

# Dissolution Testing

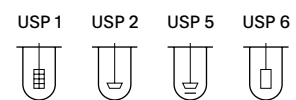
USP  
1/2/5/6

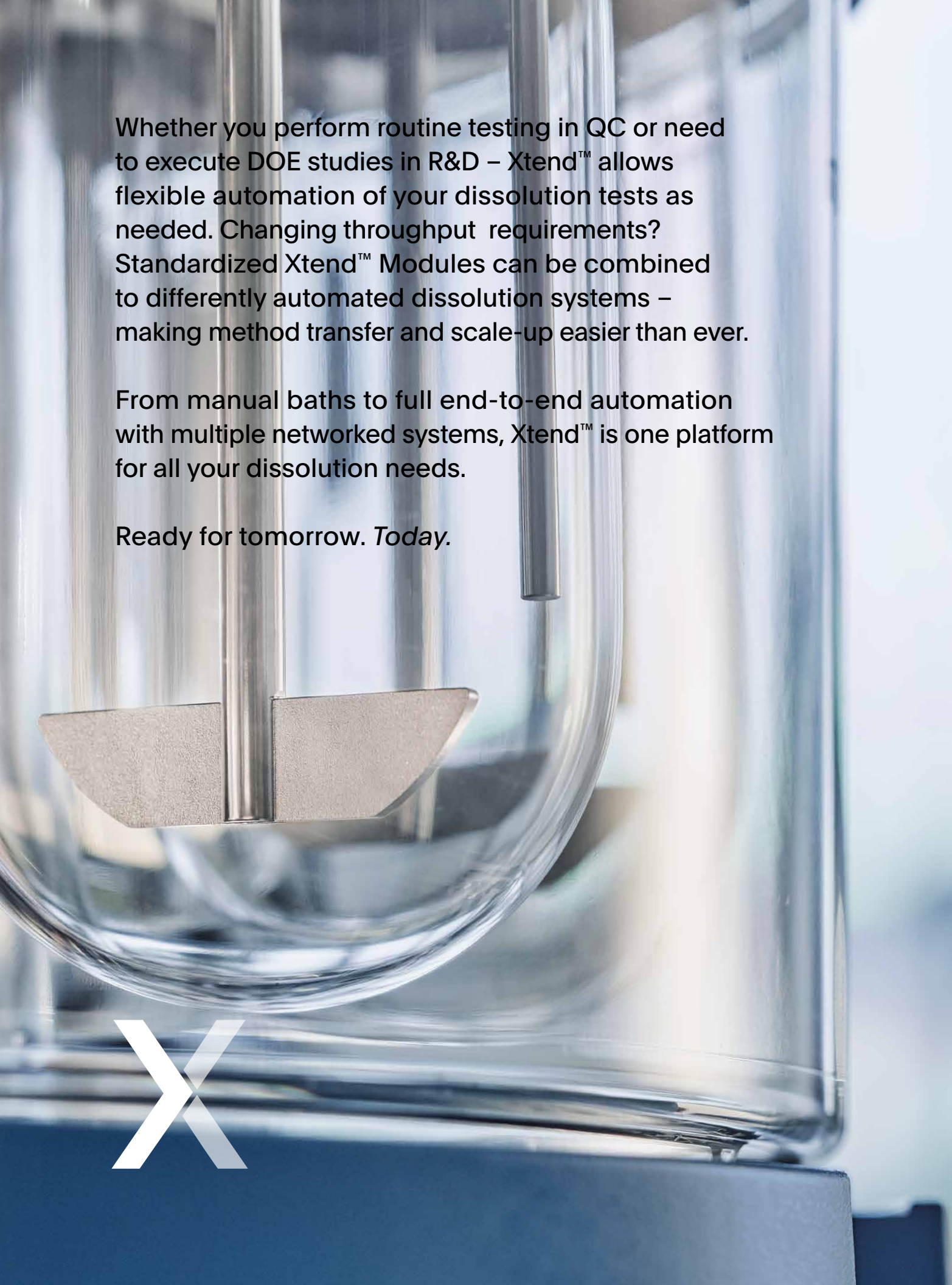
The Sotax logo consists of a solid blue square. Inside the square, the word "SOTAX" is written in a white, sans-serif, uppercase font, positioned in the lower right area of the square.

SOTAX

Modular. Scalable.  
Future-proof.

# Xtend™





Whether you perform routine testing in QC or need to execute DOE studies in R&D – Xtend™ allows flexible automation of your dissolution tests as needed. Changing throughput requirements? Standardized Xtend™ Modules can be combined to differently automated dissolution systems – making method transfer and scale-up easier than ever.

From manual baths to full end-to-end automation with multiple networked systems, Xtend™ is one platform for all your dissolution needs.

Ready for tomorrow. *Today.*



# Manual

AT Xtend™

Simple & User-friendly Operation

Maximum Flexibility

Integrated Monitoring Functions

AutoCompliance™

Data Integrity

Manual dissolution testing has never been easier. Share methods, automatically record individual vessel temperatures, and ensure traceability with video monitoring.



# Semi-Automated

ATS Xtend™

Unattended Sampling & Filtering

Automated Sample Collection & Analysis

Media Replacement

Delayed Release Testing (DR / MR)

Data Integrity

Automate sampling and filtration of your dissolution methods – including media replacement and pH change. Collect samples offline or integrate analytics into your system.



# Fully Automated

ATF Xtend™

Multiple Runs

100% Unattended Operation

Self-Cleaning

Integrated Media Preparation

Data Integrity

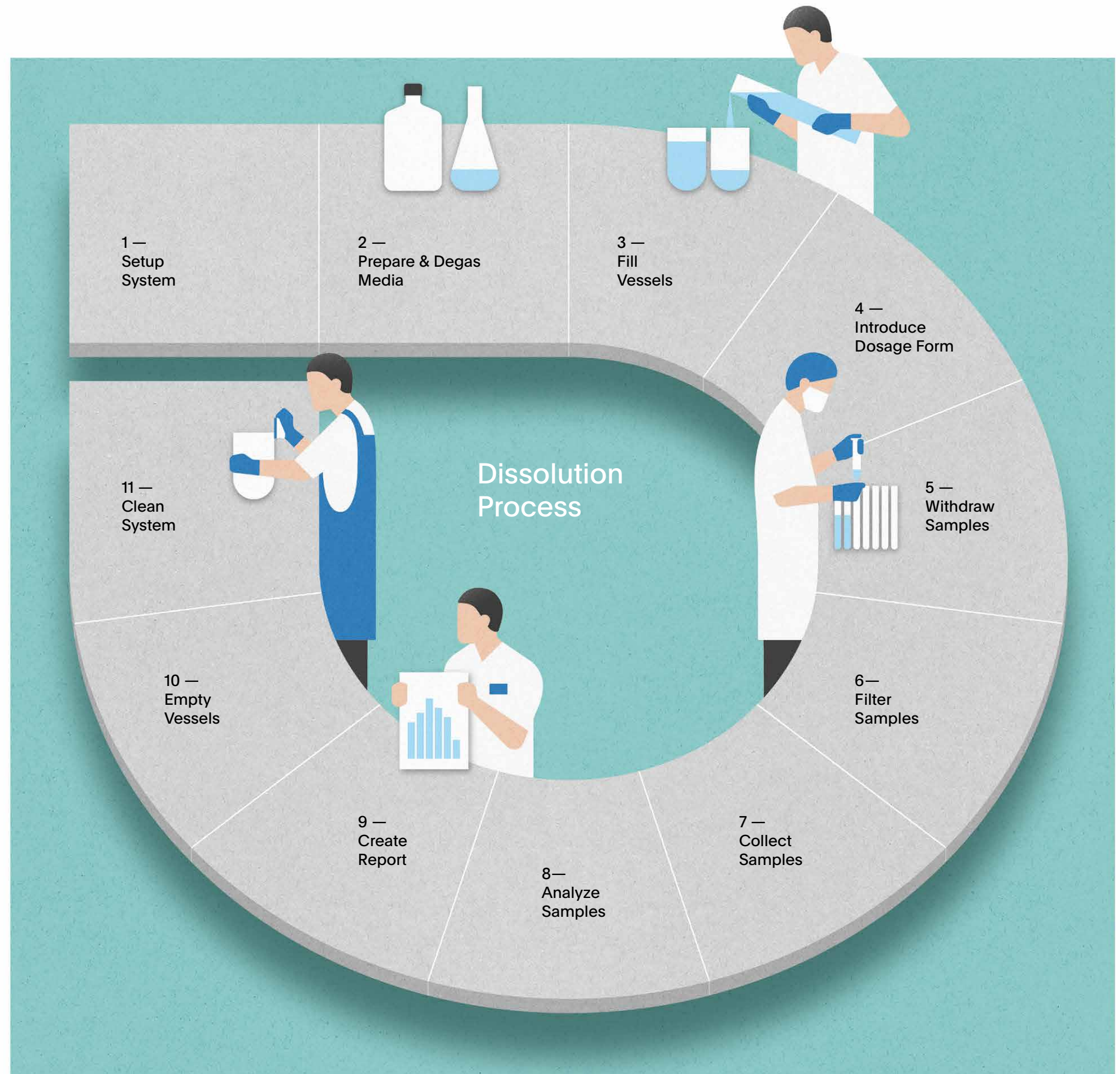
Execute and record all dissolution steps from media preparation to vessel filling including gravimetric verification of vessel volumes, sampling & filtration, to cleaning of the entire system.





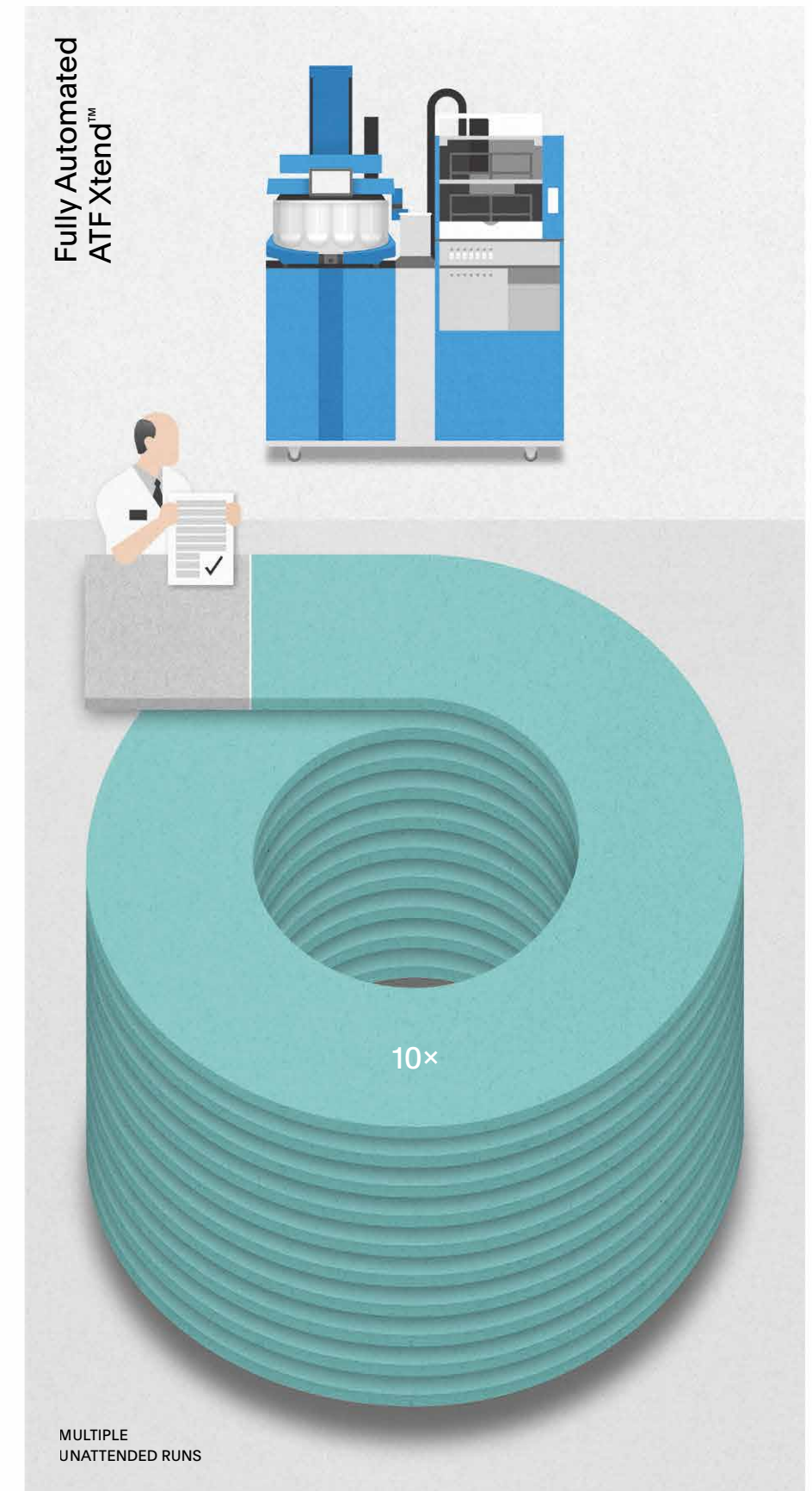
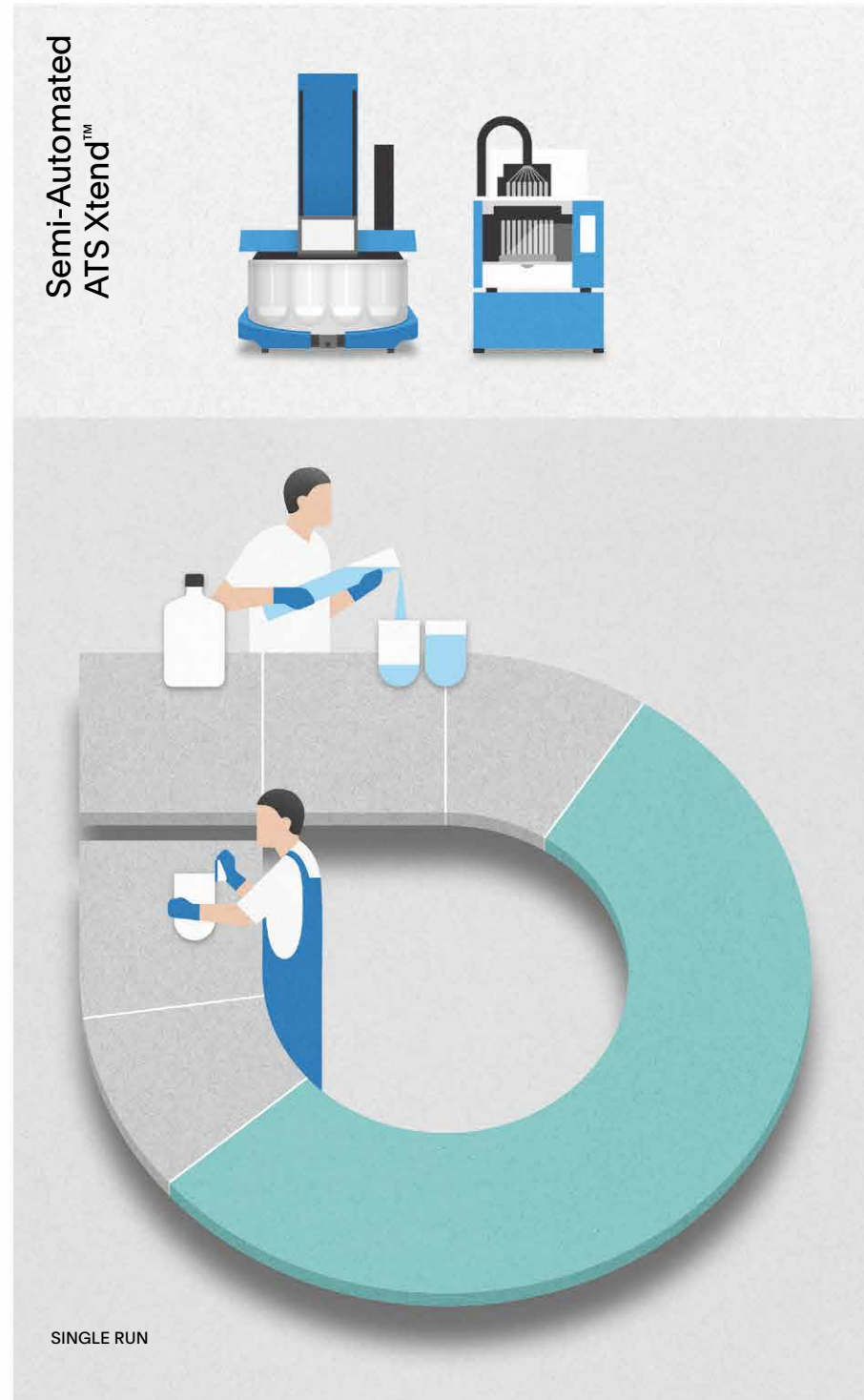
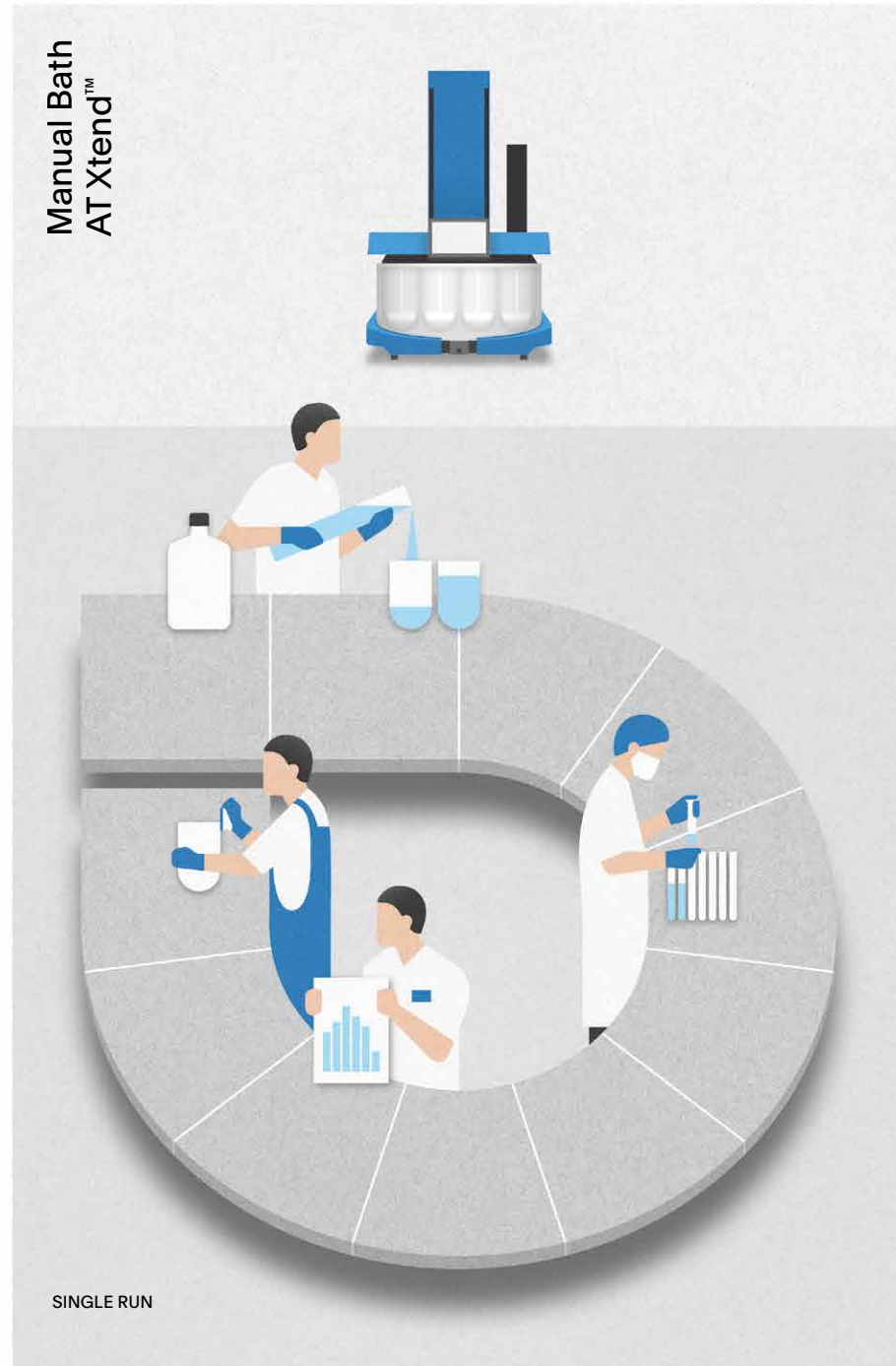
# What do you *not* want to automate?

How much time does your laboratory team spend on tasks such as filling vessels and cleaning? Automation allows qualified staff to focus on critical tasks rather than spending their time on supporting activities. With Xtend™, all dissolution steps from media preparation to cleaning of the system can be performed automatically.





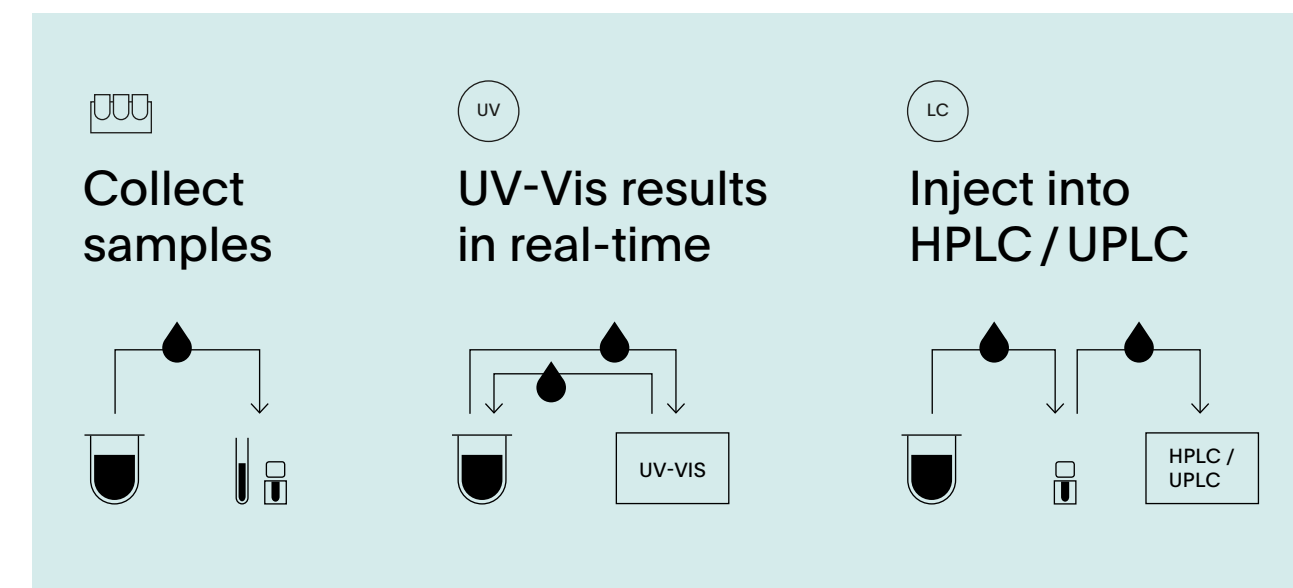
# How *efficient* do you want to be?






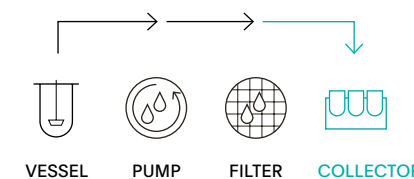
● MANUAL ● AUTOMATED

# Integrate Analytics *as needed.*

All samples need to be analyzed – regardless whether sampling was performed manually or automatically. As data integrity requirements continue to increase, automated consolidation of protocolled test conditions and analytical results into one report drive the implementation of integrated systems.

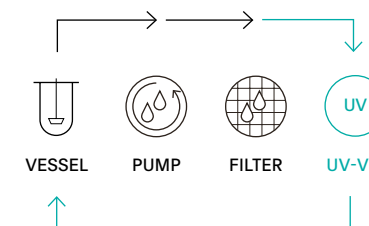


ANALYTICAL CONFIGURATION			
OFFLINE	●	–	–
UV ONLINE	–	●	–
UV ON-/OFFLINE	●	●	–
LC ON-/OFFLINE	●	–	●



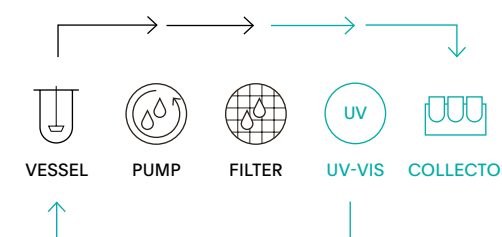
## Offline

Remain 100% flexible without dedicating your system to any analytical method. Offline systems automatically collect samples in standardized tubes, vials, or wellplates for manual transfer by the operator to an analytical device. For methods with multiple timepoints, the system can automatically replace withdrawn sample volumes if needed.



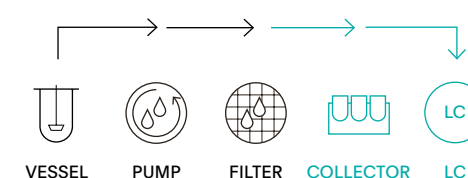
## UV Online

Gather analytical data in real-time and eliminate waiting times by integrating a UV-Vis spectrophotometer into your sampling process. Withdrawn volumes are immediately returned to the vessels – no medium replacement required. Results including protocolled test conditions are readily available in one consolidated report at the end of each test run.



## UV On-/Offline

Get the best of both worlds and combine the advantages of UV Online with the flexibility of an Offline system. Perform UV-Vis measuring in real-time and collect samples for more complex analytical methods offline. Add cooling of collected samples if needed and let the system perform medium replacement or pH change automatically.



## LC On-/Offline

Collect samples offline – and automatically inject them into an HPLC/UPLC without any manual transfer. The SAM sample manager buffers collected sampling volumes from all vessels and sequentially injects them into your chromatography system. Reduce the time from sampling to analysis to an absolute minimum – particularly for your most critical products.

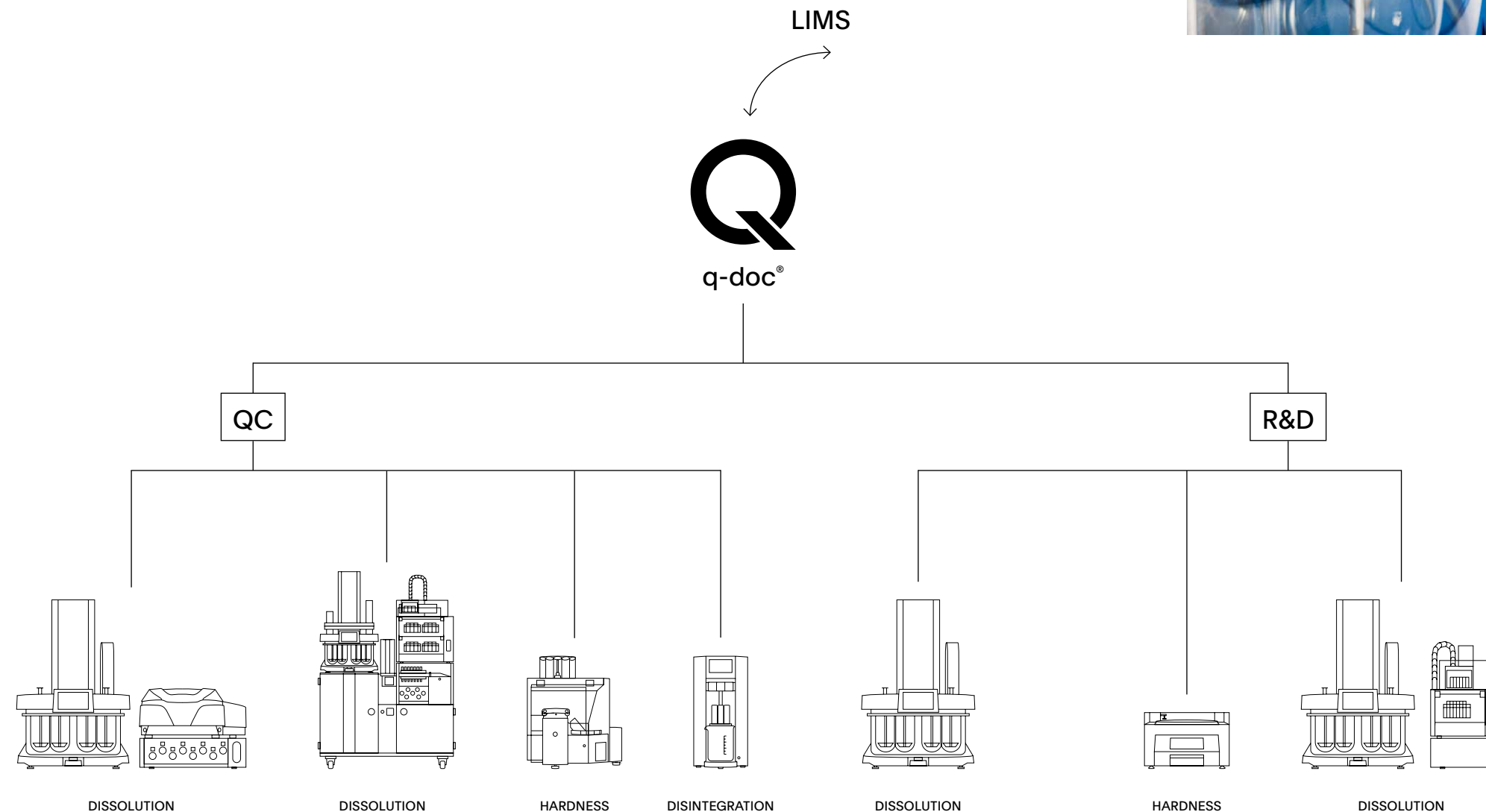
# Your Data. Simply Managed.

Actively managing your dissolution data saves costs and ensures regulatory compliance. Avoid error-prone manual transcription of test results and other time-consuming activities to consolidate test protocols. Depending on your data management requirements, Xtend™ systems can be operated stand-alone or networked, allowing you to flexibly choose your desired level of integration.



## EasyTouch™ Intuitive stand-alone control.

The EasyTouch™ user interface is designed for fast and intuitive operation. Requiring only minimum training, operators can quickly perform dissolution tests, print test protocols, and run the cleaning routine. Programming methods with one or multiple time-points is easy – and can be restricted to authorized personnel only. Method version control and an integrated user management with different access levels make the EasyTouch™ a true alternative to conventional PC software.



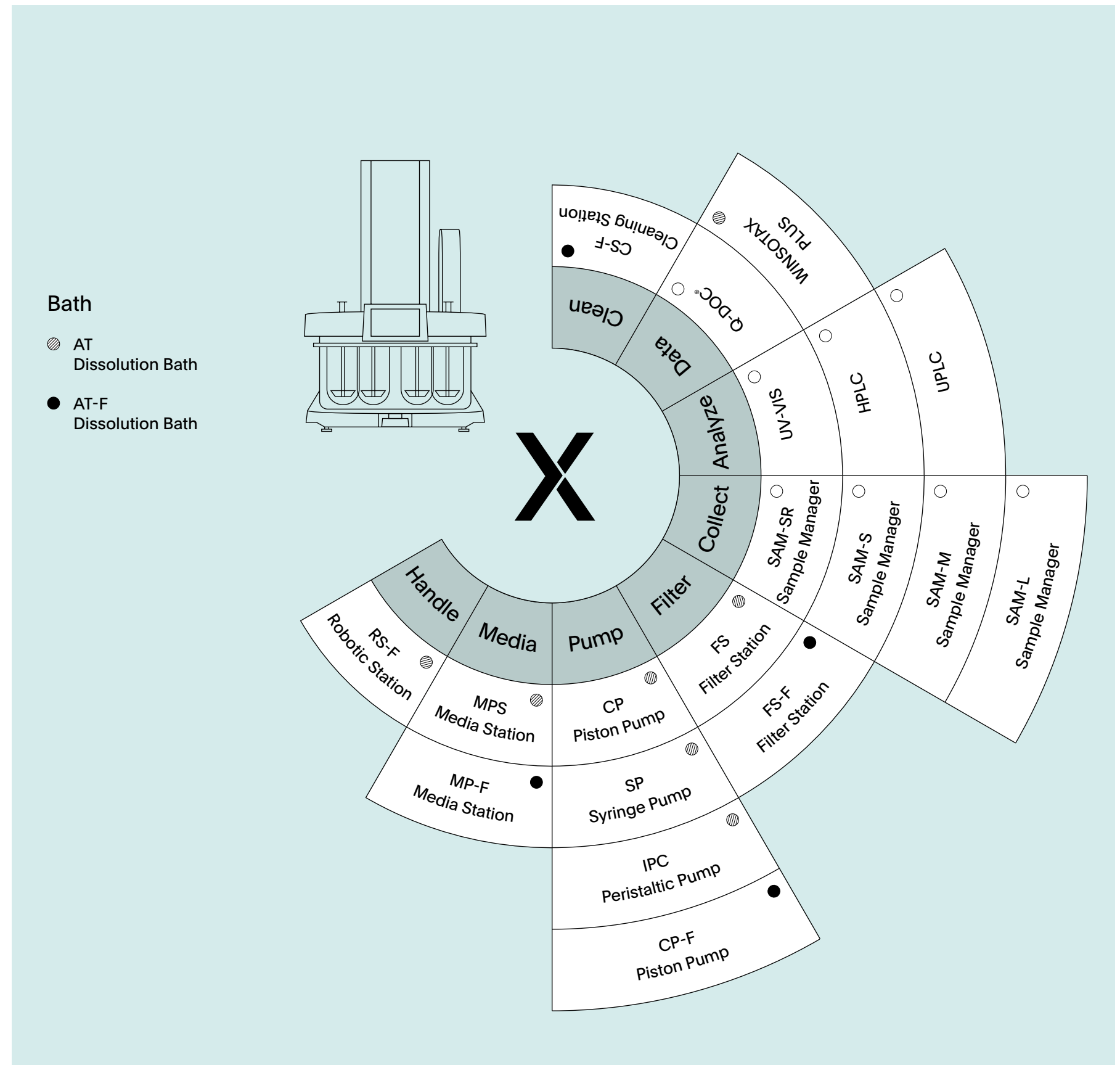
## q-doc® All your data in one place.

Take full control of your data and manage all your methods, results, and users with q-doc®. Use the same method on different systems, consolidate data from multiple test runs in a single report, and avoid redundant management of users and their passwords. Whether operated with a single PC workstation or in a networked environment, the modular q-doc® data management software offers built-in data integrity and ease of regulatory compliance. From electronic signatures, audit trail, and advanced user management to LDAP integration, batch comparison, and LIMS import / export functions – the q-doc® framework is designed for implementation of an efficient, fully 21 CFR Part 11 compliant system.

# Configure your Xtend™ System.

Thanks to its modular design, all Xtend™ components that are in contact with your product are always 100% identical – irrespective of your system’s automation level. Use the same dissolution method for different configurations and flexibly handle changing workloads. From qualification to writing SOP’s: keep in place what is already used, described, and validated.

- ○ ATF Xtend™ Fully Automated System
- ◐ ○ ATS Xtend™ Semi-Automated System
- ◑ ○ AT Xtend™ Manual Bath





# AT Xtend™ Manual

Flexible sampling possibilities including HollowShaft™

AutoCompliance™ with fixed shaft height and self-centering vessels

Temperature monitoring of all vessels

6 – 8 vessels

Circular bath design for excellent visibility of all vessel

Integrated CenterView™ video monitoring

Manual or motorized bath closing mechanism

Simple & User-friendly Operation

Maximum Flexibility

Integrated Monitoring Functions

AutoCompliance™

Data Integrity

Audible signal to alert operator for sampling at next timepoint

Stand-alone EasyTouch™ control with advanced user administration and method version control

Use pre-programmed methods or simply operate in manual mode

Networking and data management with q-doc®

Simple draining of water bath



# ATS Xtend™ Semi-Automated

Stand-alone operation with EasyTouch™ control or data management with q-doc®

Automated replacement of withdrawn sampling volumes (media replacement)

Automated pH change (media addition)

Integrated sample analysis with UV-Vis or HPLC / UPLC

Automated Sampling with HollowShaft™, AutoLift™ probes, or resident cannulas

Temperature monitoring of all vessels

Timed start with automatic tablet drop

Integrated CenterView™ video monitoring

System-supported cleaning routine

Optimized pumping for your application (piston pump / syringe pump / peristaltic pump)

Automatic syringe filter change

Sample collection in tubes, vials, or wellplates

- Unattended Sampling & Filtering
- Automated Sample Collection & Analysis
- Media Replacement
- Delayed Release Testing (DR / MR)
- Data Integrity



# Automate Sampling. *Integrate Analytics.*

Take your samples the same way every time. Automated sampling with identical withdrawal positions ensures repeatability – and allows for fast sampling timepoints pushing through fine filtration even when using surfactants. Take full advantage of your semi-automated system by integrating analytics.



## Offline

Automatically withdraw, filter, and collect samples in tubes, vials, or wellplates.



## UV Online

Integrated UV-Vis analysis of samples in real-time for each timepoint.



## UV On-/Offline

Get the best of both worlds. Online UV-Vis measuring and offline sample collection.



## LC On-/Offline

Automated injection of collected samples directly into your HPLC / UPLC.





# Share Modules. Double Capacities.

Double your throughput and execute two dissolution tests with one semi-automated system. Available for all analytical configurations, double systems allow simultaneous sampling from two dissolution baths into one sample manager or one analytical device.



## Double Offline

Automatically collect samples from two baths in one SAM Sample Manager.



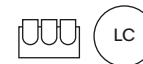
## Double UV Online

Real-time UV-Vis analysis of two dissolution tests with one spectrophotometer.



## Double UV On-/Offline

Share your Sample Manager and UV-Vis for online testing and offline collection.



## Double LC On-/Offline

Collect samples from two simultaneous runs and inject automatically into your HPLC/UPLC.

# ATF Xtend™ Fully Automated

Quick-change tablet magazine for multiple test runs

Sampling with HollowShaft™ or AutoLift™ probes

Temperature monitoring of all vessels

In-vessel volume monitoring

Automatic emptying of vessels

Efficient self-cleaning with integrated spray nozzles and programmable cleaning routines

Integrated media preparation with vacuum degassing

Gravimetric volume control

Integrated sample analysis with UV-Vis or HPLC / UPLC

Multiple Unattended Runs

Self-cleaning

Integrated Media Preparation

Automated Sample Collection & Analysis

Data Integrity

Sample collection in tubes, vials, or wellplates

Automatic syringe filter change

Fast and powerful piston pumps for highly efficient sampling

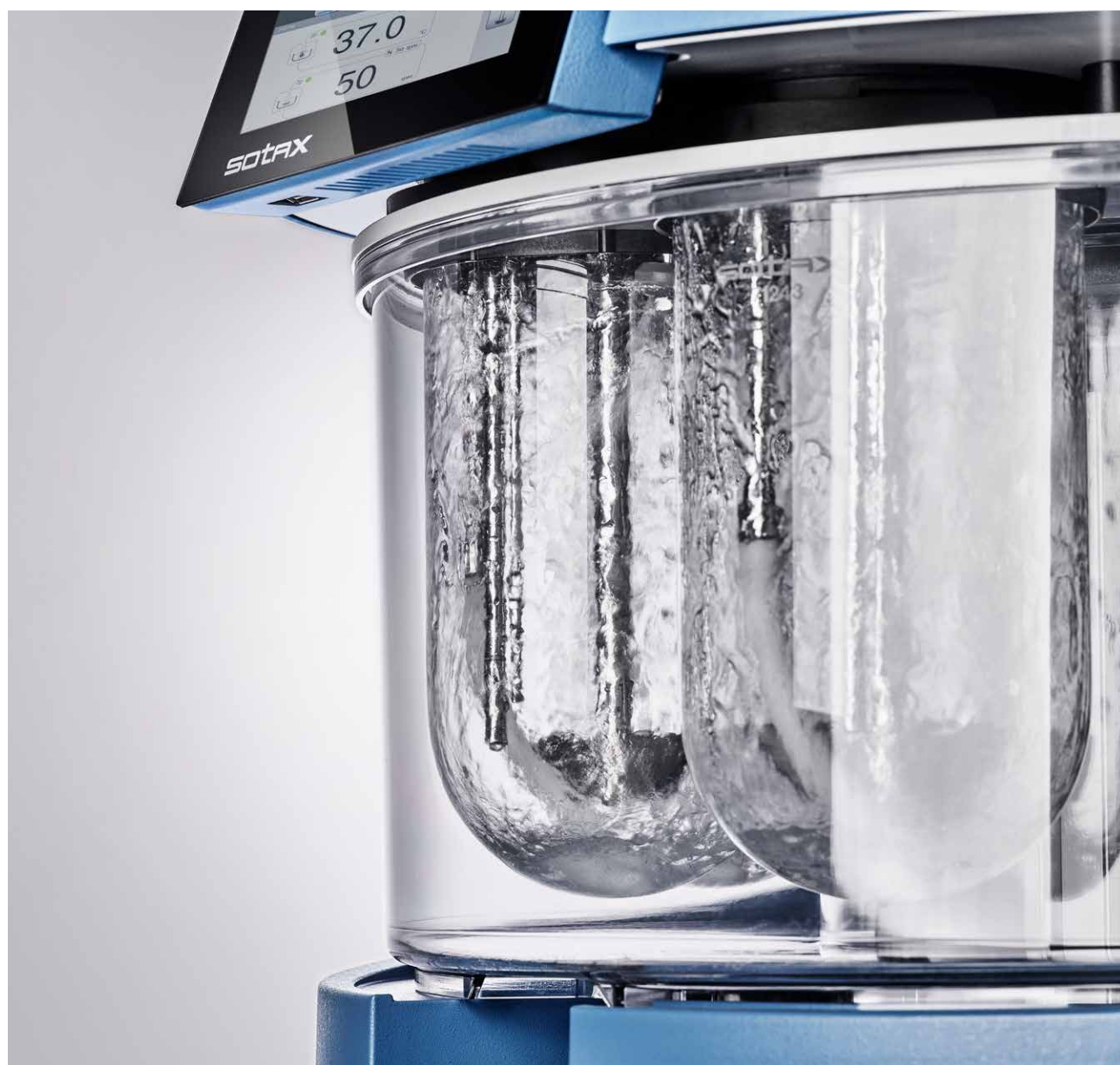
Stand-alone operation with EasyTouch™ control or data management with q-doc®





# True Automation. 100% Unattended.

Repeatable operation of simple laborious steps is the heart of the fully automated system. Execute and record all steps from media preparation to vessel filling including gravimetric verification of vessel volumes, sampling & filtration, to cleaning of the entire system.



## Fill

Fill vessels automatically and record individual volumes. Media is dispensed down the vessel wall avoiding media re-aeration. Delivered volumes are confirmed gravimetrically and in-vessel volumes are monitored throughout the test.



## Test

Take samples the same way every time – from repeatable sampling positioning to automatic filter change and replacement of collected sample volumes. Require a pH change? Let your system do it for you.



## Empty

No need to remove vessels anymore. The self-cleaning system automatically empties all vessels on completion of a test run and starts the washing routine.

## Clean

Clean in place the same way every time – and let your system prepare itself for the next run. Have a sticky product? Customized self-cleaning procedures can be saved per product allowing for enhanced routines.



# Fill, Rinse. Repeat.

Medium preparation the efficient way – let your system do it for you. The integrated multi-purpose station allows preparation & degassing of media using different recipes and sources. Automatically prepare media to fill vessels, to replace withdrawn sample volumes, and to perform pH changes.



## Prepare

Prepare media in-line with concentrate using your house DI source or connect different media types for automated preparation. Save time by preparing the next medium while a test is running.

## Degas

No more helium sparge! Pull a vacuum on your media at temperature for complete & cost-efficient deaeration. Use effectively on all media types including foaming media with surfactants.

## Clean

Power wash the tank for efficient cleaning. Robust cleaning routines facilitate easy media change for DR / MR methods as well as entirely different products within a series of test runs.



# SmartAdd™

## *Keep on running.*

Make your testing continuous – or prepare a new series of tests while the system is running. Whether you automate dissolution DOE in R&D or routine testing in QC, SmartAdd™ allows flexible interaction and avoids downtime. Simply exchange complete tablet magazines or add new samples to a running sequence.

SmartAdd™  
it to the sequence

### Design of Experiment (DOE)

Decide to include another parameter into your DOE study?

### Release Testing

Receive a new lot from production for urgent testing?

### Stability Testing

New stability timepoint comes into the lab?





# Efficiency. *Maximized.*

Maximize the efficiency and repeatability of your dissolution tests with full end-to-end automation. From media preparation to self-cleaning – automate all process steps for highly effective & fully unattended execution of multiple dissolution runs.



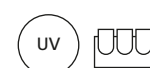
## Offline

Automatically withdraw, filter, and collect samples in tubes, vials, or wellplates for up to 90 timepoints.



## UV Online

Integrated UV-Vis analysis of samples in real-time for a virtually unlimited number of timepoints.



## UV On-/Offline

Unlimited real-time UV-Vis measuring and offline sample collection for up to 90 timepoints.



## LC On-/Offline

Automated injection of collected samples from up to 90 timepoints directly into your HPLC / UPLC.





© Roger Frei, Zürich

**Contact us.  
Wherever you are.**

# SOTAX *Worldwide*

## Europe

**Switzerland (HQ Europe)**  
AESCH / BASEL  
P TECH SUPPORT +41 61 487 5460  
P OFFICE +41 61 487 5454  
INFO@SOTAX.COM

**Czech Republic**  
PRAGUE  
P TECH SUPPORT +41 61 487 5460  
P OFFICE +420 246 039 260  
INFO@SOTAX.COM

**France**  
SAINT-LOUIS  
P TECH SUPPORT +41 61 487 5460  
P OFFICE +33 3 8970 0846  
INFO@SOTAX.COM

**Germany**  
LÖRRACH  
P TECH SUPPORT +41 61 487 5460  
P OFFICE +49 7621 16 5635  
INFO@SOTAX.COM

**Great Britain**  
LONDON  
P TECH SUPPORT +44 20 8349 6946  
P OFFICE +44 20 8349 6947  
INFO@SOTAX.COM

**Italy**  
MILAN  
P TECH SUPPORT +41 61 487 5460  
P OFFICE +39 02 8363 2641  
SOTAXITALIA@SOTAX.COM

## Americas

**USA (HQ Americas)**  
WESTBOROUGH, MA  
P TECH SUPPORT +1 508 544 4040  
P OFFICE +1 508 417 1112  
SOTAXUSA@SOTAX.COM

**Canada**  
BRAMPTON  
P TECH SUPPORT +1 800 931 4151  
P OFFICE +1 905 494 0114  
SOTAXCANADA@SOTAX.COM

## Asia-Pacific

**India (HQ Asia-Pacific)**  
MUMBAI  
P TECH SUPPORT +41 61 487 5460  
P OFFICE +91 22 42 95 01 -91 / -92  
SOTAXINDIA@SOTAX.COM

**China**  
SHANGHAI  
P TECH SUPPORT +41 61 487 5460  
P OFFICE +8621-6135 6268, EXT. 205  
SOTAXCHINA@SOTAX.COM

**Thailand**  
BANGKOK  
P TECH SUPPORT +91 99 202 11 211  
P OFFICE +66 26 42 68 62  
SOTAXASIA@SOTAX.COM

[sotax.com/contact](https://www.sotax.com/contact)

