DataApex

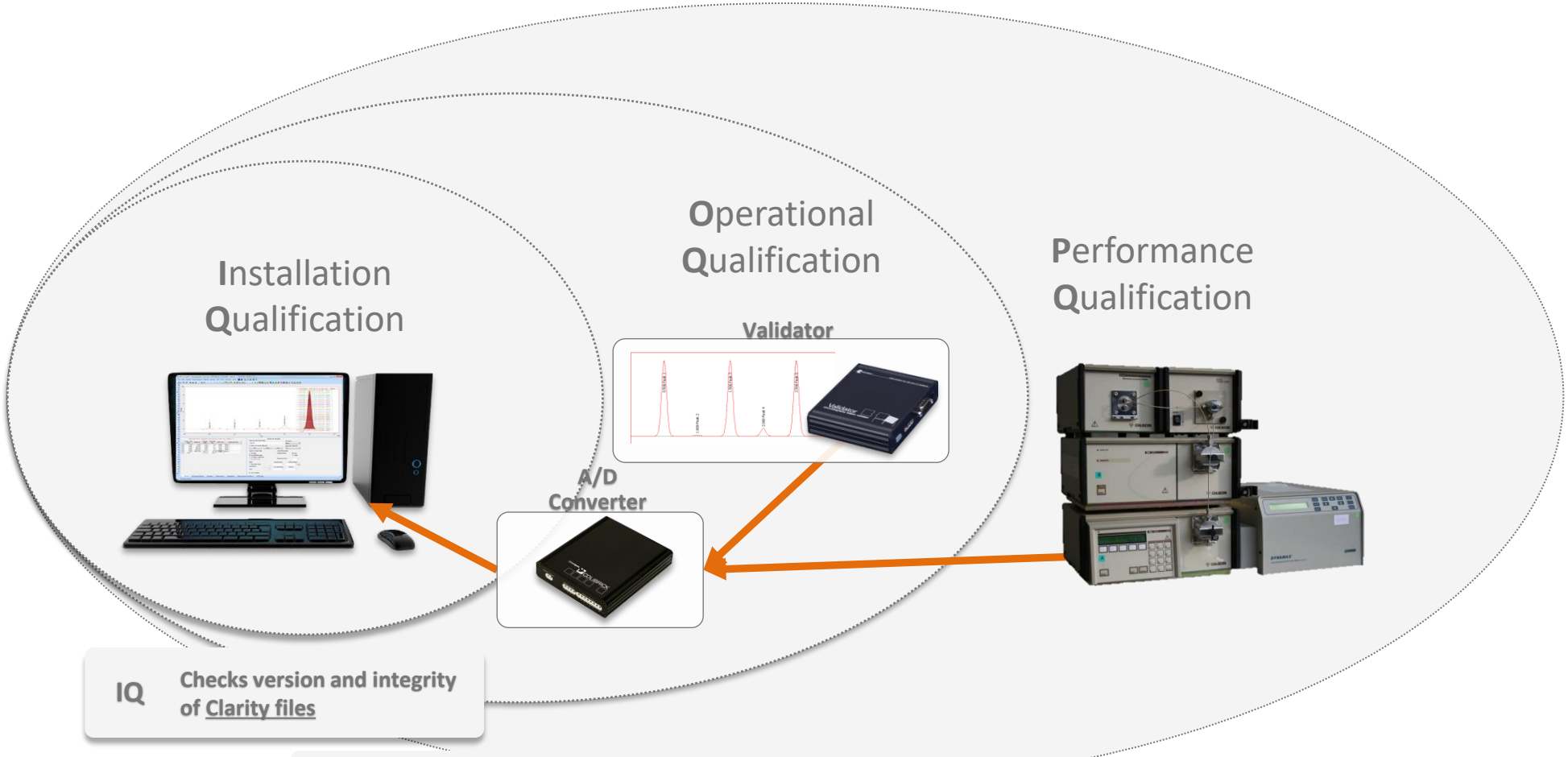
SMART SOLUTION FOR LABORATORIES

Clarity™

advanced chromatography software

VALIDATION

P019/80F 01/2023



IQ Checks version and integrity of Clarity files

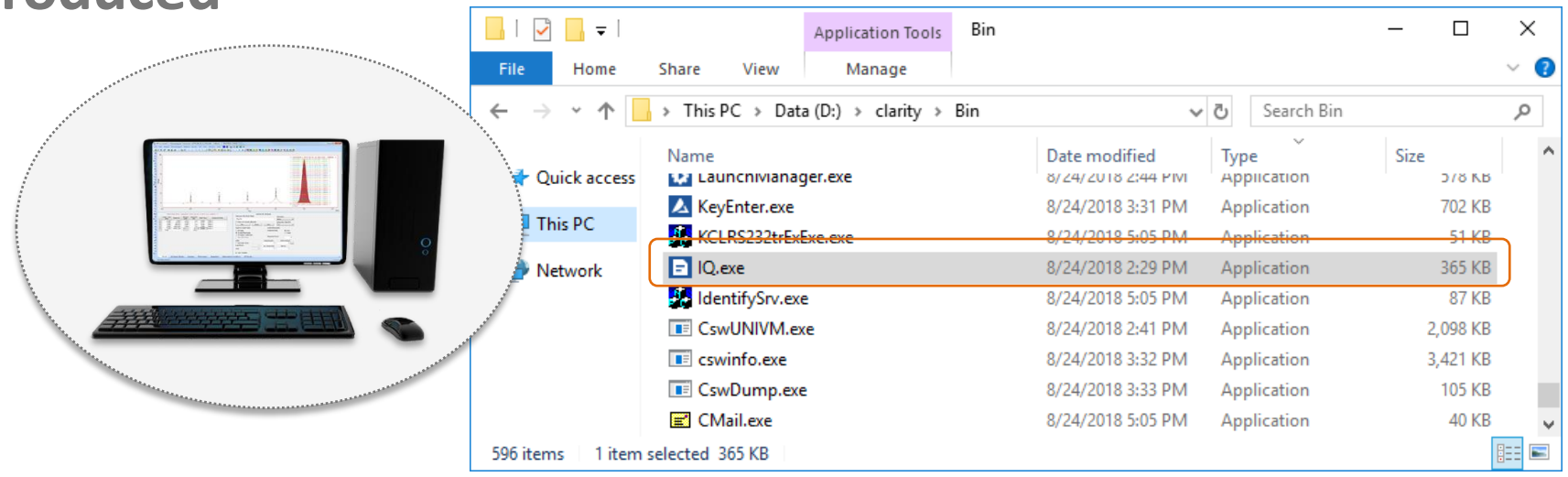
OQ Tests data acquisition and processing

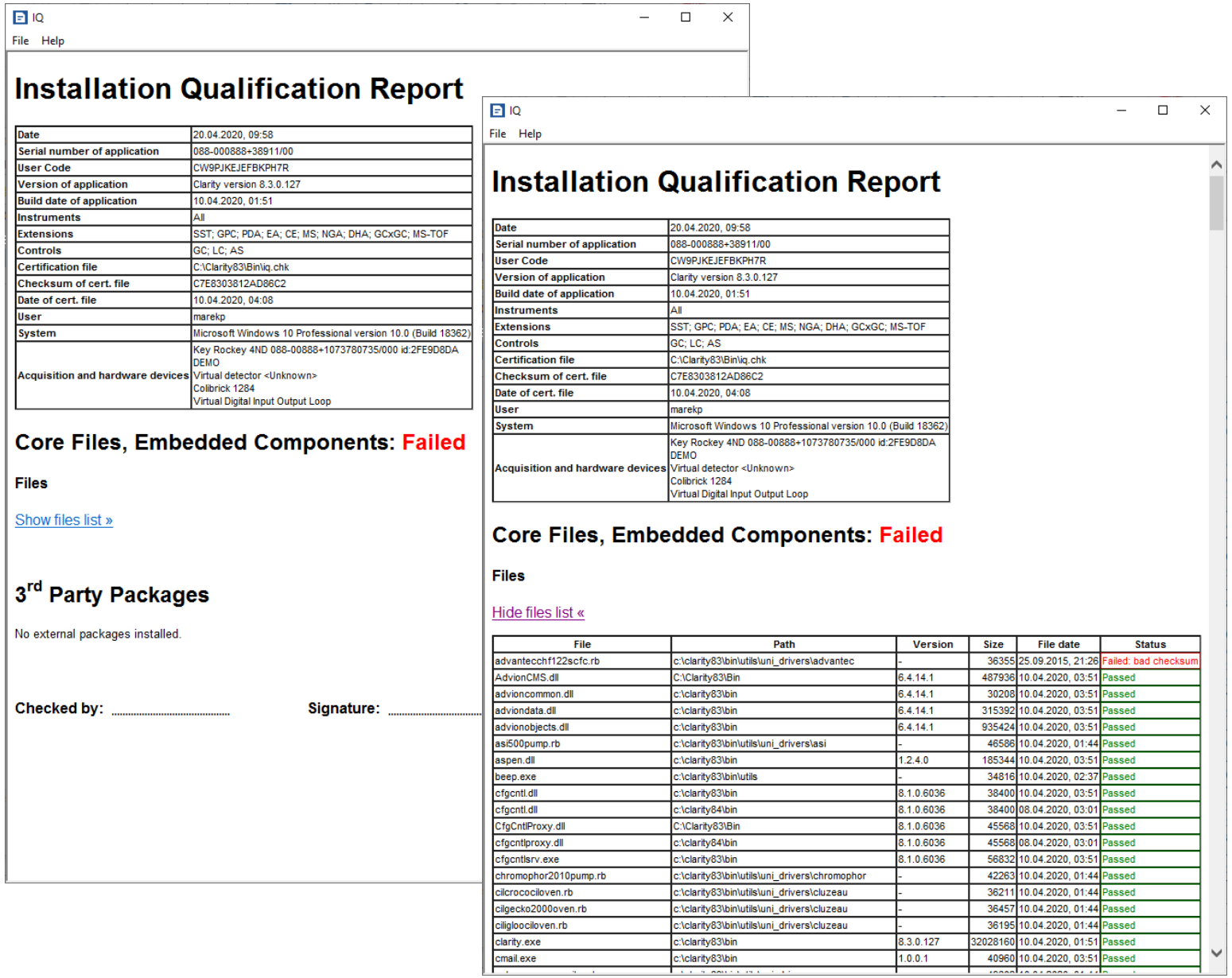
Hardware (HW) generated data – Validator
Software (SW) generated data – Clarity Virtual Detector

PQ Tests the overall analytical system performance

Installation Qualification (IQ)

- The IQ checks the **version** and **integrity** of Clarity files for correct functionality
- Run the **IQ utility** from the Clarity folder - an **IQ Report will be produced**





- General **information** about your Clarity **installation**
- Indicates if the installation has Passed, Passed with warnings or Failed the test
- Indicates which files have passed or failed

Operational Qualification (OQ)

- Part of validation is the OQ which **tests data acquisition** and **processing**
- OQ is part of the tools supporting **21 CFR Part 11 Regulations**
- **System Suitability Test** (SST) extension is required
- **Validation Kit** is required only for station with A/D converters

Validation Kit manual

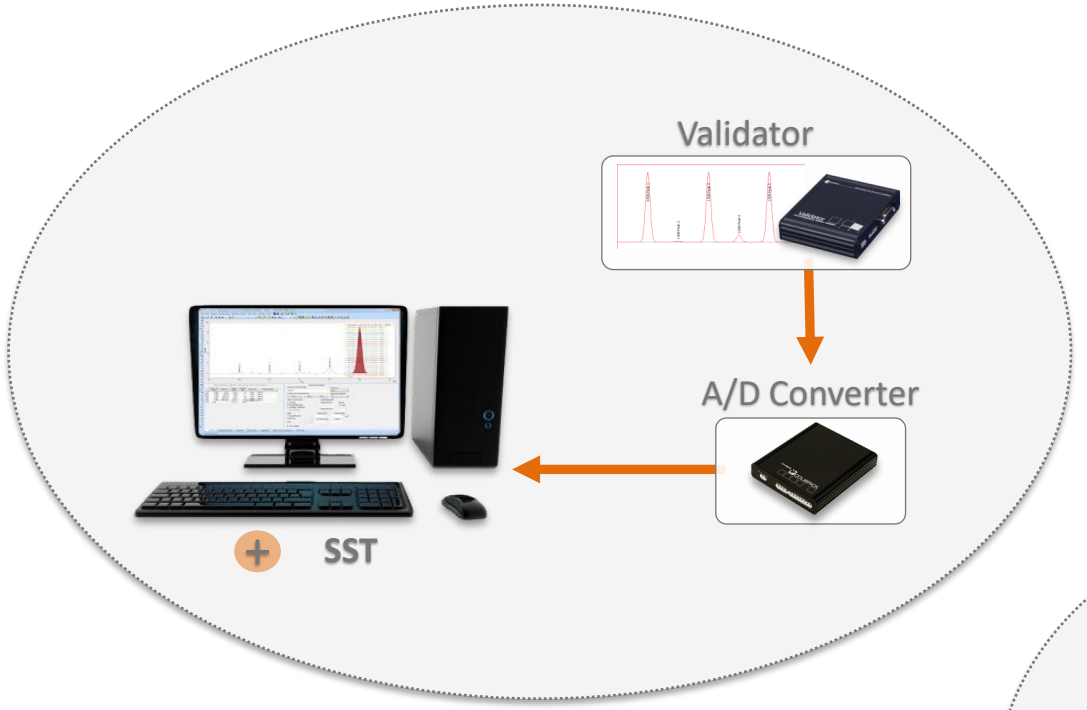
Validator Certificate

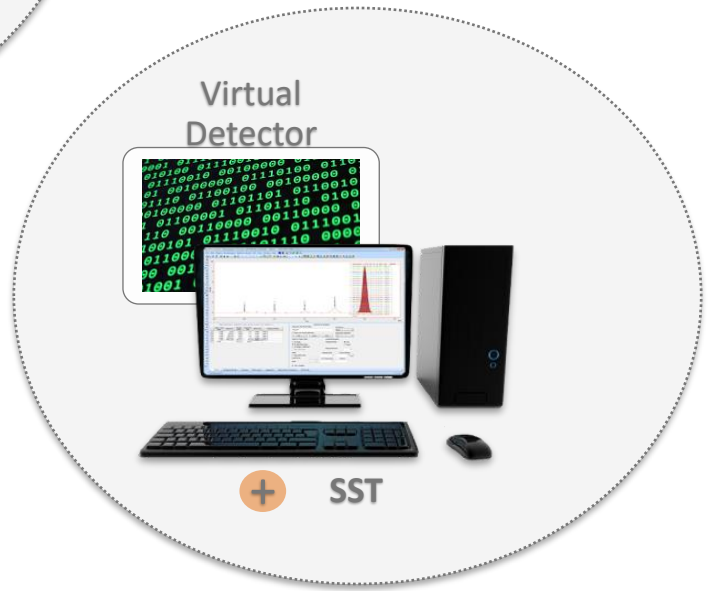
Terminal Board

Cable for the A/D Converter

AC/DC Power Adapter

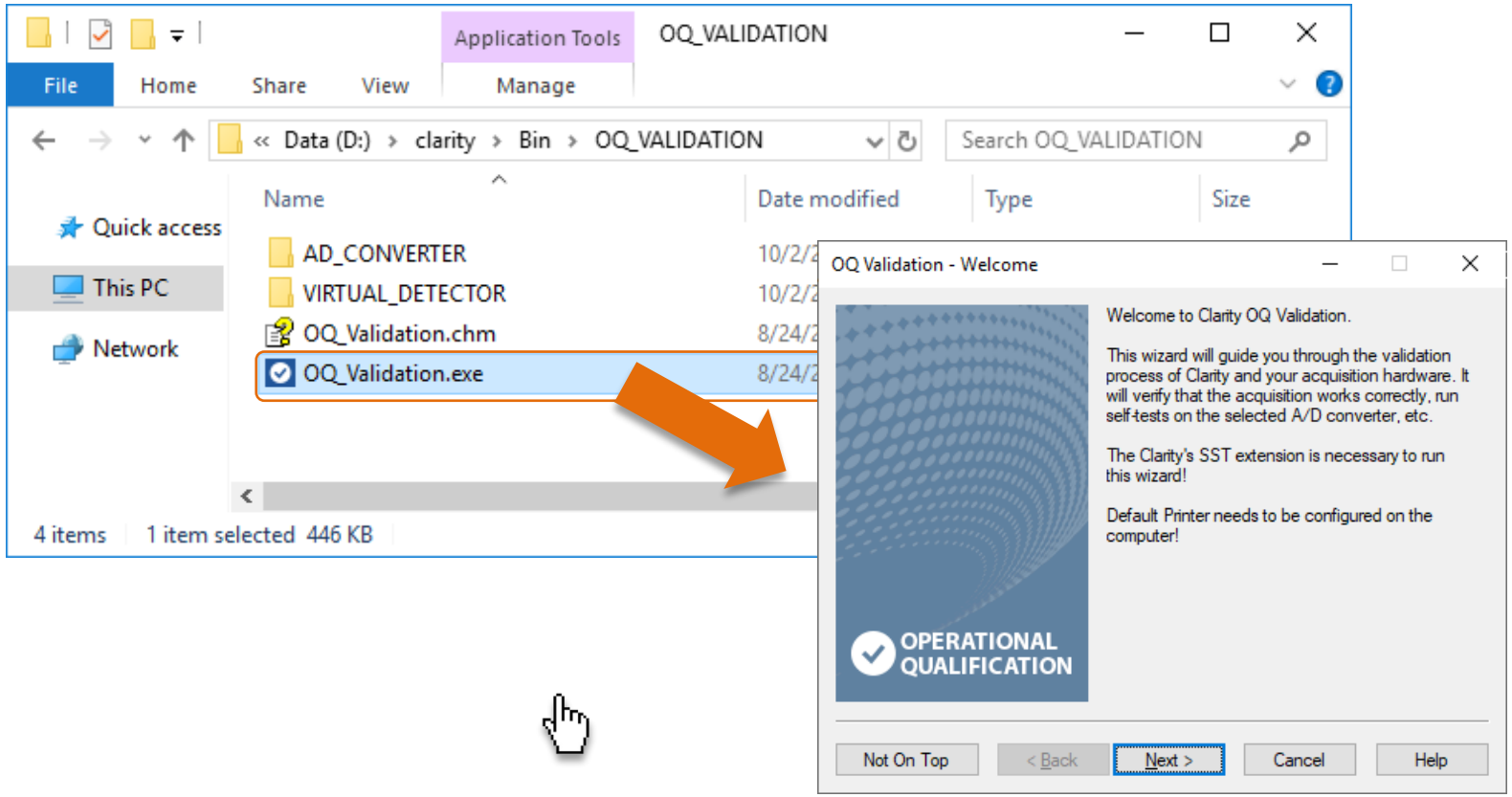
Validator

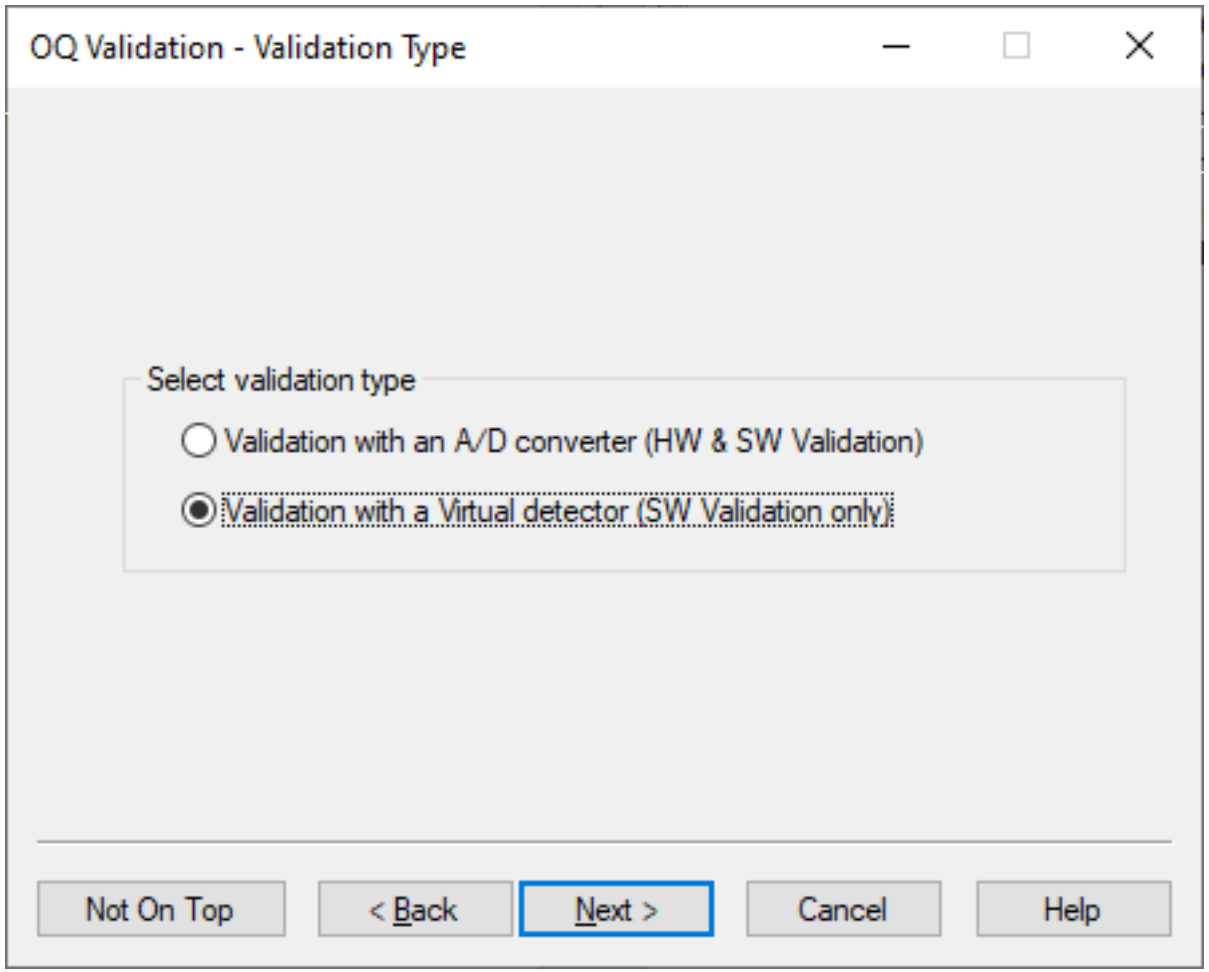




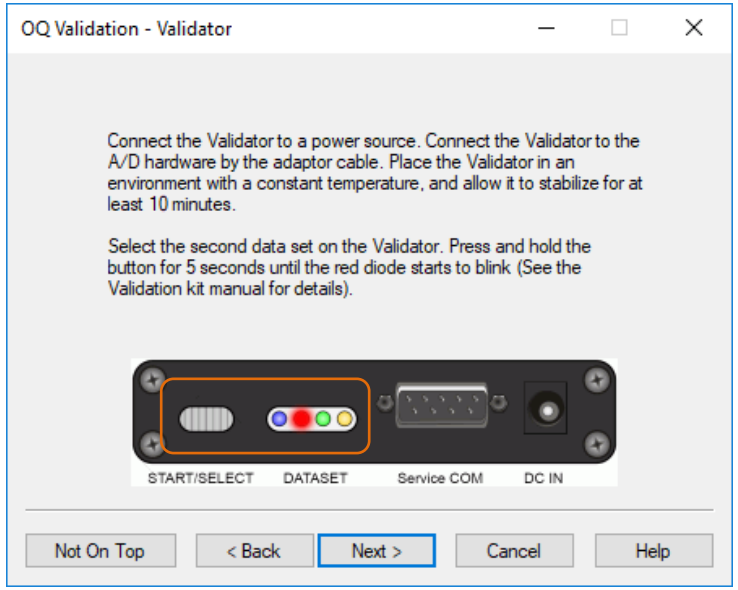
- Chromatograms are either generated by our **Validator** (HW)
- … or via **Virtual Detector** (SW) from Clarity

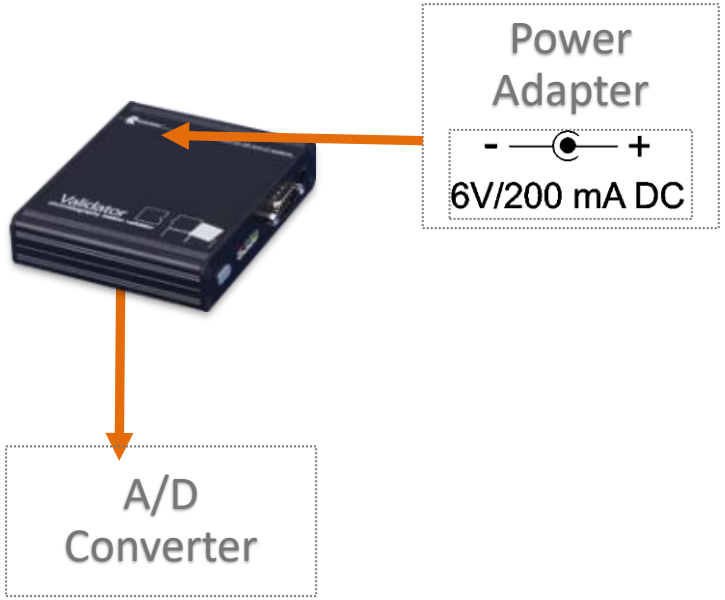
- To start the OQ test, run the OQ_Validation wizard in the Clarity – OQ_Validation folder



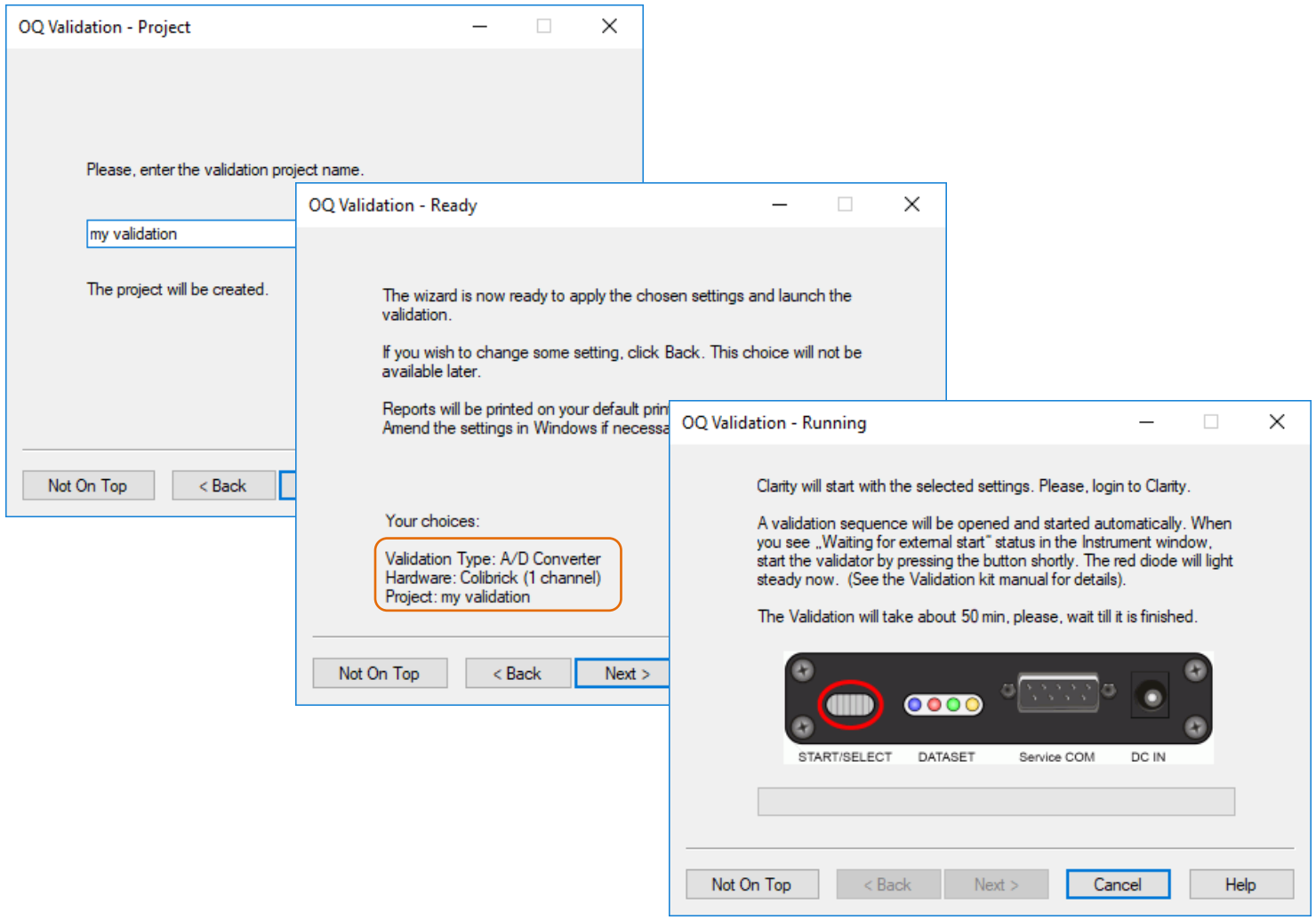


- Select if you want to validate:
- With a **Validator** (validation of SW & A/D converter)
- or with Clarity **Virtual Detector** (validation of SW only)
- the only feasible way for instruments with **digital acquisition** (see Validation Kit manual)



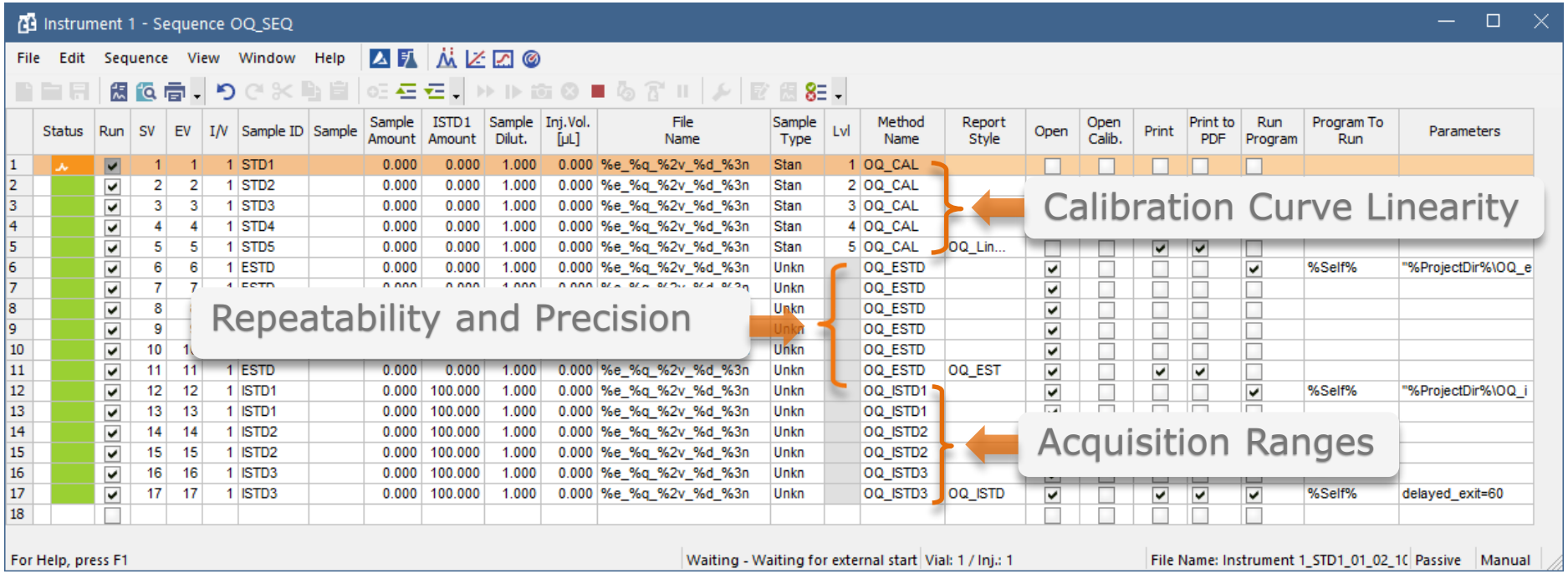


- If you selected the **Validator**
- **Power** it and connect it to the **A/D converter**
- **Press & hold** the button for 5 sec to select the **2nd** dataset (red)

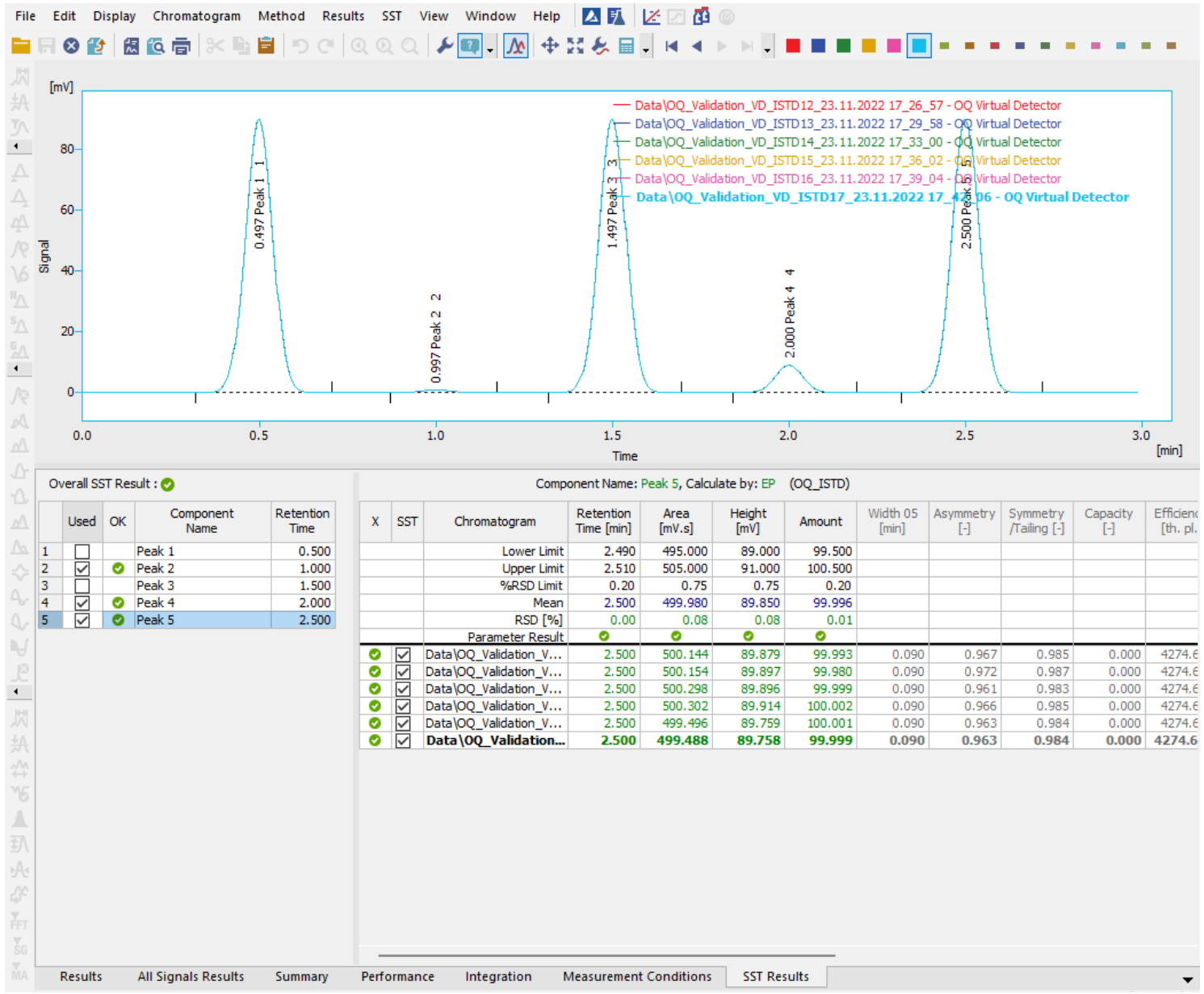


- Enter the validation **project name**
- **Confirm your settings** or click back if you need to change them
- Then login to Clarity and press the **Start button on the Validator** to start the validation

- The OQ will run **a sequence of analyses**
- Each set of analyses, **tests** a different set of **parameters**
- Each **set** is associated with a **method** and a **report style**



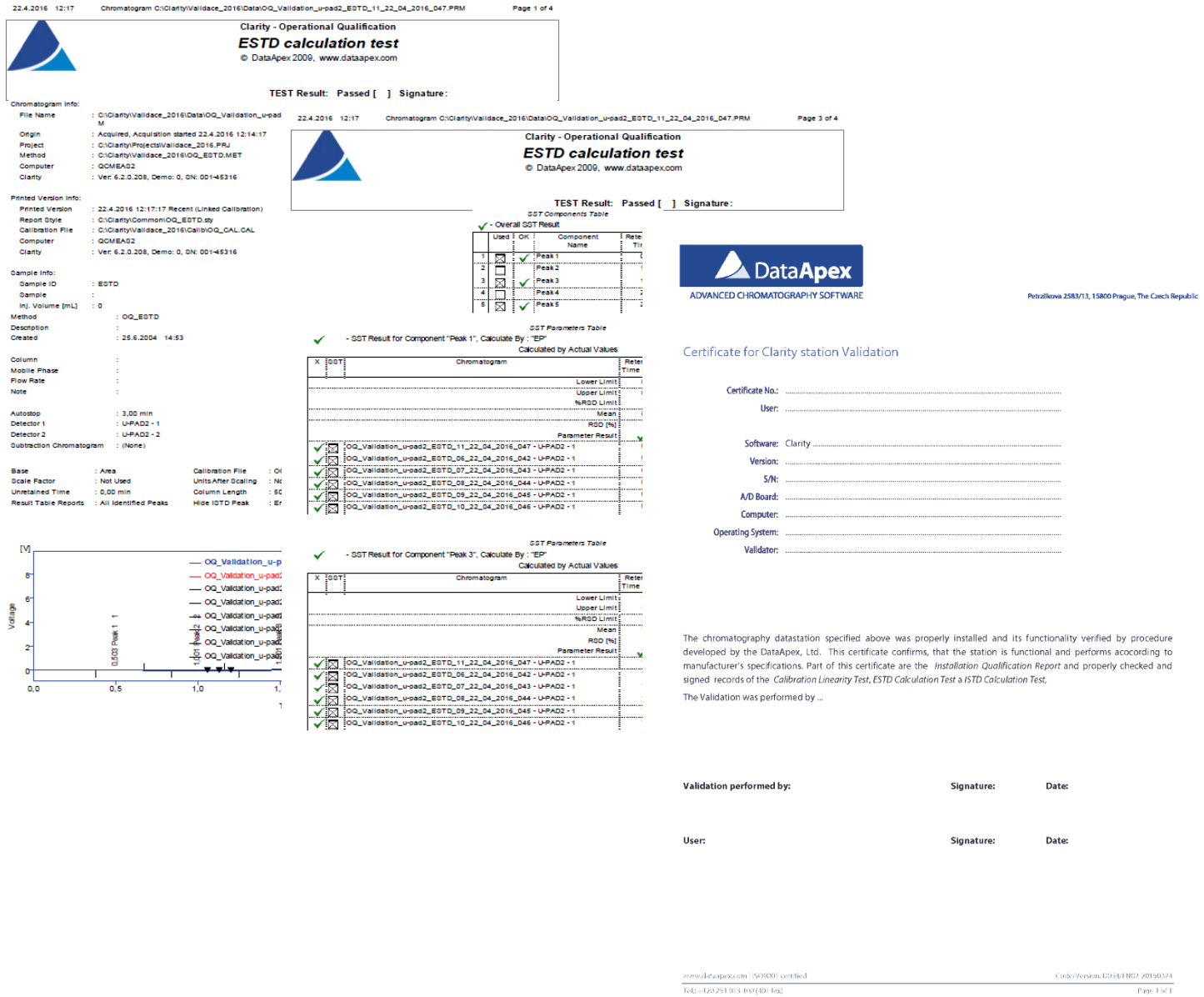
	Status	Run	SV	EV	I/V	Sample ID	Sample	Sample Amount	ISTD1 Amount	Sample Dilut.	Inj.Vol. [µL]	File Name	Sample Type	Lvl	Method Name	Report Style	Open	Open Calib.	Print	Print to PDF	Run Program	Program To Run	Parameters
1		✓	1	1	1	STD1		0.000	0.000	1.000	0.000	%e_%q_%2v_%d_%3n	Stan	1	OQ_CAL								
2		✓	2	2	1	STD2		0.000	0.000	1.000	0.000	%e_%q_%2v_%d_%3n	Stan	2	OQ_CAL								
3		✓	3	3	1	STD3		0.000	0.000	1.000	0.000	%e_%q_%2v_%d_%3n	Stan	3	OQ_CAL								
4		✓	4	4	1	STD4		0.000	0.000	1.000	0.000	%e_%q_%2v_%d_%3n	Stan	4	OQ_CAL								
5		✓	5	5	1	STD5		0.000	0.000	1.000	0.000	%e_%q_%2v_%d_%3n	Stan	5	OQ_CAL	OQ_Lin...			✓	✓			
6		✓	6	6	1	ESTD		0.000	0.000	1.000	0.000	%e_%q_%2v_%d_%3n	Unkn		OQ_ESTD		✓				✓	%Self%	"%ProjectDir%\OQ_e
7		✓	7	7	1	ESTD		0.000	0.000	1.000	0.000	%e_%q_%2v_%d_%3n	Unkn		OQ_ESTD		✓						
8		✓	8										Unkn		OQ_ESTD		✓						
9		✓	9										Unkn		OQ_ESTD		✓						
10		✓	10	1									Unkn		OQ_ESTD		✓						
11		✓	11	11	1	ESTD		0.000	0.000	1.000	0.000	%e_%q_%2v_%d_%3n	Unkn		OQ_ESTD	OQ_EST	✓		✓	✓			
12		✓	12	12	1	ISTD1		0.000	100.000	1.000	0.000	%e_%q_%2v_%d_%3n	Unkn		OQ_ISTD1		✓				✓	%Self%	"%ProjectDir%\OQ_i
13		✓	13	13	1	ISTD1		0.000	100.000	1.000	0.000	%e_%q_%2v_%d_%3n	Unkn		OQ_ISTD1		✓				✓		
14		✓	14	14	1	ISTD2		0.000	100.000	1.000	0.000	%e_%q_%2v_%d_%3n	Unkn		OQ_ISTD2		✓				✓		
15		✓	15	15	1	ISTD2		0.000	100.000	1.000	0.000	%e_%q_%2v_%d_%3n	Unkn		OQ_ISTD2		✓				✓		
16		✓	16	16	1	ISTD3		0.000	100.000	1.000	0.000	%e_%q_%2v_%d_%3n	Unkn		OQ_ISTD3		✓				✓		
17		✓	17	17	1	ISTD3		0.000	100.000	1.000	0.000	%e_%q_%2v_%d_%3n	Unkn		OQ_ISTD3	OQ_ISTD	✓		✓	✓	✓	%Self%	delayed_exit=60
18																							



	Used	OK	Component Name	Retention Time
1	☐		Peak 1	0.500
2	☑	✓	Peak 2	1.000
3	☐		Peak 3	1.500
4	☑	✓	Peak 4	2.000
5	☑	✓	Peak 5	2.500

X	SST	Chromatogram	Retention Time [min]	Area [mV.s]	Height [mV]	Amount	Width 05 [min]	Asymmetry [-]	Symmetry /Tailing [-]	Capacity [-]	Efficienc [th. pl.
		Lower Limit	2.490	495.000	89.000	99.500					
		Upper Limit	2.510	505.000	91.000	100.500					
		%RSD Limit	0.20	0.75	0.75	0.20					
		Mean	2.500	499.980	89.850	99.996					
		RSD [%]	0.00	0.08	0.08	0.01					
		Parameter Result	✓	✓	✓	✓					
✓	☑	Data\OQ_Validation_V...	2.500	500.144	89.879	99.993	0.090	0.967	0.985	0.000	4274.6
✓	☑	Data\OQ_Validation_V...	2.500	500.154	89.897	99.980	0.090	0.972	0.987	0.000	4274.6
✓	☑	Data\OQ_Validation_V...	2.500	500.298	89.896	99.999	0.090	0.961	0.983	0.000	4274.6
✓	☑	Data\OQ_Validation_V...	2.500	500.302	89.914	100.002	0.090	0.966	0.985	0.000	4274.6
✓	☑	Data\OQ_Validation_V...	2.500	499.496	89.759	100.001	0.090	0.963	0.984	0.000	4274.6
✓	☑	**Data\OQ_Validation...**	**2.500**	**499.488**	**89.758**	**99.999**	**0.090**	**0.963**	**0.984**	**0.000**	**4274.6**

- Once the data is **acquired** and **integrated**, the **SST** extension will check if the parameters fall within the set limits
- **Overall results** are clearly **indicated** in the OK column



Clarity - Operational Qualification

ESTD calculation test

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TEST Result: Passed [ ] Signature:

Chromatogram Info:

File Name	: C:\Clarity\Validace_2016\Data\OQ_Validation_u-pad2_ESTD_11_22_04_2016_047.PRM
Origin	: Acquired, Acquisition started 22.4.2016 12:14:17
Project	: C:\Clarity\Projects\Validace_2016.PRJ
Method	: C:\Clarity\Validace_2016\OQ_ESTD.MET
Computer	: QCMEAD2
Clarity	: Ver. 6.2.0.208, Demo: 0, SN: 001-45316

Printed Version Info:

Printed Version	: 22.4.2016 12:17:17 Recent (Linked Calibration)
Report Style	: C:\Clarity\Common\OQ_ESTD.sty
Calibration File	: C:\Clarity\Validace_2016\Calib\OQ_CAL.CAL
Computer	: QCMEAD2
Clarity	: Ver. 6.2.0.208, Demo: 0, SN: 001-45316

Sample Info:

Sample ID	: ESTD
Sample	:
Inj. Volume [mL]	: 0
Method	: OQ_ESTD
Description	:
Created	: 25.6.2004 14:53
Column	:
Mobile Phase	:
Flow Rate	:
Note	:
Autostop	: 3,00 min
Detector 1	: U-PAD2 - 1
Detector 2	: U-PAD2 - 2
Subtraction Chromatogram	: (None)

Base	: Area	Calibration File	: O
Scale Factor	: Not Used	Units After Scaling	: N
Unretained Time	: 0,00 min	Column Length	: 5
Result Table Reports	: All Identified Peaks	Hide ISTD Peak	: E

22.4.2016 12:17 Chromatogram C:\Clarity\Validace_2016\Data\OQ_Validation_u-pad2_ESTD_11_22_04_2016_047.PRM Page 3 of 4

Clarity - Operational Qualification

ESTD calculation test

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TEST Result: Passed [ ] Signature:

SST Components Table

- Overall SST Result

	Used	OK	Component Name	Rete Tir
1	☒	✓	Peak 1	
2	☐		Peak 2	
3	☒	✓	Peak 3	
4	☐		Peak 4	
5	☒	✓	Peak 5	

SST Parameters Table

- SST Result for Component "Peak 1", Calculate By : "EP"

Calculated by Actual Values

X	SST	Chromatogram	Rete Time
		Lower Limit	
		Upper Limit	
		%RSD Limit	
		Mean	
		RSD [%]	
		Parameter Result	
✓	☒	OQ_Validation_u-pad2_ESTD_11_22_04_2016_047 - U-PAD2 - 1	
✓	☒	OQ_Validation_u-pad2_ESTD_06_22_04_2016_042 - U-PAD2 - 1	
✓	☒	OQ_Validation_u-pad2_ESTD_07_22_04_2016_043 - U-PAD2 - 1	
✓	☒	OQ_Validation_u-pad2_ESTD_08_22_04_2016_044 - U-PAD2 - 1	
✓	☒	OQ_Validation_u-pad2_ESTD_09_22_04_2016_045 - U-PAD2 - 1	
✓	☒	OQ_Validation_u-pad2_ESTD_10_22_04_2016_046 - U-PAD2 - 1	

SST Parameters Table

- SST Result for Component "Peak 3", Calculate By : "EP"

Calculated by Actual Values

X	SST	Chromatogram	Rete Time
		Lower Limit	
		Upper Limit	
		%RSD Limit	
		Mean	
		RSD [%]	
		Parameter Result	
✓	☒	OQ_Validation_u-pad2_ESTD_11_22_04_2016_047 - U-PAD2 - 1	
✓	☒	OQ_Validation_u-pad2_ESTD_06_22_04_2016_042 - U-PAD2 - 1	
✓	☒	OQ_Validation_u-pad2_ESTD_07_22_04_2016_043 - U-PAD2 - 1	
✓	☒	OQ_Validation_u-pad2_ESTD_08_22_04_2016_044 - U-PAD2 - 1	
✓	☒	OQ_Validation_u-pad2_ESTD_09_22_04_2016_045 - U-PAD2 - 1	
✓	☒	OQ_Validation_u-pad2_ESTD_10_22_04_2016_046 - U-PAD2 - 1	

DataApex

ADVANCED CHROMATOGRAPHY SOFTWARE

Petrzilkova 2583/13, 15800 Prague, The Czech Republic

Certificate for Clarity station Validation

Certificate No.: .....

User: .....

Software: Clarity .....

Version: .....

S/N: .....

A/D Board: .....

Computer: .....

Operating System: .....

Validator: .....

The chromatography datastation specified above was properly installed and its functionality verified by procedure developed by the DataApex, Ltd. This certificate confirms, that the station is functional and performs acoording to manufacturer's specifications. Part of this certificate are the *Installation Qualification Report* and properly checked and signed records of the *Calibration Linearity Test, ESTD Calculation Test* a *ISTD Calculation Test*,

The Validation was performed by ...

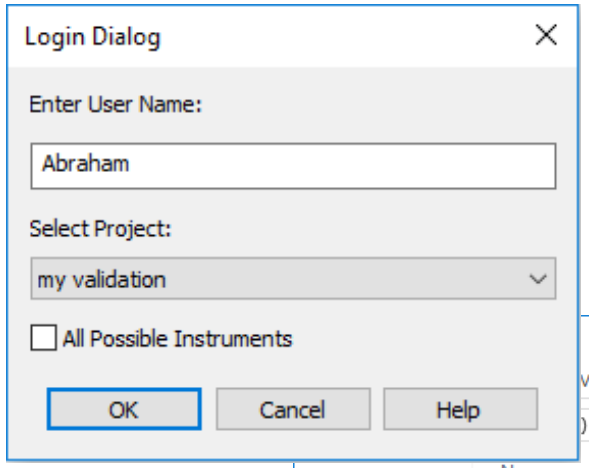
Validation performed by: **Signature:** **Date:**

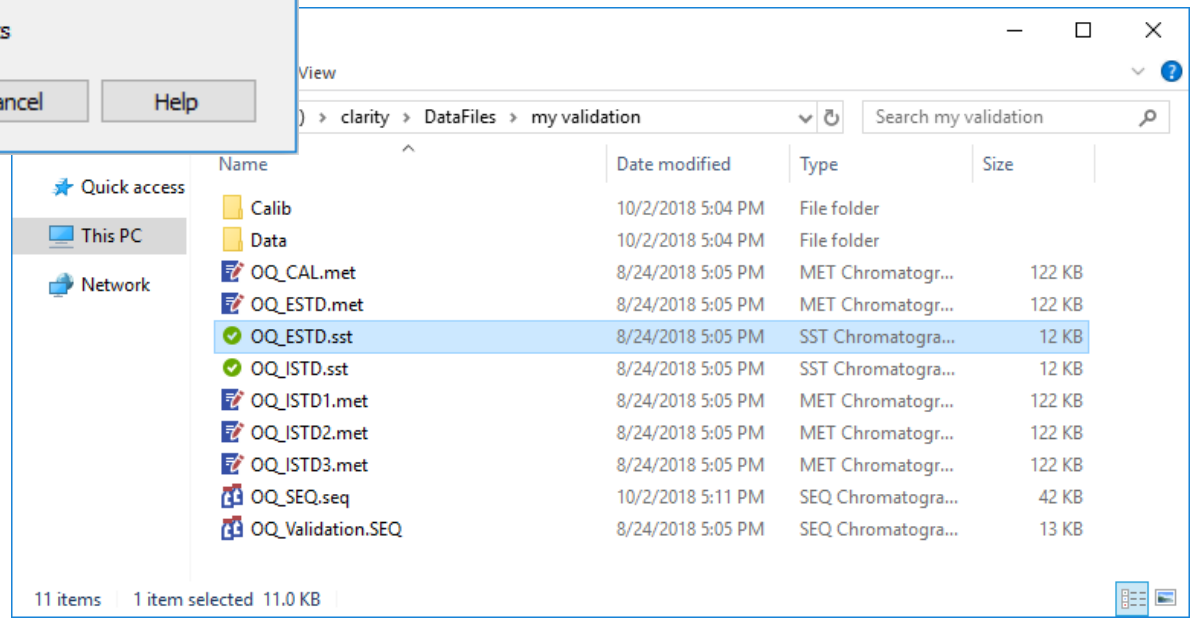
User: **Signature:** **Date:**

www.dataapex.com | ISO9001 certified Code/Version: DOS4/EN02-20150324

Tel.: +420 251 013 400 (401 fax) Page 1 of 1

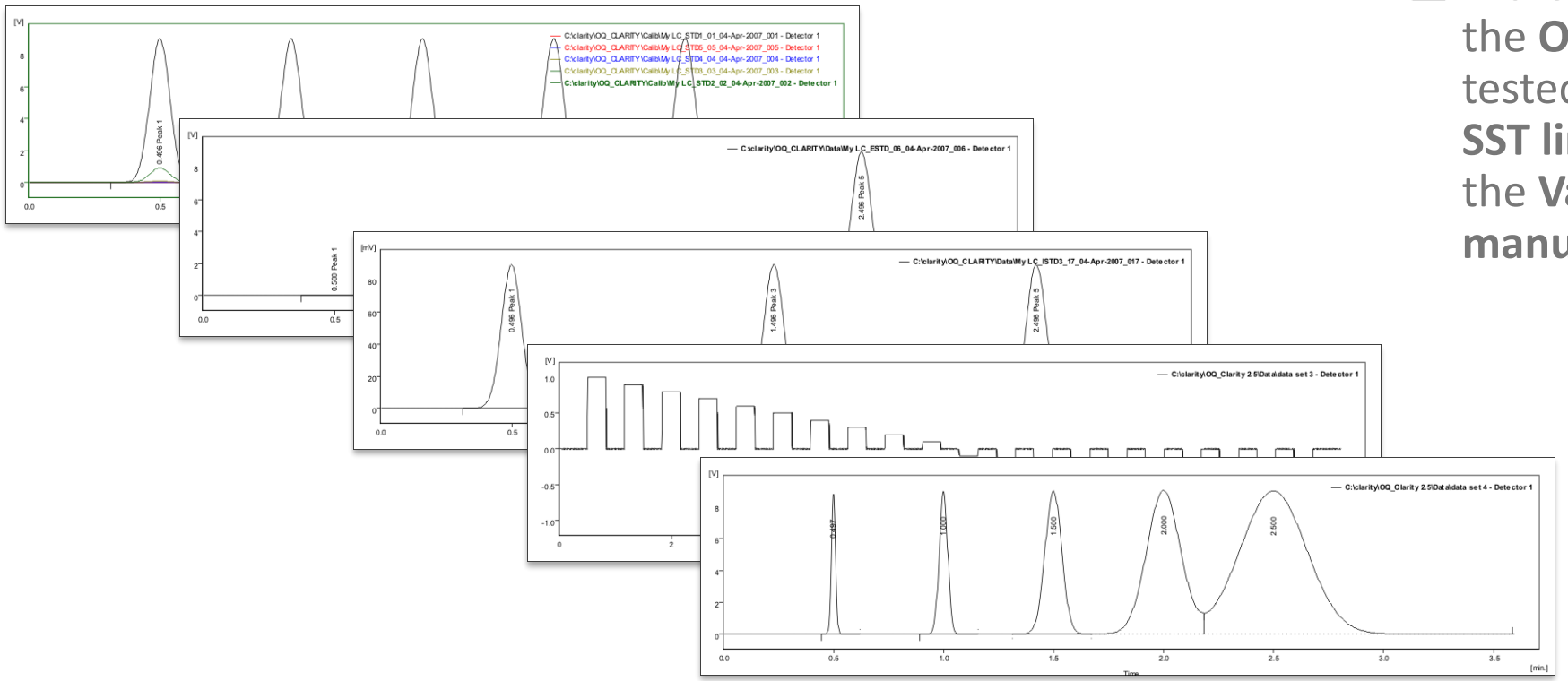
- After each set of analyses, Clarity generates a multipage **OQ report in PDF format** ready to be date stamped and signed
- These reports are **located in the Validation project directory** (specified at the start)





- Your **validation project** is **accessible as any** other Clarity project
- In the project folder you will find chromatograms, methods, calibration files, sequences, reports etc.

- **Service Personnel trained** by DataApex in the use of the Validation Kit will receive a **certificate entitling them to perform validations**



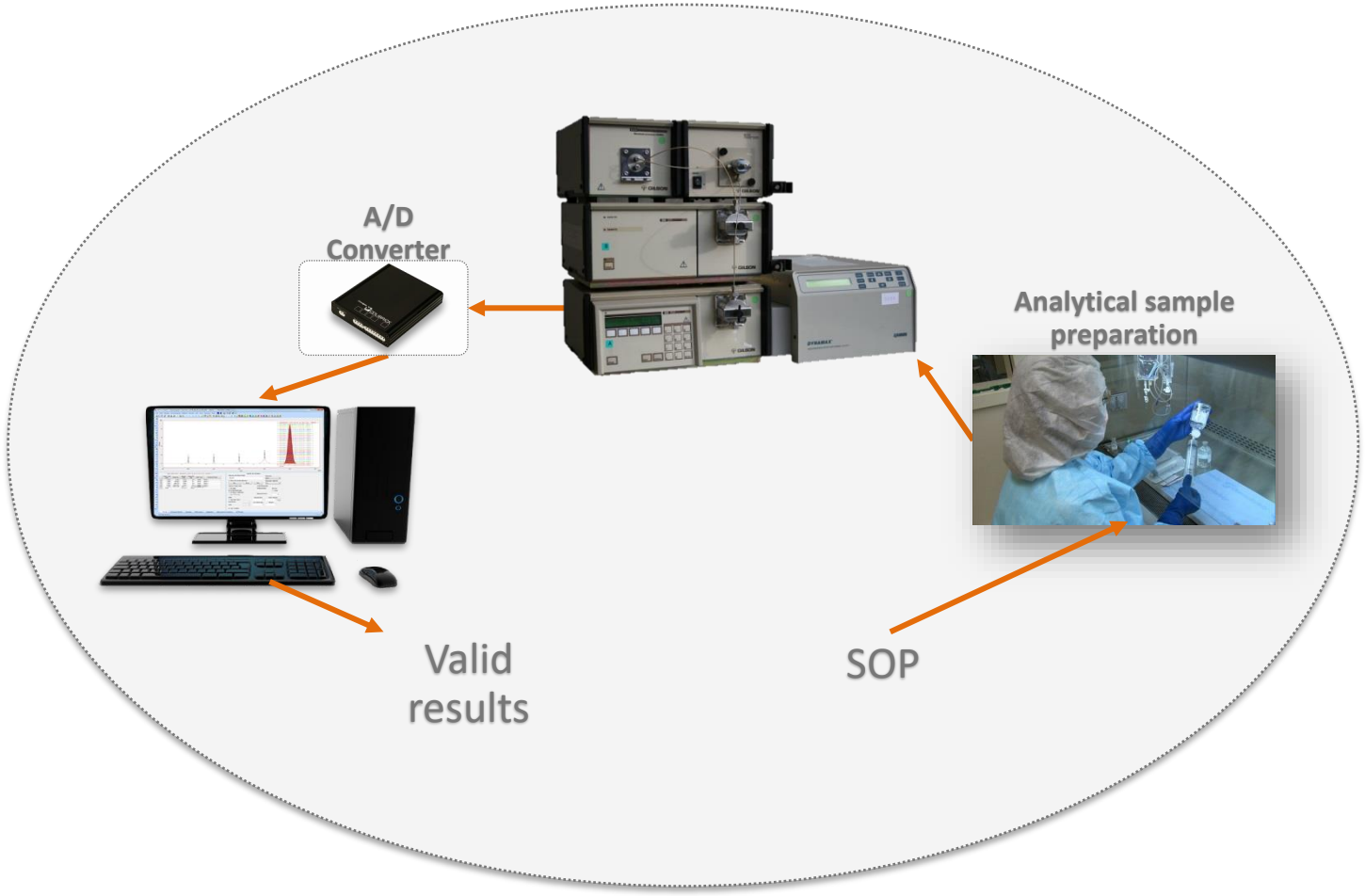
- More information on the **OQ chromatograms**, tested **parameters** and **SST limits** is located in the **Validation Kit manual**

Parameter	Expected value
Calibration curve slope	500 +/- 2
Calibration curve intercept	0,0 +/- 0,5
Correlation factor	min 0,999999

Peak	Limit	RT min	Area mV.s	Height mV	Amount
PEAK 1	Lower	0,49	4,5	0,85	0,009
	Upper	0,51	5,5	0,95	0,011
	RSD%	1,5	2	2	2

Performance Qualification

- Confirms that the analytical system complies with the standards (SOP) set for a specific type of analysis
- SST can be used for the purposes of PQ but the tests and criteria must be prepared by the laboratory personnel based on the specification of the instrument set by the manufacturer



- **PQ is not tested nor any certificate is issued by DataApex**
- Before the PQ, the system **must pass the IQ and the OQ first**

DataApex

SMART SOLUTION FOR LABORATORIES

…THANK YOU FOR YOUR TIME

SUPPORT@DATAAPEX.COM
WWW.DATAAPEX.COM