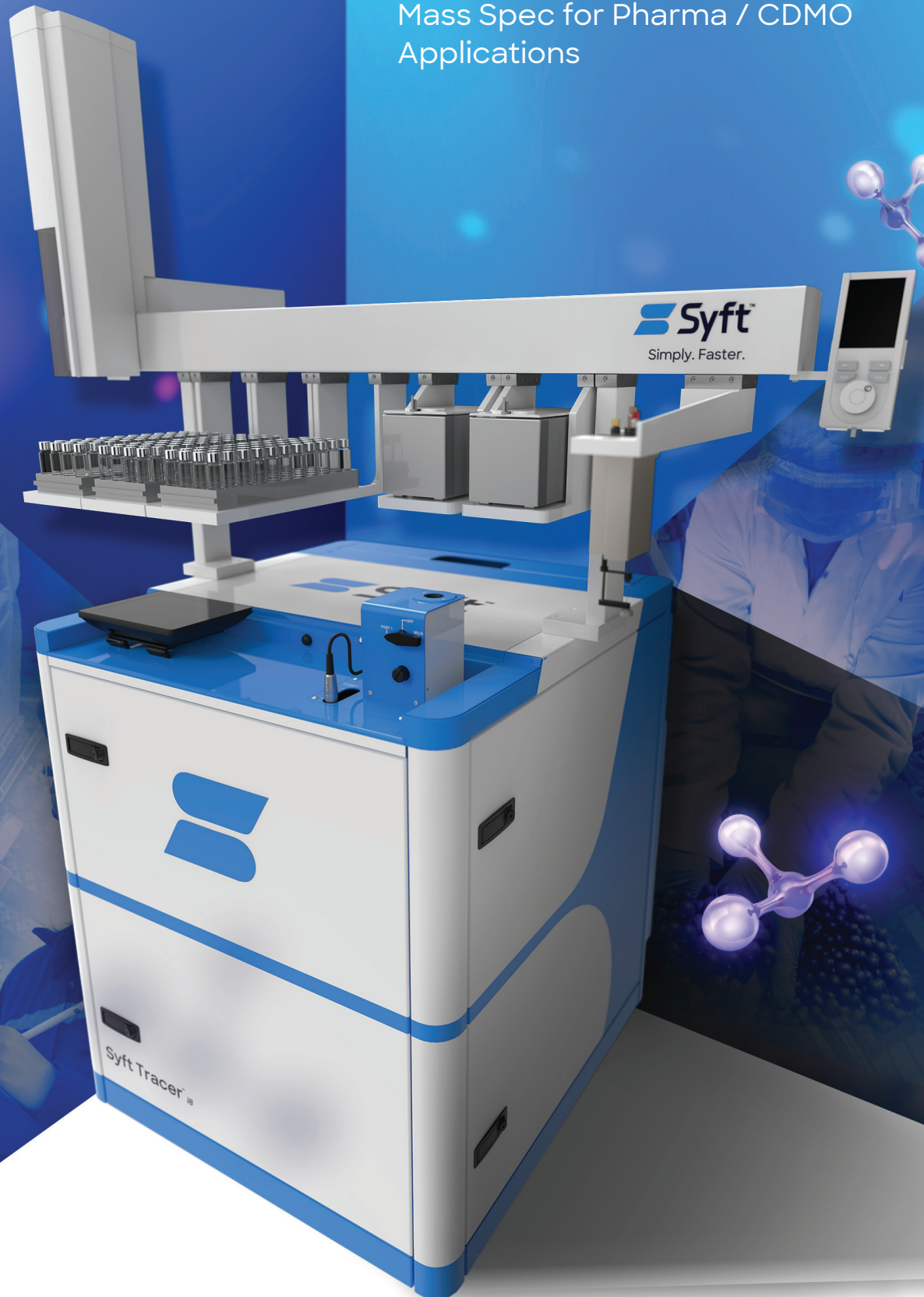


Syft Tracer Pharm11

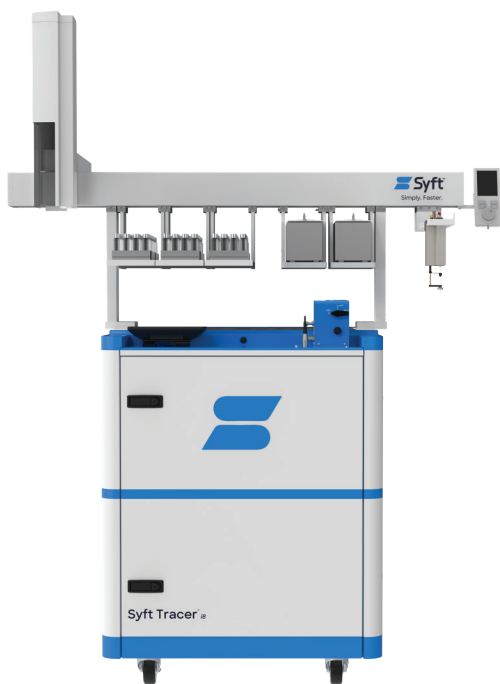
The **Only** Compliant Real-Time
Mass Spec for Pharma / CDMO
Applications



A complete solution for high-throughput, 21 CFR Part 11 compliant, automated workflows

Syft Tracer Pharm11 is a bundle solution for high-throughput, 21 CFR Part 11 compliant, automated workflows in pharmaceutical and CDMO applications. It includes Syft Tracer, a CTC autosampler, a High Throughput (HTP) Inlet, and SyftAuditTracer 21 CFR Part 11 compliant software. Syft Tracer™ is the next generation of real-time, direct injection mass spectrometry (MS) that is built to solve the most difficult analytical challenges. It delivers trace-level detection sensitivity, unparalleled performance stability, and highly reproducible data.

Syft Tracer Pharm11 provides a single configuration for analyzing chemically diverse compounds with a single method or between multiple methods without the need for column changeover or other chromatographic delays. Perform headspace extraction, dissolution in aqueous solvents or non-polar alternatives, and direct sampling from powder or solid headspace back-to-back using the same instrument configuration. Syft Tracer Pharm11 enables the analysis of >200 samples daily with full user and data traceability. SyftAuditTracer software is fully compliant with 21 CFR Part 11 and includes a user-friendly interface for easy operation and data analysis.



Syft Tracer Pharm11 equips you to make critical decisions faster

- The first and only compliant solution for direct MS
- One configuration for multiple, diverse analyses
- Autosampler integration tailored to high-throughput SIFT-MS analysis, enabling the analysis of >200 samples / day
- Includes HTP Inlet designed for high-throughput applications
- Flexibility to append sequences to running batches
- Batch processing of quantitative run results
- Trace level multi-analyte detection sensitivity
- Highly selective and quantitative
- No chromatography or sample prep required
- Easy to operate and interpret data

SyftAuditTracer compliant software provides everything needed for user & data traceability

SyftAuditTracer delivers a complete software package for user and data traceability. This is the first and only real-time mass spectrometry software that is fully compliant with 21 CFR Part 11 guidelines. An audit trail is created in every step of the workflow including the login process, user logs and permissions, data acquisition, and data processing.

SyftAuditTracer

Login

Username

Password

Analyzer IP

Login process

SyftAuditTracer is a password protected system, requiring login to gain access to the interface. Only authorized users are permitted to engage the software. Security settings are included such as password expiry, password requirements, and automatic logout after inactivity.

Audit logs and reporting

Syft

Users

User: murraym

Username: murraym

First Name: Murray

Last Name: McEwan

Password: ••••••••

Access Profile: Analyst

New Reset Password Disable Save

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The audit logs of **SyftAuditTracer** record *which* actions were taken, by *whom*, and *when*, ensuring full traceability from before data acquisition, through analysis and completion of reporting. Important records (data, methods, audit log, reports, etc.) are retained in a non-editable format. The software enables users to periodically backup their systems (daily, overnight, etc.).

Syft

Access Profiles

Access Profile: Analyst

Actions

☒ Enable developer mode ☒ Develop methods ☐ Approve methods

☐ Approve own methods ☒ Use approved methods ☒ Start sequences

☒ Process data ☒ Export data ☐ Approve reports

☐ Enable service mode

Access

☐ Users screen ☐ Profiles screen ☒ Audit log screen

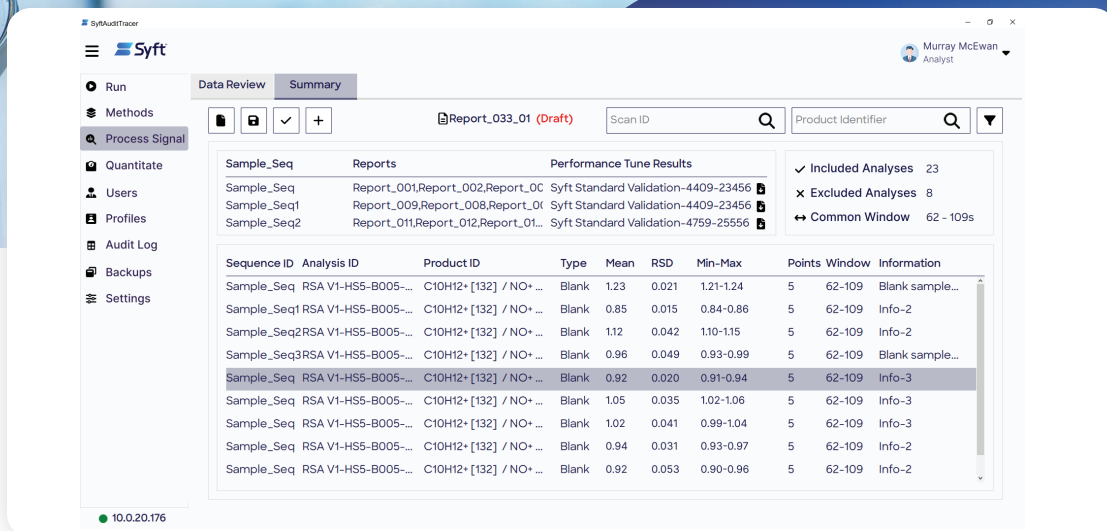
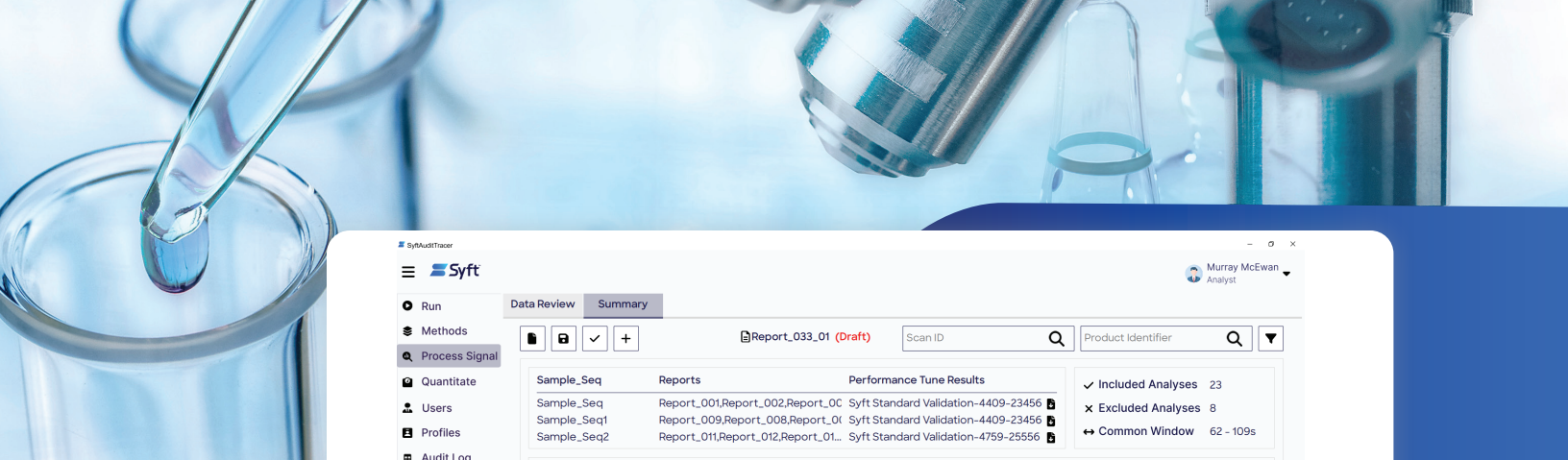
☐ Backups screen ☐ Settings screen

Save

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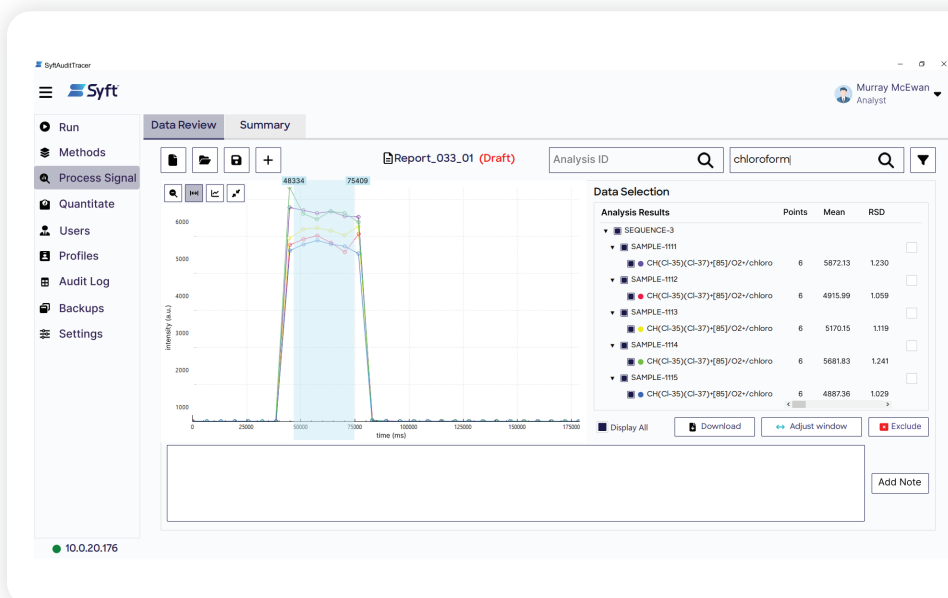
User profile permissions

The user roles and rights are configurable in **SyftAuditTracer** software. Different rights (create methods, run methods, sign off reports, user management, etc.) can be selected to match the responsibilities of defined roles (admin, analyst, lab manager, etc.). Syft can provide default rights for defined roles as needed.



Data acquisition & processing

SyftAuditTracer allows you to build, import, and manage SIFT-MS and autosampler methods with an intuitive user interface. This walk-up solution allows users to choose from pre-validated methods, initiate and monitor running sequences, view system status and metrics, append running batches, and batch process data. Steps and results of the daily Performance Tune procedure are recorded automatically. SyftAuditTracer makes it easy to track steps in your entire workflow from login and permissions setting to sequence setup and data processing.



Standard data processing tools are included with SyftAuditTracer including data viewing, raw signal processing, blank subtraction, quantitation using calibration curves or single point calibration, and the ability to export data as CSV files for further processing in other programs.

Physical Specifications

Instrument Size (including autosampler rail)	- Width: 135 cm (max, rail option may decrease) - Height: 185 cm - Depth: 114 cm
Computers	- Integrated into the instrument: Debian Linux - Mini PC
Minimum Computer Specs	- OS: Windows 11 pro - CPU: Intel Core i5 - Processor: 4.2GHz 64-bit processor - Memory: 16 GB RAM - Storage: 500 GB 1 built in Ethernet port - USB-C to Gigabit Ethernet adapter included 3 USB 3.2 ports, 1 USB 2.0 port, 1 free USB 4 (type C) port - Wi-Fi 6
Power	110-240 VAC
Syft CTC Autosampler Options	Lite, High-throughput, High-throughput flex
Headspace Syringe Temperature (°C)	40 - 150
Injection Volume Range (mL)	1 - 5 (Headspace Autosampler Dependent)
Incubation Temperature (°C)	50 - 100 recommended, up to 200 °C
Typical Incubation Time (min)	20 - 45
Typical Injection Time (s)	50 - 100
Typical Injection Speed (µL/s)	10 - 100
Incubator Capacity (n samples)	6
Samples per Hour	Method dependent up to 12
Inlet Temperature (°C)	120
Samples on Autosampler Rail	Up to 180

Syft CTC Autosampler Specifications

Lite	85 cm RSI, 1 x agitator, 2 x sample tray with rack, 2.5 mL HS syringe (+ extra syringe)
High-throughput	120 cm RSI, 2 x agitator, 3 x sample tray with rack, 2.5 mL HS syringe (+ extra syringe)
High-throughput Flex	120 cm RTC, 2 x agitator, 3 x sample tray with rack, 2.5 mL HS syringe (+ extra syringe)

Performance Parameters

Linearity	$R^2 > 0.99$
Mass Range	15 - 400 amu
Compound Coverage	1500+ compounds, expandable library of VOCs and inorganics

Example Working Concentration Ranges*

Ethylene Oxide ¹	100 - 5000 ng/g
Nitrosamines ²	2 - 160 ng/g
Class 2A & 2B Residual Solvents ³	9 - 90000 ng/mL (analyte dependent)
Benzene ³	0.1 - 600 ng/mL
Xylene (all isomers; ethylbenzene) ³	0.1 - 600 ng/mL

*Ranges can be much wider and vary from analyte to analyte; typical SIFT-MS LDR is >5 orders of magnitude

¹EtO measurement in polysorbate materials

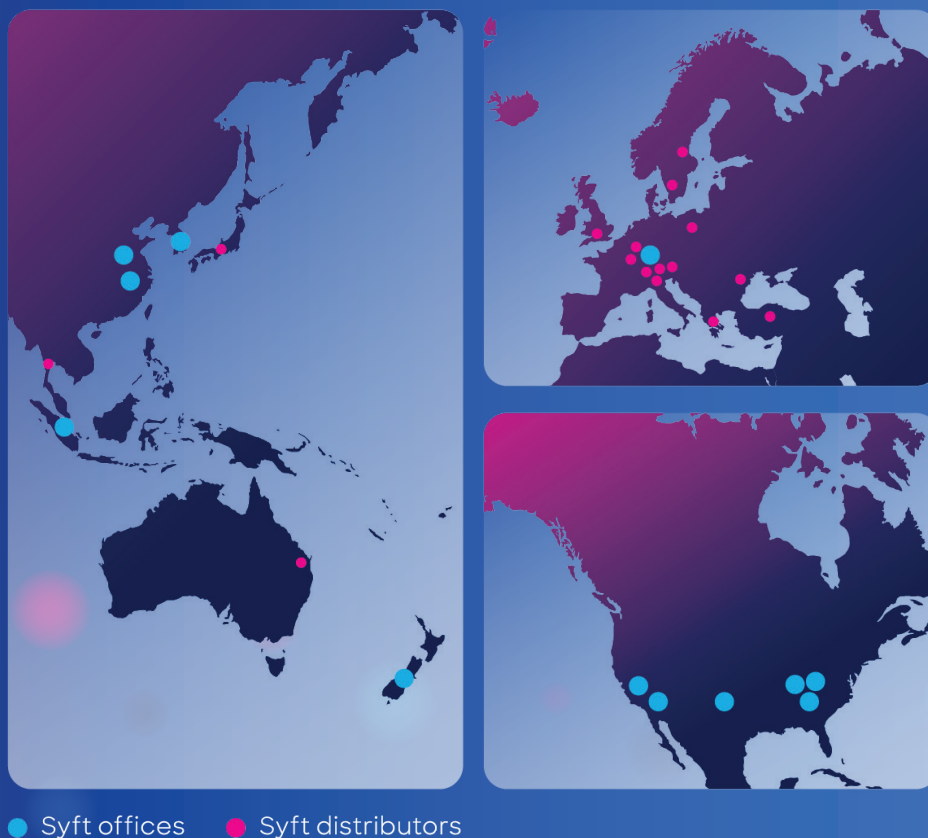
²NDMA measurement across full concentration range using NO⁺ m/z 74 quantitation ion.

³Concentration in 10 mL aqueous solution contained in 20 mL headspace vial.

About Syft: the trusted partner for real-time volatile analysis solutions.

Syft was founded in 2002 and has over 150 professionals in 7 countries. Syft is considered the world leader in real-time, direct injection mass spectrometry with more than 20 years of SIFT-MS expertise. Syft instruments support a broad range of industries worldwide including semiconductor manufacturing, pharma and CDMO, environmental protection, automotive, food, flavor and fragrances, and many more.

Customer Support offices are located throughout the world offering 24/7 service and support including those in New Zealand, Korea, Taiwan, Singapore, Germany and the U.S. Factory trained field support engineers and field application scientists are staffed in each Customer Support office. Regional service and application development support is available to assist with expanding your analyte compound list of interest.



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Simply. Faster.

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