Apex-Guard™

SOFTWARE

Apex-Guard™

Gamma Spectroscopy for Your Regulated Count Room

Apex-Guard Lab Productivity Software integrates enhanced controls, security, and audit features with Apex-Gamma™ software for improved quality assurance and regulatory compliance.

FEATURES

- Enhanced data integrity and security features integrated into lab productivity suite
- Features and controls necessary for compliance to US FDA Title 21 CFR Part 11 Electronic Records and Electronic Signatures for pharmaceutical customers
- Role-based security for user log-ons using MS Windows Policy settings for password and renewal
- Automatic timed log-off feature
- Enhanced security for analysis and processing files
- Enhanced security on detector and MCA configuration
- Dramatically improved audit capability
- Comprehensive audit log
  - Parameter modified
  - User who made the modification
  - Date/Time change was made
  - Value prior to modification
  - Value after modification
  - Justification or comment for modification
- Enhanced data review features to view and restore analysis records
- Electronic Signatures
- Electronic software licensing with flexible terms (1 year or perpetual), and activation methods (direct online and remote offline)
- Available Comprehensive Service Bundle including Apex-Guard software (3-year term), IQ/OQ Installation and customization, virtual training classes, and technical support credit

DESCRIPTION

Apex-Guard application builds on Apex-Gamma software to provide extra security, audit log, and data integrity to meet specific needs of our pharmaceutical customers. These features are also of interest to many of our non-pharmaceutical customers.

The following features are implemented in Apex-Guard application, above and beyond the current functionality of Apex-Gamma software:

Role-based security with Windows Credentials Authentication – User profiles are linked to the Windows domain user which allows Windows Policy settings to manage the password complexity and renewal frequency.

Automatic timed log-off feature – Administrator user setting defines an inactivity time limit and logs the user off the system when the limit is exceeded.

Enhanced security for analysis and data processing files - Editing permissions on essential files for analysis and data are allowed only within the application. This includes calibration, nuclide library, ISOCS™ and LabSOCS™ associated files (for efficiency calibration and cascade summing correction), QA, and scripts.

Enhanced security on detector and MCA controls – Modification of detector settings configured and active in an Apex-Guard system is not possible outside the Apex-Gamma application, including from Genie™ Acquisition and Analysis software.
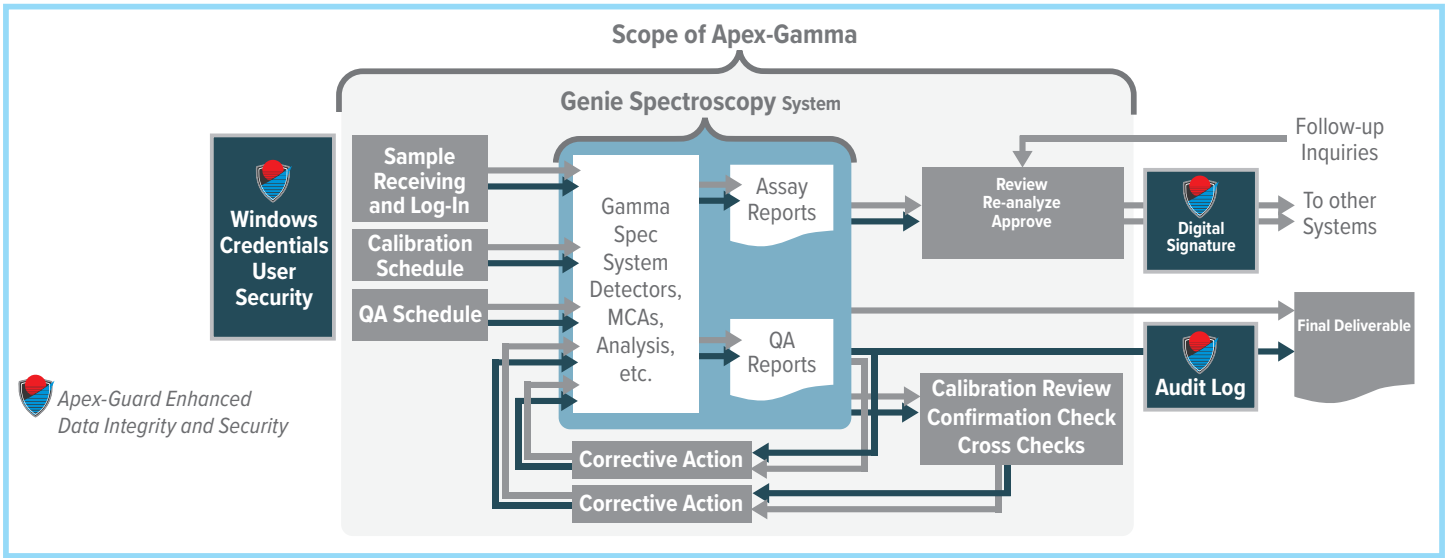
Schematic Workflow and Scope of Software Applications

Dramatically improved auditing capabilities – For each change in an application editor, procedure, or QA file, the user is presented with a dialog summarizing the changes during the editing session and presented with a free form text field. The purpose of this text field is to record a justification for the changes, which will be saved to the audit log along with a record of the changes made. The text field has optional input and mandatory text input settings. There is also a setting to enable requesting of user credentials and password at the time of authorizing the modification.

Enhanced audit log to record and display the following data for a given change:

- Parameter modified
- User who made the modification
- Date/Time stamp of modification
- Value prior to modification
- Value after modification
- Justification/comment of modification

Example Audit Log Entry: Library Modification

Enhanced Data Review – Data review now has ability to display each analysis of a given sample as a separate record. This allows the user to view and restore previous analysis settings, including the date/time.

Example of analysis records for a given sample

Electronic signatures for signing and approving sample counts – These include username, function, date/time stamp, and user comments. These conform to the requirements in US FDA Title 21 CFR Part 11, Electronic Records, Electronic Signature.
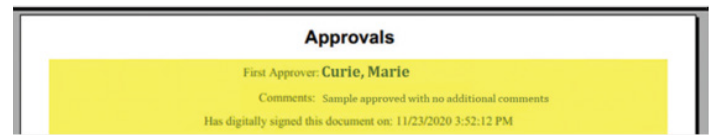
Example of electronic signature on data review approval

IQ/OQ Service – Mirion also offers an Installation Qualification and Operational Qualification Service, a critical component of a Title 21 CFR Part 11 compliant solution. A trained Mirion professional will install your system and go through a comprehensive step-by-step IQ/OQ checklist to satisfy this requirement.*

MIRION TECHNOLOGIES

Apex-Guard Comprehensive Service Bundle

Keep your operations up to date and optimized with a single turn-key annual subscription service including:

- Apex-Guard application including Apex-Gamma, Genie, LabSOCS software (3-year license, updates and support)
- IQ/OQ Installation and Qualification Services
- Virtual Training Classes
- Technical services

Apex-Guard Lab Productivity Suite adds an extra layer of security and audit-supporting documentation to the industry-standard Apex-Gamma software.

Apex-Guard application supports both the pharmaceutical (US FDA Title 21 CFR Part 11) and non-pharmaceutical customers.

Apex-Guard Supported Platforms and MCAs

Apex-Guard application supports the following operating systems, databases, and MCAs. Available Apex-Guard Models for Ordering:

	Supported	Not Supported
Operating System	Windows 10 Windows Server 2019	Windows 7 Windows 8.1 Windows Server 2016
Databases	SQL 2019 SQL 2017	SQL 2014 SQL 2012 Oracle 11g
MCA Devices	Lynx® Analyzer DSA-LX® Analyzer Osprey® MCA Multiport II™ Analyzer Sample Changers	AIM InSpector™ 2000 DSP DSA-1000 Analyzer RPI Sample Changer

Available Apex-Guard Models for Ordering

S707C Apex-Guard Software Option
- Requires previous purchase of Genie Suite V3.4.1 (S500C, S501C, S505C, and S506C)
- Requires previous purchase of Apex-Gamma V1.4.1 (S700C or S701C/S702C)
- Licensed to one computer for unlimited time. Upgrades are not included.
- If deployed on an Apex-Gamma Client/Server system, one license required for each networked computer.

S707-SS   Apex-Guard Software Subscription Bundle
- 1 Year Subscription for Genie Suite, Apex-Gamma, and Apex-Guard software for one computer
- Includes complimentary software updates, as released
- Includes complimentary LabSOCS Mathematical Calibration Software
- Includes participation in Mirion's Customer Community Portal
- Automatically renews annually unless otherwise canceled
- Installation and setup is not included

S707-CB-1 Apex-Guard 3 Year Comprehensive Bundle: Desktop
- 3 Year Subscription for Genie Suite, Apex-Gamma, and Apex-Guard software for one computer
- Includes complimentary software updates, as released
- Includes complimentary LabSOCS Mathematical Calibration Software
- Includes participation in Mirion's Customer Community Portal
- Each Year, option of one of the following services:
  a. IQ/OQ-1: Mirion Install and IQ/OQ Service
    OR
  b. Virtual open enrollment training class credit for two people
    OR
  c. 20 hours Tech Services customization or consultation credit
- Unused Training or Service credit may roll over for one year

S707-CB-2 Apex-Guard 3 Year Comprehensive Bundle: Client/Server
- 3 Year Subscription for Genie, Apex-Gamma, and Apex-Guard software for up to four computers
- Includes complimentary software updates, as released
- Includes complimentary LabSOCS Mathematical Calibration Software
- Includes participation in Mirion's Customer Community Portal
- Each Year, option of one of the following services:
  a. IQ/OQ-2: Mirion Install and IQ/OQ Service
    OR
  b. Four days virtual training group class (up to six participants)
    OR
  c. 40 hours Tech Services customization or consultation
- Unused Training or Service credit may roll over for one year

S707-CB-3 Apex-Guard 3 Year Comprehensive Bundle: XL
- 3 Year Subscription for Genie, Apex-Gamma, and Apex-Guard software for more than four computers
- Includes complimentary software updates, as released
- Includes complimentary LabSOCS Mathematical Calibration Software
- Includes participation in Mirion's Customer Community Portal
- Each Year, option of one of the following Services:
  a. IQ/OQ-2: Mirion Install and IQ/OQ Service
    OR
  b. Four days virtual training group class (up to six participants)
    OR
  c. 40 hours Tech Services customization or consultation credit
- Unused Training or Service credit may roll over for one year

*Apex-Guard Software and Mirion's IQ/OQ Service are designed to ensure our customers can meet Title 21 CFR Part 11 readily and easily. Please note that Apex-Guard software as a standalone product is not Part 11 compliant and must be integrated with customers' processes and procedures for laboratory Part 11 compliance.

MIRION TECHNOLOGIES

www.mirion.com