q-doc®

SOTAX

Take control of your data with q-doc® software. Built-in compliance and efficient recording, protocolling, and analysis of test data from more than 35 different instrument types.

Data Management Software

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. 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.
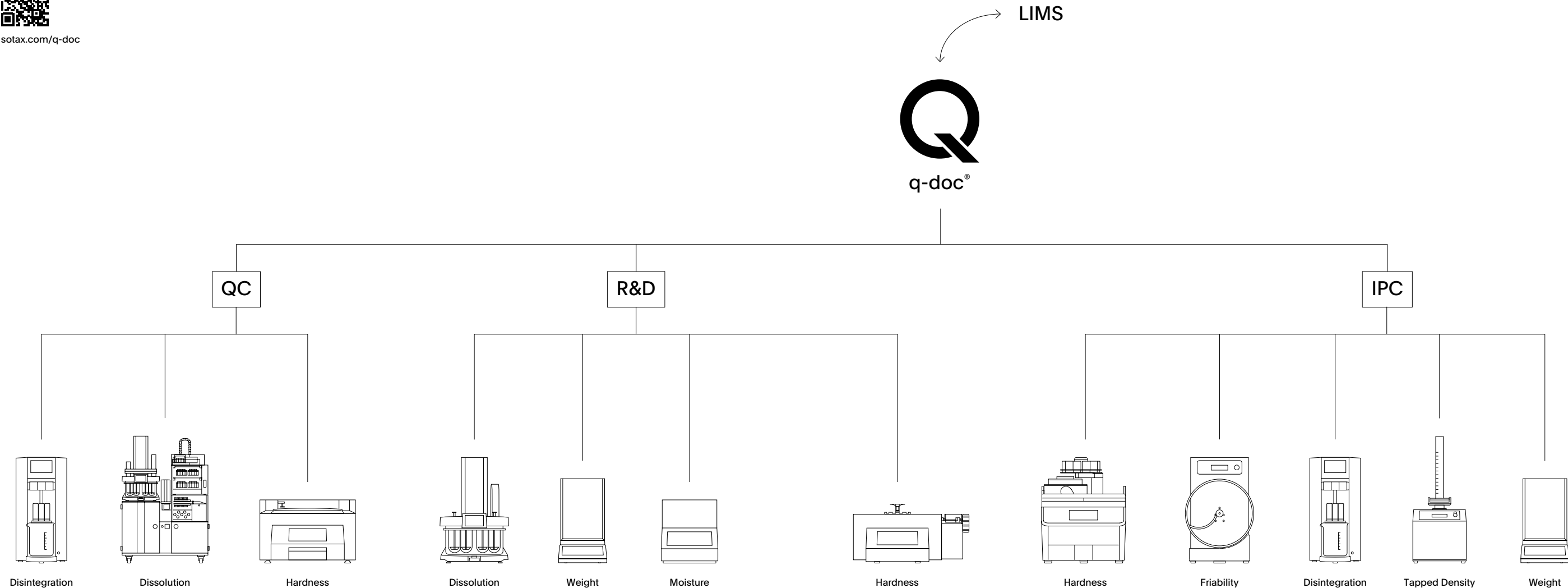
sotax.com/q-doc

One solution for all instruments

———

Networking

———

21 CFR part 11

———

Consolidated batch reporting

———

Data integrity

LIMS

Q

q-doc®

QC

R&D

IPC

Disintegration

Dissolution

Hardness

Dissolution

Weight

Moisture

Hardness

Hardness

Friability

Disintegration

Tapped Density

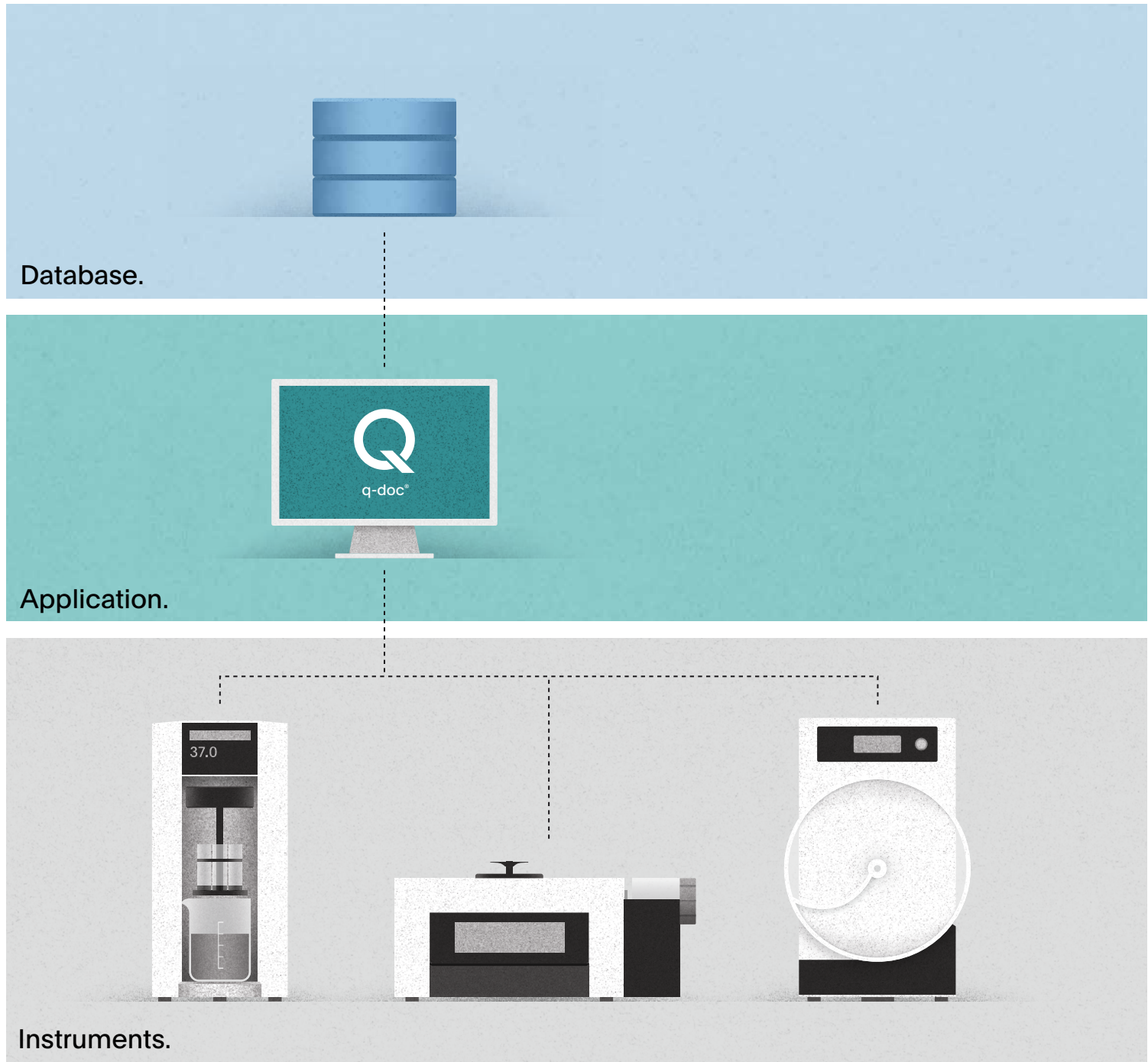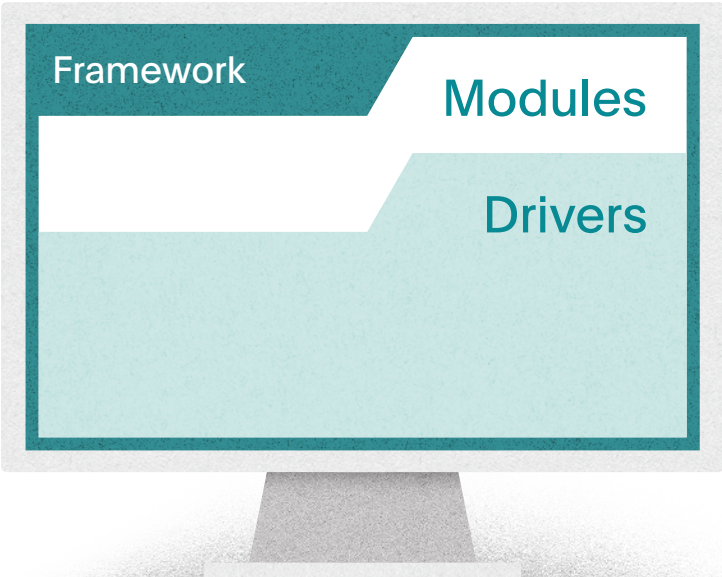Weight

Framework.
Modules. Drivers.

Example: q-doc® single workstation with three connected instruments

Database.

Application.

Instruments.

Framework — All key functions.

Whether installed on a single PC or on multiple networked computers, the q-doc® framework with central SQL database is designed for both stand-alone and networked operation alike. It includes all basic functions to collect, record, analyze, evaluate, report, and manage test data in full compliance with 21 CFR part 11 requirements. To simplify daily processes, login with chip ID, barcode printing, and touchscreen-supported operation are standard.

Framework

Modules

Drivers

Modules —
Extend as needed.

Modules further extend the q-doc® framework with import / export functions, LDAP integration for simplified user administration by IT administrators, data trending and batch comparison to analyze results over a period of time, data evaluation including re-test procedures according to pre-defined USP and Ph. Eur. specifications, and other data management possibilities to simplify operation in large interdisciplinary networks.

Framework

Modules

Job Import

Automate daily routine tasks such as registration of new batch numbers or creation of new test runs – and avoid common mistakes caused by manual transcription of complex data strings. The powerful import module allows to automatically transfer information directly from your LIMS, MES, or ERP system to q-doc® without any operator action required.
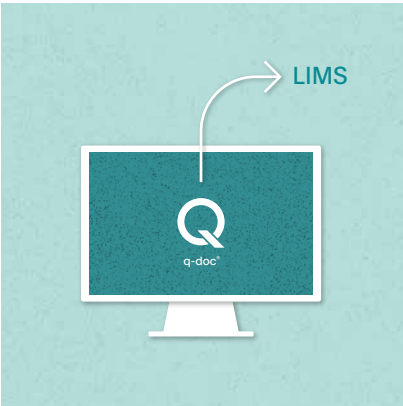
LIMS Export

How do you want to evaluate your test results? The LIMS export module allows to automatically transfer individual results, test run statistics, and complete batch records to third party systems. Whether you would like to export evaluated test runs (checked & judged) or simply transfer recorded results – the automated process can be flexibly adapted to your needs.
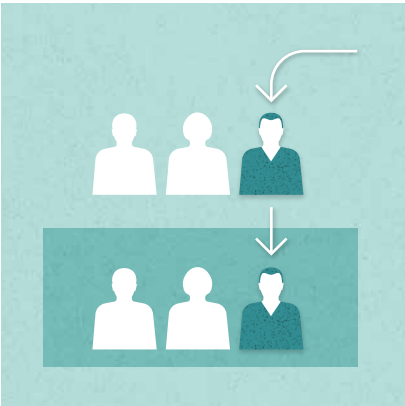
LDAP Integration

Ensure that your company's password policy is "automatically" followed without creating any additional workload. Avoid redundant local user management and directly integrate q-doc® with user groups in your company's Active Directory (AD). No need to remember multiple passwords anymore – operators can simply use their current Windows® password.
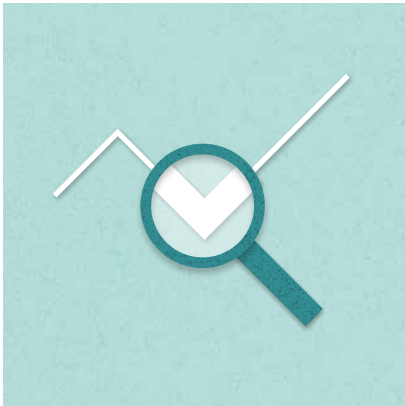
Data Trending

No need to export your test results to perform batch comparisons. Use the seamlessly integrated q-doc® data trending module to analyze individual results from all test runs within a batch – or compare multiple batch records over a defined period of time. In IPC, the module allows to view data in real-time on a separate monitor to quickly identify trends.
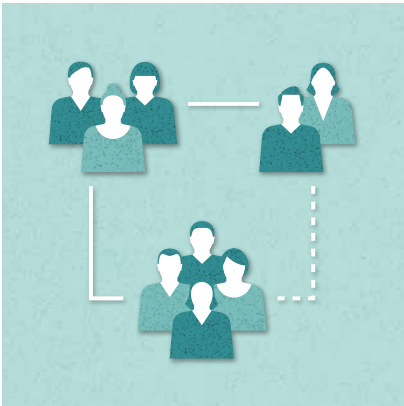
Workgroups

Limit what operators can see on "their" networked q-doc® workstation. Particularly useful for large installations with multiple PCs, the workgroups module allows to flexibly restrict usage by product, batch, or PC – independently from general user rights. People within a workgroup only see the jobs, batches, and tests relevant for their tasks at hand.

Extended Evaluation

- Pass / Fail evaluation and automated re-test procedure <USP 701> and Ph. Eur. 2.9.1
- Evaluate content uniformity based on weight variation <USP 905>
- Calculate tensile strength <USP 1217>
- Pass / Fail evaluation based on Uniformity of Mass according to Ph. Eur. 2.9.5

Drivers —
Connect your instruments.

Record weight measurements from your balances, connect different physical and dissolution testing systems, and seamlessly protocol everything in one place. Standard q-doc® drivers for more than 35 different instrument types and system configurations are readily available for establishing a highly efficient data management system in R&D, QC, and IPC departments.

Framework

Drivers

DT50 MT50 FT2

DT50

37.0

MT50

FT2
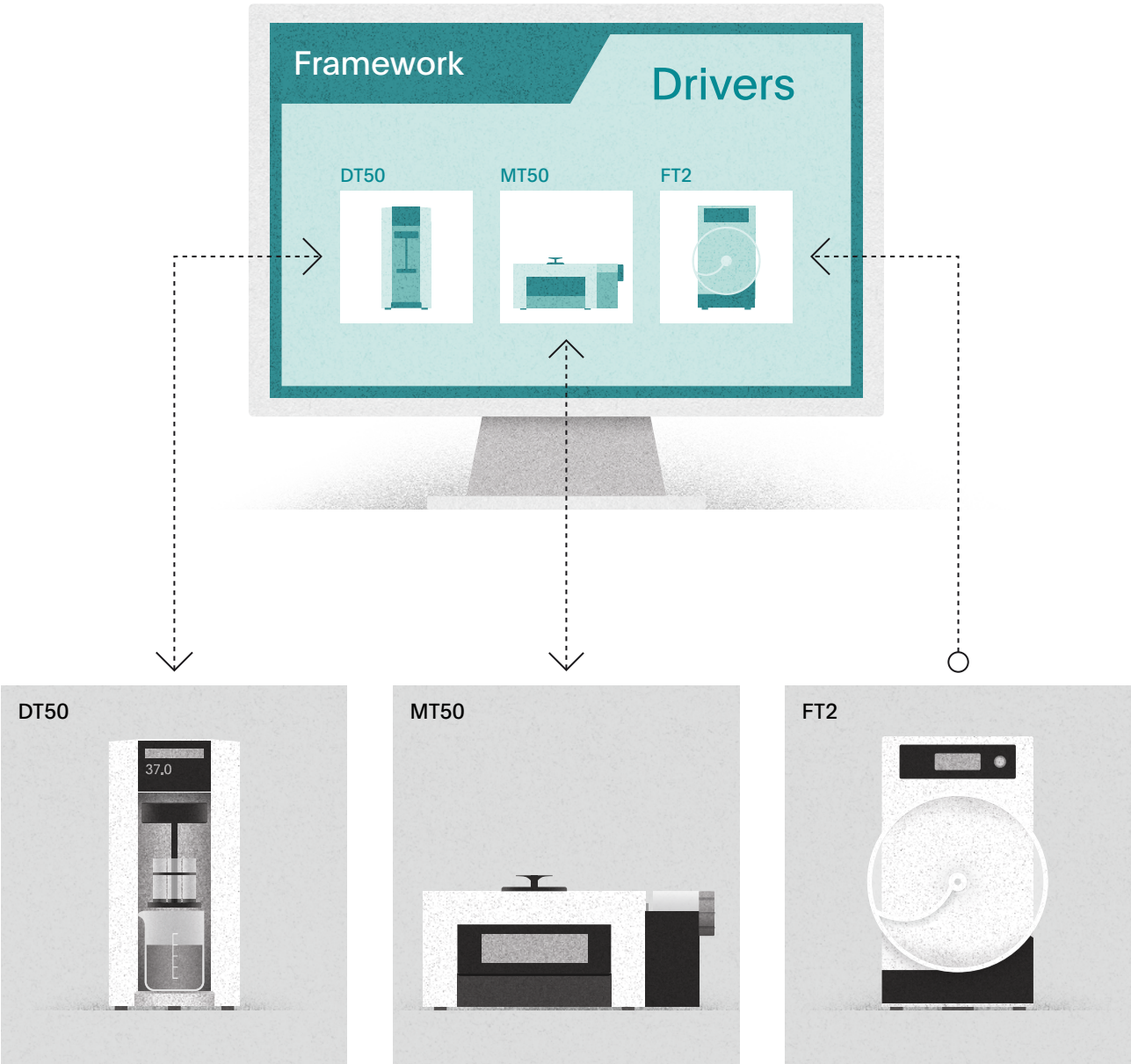
Instrument		Weight (Mass)	Thickness	Width	Diameter / Length	Hardness	Disintegration	Friability	Tapped Density	Flowability	Moisture	Cap Torque	Dissolution
	Physical Testing												
AT50	Automatic tablet testing system	●	●	●	●	●							
AT4	Automatic tablet testing system	●	●		●	●							
HT100	Automatic tablet testing system	●	●	●	●	●							
ST50	Semi-automatic tablet testing system	●	●	●	●	●							
HT10	Semi-automatic tablet testing system	●	●	●	●	●							
MT50	Manual tablet hardness tester	●	●	●	●	●							
HT1	Manual tablet hardness tester	●	●	●	●	●							
8M	Manual tablet hardness tester	●	●		●	●							
6D	Manual tablet hardness tester				●	●							
DT50	Automatic disintegration tester (1 – 4 stations)						●						
DISI	Automatic disintegration tester (1 – 4 stations)						●						
DT2	Manual disintegration tester (2 stations)						○						
FT2	Friability tester (1 – 2 drums)							●					
TD1	Tapped density tester								●				
FT300	Flowability tester									●			
PF1	Powder and granulate flow tester									○			
TM200	Cap torque tester											●	
Balance	Mettler Toledo® (different models)	●											
Balance	Sartorius® (different models)	●											
Gauge	Mitutoyo® (different models)		●	●	●								
Gauge	Preisser® (different models)		●	●	●								
HR83	Mettler Toledo® moisture analyzer										●		
HX204	Mettler Toledo® moisture analyzer										●		
HS153	Mettler Toledo® moisture analyzer										●		
HB43	Mettler Toledo® moisture analyzer										●		
	Dissolution Testing												
ATF Xtend™	Fully automated dissolution testing system *												●
ATS Xtend™	Semi-automated dissolution testing system *												●
AT Xtend™	Manual dissolution tester												●

* different configurations

● standard q-doc® driver available
○ manual input

Data integrity.
Built-in.

From version control to advanced user access right management and a human readable audit trail – q-doc® fulfills all requirements for implementation of a fully 21 CFR part 11 compliant system. Modular documentation packages for qualification / computer system validation ensure ease of regulatory compliance and are proven to be accepted by local authorities all over the world.

No modification of original records
Measurement data ("raw data") is automatically stored in an SQL database and cannot be edited or deleted.

Audit trail
All relevant user interactions and changes are documented. In case of investigations, entries can be easily searched, filtered, printed, and exported.

Version control
Full traceability of product and method modifications with automatic version control including configurable release procedure with electronic signature.

Electronic signature
q-doc® can be configured to explicitly require an electronic signature to complete critical actions like making changes to method data.

User access restriction
User groups and their access rights can be defined and configured to ensure that only authorized persons can perform certain tasks.

Password security
Even without LDAP integration, q-doc® allows to define several password security rules according to your company policy.

Auto-locking
If there is no user action performed within a configurable time period, q-doc® will automatically lock the application.

q-doc® — Installation requirements

Operating system (OS)	Microsoft®	Windows® 7 / 10, Windows® Server 2008 R2 / 2012 / 2012 R2 / 2016
	System	32 bit, 64 bit
Hardware	RAM	min. 4 GB, better 8 GB
	CPU	min. 2 GHz, better Dual core / Quad core
	Free disc space	min. 20 GB
	Display resolution	1920 × 1080
	Mouse	●
	Keyboard	●
	Communication ports	Depending on connected instruments / systems
Database	MS-SQL® (Express or full version)	2008 R2, 2012, 2014, 2016

● required

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.