

Biopharma

By your side

Accelerating biotherapeutic development

Enabling every step of your biotherapeutic development

We equip you to overcome today's and tomorrow's challenges with tools and expertise to advance life-changing biotherapeutics to market faster than ever before.

Why? Like you, we are inspired to make the world healthier, cleaner, and safer. By enabling scientists, we believe that together we can make a significant impact by improving the lives of countless individuals.

Your molecules are complex

Biotherapeutics such as monoclonal antibodies, biosimilars, antibody-drug conjugates, and nucleotide-based therapies are increasingly important drug classes. Most biotherapeutic drug products are fundamentally more complex than traditional chemically synthesized products, and are subject to modification events, throughout development, manufacturing and storage.

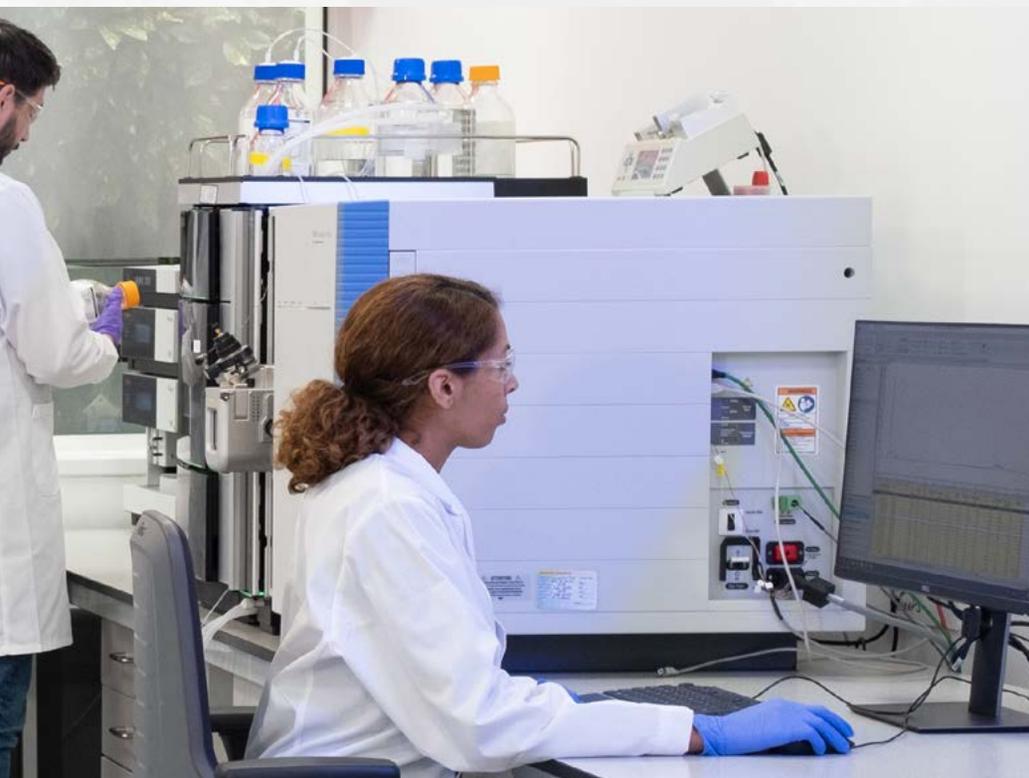
You need fit-for-purpose tools at each development stage

Well-designed characterization technologies provide unique insights which advance the development of biotherapeutics. Comprehensive characterization, allowing for full product understanding can save significant time and development costs. Throughout process development and manufacturing, tools are required for reliable monitoring of product microheterogeneity to ensure drug safety and efficacy. Together, we can address the challenges of biotherapeutic drug development.



Technology innovations to help you on your drug development journey

Our technology innovations have been specifically designed with the rapid pace and complexity challenges of biotherapeutic development in mind. From early discovery through to delivery of a commercial product, we provide technologies to confidently answer your analytical questions, bringing life-changing biotherapeutics to market faster than ever before.



Enabling analytical tools for each stage of biopharmaceutical development



Early discovery and research

Early development phases identify potential molecules to develop as drug candidates. Includes the search for pipeline candidates.

Requires: High-throughput capabilities and versatile, advanced tools.



Process and analytical development

In process development, an in-depth understanding of process effect on biomolecules allows for quicker progression through the development pipeline.

Requires: Robust and reproducible analyses to monitor molecular attribute changes with speed and confidence.



Product characterization

At this stage, the analytical focus shifts to gaining a deep product understanding.

Requires: Advanced tools to answer in-depth molecular questions with full confidence.



Quality control and manufacturing

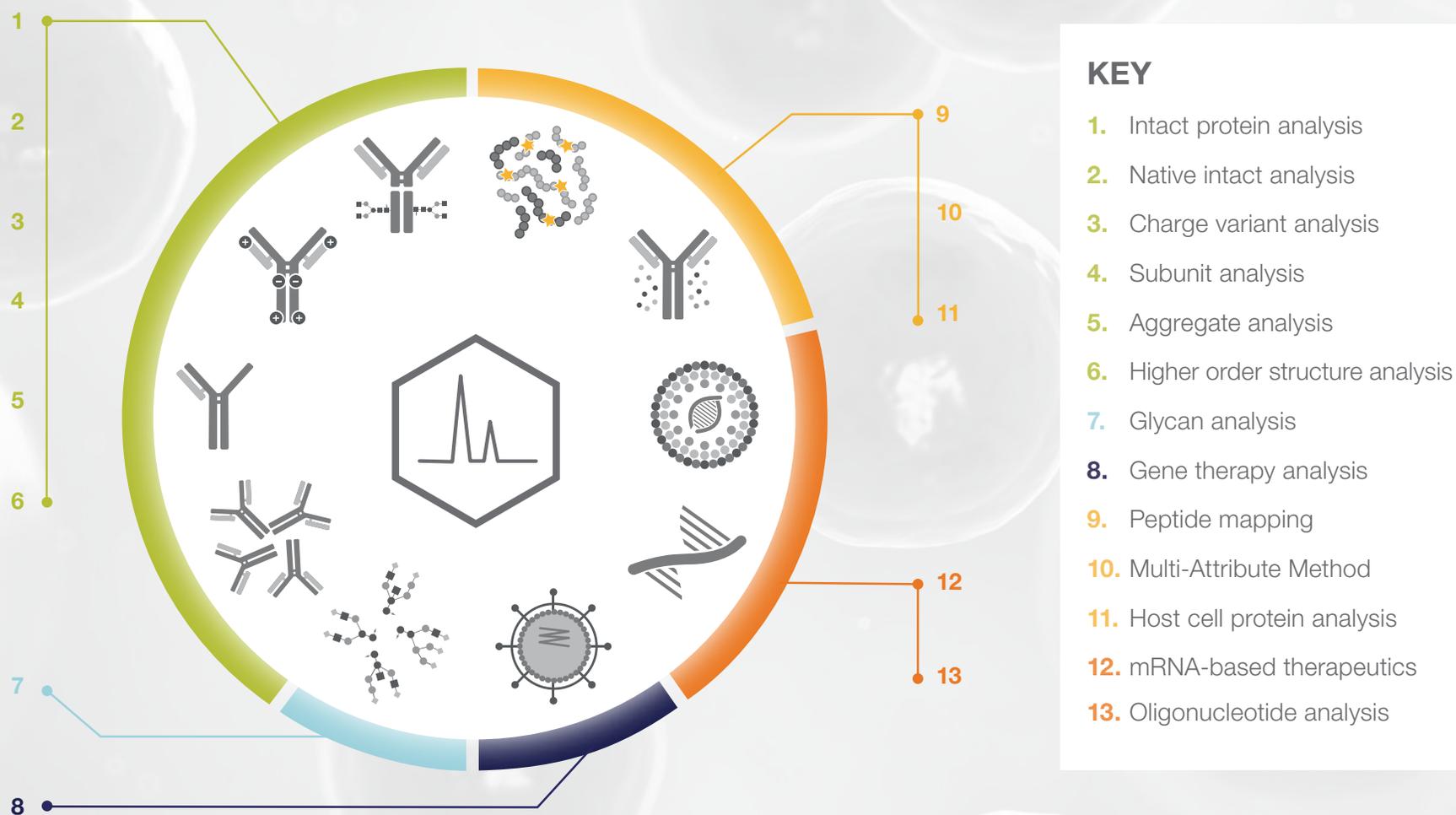
Small changes in manufacturing conditions can have a significant impact on product quality. To ensure the release of safe and effective products, advanced analytical methods are implemented to closely monitor CQAs for each batch.

Requires: Reproducible, robust, GMP compliance-ready methods.

From discovery to commercialization, Thermo Fisher Scientific provides expertise and a superior array of scalable tools, services, and support, designed to deliver high-quality results and accelerate your productivity and innovation.

Analytical solutions for all your biopharmaceutical workflows

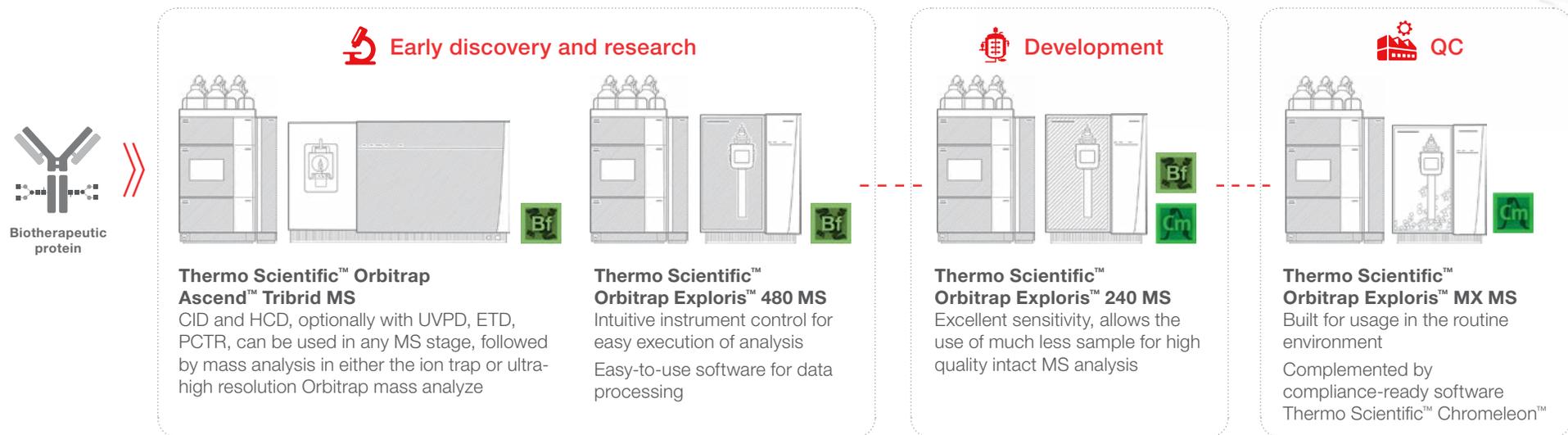
Thermo Scientific offers a superior set of fit-for-purpose workflow solutions to meet your biopharmaceutical characterization, control, and compliance needs with confidence. Our solutions enhance your productivity and innovation with high-quality results to answer your most difficult analytical questions more quickly for a broad range of biopharmaceutical workflows.



Intact protein analysis

Efficient intact protein analysis for rapid assessment enabling confident identification

There is a need for a more efficient protein analysis approach that saves time on sample preparation and offers simple data analysis. The ideal solution provides high throughput, information-rich data, and fast assessment of post-translational modification levels.

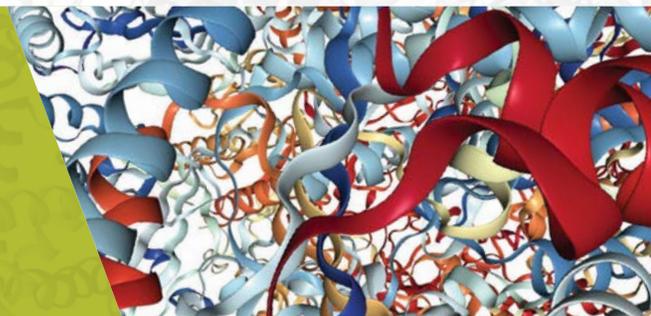


Value-added workflow benefits

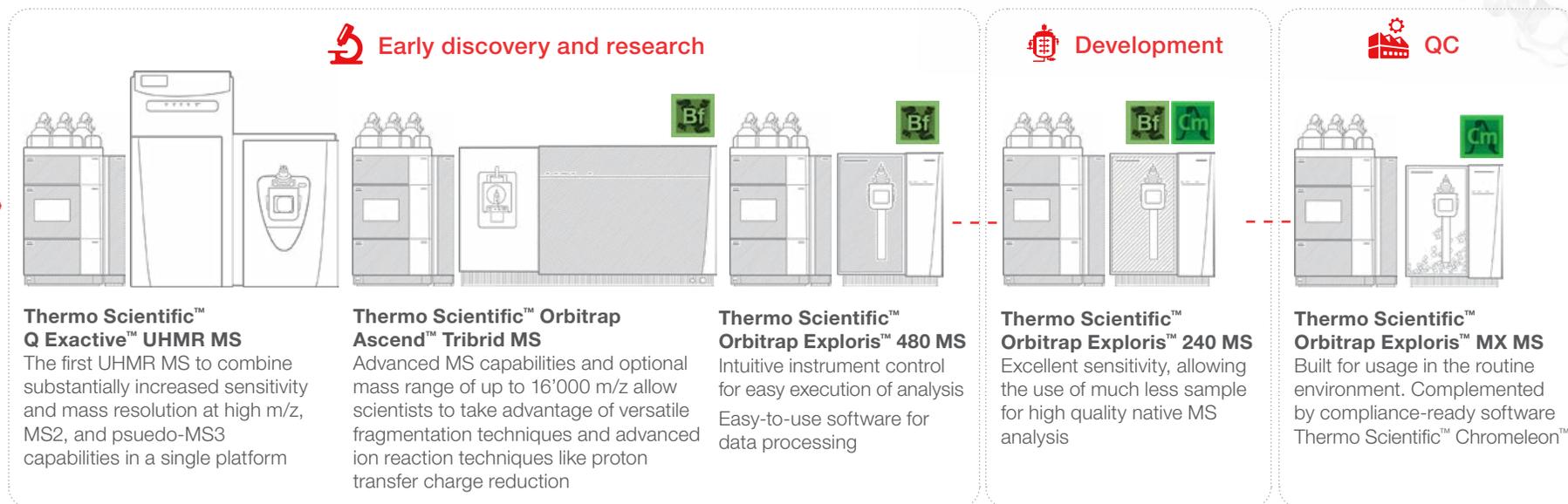
- Direct infusion techniques or separation allow intact protein analysis
- Screen, identify, and characterize intact proteins with higher productivity and confidence using the Intact Protein workflow in Thermo Scientific™ BioPharma Finder™ software
- BioPharma mass extension available for Orbitrap Exploris 240 and 480
- Quickly confirm intact protein molecular weight and determine glycoform heterogeneity of biopharmaceuticals

Intact protein analysis under near-native conditions

Analysis of intact proteins and protein-complexes, in their true biological states



Analyzing complex therapeutic proteins like antibody-drug conjugates (ADCs) is a significant challenge. The Thermo Scientific Orbitrap Exploris mass spectrometers, coupled with size exclusion or ion exchange chromatography and compatible buffers, enable routine intact protein analysis under native conditions.



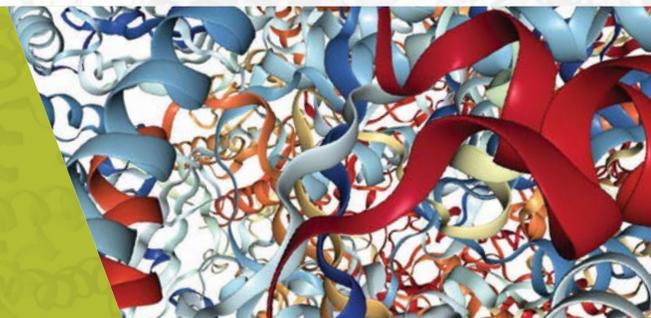
Value-added workflow benefits

- Use Thermo Scientific MAbPac SEC-1 Size Exclusion Columns for high-resolution separation of monoclonal antibody (mAb) analysis, including monomers and aggregates
- BioPharma option to extend mass range available for the Orbitrap Exploris 240 and 480 MS systems
- Excellent mass spectrometric data, intuitive instrument control and easy-to-use software for data processing
- Q Exactive™ UHMR Hybrid Quadrupole Orbitrap™ Mass Spectrometer offers precise mass determination, peak interference mitigation, and the ability to study heterogeneous protein assemblies



Charge variant analysis

Full solutions from mobile phase preparation to purpose-built software

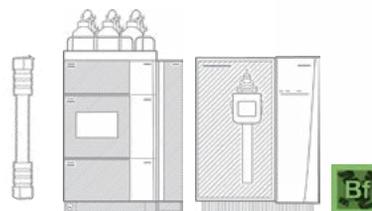


Heterogeneity of monoclonal antibodies must be monitored and revealed by charge sensitive techniques. Two workflows specific to your needs:

1. Separation by charge followed by mass spectrometry (CVA-MS) allows for characterization of post-translational modifications (PTMs) at the intact protein level.
2. Salt gradient cation-exchange chromatography can be used to monitor mAb charge variants.



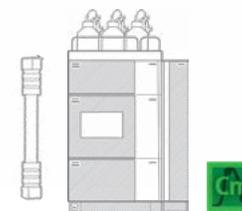
Characterization



Thermo Scientific™ Vanquish™ UHPLC System & Orbitrap Exploris 240 MS

Speed and accuracy are key criteria for laboratories performing charge variant profiling with an out of the box sample capacity of 216 samples. The Vanquish UHPLC system and the Orbitrap Exploris 240 MS offers the speed and accuracy required for charge variant profiling

Routine monitoring



Vanquish™ UHPLC System

Obtain new benchmarks in accuracy, precision and sensitivity in charge variant analysis with the Thermo Scientific™ Vanquish™ UHPLC systems. Providing biocompatibility with a state-of-the-art quaternary or binary high-pressure solvent blending, these ultra-high performance liquid chromatography systems share all Vanquish values, such as a design focused on uptime, robustness and reliability



Value-added workflow benefits

- Simplified and fast ion exchange analysis (IEX) of charge variants using a pH gradient
- Obtain fast and highly robust, reproducible HPLC gradients using Thermo Scientific™ CX-1 pH gradient buffer kits. The CX-1 buffers save time in method development, facilitate method transfer to QA/QC
- The Orbitrap Exploris 240 MS offers high sensitivity, allowing for the detection and quantification of low abundance charge variants
- Vanquish UHPLC systems offer dependable, flexible, and productive separations



Learn more about charge variant analysis



Webinar - Taking Charged Variant Analysis to the next level

Subunit analysis

Easy deconvolution by harnessing the power of Thermo Scientific BioPharma Finder Software

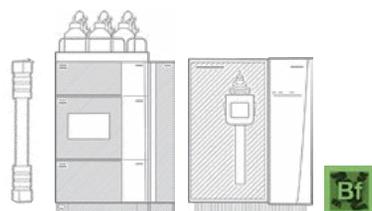
Monoclonal antibody (mAb) subunit analysis involves the antibody fragmentation through digestion and reduction of IgG antibody molecules. The cysteine protease produced by *S.pyogenes*, known as IdeS, is highly specific. IdeS digestion followed by reduction generates three subunits that are readily separated by reversed-phase (RP) UHPLC using Thermo Scientific MAbPac RP columns. Deconvolution of subunit mass spectrometry (MS) spectra is easy with powerful Thermo Scientific BioPharma Finder software.



Subunits

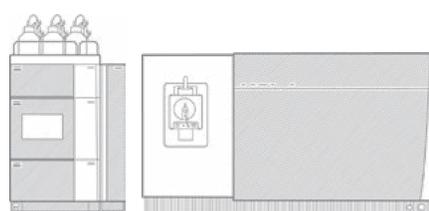


Characterization



Vanquish UHPLC System & Orbitrap Exploris 240 MS

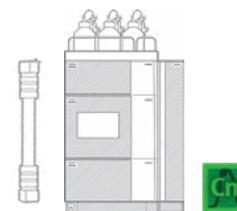
The extreme resolving power of the Thermo Scientific Orbitrap mass analyzer ensures isotopic resolution of monoclonal antibody subunits and facilitates middle-down sequencing.



Thermo Scientific™ Orbitrap Ascend™ Tribid MS

Quantify more samples at lower concentrations using faster acquisition, while achieving greater coverage using a revolutionary new hardware design featuring dual ion routing multipoles

Routine monitoring



Thermo Scientific™ Vanquish UHPLC System

Take advantage of MAbPac SEC-1 columns which offer superior, reproducible separation of monomers, aggregates, and fragments resulting from proteolysis



Value-added workflow benefits

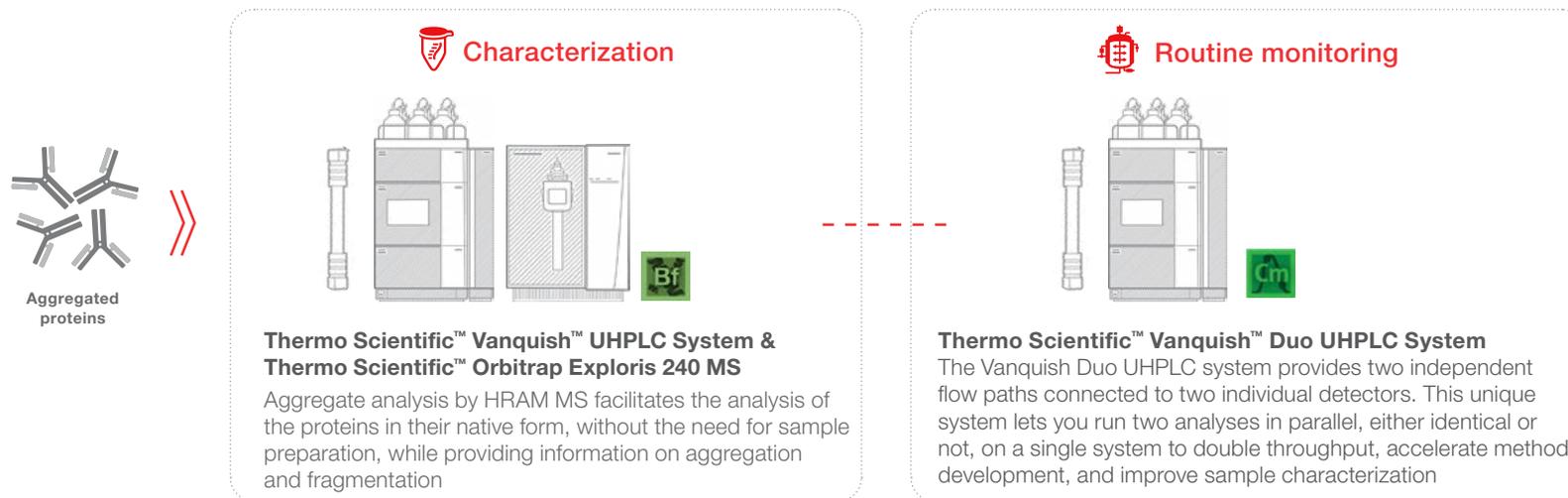
- Subunits are readily separated by reversed-phase (RP) UHPLC using Thermo Scientific MAbPac RP columns
- Deconvolution of subunit mass spectrometry (MS) spectra is easy with powerful Thermo Scientific BioPharma Finder software
- Thermo Scientific™ Pierce Fab Preparation Kit uses immobilized pepsin protease to digest human or mouse IgG antibodies to make separate Fab and Fc antibody fragments



Aggregate analysis

High resolution separation of monomers and aggregate peaks

The consistent quality of biologic products must be ensured by monitoring protein aggregates throughout the production process, as aggregates can have serious negative effects. Failure to monitor protein aggregates can result in incorrect drug dosage, decreased solubility, and activity loss.



Value-added workflow benefits

- High resolution separation of fragments, monomers and aggregates
- BioPharma option to extend mass range available for the Orbitrap Exploris 240 MS
- Thermo Scientific™ Vanquish™ Duo UHPLC system for Dual LC provides simple and rapid high-throughput analysis of aggregates
- Compliance-ready analytical setup using Thermo Scientific™ Chromeleon™ software for the monitoring stage



Learn more about aggregate analysis



Webinar - Application Note Video - A universal Chromatography Method for Aggregate Analysis of Monoclonal Antibodies

Higher order structure analysis

A robust method for the analysis of protein conformation, conformation dynamics, and protein-protein interactions

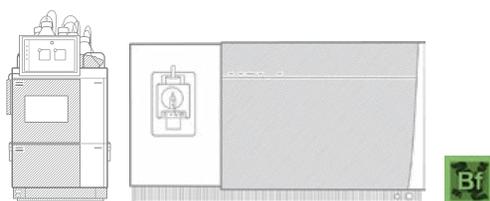
Full structural characterization is critical where local conformational changes can impact safety and efficacy. Hydrogen deuterium exchange (HDX) mass spectrometry (MS) is a powerful analytical approach for studying the dynamics of higher order structure of protein-based therapeutics. We offer a unique total solution for your HDX workflow.



Biotherapeutic protein

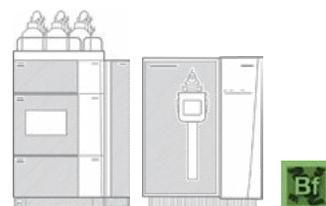


Early discovery and research



Thermo Scientific™ Neo™ Nano LC & Orbitrap Ascend Tribrid MS

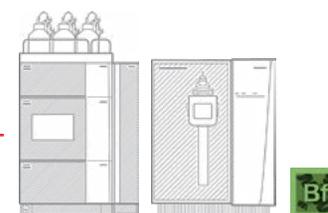
Delivering the ultimate flexibility to expand experimental scope, and with built-in intelligence, Orbitrap Ascend Tribrid Mass Spectrometer ensures the highest data quality for HDX-MS experiments



Orbitrap Exploris 480 MS

Intuitive instrument control for easy execution of analysis
Easy-to-use software for data processing

Development



Orbitrap Exploris 240 MS

Thermo Scientific™ Orbitrap Exploris™ 240 mass spectrometer fast tracks your path to high-confidence data and identification



Value-added workflow benefits

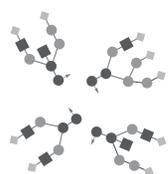
- Sample preparation and labelling is made easy by our partners, Trajan Scientific and Medical. Trajan's LEAP HDX sampler system enables automated labelling and digestion
- The Vanquish Neo UHPLC system combines an unrivaled degree of innovation to deliver 24/7 reproducible separations of complex mixtures at maximum performance for a variety of high-sensitivity LC-MS workflows
- Thermo Scientific BioPharma Finder software supports all HDX-MS data analysis, including peptide identification, PTM analysis and HDX-unique protection factor plots at the single residue level



Glycan analysis

Comprehensive toolbox for glycan analysis

Analysis of glycans can be complex as no single method will provide all information, but there are many different approaches for glycan analysis. Thermo Fisher Scientific offer full solutions to analyze glycans utilizing UHPLC, UHPLC-MS and IC for analysis of glycoforms.



Glycans

Characterization



Thermo Scientific™ Orbitrap Ascend™ Tribrid MS
Quantify more samples at lower concentrations using faster acquisition, while achieving greater coverage using a revolutionary new hardware design featuring dual ion routing multipoles

Routine monitoring



Vanquish UHPLC System & Orbitrap Exploris Platform or Thermo Scientific™ ICS-6000™ Ion Chromatography system

Monitor released N- & O-glycan without labelling
Flexibility: Ion chromatography with pulsed amperometric detection (HPAE-PAD) OR LC with charged aerosol detection (CAD)



Value-added workflow benefits

- Flexible solutions for all analytical strategies
- Fit for purpose sample preparation options
- HRAM MS for outstanding intact protein or glycopeptide analysis
- Easy-to use fit for purpose software capabilities from discovery to control



Learn more about glycan analysis



Webinar - Advancing carbohydrate analysis - Glycans

Gene therapy analysis

Fast, accurate, and scalable methods for gene-therapy-based products

For gene therapy products, vector attributes need to be monitored, including purity, identity, and empty: full capsid ratio. Considerations that should be made whilst evaluating analysis options include: Sensitivity for low sample amounts, fast, robust LC separation and confident mass confirmation to ensure the development of safe, high-quality gene therapy products while reducing time-to-market and reducing costs of manufacturing.

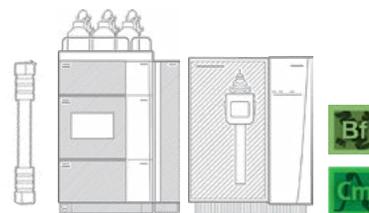


Intact capsid mass analysis



**Thermo Scientific™ Q Exactive™
UHMR Hybrid-Quadrupole Orbitrap MS**
Native mass spectrometry-based approach to assess the ratio of empty to full AAV-capsids
Ultra-high mass range (up to m/z 80,000)

Capsid protein characterization



Vanquish UHPLC-Orbitrap Exploris 240 MS
The correct AAV serotype is selected, then identity and purity are monitored; either on the intact protein level or by peptide mapping



Value-added workflow benefits

- Robust and reliable separation for rapid monitoring using Vanquish UHPLC
- Analysis of megadalton biomolecular assemblies
- Confident characterization of virus capsid proteins
- Determine molecular weight and heterogeneity with Direct Mass Technology mode

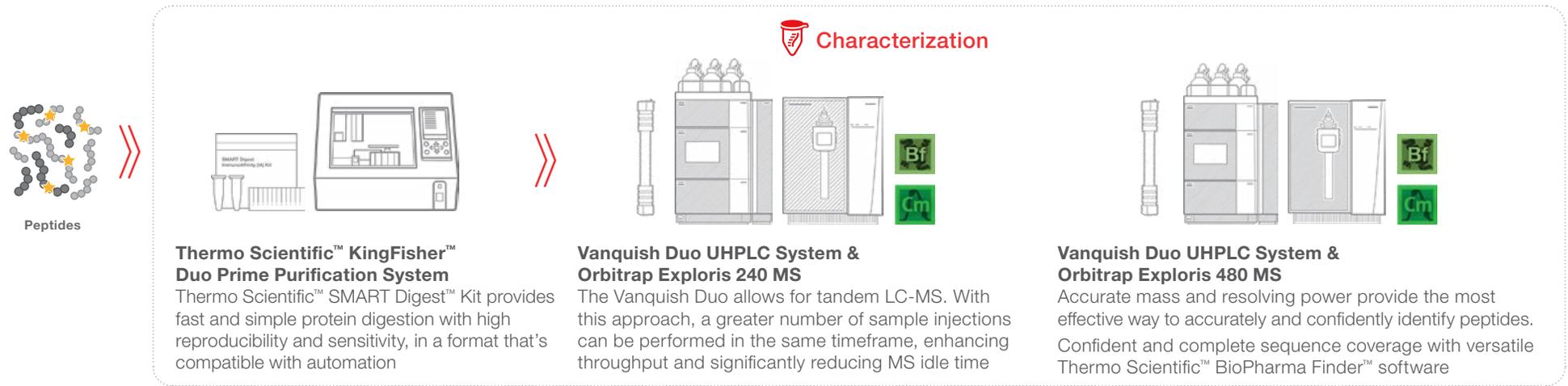


Peptide mapping

High throughput peptide mapping with Vanquish Duo UHPLC system



Accurate peptide mapping is crucial for determining sequence coverage, identifying and quantitating post-translational modifications, determining disulphide bonds, identifying sequence variants, and performing de novo sequencing of proteins. Failure to accurately perform peptide mapping can result in incomplete or incorrect protein characterization, compromising the safety and efficacy of biologic products.



Value-added workflow benefits

- Automation options and kit-based protein digestion for the reproducible results
- High throughput peptide mapping with Vanquish Duo UHPLC system
- Complete product characterization: Sequence coverage, PTMs, Disulfide bonds and Sequence variants



Learn more about peptide mapping



Webinar - Rapid Automated Peptide Mapping

Multi-Attribute Method

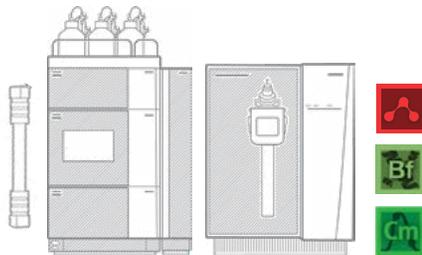
A platform from discovery and development to QC

The Multi-Attribute Method (MAM) is a peptide mapping-based method used to quantify multiple potential CQAs simultaneously. Thermo Scientific™ MAM 2.0 is a powerful high resolution accurate mass-based workflow that enables comprehensive characterization and monitoring of quality attributes from research to quality control (QC). MAM is in alignment with the QbD approach to the development of biopharmaceuticals, which is advocated by regulatory agencies and is being adopted by biopharmaceutical companies.



Characterization

Research & Development
Attribute Characterization | Product Quality Attribute Monitoring

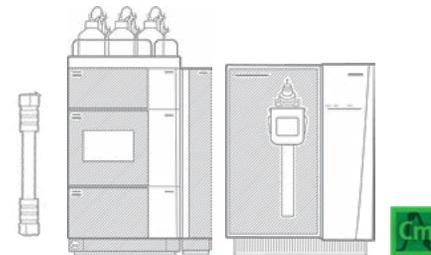


Thermo Scientific™ Vanquish™ Flex or Horizon UHPLC System & Orbitrap Exploris 240 enables comprehensive characterization of product quality attributes



Routine monitoring

Manufacturing & QC
Critical Quality Attribute Monitoring | New Peak Detection



Vanquish Flex or Horizon UHPLC System & Thermo Scientific™ Orbitrap Exploris™ MX enables confident monitoring of critical quality attributes



Value-added workflow benefits

- Seamless and direct method transfer from lab-to-lab
- End-to-end, compliance-ready platform for deployment from development to QC
- Enterprise software platform for connectivity at global scale leveraging the power of enterprise Chromeleon and Ardia Platform software.
- Confident and consistent attribute identification and monitoring with high resolution and accurate mass data



Host cell protein analysis

Fast analysis achieved by harnessing the power of Orbitrap technology



The analytical solution for Host Cell Protein (HCP) monitoring must be both robust and fast, and capable of identifying and quantifying multiple HCPs in a single chromatographic separation. To meet the growing demand for increased process understanding, scientists are turning to reliable UHPLC systems coupled with HRAM mass spectrometers for accurate and reliable HCP monitoring throughout the purification process.



HCPs



KingFisher Duo Prime Purification System

Non-denaturing protein digestion with SMART Digest kit reduces intra-sample dynamic range and increases host cell protein (HCP) identifications

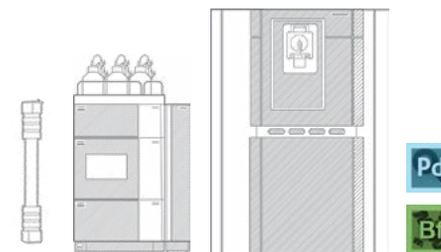


Characterization

Vanquish™ Duo UHPLC System & Orbitrap Exploris 480 MS

Detection of HCPs ranging in concentrations from <0.5 ppm to 200 ppm

Identify and quantify multiple HCPs in a single chromatographic separation, allowing for reliable HCP monitoring throughout the purification process



Vanquish Neo Nano LC & Thermo Scientific™ Orbitrap™ Astral™ MS

The Orbitrap Astral Mass Spectrometer helps overcome the challenges of insufficient throughput, low abundant HCP ID and provides sub ppm quantification



Value-added workflow benefits

- Ready-to-use single informatics workflow for peptide mapping and HCP data processing and visualization
- HRAM MS data combined with Thermo Scientific™ Proteome Discoverer™ software provides confident HCP identifications
- Increased sensitivity enabled by micro-flow rate separation allows detection of low abundant HCPs



Learn more about host cell protein analysis



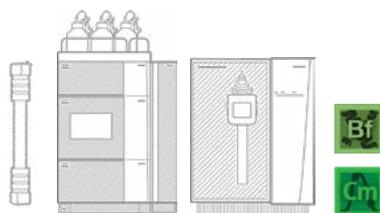
Video - Optimized sample preparation for low ppm detection of Host Cell Proteins (HCPs) in biopharmaceuticals with Orbitrap-based MS detection

mRNA-based therapeutics

A portfolio of solutions to fully understand mRNA-based drug products

mRNA based therapeutics are a fast growing market but the analysis of these drugs is extensive. Analysis includes Intact mRNA analysis, mRNA mapping, lipid nanoparticle analysis, mRNA capping efficiency and poly(A) tail analysis. Choosing the right hardware and software solution will enable confident and fast analysis of mRNA-based therapeutics.

mRNA mapping



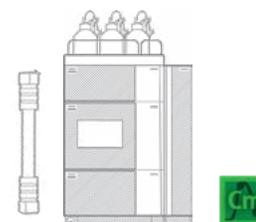
Vanquish UHPLC-Orbitrap Exploris 240 MS

Accurate sequence identification through automated annotation of high quality HRAM MS and MS/MS spectra in BioPharma Finder software



mRNA Therapeutic

Lipid nanoparticle analysis



Vanquish UHPLC-Charge Aerosol Detector (CAD)

Fast high-resolution separation on the Thermo Scientific™ Accucore™ C30 column in 10 minutes
Universal detection with wide dynamic range up to 105, quantification of impurities and high-level API in a single run



Value-added workflow benefits

mRNA Mapping

- Direct sequence analysis of large mRNAs by LC-HRMS
- Simple automated workflow suitable for unmodified and modified mRNA

Lipid Nanoparticle Analysis

- CAD - Industry leading technique for determination of lipid nanoparticle (LNP) composition



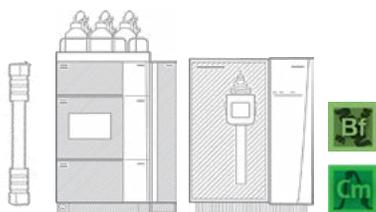
Oligonucleotide analysis

Versatile solutions for oligonucleotide analysis

Oligonucleotides are being developed as therapeutic agents and vaccines against a wide range of disease conditions. Oligonucleotides must be analyzed to understand their sequence and to identify, quantify and monitor their modifications and impurities.

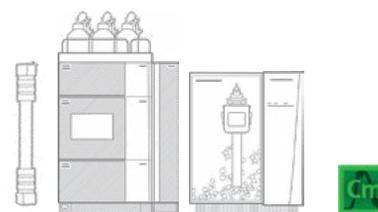


Characterization



Vanquish UHPLC-Orbitrap Exploris 240 MS
Using the high-resolution accurate mass and data, one can confidently identify, map, and relatively quantitate oligonucleotides, impurities, and degradation products in a single experiment

Routine monitoring



Vanquish UHPLC-Orbitrap Exploris MX MS
Orbitrap-based mass spectrometers with class leading accurate mass and resolving power



Value-added workflow benefits

- Oligonucleotide-designed DNAPac LC column family to fit wide oligonucleotide needs
- Rapid assessment of oligonucleotide purity
- Excellent separation of 21mer oligonucleotide and its impurities using the Thermo Scientific™ DNAPac™ RP column with the Vanquish Horizon UHPLC system
- Unique fit-for-use oligonucleotide analysis workflow in BioPharma Finder software

By your side goes beyond products

As a company with a deep understanding of the challenges of biotherapeutic development, we are driven to perfect the technologies that help you deliver next-generation drugs to market faster. You're gaining ground and advancing science at every step. It's a lot of pressure, but you've got the knowledge and we're here to help. That's why being by your side extends well beyond our technologies. Thermo Fisher Scientific also supports you with superior services and application expertise that we've spent over decades curating. By getting the most out of your Thermo Scientific workflow solutions, you can put your focus where it needs to be—making a positive impact.

**Learn more about how Thermo Fisher Scientific
can power your biotherapeutic discovery**

 Learn more at thermofisher.com/byyourside

thermo scientific