thermoscientific

Thermo Scientific MAM 2.0

Straight through to breakthrough





End-to-end, Multi-Attribute Method solution from development to quality control

Thermo Scientific MAM 2.0 is a single-vendor, end-to-end solution developed for the biopharmaceutical industry. This holistic, compliance-ready platform contains tailor-made hardware and software products optimized for the needs and requirements of development through QC.

In addition to consistent and reproducible high-quality results at every stage, Thermo Scientific MAM 2.0 provides seamless connectivity for knowledge sharing on a global scale, giving you the confidence to make critical decisions fast.

HyperBridge Software

Complemented with expert support and service, the total Thermo Scientific MAM 2.0 solution enables any biopharmaceutical company to implement MAM as a reliable, future-proof analysis platform for biopharmaceutical development and production.

DEVELOPMENT

Vanguish Flex/Horizon UHPLC System

Orbitrap Exploris 240 Mass Spectrometer

Chromeleon CDS ----
MAM Workbook -----

BioPharma Finder Software -

MAM eWorkflow

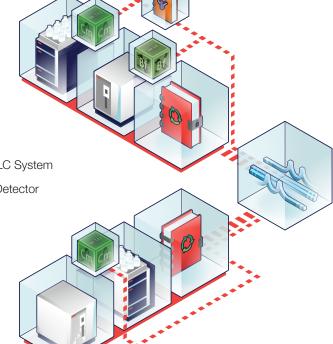
QC

MAM eWorkflow

Vanquish Flex/Horizon UHPLC System

Orbitrap Exploris MX Mass Detector

Chromeleon CDS



Data Management

Full, compliance-ready ecosystem with integrated data management and knowledge sharing for simplified MAM implementation from a single lab to a global scale.



Thermo Scientific™ Chromeleon™ Software

- Full, compliance-ready enterprise software designed to meet the needs from research through manufacturing and QA/QC.
- Single-software interface integrates data acquisition, data processing and reporting to seamlessly connect instruments for knowledge sharing.



Thermo Scientific™ BioPharma Finder™ Software

- Confident amino acid sequences confirmation and PQA identification with advanced data processing algorithms.
- Collaborative data processing and reporting while maintaining data security and integrity.
- Integration with Chromeleon Software for accelerated CQA identification.



Thermo Scientific™ HyperBridge™ Software

 Centralized and secure data storage to facilitate data connectivity from discovery to QC at a global scale.

Mass Spectrometers

High-quality HRAM data to ensure confident CQA identification and quantification using industry proven high performance Orbitrap mass spectrometers with enhanced robustness, stability and an extended product life cycle to meet MAM implementation needs in QC.



Thermo Scientific™ Orbitrap Exploris™ 240 Mass Spectrometer

- Full scan MS and MS/MS capability with resolution up to 240 K @ m/z 200.
- Stable mass accuracy with <3 ppm RMS drift in five days with EASY-IC.
- Fast scan speed of up to 22 Hz to ensure accurate PQA quantification.



Thermo Scientific™ Orbitrap Exploris™ MX Mass Detector

- Full scan capability with resolution up to 180 K @ m/z 200.
- Stable mass accuracy with <3 ppm RMS drift over at least four weeks using one-point calibration.
- Consistent unit-to-unit performance.
- Extended life cycle to meet the needs of manufacturing and QC.
- Full 21 CFR Part 11 and GxP compliance-readiness for data acquisition, processing and reporting.
- Easy method transfer from Orbitrap Exploris 240 system.

Liquid Chromatography

Full biocompatibility system with industry-leading flow and gradient precision ensures unsurpassed retention time reproducibility and peak area precision for high resolution separation and accurate quantification of PQAs.



Thermo Scientific™ Vanquish™ Horizon UHPLC System

- Pump pressure up to 1,500 bar (22,000 psi) allowing use of extra-long sub 2 um particle Vanquish columns for exceptional separation.
- Flow rate up to 5 mL/min.
- Up to nine solvent channels for binary high-pressure solvent mixing.



Thermo Scientific™ Vanquish™ Flex UHPLC System

- Pump pressure up to 1,000 bar (15,000 psi).
- Flow rates up to 8 mL/min.
- Up to six solvent channels for binary high-pressure solvent mixing.

Thermo Scientific™ Hypersil Gold™ Vanquish™ C18 UHPLC Column

These endcapped, ultrapure, silica-based columns deliver significant reduction in peak tailing, providing excellent resolution, efficiency and sensitivity.

System Performance Evaluation Tests (SET)

Thorough evaluation of whole system performance with a standardized method and a comprehensive list of acceptance criteria at installation and subsequent service calls.

Service and Support

Dedicated MAM workflow support team to ensure maximum productivity.

Application Training

Holistic MAM training on all aspects of the MAM 2.0 workflow, provided by a MAM application specialist.

Installation and Service

MAM-trained engineers to support the entire workflow.

Technical Support

Dedicated support process and resources for fast response.

