



CHROMATOGRAPHY

MASS SPECTROMETRY

INFORMATICS

DATA WORKFLOWS IN ONE PLATFORM



Waters
THE SCIENCE OF WHAT'S POSSIBLE.®

UNITING LABORATORY INFORMATICS



A more efficient way to work

Waters® UNIFI® Scientific Information System is an integrated workflow-focused, data platform that delivers significant productivity improvements. UNIFI is the first product to seamlessly combine LC, MS, and data management into a single software platform that encompasses data acquisition, processing, visualization, reporting, and configurable compliance tools within a workstation or networked laboratory environment.

UNIFI provides organizations the flexibility to deploy UNIFI-based systems within regulated and non-regulated laboratory environments while employing high resolution UPLC® separations and high performance mass spectrometry across the entirety of discovery, development, and quality control. UNIFI's data mining and comparison capabilities enhance your ability to understand results with an unparalleled capability to aggregate and manage data.

Built for your laboratory success today and for the future

The vision of the UNIFI Scientific Information System centers on harmonizing software solutions, that were once separated, into an integrated platform.

To achieve the vision, UNIFI is deployed in application-specific solutions such as Biopharmaceutical, Bioanalysis, Metabolite Identification, Natural Products, Toxicology, Pesticide Screening and other screening solutions, such as Extractables and Leachables. Solutions are deployed as either workstations or in a network environment. As subsequent versions of UNIFI are released, its powerful capabilities will extend from workstation to enterprise-scale deployments so that organizations can realize scientific, productivity, and financial gains from their scientific data.

Key benefits of the UNIFI Scientific Information System



Streamline analytical laboratory processes by standardizing workflows across laboratories, and expedite development decisions and regulatory filings with efficient information consolidation.



By applying data management policies based on your corporate data retention policies, you can move data from the relational database (using off-line storage manager) to a remote storage location, freeing up space in the repository. Data stored off-line remains accessible and can be easily retrieved by the end user at anytime.



Enables easier transfer of information between users and departments, to reduce the waste and variability in data management and sharing during product innovation, development, and manufacturing support.



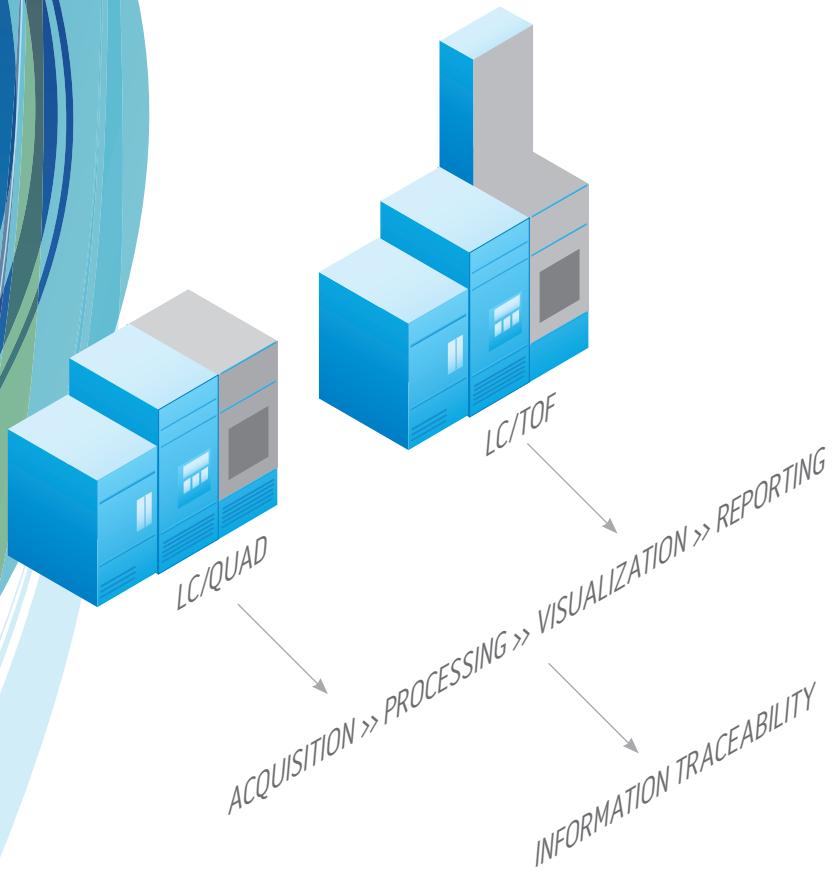
With UNIFI's Network configuration, centralized data management improves data processing since reporting, methods, and processing steps can be initiated at a client computer and run on the server without the need to move large data files.



Your organization knows best how to meet your regulatory compliance requirements; Waters provides you with configurable tools to enable your company to deploy analytical technologies with the greatest efficiency.



Reduce your workflow times with ready-to-use comprehensive scientific libraries and easily create fully-customizable user libraries. Secure storage of detection results for compounds, spectra, documents, and relevant chemical information – everything in one place and completely searchable. All of the information you store can be easily retrieved and shared with colleagues and collaborators across laboratories.



MINIMIZE

TRAINING AND IMPROVE COLLABORATION

A single platform for chromatography, mass spectrometry, data management, and laboratory workflow

The UNIFI Scientific Information System was designed to meet the converging needs of analytical researchers, QC analysts, QA/QC reviewers, and IT departments. Built with an extensible software architecture that meets the future demands of both internal and outsourced functions, the platform manages the diverse needs of acquiring, processing, reporting, storing, and permission-based access to the complex scientific information generated by UPLC-MS and UPLC-MS/MS systems.

By uniting UPLC and MS analytical technologies with a single software platform that has been purposefully designed to facilitate data analysis in a specific workflow, and built upon the infrastructure necessary to meet GxP compliance and IT best practices, the UNIFI Scientific Information System combines capabilities that were previously only available in separate software solutions.

ADAPTS

TO YOUR DEPLOYMENT NEEDS

Scalable from workstation to network and beyond

UNIFI software can be deployed as part of a workstation-based solution and can grow with your laboratory to support multi-user, server-based networks to capture, store, and manage LC, LC-MS, and LC-MS/MS data.

UNIFI provides tools for mining and sharing of data, thereby improving the productivity of your collaborative efforts. Its open architecture enables interfacing to Waters instruments and software systems, and the print and file capture ability of UNIFI allows the consolidation of disparate scientific information.

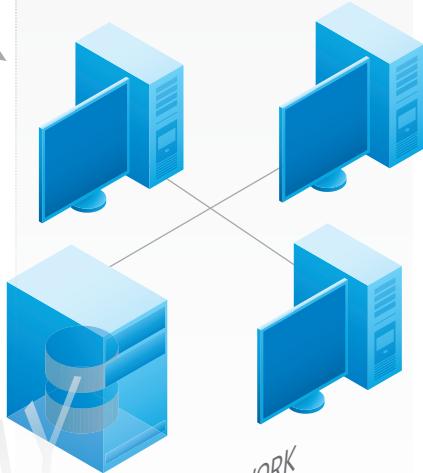
Scalable configurations include:

A workstation supporting a single user at a time.



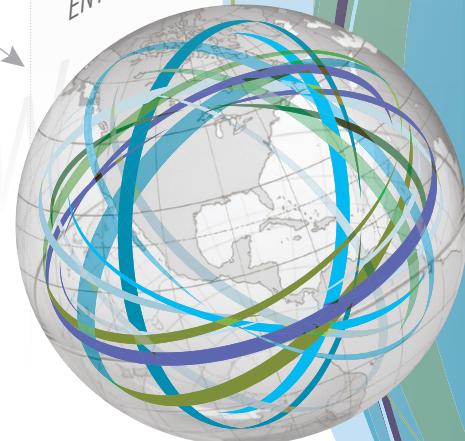
WORKSTATION

A network capable of supporting a laboratory or small department with up to 25 simultaneously logged-in users.



NETWORK

The UNIFI network architecture will allow for a future enterprise-scale network that supports multiple laboratories or large departments with hundreds or thousands of simultaneously logged-in users across different sites and, in many cases, across geographies.

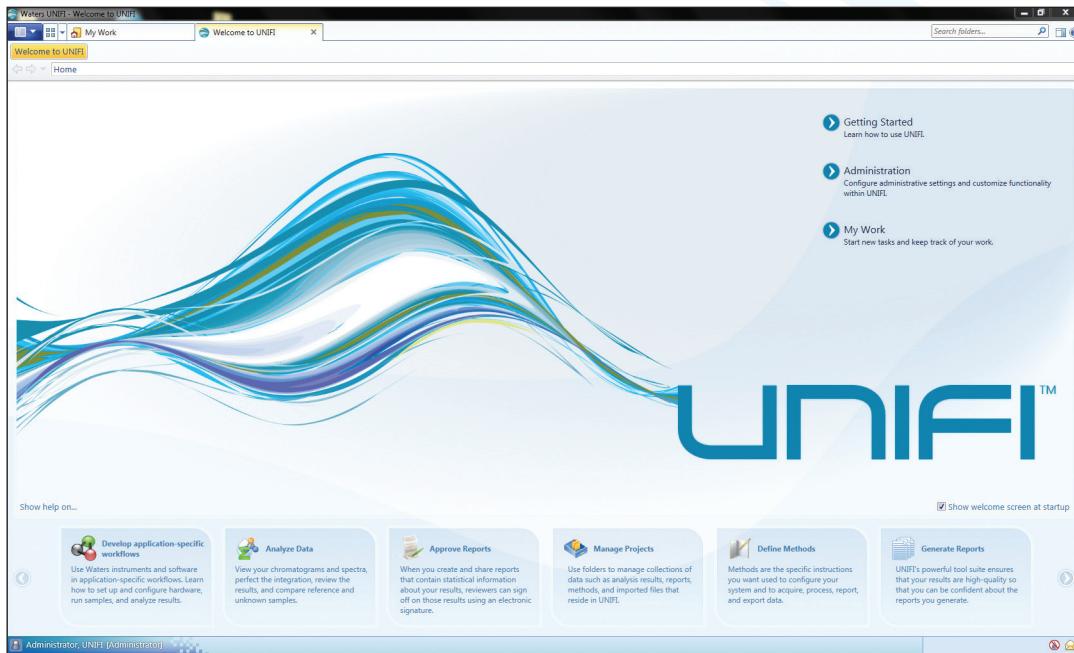


ENTERPRISE

TODAY

TOMORROW

MAXIMIZE SYSTEM USABILITY

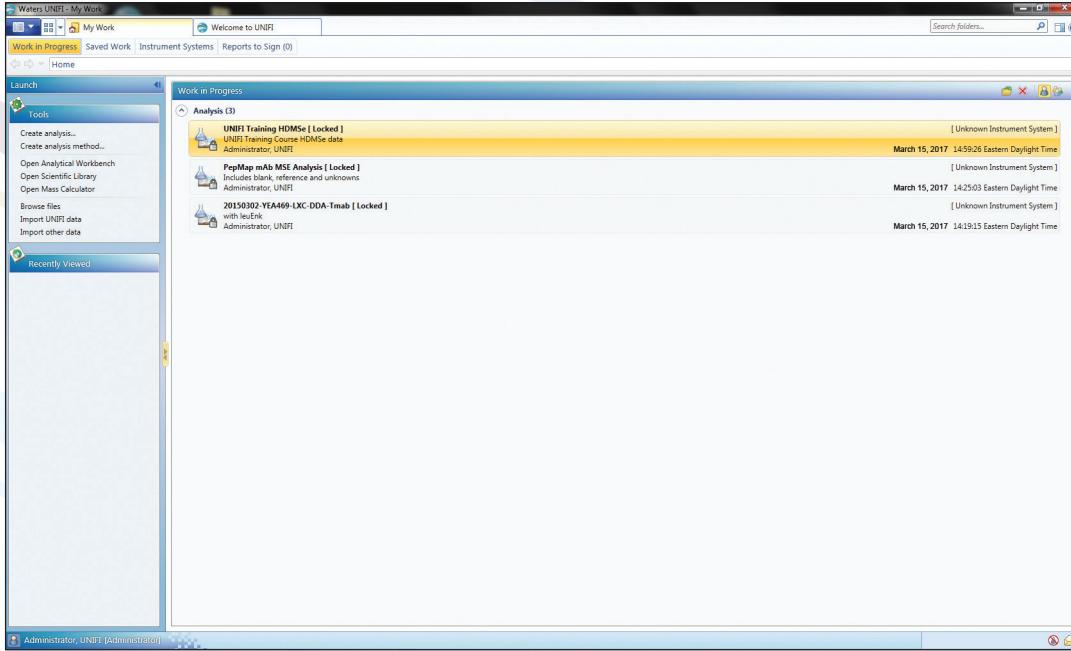


From its Welcome page, UNIFI provides quick access to the tasks you need to accomplish.

Intuitive user interface based on user-centered design and tailored workflows

The key to the characterization of complex samples lies in the use of appropriate combinations of analytical methods to analyze samples using orthogonal detection methodologies. Many analytical methods in process require an integrated workflow – a process through which comprehensive molecular characterization information can be acquired both reliably and in a routine manner.

The UNIFI solution features innovative functionality that was developed to support the day-to-day realities of a dynamic and complex laboratory environment. Important features include the software's approach to managing methods and analyses and its ability to save active work in an active workspace even when the user logs out.

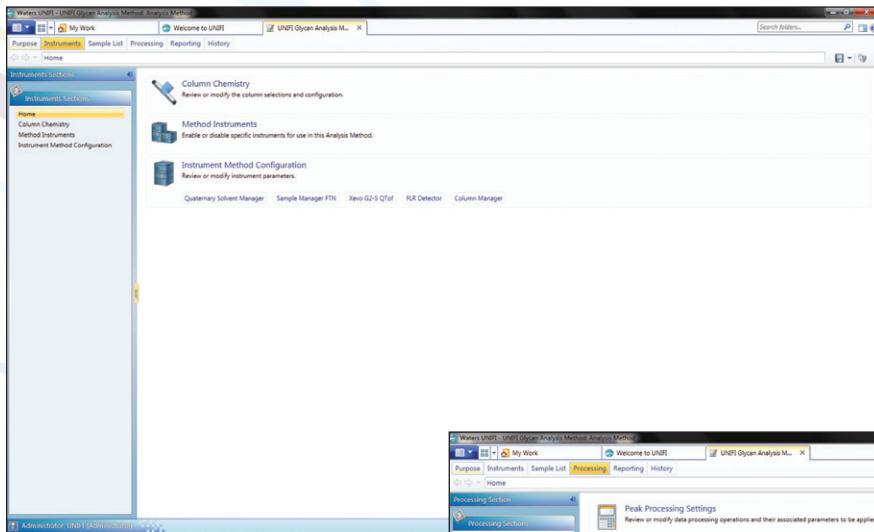


In the *My Work* page of UNIFI, researchers access work or initiate tasks that open a powerful set of features to analyze and investigate data. Results are maintained in the *My Work* area until user review is complete. The completed results are saved and locked. Further revisions will be stored as distinct incremented versions of the results.

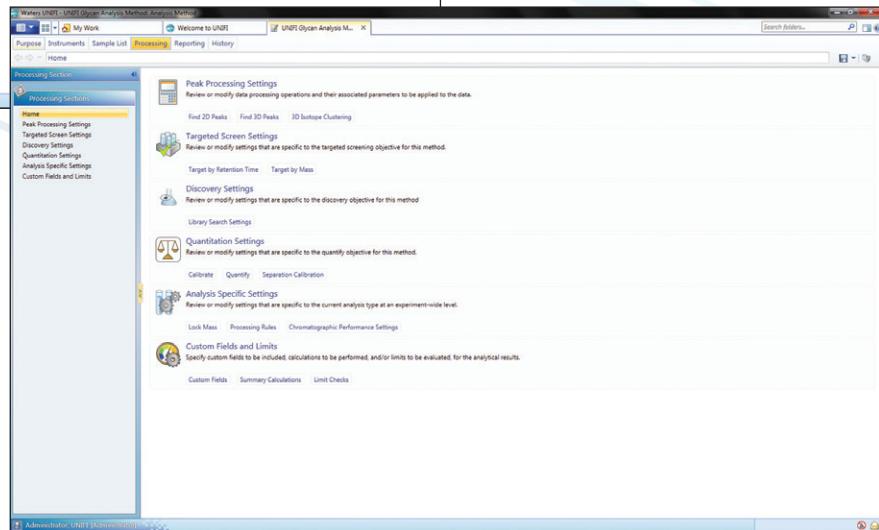
Personalized Workspace

The reality of today's laboratory environment is that users get interrupted. When logged into scientific software, those interruptions can mean not just loss of attention, but either loss of active work or a discarding of what would be a recorded change. Waters has developed a new approach in UNIFI called the *My Work* area built around the realities of daily use.

My Work is a user-protected active work space where in-progress work can be temporarily saved, similar to an auto backup. Information is saved independently from the scientific content system until a data point or action is deliberately input. The workspace also includes easy access to common tasks, recently view items, instrument systems, and workflow notifications.



UNIFI's method management feature follows the chemist's logic to setting up a method. Methods describe the purpose of the analysis, separation and MS parameters, spectral processing and bioinformatics analysis tasks, with links to automated reporting templates. The method itself is saved and protected to the same degree as are results. To eliminate potential ambiguities following data collection, a copy of the method is always stored as part of each analysis.



The Analysis Method

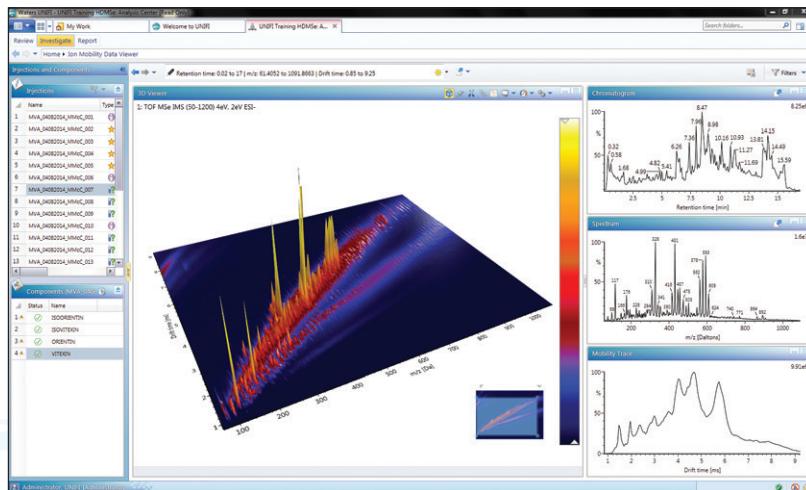
UNIFI stores all parameters necessary to acquire, process, and report data. This approach was developed to solve a method management challenge present in other software packages where the user has to separately keep track of chromatography, mass spectrometry, processing, and report methods.

The analysis method contains all of these parameters, while managing potential complexity through an editor. The editor automatically configures pages so that only the relevant set of analytical parameters are presented, in order of priority, to either use as is or dig deeper into more complex settings.

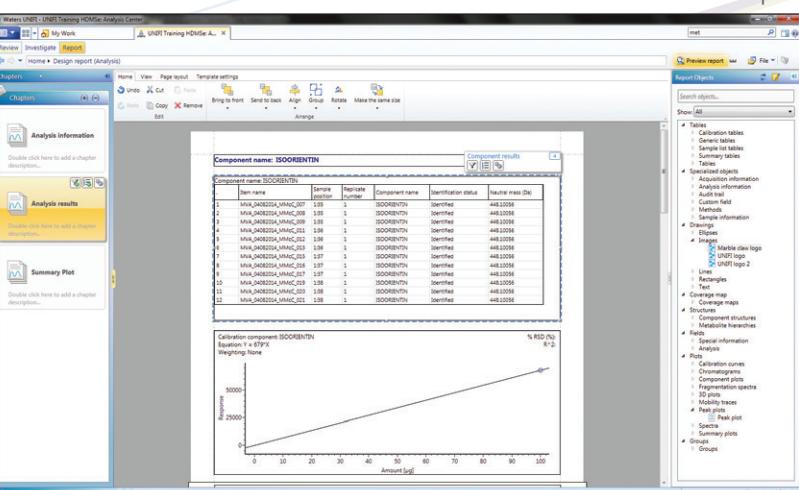


Analysis

UNIFI reporting templates can be specified in analysis methods and used to automate production of standardized reports, that are automatically generated and saved in GxP analyses. Report approval workflows using electronic signatures that follow 21 CFR 11 guidelines are specified with a method that can also be specified for the analysis.



Investigate



Report

The Analysis

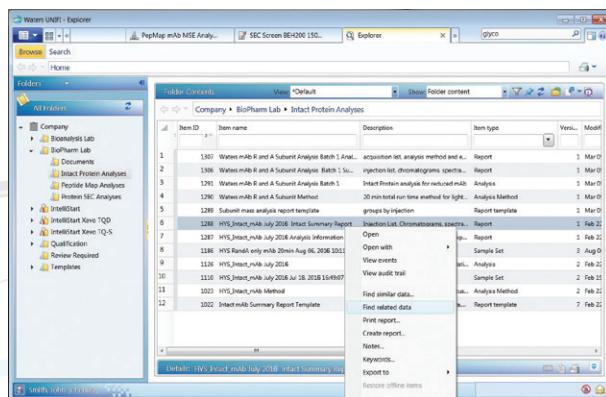
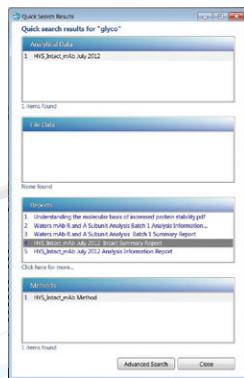
UNIFI manages analytical tasks as a complete analysis, or a single, self-describing container that includes all of the results, the analysis method, and all of the audit trail history. Analyses contain all of the items necessary to allow for review and regeneration of the results.

This allows them to easily be shared, reviewed or reported. Simultaneously, a record is maintained of who, what, where, and when analyses were made to comply with lab management, troubleshooting, or regulatory purposes.

DATA TRACEABILITY

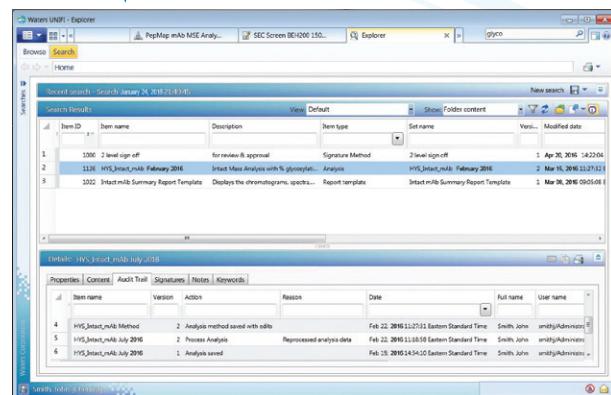
FOR RESEARCH AND GxP

Searching for "glyco" and selecting the resulting report.



Using "find related data" to identify similar data sets.

Opening data set and reviewing results.



Selecting a data set and reviewing associated audit trail.

UNIFI provides a versatile set of tools for maintaining compliance settings. From the entry administration screen (top) there is quick access to manage users, roles, access, policies, and approvals. Individual settings can be managed with great granularity (bottom).

Electronic signatures, comprehensive audit trails, and embedded relational database for data traceability

UNIFI uses an embedded relational database architecture to securely manage all system data and to provide data traceability. Security is ensured because raw data, results, reports, and methods are stored in the database, which can only be accessed by a user account login, and thus are protected from user access through the operating system.

The network version of UNIFI offers additional levels of data security – at the operating system, application level, database level, as well as physical security (i.e., when the server is residing in a secured data center) to ensure that testing data captured is trustworthy and reliable.

UNIFI contains software features that can be configured based upon the GLP, GMP, regulatory, or other quality standards that the laboratory is required to follow. An administrator can manage user name/passwords for access, set permission levels, and require e-signatures. Full audit trails record activities from acquisition of raw data to its processing, the settings of a method and who ran them when. While the choice to use audit trails, permissions, and other such activity controls is not optional in regulated environments, many non-regulated environments will find these features useful for data traceability, data management and troubleshooting.

The ability to turn on appropriate traceability features provides the flexibility required for non-regulated environments.

Additionally, UNIFI features a Qualification Center that allows scientists to determine if their instruments, computers, and software are operating according to manufacturer's specifications while maintaining records of computer and instrument qualification protocol execution and maintenance. These GxP management tools enable the laboratory to respond efficiently to regulatory questions with the confidence that data and records are secure.

STREAMLINE

APPLICATION SPECIFIC WORKFLOWS

Solutions that leverage the power of UNIFI

- **The Biopharmaceutical Platform Solution with UNIFI** enables laboratories in biopharmaceutical organizations to efficiently acquire, process, and communicate information from high resolution analytical studies. Accomplish the most basic bioseparations to the most complex LC-MS characterization studies using a single integrated technology platform. Addressing common workflows for intact mass, peptide mapping, and glycan analysis with modern tool sets for reporting and compliance management, the UNIFI platform can bring efficiency and productivity to labs from discovery thru QC.
- **The Screening Platform Solution with UNIFI** is a comprehensive solution that allows you to target, identify, quantify, and review based on a streamlined analytical workflow enabling more accurate results across a variety of solutions, such as Extractables and Leachables.
- **The Pesticide Screening Application Solution with UNIFI** allows scientists to reliably report the presence and absence of pesticide residues, streamline workflows, and increase the speed and efficiency of analysis of complex matrices.
- **The Natural Products Application Solution with UNIFI** enables laboratories to readily move from sample extract to product knowledge using a powerful accurate mass analytical platform integrated with fit-for-purpose workflows and reporting. The solution features a Traditional Medicines library to streamline the process of confirming chemical structures. Laboratories can now understand a sample's ingredients more readily, providing more confidence in the building blocks of natural product research.

- **The Metabolite Identification Application Solution with UNIFI** provides biotransformation scientists with the most comprehensive tools for identifying and characterizing metabolites. Chemically intelligent, yet flexible workflows are at the core of UNIFI's design. This workflow approach integrates both quantitative and qualitative datasets into a single analysis. UNIFI brings ease and efficiency to routine MetID analyses, enabling scientists to rapidly derive results from complex data sets – freeing up time for critical tasks such as data review and interpretation for regulatory submission.
- **The Regulated Bioanalysis Platform Solution with UNIFI** features workflow-driven software that streamlines compliant-ready acquisition, processing, and reporting for UPLC-MS/MS quantification of large and small molecules. UNIFI enables the bioanalyst to develop and implement routine LC-MS methods with Waters' tandem quadrupole platforms. The system and software integrate to transform a laboratory's ability to generate customized reports that help streamline knowledge transfer amongst collaborators within and between DMPK organizations, and to support business-critical decisions in drug development.
- **The Forensic Toxicology Screening Application Solution with UNIFI** offers forensic toxicologists a powerful solution to streamline workflow and improve confidence in data accuracy for the identification of toxicants of interest in even the most challenging cases.

SALES OFFICES:

Australia 61 2 9933 1777
Austria 43 1 877 18 07
Belgium and Luxembourg 32 2 726 1000
Brazil 55 11 4134 3788
Canada 1 800 252 4752
China 86 21 6156 2666
Czech Republic 420 2 617 11384
Denmark 45 46 59 8080
Finland 358 9 5659 6288
France 33 1 30 48 72 00
Germany 49 6196 400 600
Hong Kong 852 2964 1800
Hungary 36 1 350 5086
India 91 080 49292200 03
Ireland 353 1 448 1500
Israel 972 3 3731391
Italy 39 02 265 0983
Japan 81 3 3471 7191
Korea 82 2 6300 9200
Malaysia 603 7841 1688
Mexico 52 55 52 00 1860
The Netherlands 31 76 508 7200
Norway 47 6 384 6050
Poland 48 22 101 5900
Portugal 351 21 893 61 77
Puerto Rico 1 787 747 8445
Singapore 65 6593 7100
Spain 34 93 600 9300
Sweden 46 8 555 115 00
Switzerland 41 56 676 7000
Taiwan 886 2 2508 5500
UAE 971 4 214 62 38
UK 44 208 238 6100
US 1 800 252 4752

Waters
THE SCIENCE OF WHAT'S POSSIBLE.®

Waters Corporation
34 Maple Street
Milford, MA 01757 U.S.A.
T: 508 478 2000
F: 508 872 1990
www.waters.com

Waters, UNIFI, UPLC, and The Science of What's Possible are registered trademarks of Waters Corporation. All other trademarks are the property of their respective owners.

©2017 Waters Corporation. Produced in the U.S.A.
April 2017 720004686EN LM-SIG