

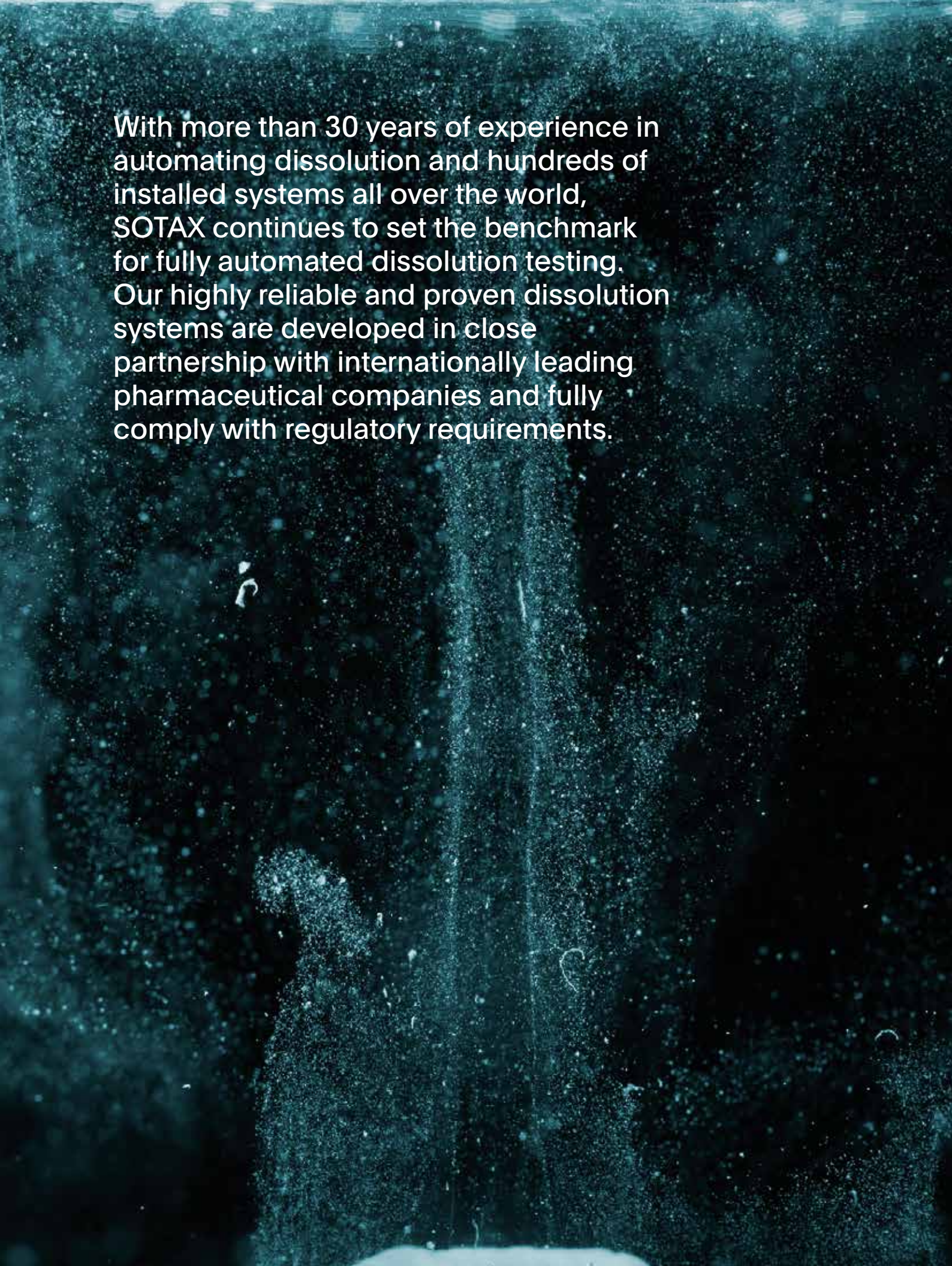
Dissolution
Fully Automated

AT MD

From pre-run to runtime to post-run system cleaning,
SOTAX streamlines your dissolution workflow and simplifies
routine operation.



Fully Automated Dissolution System



With more than 30 years of experience in automating dissolution and hundreds of installed systems all over the world, SOTAX continues to set the benchmark for fully automated dissolution testing. Our highly reliable and proven dissolution systems are developed in close partnership with internationally leading pharmaceutical companies and fully comply with regulatory requirements.

Why automate dissolution testing?

Data integrity

With the introduction of automation in the lab, you can significantly improve the quality of your data. Each dissolution test is performed the same way, every time, for more precise datasets. Every step is recorded in a secure database reducing instances of data entry errors. Test results are no longer operator dependent.

Enhance safety

Automation improves safety by reducing exposure to hazardous solvents and compound materials used in testing. In addition, automation reduces ergonomic stress by eliminating common repetitive tasks, such as vessel filling, sampling, filtering, and system cleaning.

Increase productivity

Automated dissolution improves the productivity of a lab creating “walk away time” for operators, allowing more time for mission-critical activities (e.g. method development, process validation, data checking and verification). Reducing cycle times and completing more work with existing resources.

Reduce OOS results

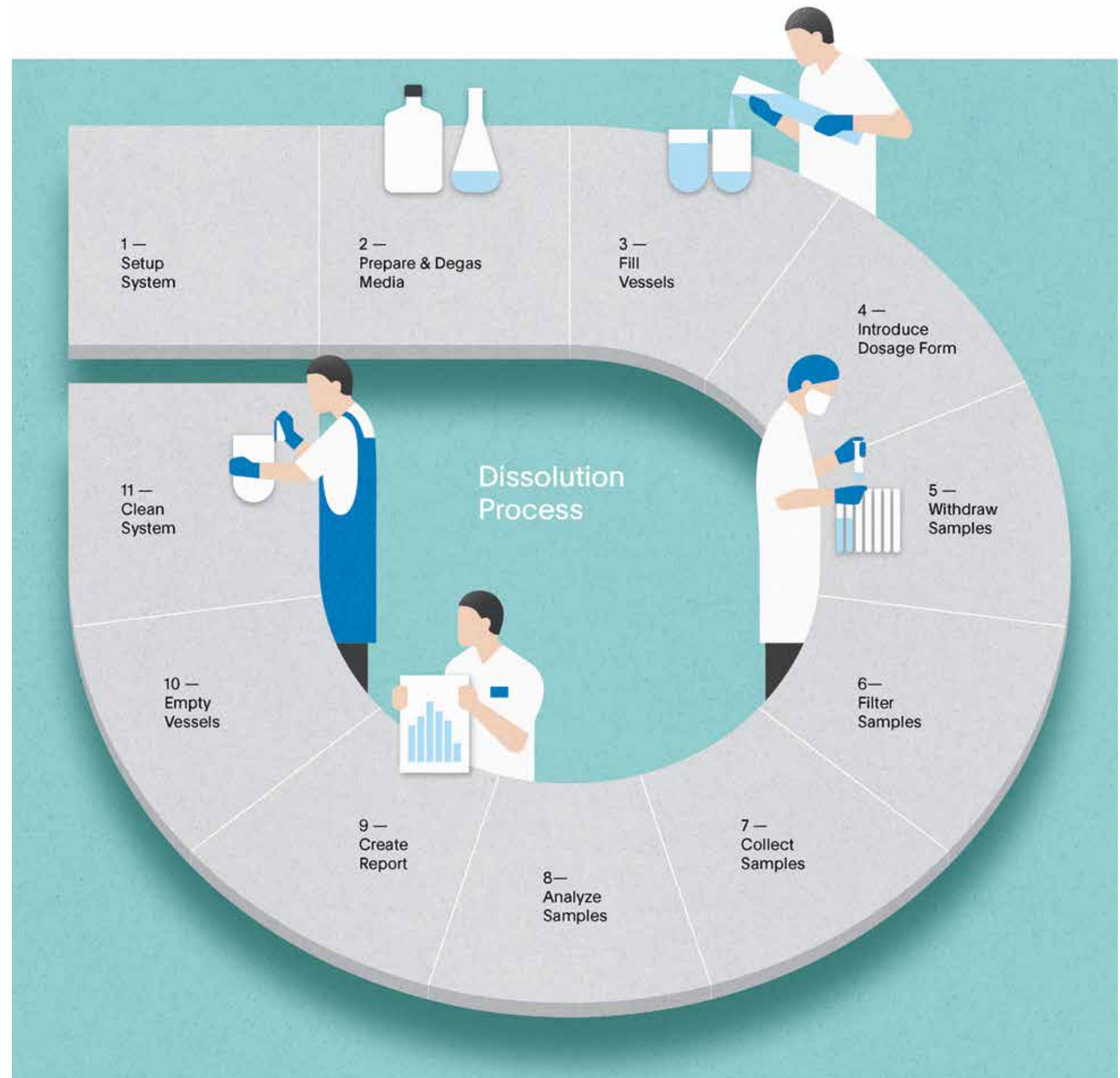
Deficiencies in laboratory investigations are a major source of warning letters in the pharmaceutical industry. Automated dissolution testing reduces the potential for human error and simplifies the investigation process with full traceability of all steps executed.

Remain competitive

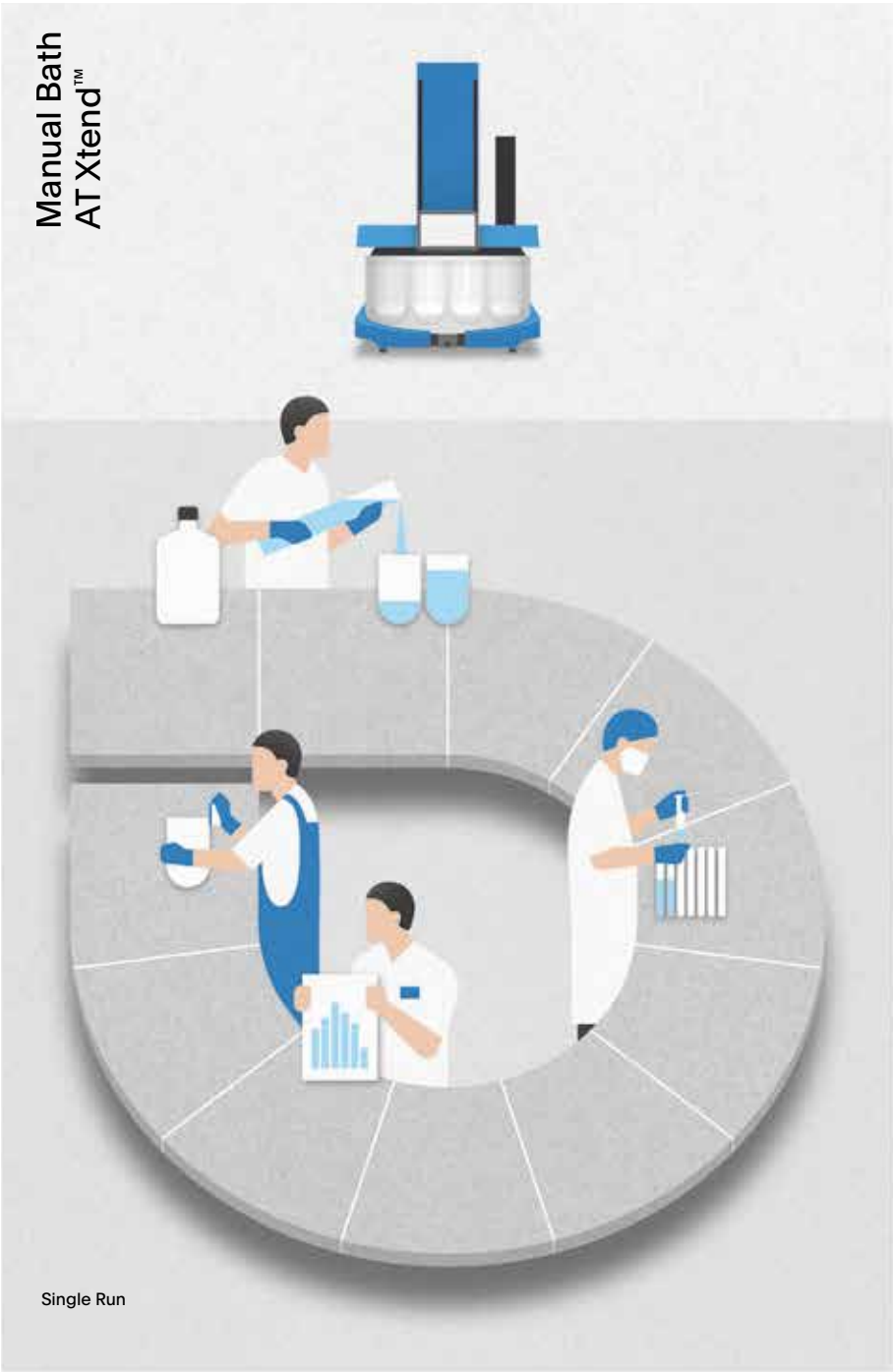
The strategic implementation of laboratory automation is helping many companies to remain competitive. By placing automation in both R&D and Quality departments, some companies have created a seamless method transfer process, helping reduce the time-to-market for new products.

What do you not want to automate?

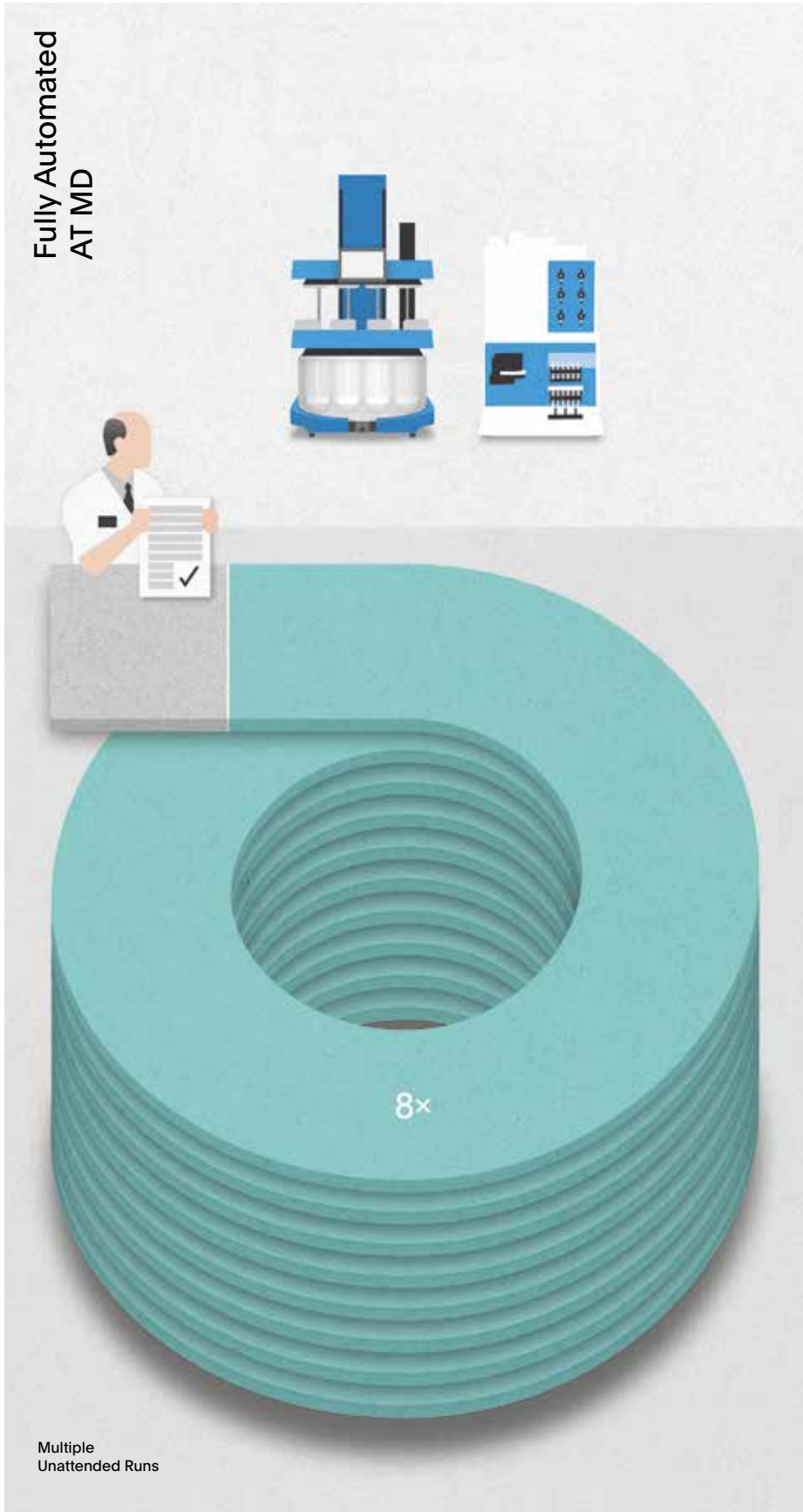
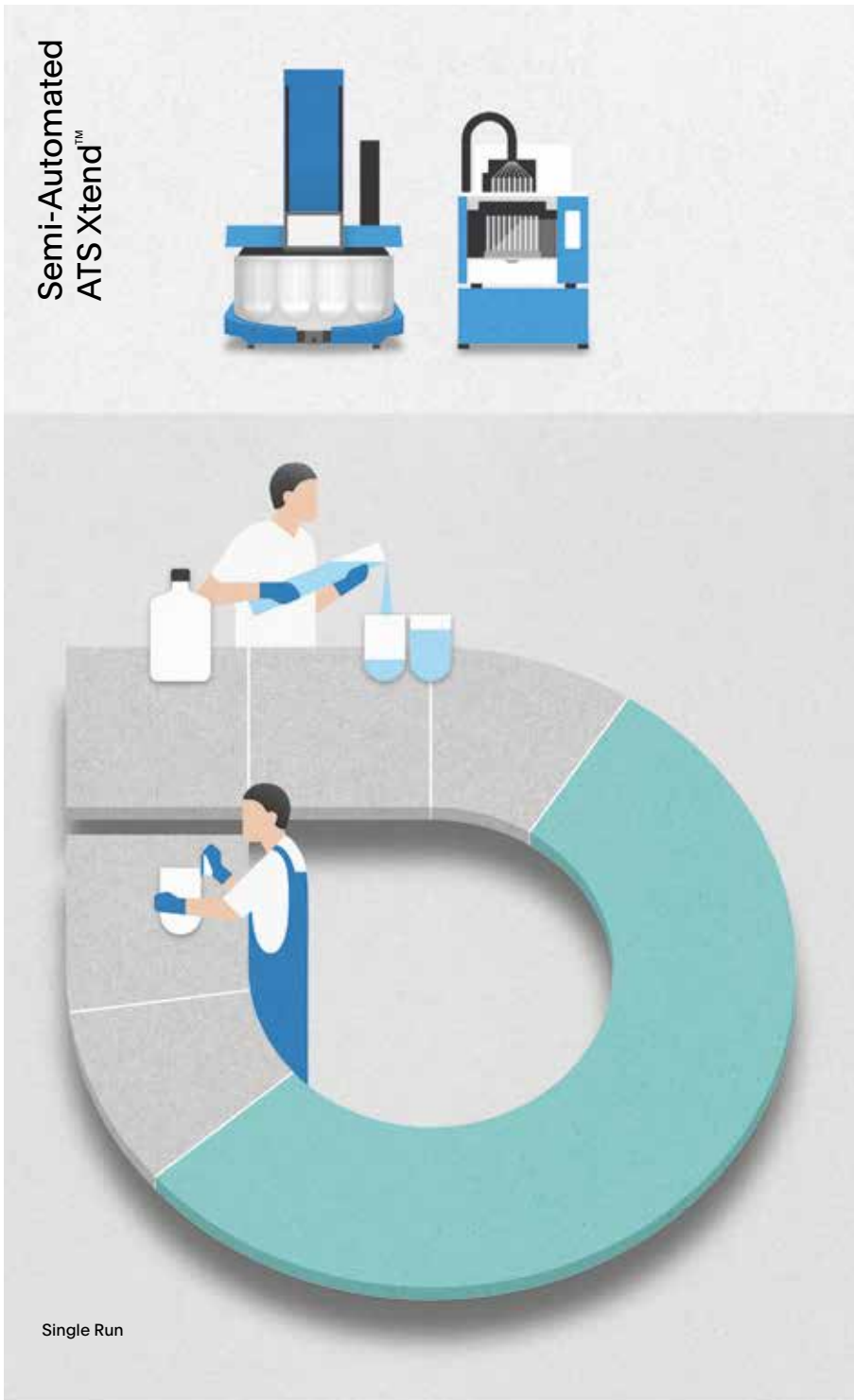
How much time does your laboratory team spend on tasks such as filling vessels and cleaning? Automation allows qualified staff to focus on critical tasks rather than spending their time on supporting activities. The AT MD automates all dissolution steps from media preparation to cleaning of the system.



How efficient do you want to be?



● Manual ● Automated



AT MD — Fully automated bench-top dissolution

Automated sampling with
AutoLift™ probes

Integrated CenterView™
video monitoring

Various fill volumes in different vessels
(from 250 mL to 1'000 mL)



AT MD dissolution bath



MD multi-purpose station

Run a series of tests in an
unattended sequence

Fully automated from media
preparation to data reporting

Automated sample collec-
tion in glass tubes, capped
HPLC vials

From vessel filling to
self-cleaning

6 integrated piston pumps for accu-
rate and reproducible sampling on all
channels

Integrated filter station to automate
the simultaneous change of 25 mm
syringe filters

Seamlessly integrates with the AT MD
bath for fully automated dissolution
testing

Modules

The AT MD fully automated dissolution system consists of benchtop modules that can be combined based on your testing requirements.



Basket station



Robotic arm



AT MD dissolution bath



MD station



SAM sample manager

Basket station

Used for USP 1 tests and USP 2 tests with sinkers, the basket station holds 8 batches of baskets and handles the used baskets and sinkers after the test.

Robotic arm

Used for USP 1 tests and USP 2 tests with sinkers, it transports the sinkers and baskets accurately between basket station and AT MD dissolution bath before and after the dissolution test.

AT MD dissolution bath

Used for USP 1 and USP 2 dissolution tests on 6 samples, the AT MD bath is the core of the fully automated benchtop dissolution system. The same bath is also available as a standalone manual bath, allowing for simplified throughput scale-up and dissolution method transfer.

MD station

Used to prepare and dispense media into the bath vessels before the dissolution test, pump and filter samples and standards through 6 individual channels, and empty & clean vessels.

SAM sample manager

Used to collect, store, and protect samples for analysis. Collection in glass tubes or capped HPLC vials.

Simplified Method Transfer

To simplify method automation, transfer, and validation, the design of SOTAX fully automated systems is based on manual instruments and integrates existing dissolution bath, components, and accessories.

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.



Dosage form introduction

For paddle testing (USP 2), dosage forms are stored in an 8-position carousel above each vessel. Inlets allow for all types of tablets and capsules including sinkers (introduction diameter: 18 mm). Dosage form introduction for basket and paddle methods is automated and simultaneous.



Sinkers

Almost any magnetic sinker larger than 15 mm in its smallest dimension (including Japanese sinkers) can be used with the system. Sinkers are introduced from the standard 8-position carousel. At the end of a test run, the sinkers are automatically removed by the robotic arm.



Baskets

For basket methods (USP 1), a robotic arm sequentially attaches prepared baskets containing the dosage form to the drive shafts of the dissolution bath. Once the test run has been completed, used baskets are automatically removed and collected in the basket station.

Vessel filling

Up to 5 different media including concentrates and surfactants can be automatically heated, degassed, and dispensed into vessels. The gravimetric delivery system assures accurate and reproducible media dispensing.



Sampling

Automated cannulas withdraw samples simultaneously. All sampling probes are equipped with temperature probes recording the temperature of each vessel when sampling. 6 automated piston pumps ensure accurate and reproducible sampling on all channels.

Filtration

The AT MD allows filtered sample transfer according to your requirements. An integrated filter station automates the change of 25 mm syringe filters on all 6 channels at each run, each timepoint, or at media change.



Video monitoring

The integrated space-saving design of the circular AT MD bath offers a protected central space for individual adjustable cameras and an indirect lighting source. Assured local distance allows standardized vessel-to-vessel video and image comparisons. Video file size can be reduced by recording only critical timepoints.



Collection

Samples are collected and stored in tubes or closed HPLC vials for subsequent analysis.

UV-Vis analysis

Integrate a UV-Vis spectrophotometer (single or double beam from different manufacturers) for immediate analysis of withdrawn samples in real-time on all channels simultaneously.

Cleaning

The AT MD offers 100% automated cleaning between test runs that can be validated. Vessels are automatically emptied and the system washing procedure is executed using cold and/or hot DI water with or without dissolution media. Product-specific cleaning routines can be incorporated into dissolution methods – assuring that appropriate line cleaning is reproducibly performed every time using a single or multiple solutions to automatically flush and empty all fluid paths.



Automate Sampling. Integrate Analytics.

SOTAX systems offer sample collection, storage, and UV-Vis integration. These options can be combined in a variety of analytical configurations and reconfigured should needs change.



Offline

- Scalable collection and storage of samples in tubes or vials
- Automated sample collection reduces sampling variability



UV Online

- Automated UV-Vis measurements for real time results
- Avoids sample transfer errors
- Dissolution software for data acquisition and analysis; no separate software required



UV On-/Offline

- Fraction collection and/or UV-Vis measurements for sample archival or UV-Vis immediate comparison
- Provides flexibility for sample analysis and method development

Data Analysis and Reporting.

The MD software is 21 CFR Part 11 compliant-ready, controlling all aspects of data capture and analysis with customized reporting and exporting. It allows data export to ELN/LIMS, user-group configuration and report configuration. MDsoft is a flexible software package designed to fulfill R&D and QC requirements.



AT MD Technical Specifications

Dosage forms	Type	Tablets, capsules, sinkers, baskets
	Introduction	Automated
Bath	Temp. range	Ambient +5 °C to 45 °C, ± 0.5 °C
	No. of stirring positions	6
Vessel	Type	1 L, Peak vessel
	Material	1 L vessels: glass, polycarbonate, Teflon-coated, inactinic glass Other vessels: on demand
Shaft	Stirring range	25 – 250 rpm, ± 1 rpm
Sampling	Type	Automated cannula
	Time points	1 to n sampling points at intervals of 5 min and less (depending on sampler size and configuration)
Temp. monitoring		6 mobile probes (1 per vessel)
Video monitoring	Position	6 cameras integrated in bath (CenterView™ design), with integrated indirect light
Power supply		115 – 230 V (±10 %) / 50 – 60 Hz
Dimensions	Width/ Depth/ Height	560 mm/ 710 mm/ 1040 mm
Capacity		48 samples (8 unattended batches of 6 samples)
Media preparation and delivery	Media types	All standard dissolution media possible (no or anic solvents)
	Volume	Up to 10 L
	Delivery accuracy	Exceeds USP / EP / JP requirements of 1 %
	Temp. range	20 – 45 °C
	Degassing capacity	De-aeration with Helium
Pumps	Sample pump	Positive displacement, ± 2.5 % accuracy, max. 12 mL/min, Kynar body, ceramic piston & liner
	Media pump	0 to 24 V DC at 1.2 A, wetted material Ryton 4-XT, max. 1.6 L/min
	Waste pump	Bellows type, 1 L/min
Filtration		Standard 25 mm syringe filters (luer)
Balance	Readability	1 g
	Reproducibility	0.5 g
	Linearity	1 g
Sampling	Time points	1 to n sampling points [depending on sampler size-SAM] at intervals of 5 min and less (configuration dependent)
	Sampling time accuracy	+ - 2%
	Collection volumes	12 mL with 16 × 100 mm tubes (sampler) 1.5 mL with 11 mm HP LC vials (sampler)
Control	Automated	Software: MDsoft
Reporting	Print	Through USB, LAN
	Export	Format csv, xls, xml, htm, pdf
Interfaces		RS 232
Power supply		115 – 230 V (±10 %) / 50 – 60 Hz
Dimensions (width x depth x height, weight)	MD station	510 × 610 × 790 mm, 105 kg
	Basket station	250 × 570 × 730 mm, 5 kg
	Robot	350 × 350 × 720 mm, 15 kg
	Robot base plate	890 × 660 × 5 mm, 6 kg

Technical specifications are subject to change without prior notice. Products illustrated in this brochure may include options or modifications not fitted as standard. No liability for errors and omissions.

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

sotaxcz@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

Foston / Derbyshire

P Tech Support +41 61 487 5460

P Office +44 20 8349 6947

sotaxgb@sotax.com

Italy

Milan

P Tech Support +41 61 487 5460

P Office +39 02 8363 2641

sotaxitalia@sotax.com

Ireland

Longford

P Office +353 43 334 7779

contact@labserv.ie

Americas

USA (HQ Americas)

Westborough, MA

P Tech Support +1 508 544 4040

P Office +1 508 417 1112

sotaxusa@sotax.com

Canada

Westborough, MA

P Tech Support +1 508 544 4040

P Office +1 508 417 1112

sotaxcanada@sotax.com

Asia-Pacific

Thailand (HQ Asia-Pacific)

Bangkok

P Tech Support +91 99 202 11 211

P Office +66 26 42 68 62

sotaxasia@sotax.com

China

Shanghai

P Tech Support +41 61 487 5460

P Office +8621-6135 6268, ext. 205

sotaxchina@sotax.com

India

Mumbai

P Tech Support +91 99 202 11 211

P Office +91 22 4295 0191

sotaxindia@sotax.com