



Fusion QbD[®]

***Experiment While You Sleep –
Walk-away CDS Automation***

Fusion QbD – Supports All Install Environments

Install Environment

Fusion QbD

Standalone (Workstation)



WorkGroup / Network



Citrix Ready Certified

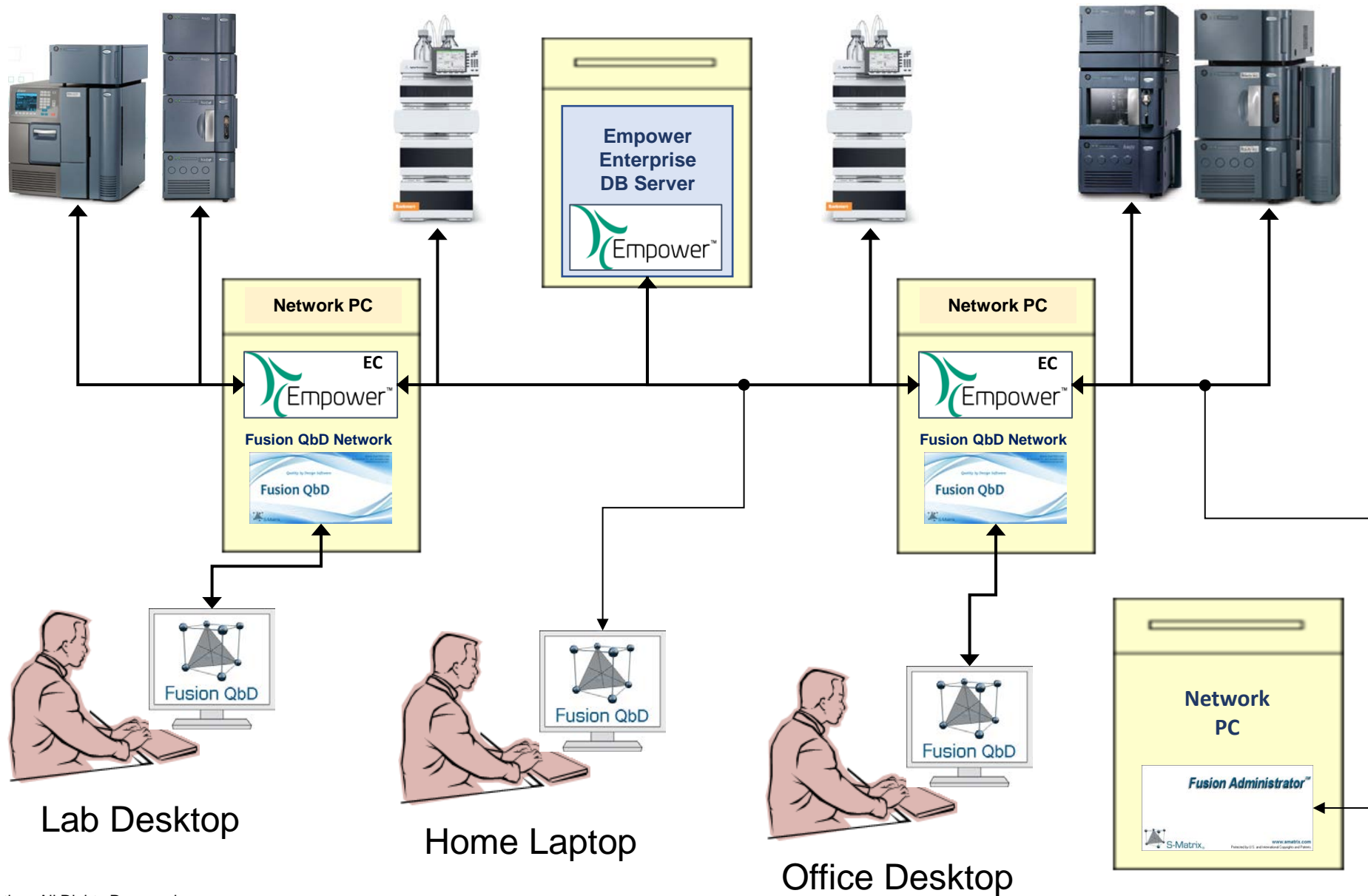


Fully Qualifiable for GxP*



- * – Fusion QbD is operating in the GxP environments of international pharmaceutical companies worldwide.

Fusion QbD – Supports All Install Environments



Key Differentiators – Automation & Compliance



Full Experiment Automation Support

- LC Systems
- Column/Solvent Valves
- Separation Modes
- Automation Supports Data Quality



Forced Degradation Studies



Bi-directional Audit Trail Support

- Automation/Auditing Support Data Integrity



Buffer Selector... pH Online Blending Mode: One Acid Base Pair ☐ pKa of Primary Compound

pH Buffer Settings: No. of Levels: 6

Buffer	Buffer Name
Acid	Formic Acid (20 mM)
Base	Ammonium Formate (20 mM)

pH Level	Acid %	Base %
2.75	100.0	0.0
3.16	80.0	20.0
3.70	50.0	50.0
4.34	20.0	80.0
5.42	5.0	95.0
6.24	0.0	100.0

Buffer Selector

Select Buffer System: pH 2.75 - 6.24 [Formate System (20 mM)]

Buffer Solutions: Formic Acid (20 mM), Ammonium Formate (20 mM)

Table with 4 columns: Included, pH, Formic Acid (%), Ammonium Formate (%). Rows show data points for pH levels from 2.75 to 6.24.

Included	pH	Formic Acid (%)	Ammonium Formate (%)
<input checked="" type="checkbox"/>	2.75	100.00	0.00
<input type="checkbox"/>	2.78	95.00	5.00
<input type="checkbox"/>	2.89	90.00	10.00
<input checked="" type="checkbox"/>	3.16	80.00	20.00
<input type="checkbox"/>	3.38	70.00	30.00
<input type="checkbox"/>	3.54	60.00	40.00
<input checked="" type="checkbox"/>	3.70	50.00	50.00
<input type="checkbox"/>	3.88	40.00	60.00
<input type="checkbox"/>	4.06	30.00	70.00
<input checked="" type="checkbox"/>	4.34	20.00	80.00
<input type="checkbox"/>	4.91	10.00	90.00
<input checked="" type="checkbox"/>	5.42	5.00	95.00
<input checked="" type="checkbox"/>	6.24	0.00	100.00

OK Cancel

Built-in pH Titration Curves for Quaternary Pump Modules!

Or Use Your Own Buffer Curve.

Extremely Precise!



Fusion QbD – LC System Automation



- ✓ Solvent Selection Valves
- ✓ Column Switching Valves

Alliance HPLC



Alliance iS HPLC



Acquity Binary



Acquity H-Class



Acquity Arc



Acquity UPC²



Fusion QbD – LC System Automation



ChemStation
OpenLab



- ✓ Solvent Selection Valves
- ✓ Column Switching Valves

Agilent 1100s
And 1200s



Agilent 1260
Infinity Series



Agilent 1260
Infinity II Series



Agilent 1290
Infinity Series



Agilent 1290
Infinity II Series



Fusion QbD – LC System Automation



- ✓ Solvent Selection Valves
- ✓ Column Switching Valves

UltiMate LCs



Vanquish Horizon
And Flex LCs



Fusion QbD – Study Parameter Flexibility

Full utilization of Quaternary Pumps, Solvent Selection Valves, and Column Switching Valves.

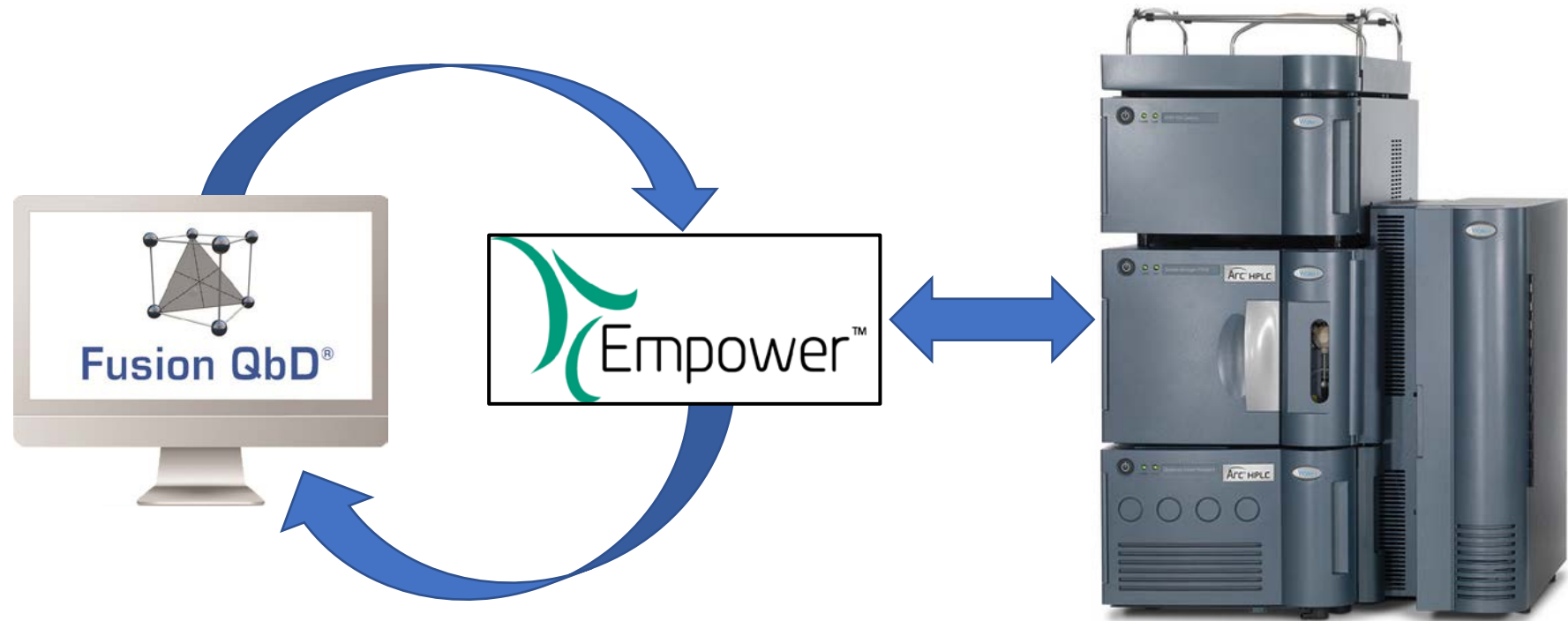
Study any combination of LC parameters which can interactively effect method performance!

- Isocratic and Gradient Methods
- Strong Solvent Type
- Any pump program steps – e.g.
 - Equilibration Time & %
 - Isocratic Hold Time & %
 - Gradient Time / Slope
 - Initial / Final Hold Time & %
 - Re-equilibration Time & %
- Column Temperature
- Column Type
- Flow Rate
- Injection Volume
- pH
- Mobile Phase Blends
- Salt, Buffer, Additive – Type & ΔC
- Wavelength

Fusion QbD Automation with Empower

Supports All These Separation Modes

Reversed Phase
Normal Phase
Chiral
HILIC
Ion Exchange
Size Exclusion
SFC



Maximum Efficiency + Maximum Data Quality:

- ✓ Automates Mobile Phase Preparation.
- ✓ Maximizes use of reservoirs and solvent selection valves.
- ✓ Incorporates column conditioning.
- ✓ Ramps on pH.
- ✓ Ramps on Temperature.

Fusion QbD – Export to CDS



Generates QbD-aligned
DOE Experiment

Automatically Builds
Sequence and All
Instrument Methods

CDS Software



RD2 Optimization in S-Matrix\Internal Development\FMD\RD2 - Optimization - 9,9,0 as System/Administrator - Sample Set Method Editor

Plate/Vial	Inj Vol (uL)	# of Inj	Label	Sample Name	Level	Function	Method Set / Report or Export Method	Label Reference	Processing	Run Time (Minutes)	Data Start (Minutes)	Next Inj Delay (Minutes)	MS Tune Method	MS Calibration Method	Column Position	Auto Additions	Sample Weight	Dilution
1						Condition Column	RD2 Optimization 001_031			6.00					Position 5			
2						Equilibrate	RD2 Optimization 001_001			4.00					No Change			
3	1 A, 1	2.0	1	Unk-001-001	1	Inject Samples	RD2 Optimization 001_001		Normal	17.00	0.00	3.50					1.00000	1.00000
4						Equilibrate	RD2 Optimization 001_002			4.00					No Change			
5	1 A, 1	2.0	1	Unk-001-002	2	Inject Samples	RD2 Optimization 001_002		Normal	9.00	0.00	3.50					1.00000	1.00000
6						Equilibrate	RD2 Optimization 001_003			4.00					No Change			
7	1 A, 1	2.0	1	Unk-001-003	3	Inject Samples	RD2 Optimization 001_003		Normal	17.00	0.00	3.50					1.00000	1.00000
8						Equilibrate	RD2 Optimization 001_004			4.00					No Change			
9	1 A, 1	2.0	1	Unk-001-004	4	Inject Samples	RD2 Optimization 001_004		Normal	9.00	0.00	3.50					1.00000	1.00000
10						Equilibrate	RD2 Optimization 001_005			4.00					No Change			
11	1 A, 1	2.0	1	Unk-001-005	5	Inject Samples	RD2 Optimization 001_005		Normal	9.00	0.00	3.50					1.00000	1.00000
12						Equilibrate	RD2 Optimization 001_006			4.00					No Change			
13	1 A, 1	2.0	1	Unk-001-006	6	Inject Samples	RD2 Optimization 001_006		Normal	9.00	0.00	3.50					1.00000	1.00000
14						Equilibrate	RD2 Optimization 001_007			4.00					No Change			
15	1 A, 1	2.0	1	Unk-001-007	7	Inject Samples	RD2 Optimization 001_007		Normal	17.00	0.00	3.50					1.00000	1.00000
16						Condition Column	RD2 Optimization 001_032			6.00					Position 5			
17						Equilibrate	RD2 Optimization 001_008			4.00					No Change			
18	1 A, 1	2.0	1	Unk-001-008	8													
19																		
20																		
21	1 A, 1	2.0	1	Unk-001-009	9													
22																		
23	1 A, 1	2.0	1	Unk-001-010	10													
24																		
25	1 A, 1	2.0	1	Unk-001-011	11													
26																		
27	1 A, 1	2.0	1	Unk-001-012	12													
28																		
29																		
30	1 A, 1	2.0	1	Unk-001-013	13													
31																		
32																		
33	1 A, 1	2.0	1	Unk-001-014	14													
34																		
35	1 A, 1	2.0	1	Unk-001-015	15													
36																		
37	1 A, 1	2.0	1	Unk-001-016	16	Inject Samples	RD2 Optimization 001_016		Normal	9.00	0.00	3.50					1.00000	1.00000
38						Equilibrate	RD2 Optimization 001_017			4.00					No Change			

For Help, press F1

**Automated, Audited Data Exchange
Under User E-signature Credentials
Preserves Data Integrity and Traceability**

Auditing assures Data Integrity and Traceability

**Automated, Audited Data Exchange –
Preserves Data Integrity and Traceability**

S-Matrix\Test as System/Administrator - Project

File Edit View Tools Database Help

Filter By: Default Edit View Update

Sample Sets Injections Channels **Methods** Result Sets Results

	Method Name	Method Type	
1	AAA_Demo	Sample Set	7/17/2018
2	AAA_Demo 001_001	Method Set	7/17/2018
	AAA_Demo 001_001	Instrument	7/17/2018
	AAA_Demo 001_002	Method Set	7/17/2018
5	AAA_Demo 001_002	Instrument	7/17/2018
6	AAA_Demo 001_003	Method Set	7/17/2018
7	AAA_Demo 001_003	Instrument	7/17/2018
8	AAA_Demo 001_004	Method Set	7/17/2018 8:28:19 AM PDT
9	AAA_Demo 001_004	Instrument	7/17/2018 8:28:16 AM PDT
10	AAA_Demo 001_005	Method Set	7/17/2018 8:28:20 AM PDT
11	AAA_Demo 001_005	Instrument	7/17/2018 8:28:19 AM PDT

166 total

Method Properties

Method Information

Name: AAA_Demo

Type: Sample Set

Last Modified By: System

Locked By:

Being Edited By:

Method History

	Method Name	Method Type	
1	AAA_Demo	Sample Set	Created by Fusion QbD: C:\Program Files

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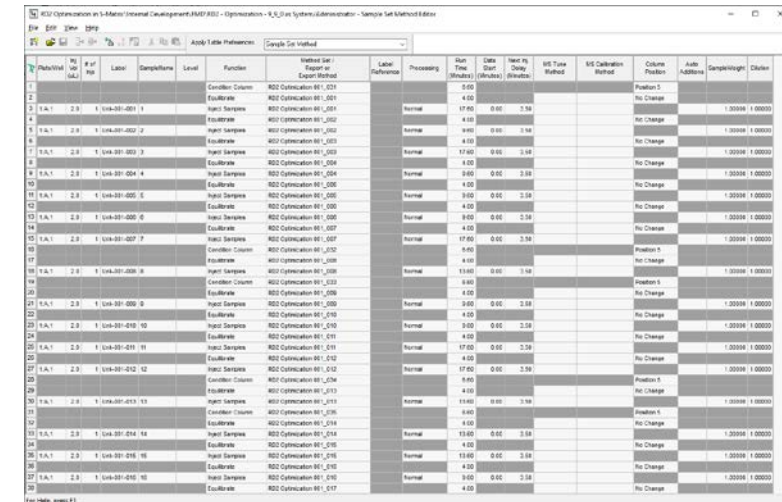
Fusion QbD – Import from CDS



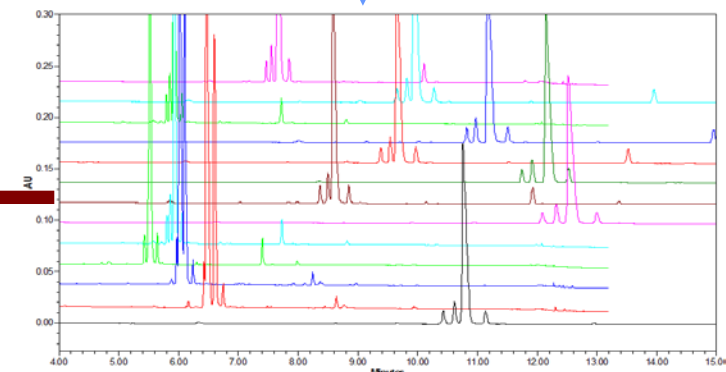
Automatically Retrieves All
Chromatograms & Results

**Automated, Audited Data Exchange
Under User E-signature Credentials
Preserves Data Integrity and Traceability**

CDS Software

Run	Sample	Label	Sample Name	Level	Function	Method Set	Report or Export Method	Label	Processing	Run Time (Minutes)	Data Start (Minutes)	Next IS Delay (Minutes)	IS Time Method	IS Calibration Method	Column	Auto Addition	Sample Weight	Check
1	1.A.1	2.0	1.100-001-001	1	Condition Column	R02 Calibration 01_001	Equilibration		Normal	3.00					Position 1	No Change		
2	1.A.1	2.0	1.100-001-001	1	Inject Samples	R02 Calibration 01_001	Equilibration		Normal	4.00	0.00	3.10			No Change		1.00000	1.00000
3	1.A.1	2.0	1.100-001-002	2	Equilibration	R02 Calibration 01_002	Equilibration		Normal	4.00	0.00	3.10			No Change		1.00000	1.00000
4	1.A.1	2.0	1.100-001-002	2	Inject Samples	R02 Calibration 01_002	Equilibration		Normal	4.00	0.00	3.10			No Change		1.00000	1.00000
5	1.A.1	2.0	1.100-001-003	3	Equilibration	R02 Calibration 01_003	Equilibration		Normal	4.00	0.00	3.10			No Change		1.00000	1.00000
6	1.A.1	2.0	1.100-001-003	3	Inject Samples	R02 Calibration 01_003	Equilibration		Normal	17.00	0.00	3.10			No Change		1.00000	1.00000
7	1.A.1	2.0	1.100-001-004	4	Equilibration	R02 Calibration 01_004	Equilibration		Normal	4.00	0.00	3.10			No Change		1.00000	1.00000
8	1.A.1	2.0	1.100-001-004	4	Inject Samples	R02 Calibration 01_004	Equilibration		Normal	4.00	0.00	3.10			No Change		1.00000	1.00000
9	1.A.1	2.0	1.100-001-005	5	Equilibration	R02 Calibration 01_005	Equilibration		Normal	4.00	0.00	3.10			No Change		1.00000	1.00000
10	1.A.1	2.0	1.100-001-005	5	Inject Samples	R02 Calibration 01_005	Equilibration		Normal	4.00	0.00	3.10			No Change		1.00000	1.00000
11	1.A.1	2.0	1.100-001-006	6	Equilibration	R02 Calibration 01_006	Equilibration		Normal	4.00	0.00	3.10			No Change		1.00000	1.00000
12	1.A.1	2.0	1.100-001-006	6	Inject Samples	R02 Calibration 01_006	Equilibration		Normal	4.00	0.00	3.10			No Change		1.00000	1.00000
13	1.A.1	2.0	1.100-001-007	7	Equilibration	R02 Calibration 01_007	Equilibration		Normal	17.00	0.00	3.10			No Change		1.00000	1.00000
14	1.A.1	2.0	1.100-001-007	7	Inject Samples	R02 Calibration 01_007	Equilibration		Normal	4.00	0.00	3.10			No Change		1.00000	1.00000
15	1.A.1	2.0	1.100-001-008	8	Equilibration	R02 Calibration 01_008	Equilibration		Normal	4.00	0.00	3.10			No Change		1.00000	1.00000
16	1.A.1	2.0	1.100-001-008	8	Inject Samples	R02 Calibration 01_008	Equilibration		Normal	17.00	0.00	3.10			No Change		1.00000	1.00000
17	1.A.1	2.0	1.100-001-009	9	Equilibration	R02 Calibration 01_009	Equilibration		Normal	4.00	0.00	3.10			No Change		1.00000	1.00000
18	1.A.1	2.0	1.100-001-009	9	Inject Samples	R02 Calibration 01_009	Equilibration		Normal	4.00	0.00	3.10			No Change		1.00000	1.00000
19	1.A.1	2.0	1.100-001-010	10	Equilibration	R02 Calibration 01_010	Equilibration		Normal	4.00	0.00	3.10			No Change		1.00000	1.00000
20	1.A.1	2.0	1.100-001-010	10	Inject Samples	R02 Calibration 01_010	Equilibration		Normal	4.00	0.00	3.10			No Change		1.00000	1.00000
21	1.A.1	2.0	1.100-001-011	11	Equilibration	R02 Calibration 01_011	Equilibration		Normal	4.00	0.00	3.10			No Change		1.00000	1.00000
22	1.A.1	2.0	1.100-001-011	11	Inject Samples	R02 Calibration 01_011	Equilibration		Normal	17.00	0.00	3.10			No Change		1.00000	1.00000
23	1.A.1	2.0	1.100-001-012	12	Equilibration	R02 Calibration 01_012	Equilibration		Normal	4.00	0.00	3.10			No Change		1.00000	1.00000
24	1.A.1	2.0	1.100-001-012	12	Inject Samples	R02 Calibration 01_012	Equilibration		Normal	17.00	0.00	3.10			No Change		1.00000	1.00000
25	1.A.1	2.0	1.100-001-013	13	Equilibration	R02 Calibration 01_013	Equilibration		Normal	4.00	0.00	3.10			No Change		1.00000	1.00000
26	1.A.1	2.0	1.100-001-013	13	Inject Samples	R02 Calibration 01_013	Equilibration		Normal	17.00	0.00	3.10			No Change		1.00000	1.00000
27	1.A.1	2.0	1.100-001-014	14	Equilibration	R02 Calibration 01_014	Equilibration		Normal	4.00	0.00	3.10			No Change		1.00000	1.00000
28	1.A.1	2.0	1.100-001-014	14	Inject Samples	R02 Calibration 01_014	Equilibration		Normal	17.00	0.00	3.10			No Change		1.00000	1.00000
29	1.A.1	2.0	1.100-001-015	15	Equilibration	R02 Calibration 01_015	Equilibration		Normal	4.00	0.00	3.10			No Change		1.00000	1.00000
30	1.A.1	2.0	1.100-001-015	15	Inject Samples	R02 Calibration 01_015	Equilibration		Normal	17.00	0.00	3.10			No Change		1.00000	1.00000
31	1.A.1	2.0	1.100-001-016	16	Equilibration	R02 Calibration 01_016	Equilibration		Normal	4.00	0.00	3.10			No Change		1.00000	1.00000
32	1.A.1	2.0	1.100-001-016	16	Inject Samples	R02 Calibration 01_016	Equilibration		Normal	4.00	0.00	3.10			No Change		1.00000	1.00000
33	1.A.1	2.0	1.100-001-017	17	Equilibration	R02 Calibration 01_017	Equilibration		Normal	4.00	0.00	3.10			No Change		1.00000	1.00000



Auditing assures Data Integrity and Traceability

Automated, Audited Data Exchange –
Preserves Data Integrity and Traceability

Method Development - FMD Tutorial - Optimization - Part 2 - 991 533.smae

File Edit Activity Tools Window Help

Generate Audit Log

Design of Experiments

- Create a Design
- Design Reports

Data Entry / Analysis

- Data Entry
- Data Analysis

Best Answer Searches

- Best Overall Answer
- Acceptable Performance Region
- Point Predictions

Visualization Graphics

- Single Response Series
- Multiple Response Series

Reporting Toolkit

- Fusion Reporter
- Audit Log Reporter**

Name: Administrator
Company: S-Matrix Corporation
Project: Project 1
Date: 07 MAY 2022 15:13:56 PDT [UTC-07:00]

Audit Log

20 JUN 2021 10:13:51 PDT [UTC-07:00] - Administrator

Event Type: Import Responses

Import Response Settings

Setting	Value
Target CDS	EMPOWER
Empower Version	Empower 3 Software Build 3471 SPs Installed: Service Release 3 DB ID: 2484307300
Empower Database	(local)
Empower User	system
Project Name	RD2 - Optimization - 9_9_0
Result Set(ID)	RD2 Optimization (9001)
Processed Channel	PDA Ch1 225nm@4.8nm, Time offset by 0.020 mins.
Activate PeakTracker	Checked
Raw PDA Channel	Unchecked
Raw MS Channel	QDa Positive Scan
MS Time Offset(min)	0.02
MS Intensity Threshold	100000
Processed MS Channel	QDa Positive Scan MS TIC, Smoothed by 59 point Savitzky-Golay Filter. (QDa Positive(+)-Scan (100.00-1250.00)Da, Centroid, CV=15)
Track Non-absorbing Peaks	Checked
Auto-imported Response(s)	Height, RetentionTime, WidthAt50Pct, USPTailing, WidthAtTangentUSPResolution, Area
Import Chromatogram Trace Data	Checked
Import Prediction Chromatogram Data	Checked
Total Import Time	00:06:42
Locale	English (United States)

Imported Data Source

Sample Name	ResultID	MS ResultID	TIC (ID/Type)	MS-Spectra (ID/Type)	UV-Spectra (ID/Type)
1	9155	9153	MS_TIC (9004/2D)	QDa Positive Scan (7036/3DMS)	
10	9048	9189	MS_TIC (9050/2D)	QDa Positive Scan (7063/3DMS)	
11	9191	9193	MS_TIC (9055/2D)	QDa Positive Scan (7066/3DMS)	
12	9058	9195	MS_TIC (9060/2D)	QDa Positive Scan (7069/3DMS)	

Ready

Why Audit Trail is Important !

Where did this data
come from?
Which Project?
Which Results Set?
Which Chromatograms?



Who imported this
data – was the data
modified?

Audit Log Filter Options

☐ Enable

Starting Date:

Sun	Mon	Tue	Wed	Thu	Fri	Sat
23	24	25	26	27	28	29
1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30	31	1	2	3	4

Ending Date:

Sun	Mon	Tue	Wed	Thu	Fri	Sat
23	24	25	26	27	28	29
1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30	31	1	2	3	4

Users

☐ Enable

Available:

Administrator

Included:

Events

☒ Enable

Available:

- Print Reports
- Experiment Setup
- Enable User Defined Option
- Generate Design
- Export Experiment Design
- Export Testing Design
- Matrix Master Wizard
- Edit Run No. Labels
- Robustness Simulator
- Create Testing Design
- Delete Testing Design
- Response Reductions

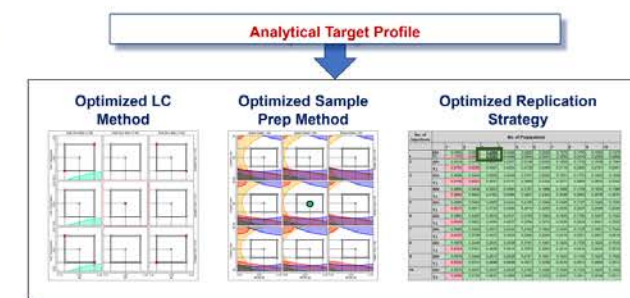
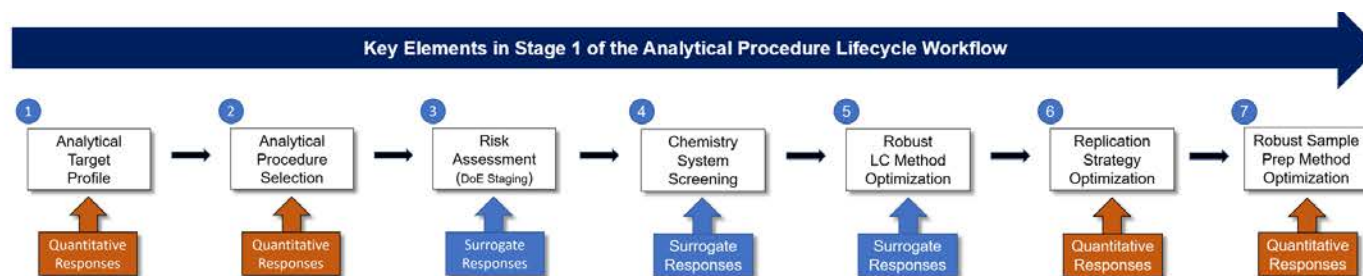
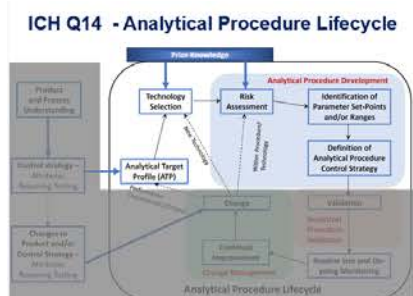
Included:

- Import Responses
- Create/Edit Response Data

OK Cancel ?

End of Presentation

Fusion QbD is the Only LC Method Development Software Which Completely Supports the AQbD / APLM Workflow in the Regulatory Guidances



ICH Q2(R2) / ICH Q14 / USP <1210> / USP <1220> / EP 11.60