXECUTION SYSTEM (LES)
- BATCH RECORDING
- PRE-INSTALLED QC METHODS
- COMPLIES WITH 21 CFR PART 11



ARGUS-RPS (RPS = Radio Pharma Solution):
The Argus-RPS incorporates a complete suite of integrated software solutions for a paperless lab. It covers the complete laboratory process including the Laboratory Execution System, the data visualization and the lab management itself.
This solution is the best choice if you have to work in a GMP/GLP compliant environment.

ELYSIA RAYTEST

With our Argus-RPS handling SOPs, managing instruments, data, results, consumables, workflows, documentation and resources becomes easy and digital.

- ARGUS-RPS will acquire, record & report results out of the individual instruments. This includes the radiopharmaceutical production (Cyclotron, synthesis unit ...) as well as the quality control.
- It will help you save time and simplify user interactions via automated workflows that guide users through lab processes. SOPs are broken down into logical pieces and give you detailed step by step instructions.
- The user-friendly interface provides easy access to frequently used functions.
- The enhanced traceability features enable more rigorous control over samples and more reliable data for decision-making and compliance.
- The solution will enable you to track, display and report samples by any required criteria.
- It covers a wide range of functions, such as:
  Sample login, sample tracking, result entry, calculations, reporting, records, instruments, stocks, staff, locations, sample points and even schedules. The software records all sensitive information required by law for the release of a radio-pharmaceutical tracer.
- Based on Oracle® Database and Thermo Scientific™ SampleManager™.

Argus-RPS is a proven tool for the efficient testing of samples that routinely pass through a typical lab – whether process testing, quality assurance, or R&D – by sorting test information and organizing it into specific report formats to meet regulatory requirements. The complete testing routine is managed, from sample login to testing, re-testing, and final reporting.

Sample Login

Sample registration can be done in a variety of ways both manual and automated. For environments where there is regularly scheduled sampling, automated pre-scheduled login will register samples at user-defined time intervals. In addition to the standard login functionality, Argus-RPS also supports the use of Sample Plans. The Sample Plan ensures that the correct tests and specifications are assigned to samples based on a decision tree workflow. This functionality is used frequently for raw material testing and supports skip lot testing.

Sample Tracking

Argus-RPS tracks, displays and reports samples by any criteria that are required by the user. A typical multi-criteria request would allow review of all the current day's samples that have results entered, are within specification, have a high priority and require authorization.

Result entry

Entry of results into Argus-RPS can be fully automated from all leading laboratory instrumentation. The Incident Management functionality allows users to record, track, and manage the unforeseen events that inevitably occur in a busy laboratory.

Stock & Instruments management

Your consumables stock can simply be integrated and managed by the Argus-RPS.
Nearly every QC or production instrument can be integrated into the LIMS.

Calculations

Argus-RPS features advanced tools to create complex calculation formulae across different samples. An already extensive library of mathematical functions can be extended with users' own calculations and formulae to meet the most complex of situations. Calculations are automatically carried out as soon as the appropriate data is available within Argus-RPS.

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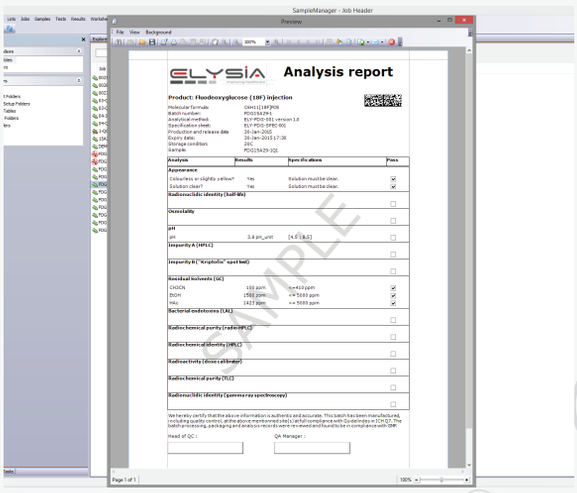
Reporting

An analysis report is created and the results are compared against the specifications.
Reports in Argus-RPS can be configured to precisely reflect user requirements; report templates are built using a graphical environment and can include statistical calculations, graphs, pie charts, bit maps, or OLE objects. Additional reporting formats include Microsoft® applications, PDF, XML and CSV outputs. The production of reports can be triggered automatically and sent to multiple destinations including printers, email or other mechanisms to notify operators in the event of an alarm.

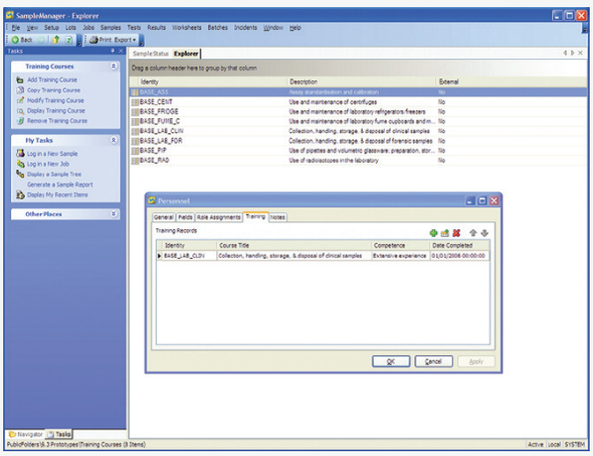
Compliance with Regulations

Argus-RPS supports GxP requirements and offers a comprehensive functionality to facilitate compliance with standards such as 21 CFR Part 11, GAMP and ISO17025. 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
- Timeouts
- Password checks
- Extensive versioning capabilities
- Sophisticated sample custody and incident management
- Ability to configure secure electronic signatures for any system operation



Argus-RPS also provides complete audit-trail functions to ensure data accuracy which in turn leads to better regulatory compliance.



ARGUS-RPS maintains records of the relevant competence, education and professional qualifications, training, skills and experience of all technical staff in accordance with ISO 17025.

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 and planning, test development and execution, and validation training. Elysia offers an integrated LIMS implementation approach with a well-defined validation methodology based on GAMP.

Recommended minimum computer requirements

OS:	Microsoft Windows Server 2012 R2
CPU:	Intel Xeon Quad-Core E3-1230LV3
RAM:	16Gb DDR-3
Disk:	SATA 2x 2Tb in RAID1
Network:	2x Gigabit Ethernet
Dimensions:	Rack 1U short-depth (HxWxD) = 4.3 x 42.6 x 35.6 cm

Based on server provided by Elysia

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Features

- New job entry: a job is composed of several samples to be analyzed grouped by dilution.
- Sample analysis using predefined instruments in the laboratory.
- Sample analysis data introduction, manual or automatic thanks to Integration Manager ™ background data acquisition. Out of range values are highlighted.
- Substances with predefined hazards labelling: NFPA and GHS.
- Laboratory management – Locations.
- Manage suppliers, instruments and stocks.
- Personnel with granular user rights.
- Trainings requirements are verified before user can introduce data.
- LES SOPs and methods can be broken down into logical steps to guide analysts through the procedure.
- Barcode reading is available.
- Check lists and signature ensure that the operator follows the SOP.
- Visual steps help the operator when he has to check his instrument.
- Results are available and recorded as soon as the analysis is completed.
- Hazard warnings embedded into the SOP remind analysts of necessary safety procedures.
- Process history provides a detailed description of every activity that has occurred against an SOP or method and their status.

Reference	Product	Short description
SW_LIM_0001	LIMS & LES - licence	Licence of SampleManager (including LIMS & LES). The licence is valid for one concurrent user and 12 months.
SW_LIM_0005	LIMS & LES – additional user licence	Additional concurrent user Licence of SampleManager (including LIMS & LES). The licence is valid for 12 months.
SW_LIM_0002	LIMS & LES - 1 Year extension	12 month extension of the SampleManager licence including updates and remote support.
SW_LIM_0006	Instrument integration of Elysia standard QC lab	Installation of LIMS and LES software on an Elysia server solution. Integration of the Elysia standard GC lab equipment (radio HPLC, GC, pH meter, dose calibrator, multi-channel analyser and TLC) into the LIMS system on the Elysia server solution. Including setup of Instrument Management.
SW_LIM_0007	Batch Recording for Elysia standard QC Lab	Installation and configuration of the Batch Recoding on the Elysia Server. Only available for an Elysia standard QC installed with the ARGUS-RPS on a Elysia Server solution.
SW_LIM_0008	Support to setup the User Management	The User management function is part of the ARGUS-RPS. The setup has to be done by the customer. With the support we follow the customer for one day and will make the first setup together with him to configure the setup to fit with his personal needs.
SW_LIM_0009	Integration of an additional Analytical Instrument into the LIMS	Integration of an additional analytical or production instrument into the ARGUS-RPS.
SW_LIM_0010	Integration of an additional Analytical Instrument into the Batch recording	Integration of an additional analytical or production instrument into the Batch Recording function.
SW_LIM_0011	Elysia small instrument control Software pack.	This pack includes different small software packages which enable the customer to control smaller lab equipment with a user interface and to integrate all systems into the LIMS. It covers the pH meter, the dose calibrator, the CCD camera, the osmometer and the analytical balance.
IT_HAW_0013	Server Solution of ARGUS-RPS	**OS:** Microsoft Windows Server **CPU:** at least Intel Xeon Quad-Core **RAM:** at least 16Gb DDR-3 **Disk:** at least SATA 2x 2Tb in RAID1 **Network:** 2x Gigabit Ethernet **Dimensions:** Rack 1U short-depth Based on server provided by Elysia
SW_LIM_0012	Pre-installed SOPs for FDG QC according to Elysia SOPs	Preinstallation of a complete set of SOPs for the quality control of FDG according to the specifications of the European pharmacopoeia. It contains a complete set of SOPs, methods, workflows, manuals and tutorials needed to perform the daily lab work. It covers small actions like simple dilution steps up to complete radio-HPLC method. All SOPs have been tested and set up by Elysia in our own laboratory and are designed for the Elysia QC equipment. This will be a perfect base to set up your own SOPs and to fulfil your local regulations.
SE_TRA_0002	Basic user training for Argus-RPS pack	A 3 day onsite training to enable the customer to use the ARGUS-RPS solution in daily work. The training will be focused on the use of the software for pre-configured systems.
SE_TRA_0021	1 day additional training for Argus-RPS	If the customer wants to use the complete features of the software solution and integrate himself instruments, new SOPs or make modifications which need advanced skills we propose additional training days. The content and the duration will be determined in function of the customer's personal needs.