

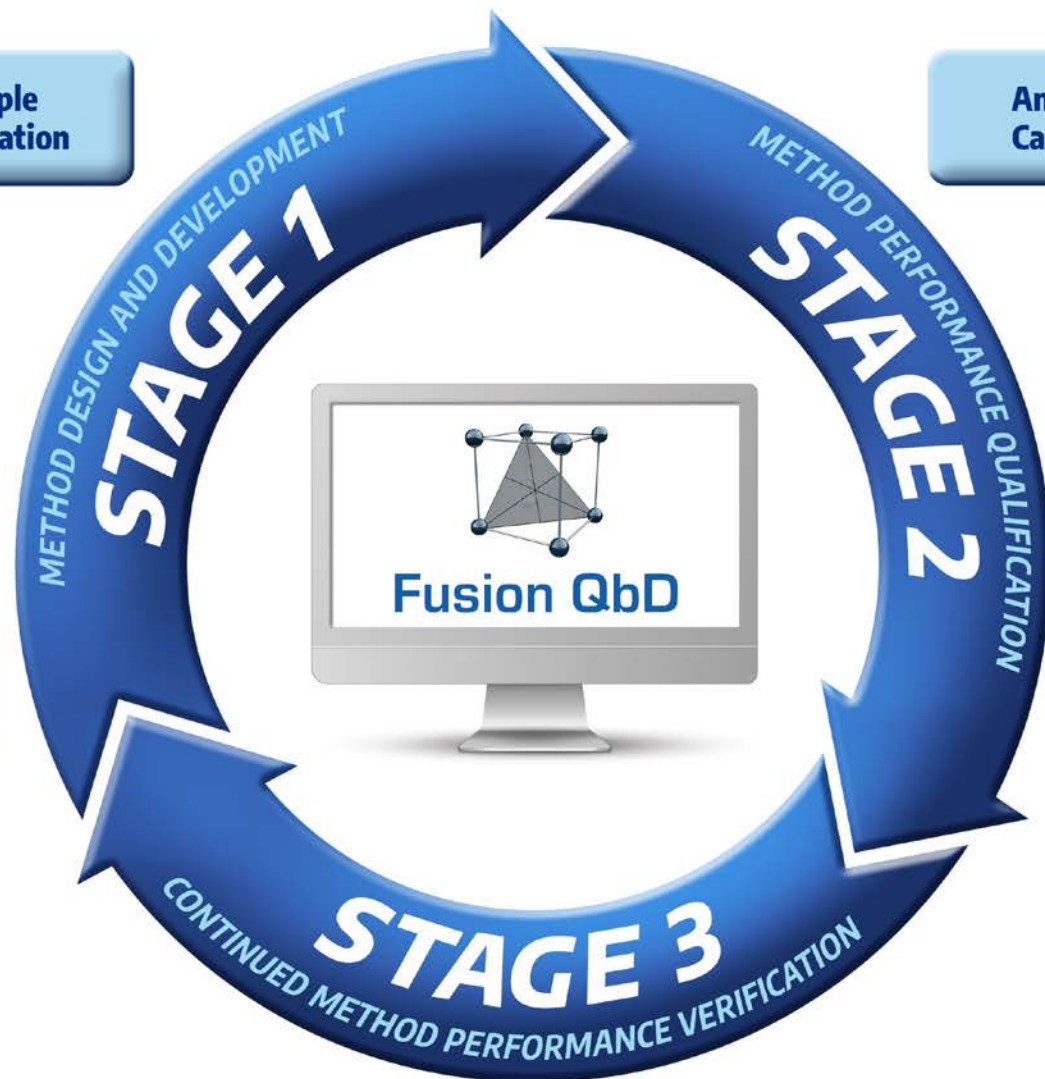


Fusion QbD

Case Study – Dissolution Method Development

A Complete Solution for APLM Stages 1 and 2

FUSION METHOD DEVELOPMENT



FUSION METHOD VALIDATION



Full Support
for Part 11
Compliance



Citrix-Ready
Certified

Fusion Process Development

- QbD Formulation and Process Development
- Non-LC Methods Development (e.g. GC, CE, Disso)
- Automated, Audited LC Testing and Data Acquisition
Standard LC, Time Series, Respiratory

Why Compliance is Important!

FDA Statement* –

As long as the **data integrity** associated with the method development work matches what would be done in a formal Validation Robustness effort, then the results are acceptable.

Same Regulatory Expectation for Claims of Formulation and Process Robustness

* – USP Workshop – Enhanced Approaches for Analytical Procedure Lifecycle: An Alternative to Traditional Validation
(Sept. 24-25, 2018)

Why Audit Trail is Important!

Who entered this data – was the data modified?



What Empower Project did this data come from?

Audit Log Filter Options

Enable

Starting Date:

March 2020						
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:

March 2020						
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:

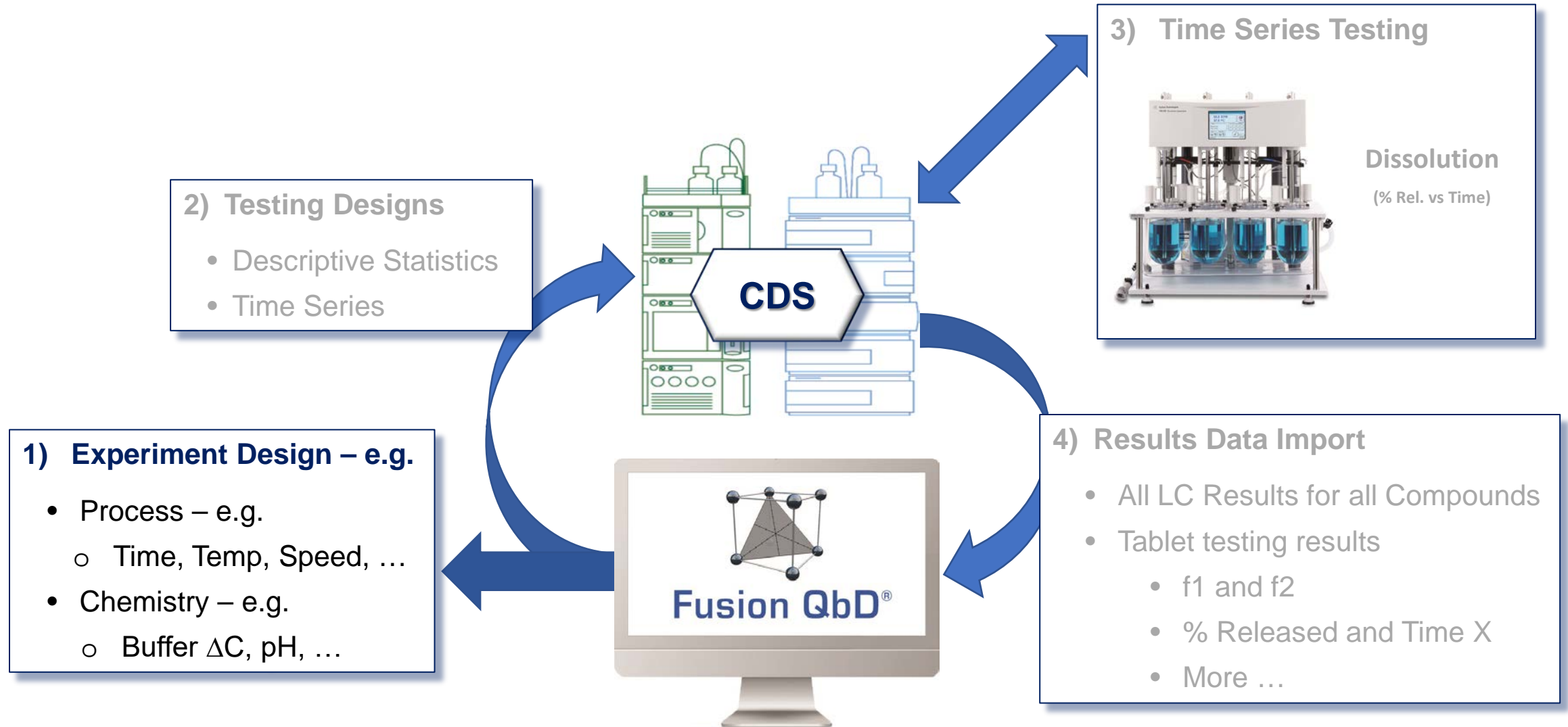
- Print Reports
- Experiment Setup
- Enable User Defined Option
- Generate Design
- Export Experiment Design
- Export Testing Design
- Matrix Master Wizard
- Edit Run No. Labels
- Robustness Simulator
- Create Testing Design
- Delete Testing Design
- Response Reductions

Included:

- Import Responses
- Create/Edit Response Data

OK Cancel ?

Dissolution Experiment Dataflow

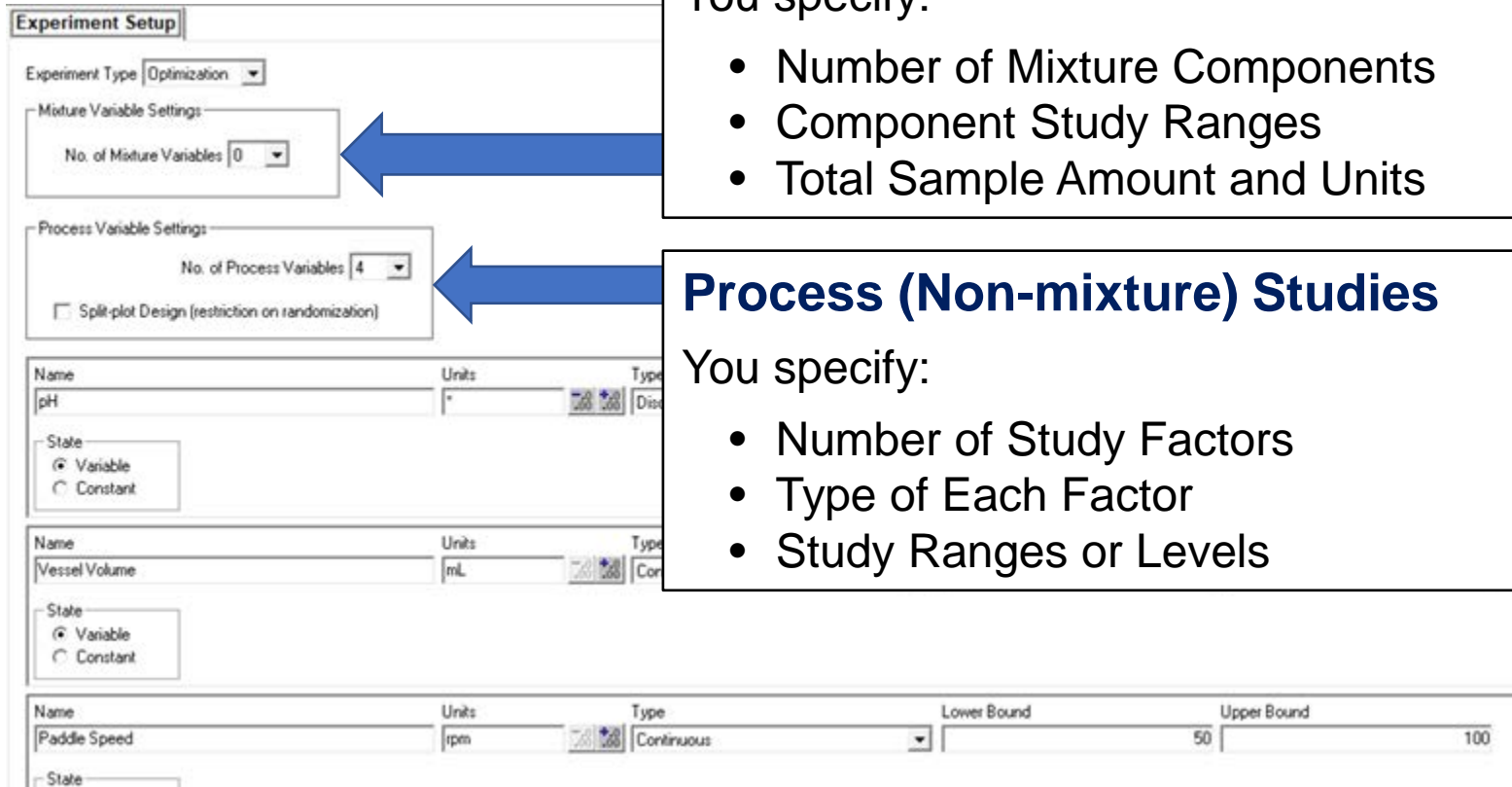


Flexible Experiment Setup

Formulation (Mixture) Studies

You specify:

- Number of Mixture Components
- Component Study Ranges
- Total Sample Amount and Units



Experiment Setup

Experiment Type: Optimization

Mixture Variable Settings:
No. of Mixture Variables: 0

Process Variable Settings:
No. of Process Variables: 4
 Split-plot Design (restriction on randomization)

Name	Units	Type		
pH	*	Disc		
State: <input checked="" type="radio"/> Variable <input type="radio"/> Constant				
Vessel Volume	mL	Con		
State: <input checked="" type="radio"/> Variable <input type="radio"/> Constant				
Name	Units	Type	Lower Bound	Upper Bound
Paddle Speed	rpm	Continuous	50	100
State:				

Process (Non-mixture) Studies

You specify:

- Number of Study Factors
- Type of Each Factor
- Study Ranges or Levels

Combined Mixture-Process Studies

Enable you to characterize interactions between the two!

Experiment Setup

Experiment Type: Optimization

Mixture Variable Settings

No. of Mixture Variables: 0

Process Variable Settings

No. of Process Variables: 4

Split-plot Design (restriction on randomization)

Name	Units	Type	Level Settings		
pH	*	Discrete Numeric	No. of Levels: 3	Level 1	4.10
				Level 2	4.50
				Level 3	4.90

Name	Units	Type	Lower Bound	Upper Bound
Vessel Volume	mL	Continuous	500	1.000

Name	Units	Type	Lower Bound	Upper Bound
Paddle Speed	rpm	Continuous	50	100

Name	Units	Type	Lower Bound	Upper Bound
Surfactant	%	Continuous	0.50	1.50

Automatically Selects and Generates the Most Defensible and Efficient DOE Design

Experiment Design Matrix

Run No.	pH (*)	Vessel Volume (mL)	Paddle Speed (rpm)	Surfactant (%)
1	4.10	750	100	0.5
2	4.10	1,000	100	0.50
3	4.10	1,000	50	0.50
4	4.10	500	50	0.50
5	4.50	500	100	0.50
6	4.90	500	50	0.50
7	4.90	500	100	0.50
8	4.90	1,000	50	0.50
9	4.90	750	100	0.50
10	4.90	500	100	0.50
11	4.90	1,000	50	0.50
12	4.10	750	100	1.00
13	4.10	500	50	1.00
14	4.10	750	50	1.00
15	4.50	750	75	1.00
16	4.50	750	75	1.00

Grid Sort Options

Filters

 Hide Runs with no Response Data

Column

Surfactant

pH

Order

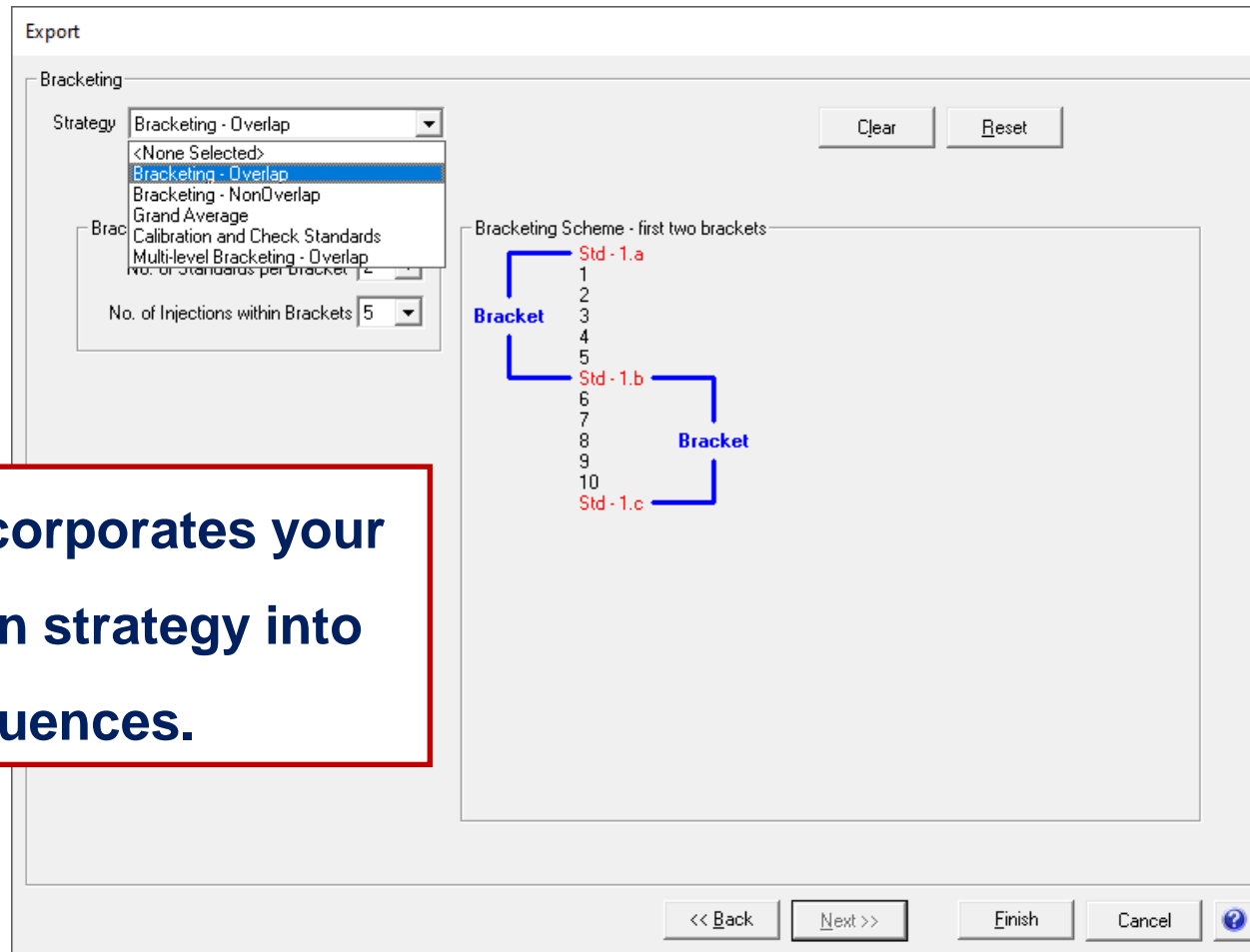
Smallest to Largest

Smallest to Largest



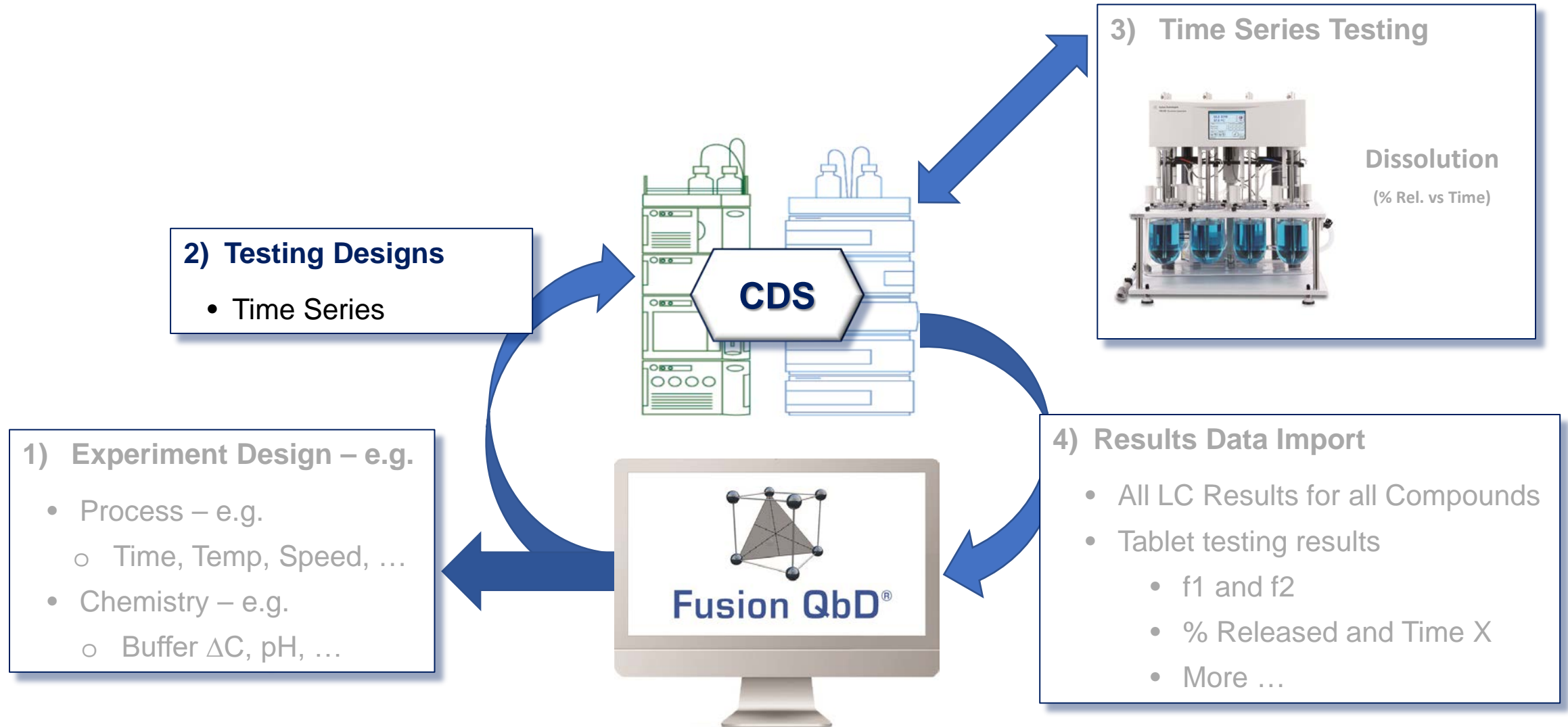
Built-in Design Logic Accounts for:

- **Stage of the Work**
(Screening or Optimization)
- **Number of Variables**
- **Types of Variables**
 - Numeric or Categorical
 - # of Defined Levels



Automatically incorporates your standard injection strategy into the exported sequences.

Dissolution Experiment Dataflow



Create Testing Design

Testing Design Name: Testing Design (3)

Testing Design Type: Time Series

Reference Standards: 1

Reference Standard Runs: 1

Apply Replication Scheme

Replication Scheme: Standard LC

No. of Preparation Repeats: 1

No. of Test Repeats per Preparation: 1

* - Use this setting for the number of preparation repeats.
For example:
Dissolution – number of vessels per run.
Synthesis – number of reaction repeats per run.

Sampling Rate: Uniform

No. of Measurements: 3 per Hour

Total Time Period: 8 Hours

Start time at 0

Update

Measurement	Time Point (Minutes)
1	0.0
2	20.0
3	40.0
4	60.0
5	80.0
6	100.0
7	120.0
8	140.0
9	160.0
10	180.0
11	200.0
12	220.0
13	240.0
14	260.0
15	280.0

The settings are valid.

Back Finish Cancel

E.g., Dissolution Testing

Time Series – Instant Testing Protocol Supports:

- Uniform or variable time-point testing protocols
- Multiple sample preparation repeats
- Multiple test repeats at each time point
- Internal test standard data

Re-usable Testing Design Template

Fusion Product Development - Fusion Product Development Tutorial - Part 2 - 990 SR2b.smae

File Edit Activity Tools Window Help

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

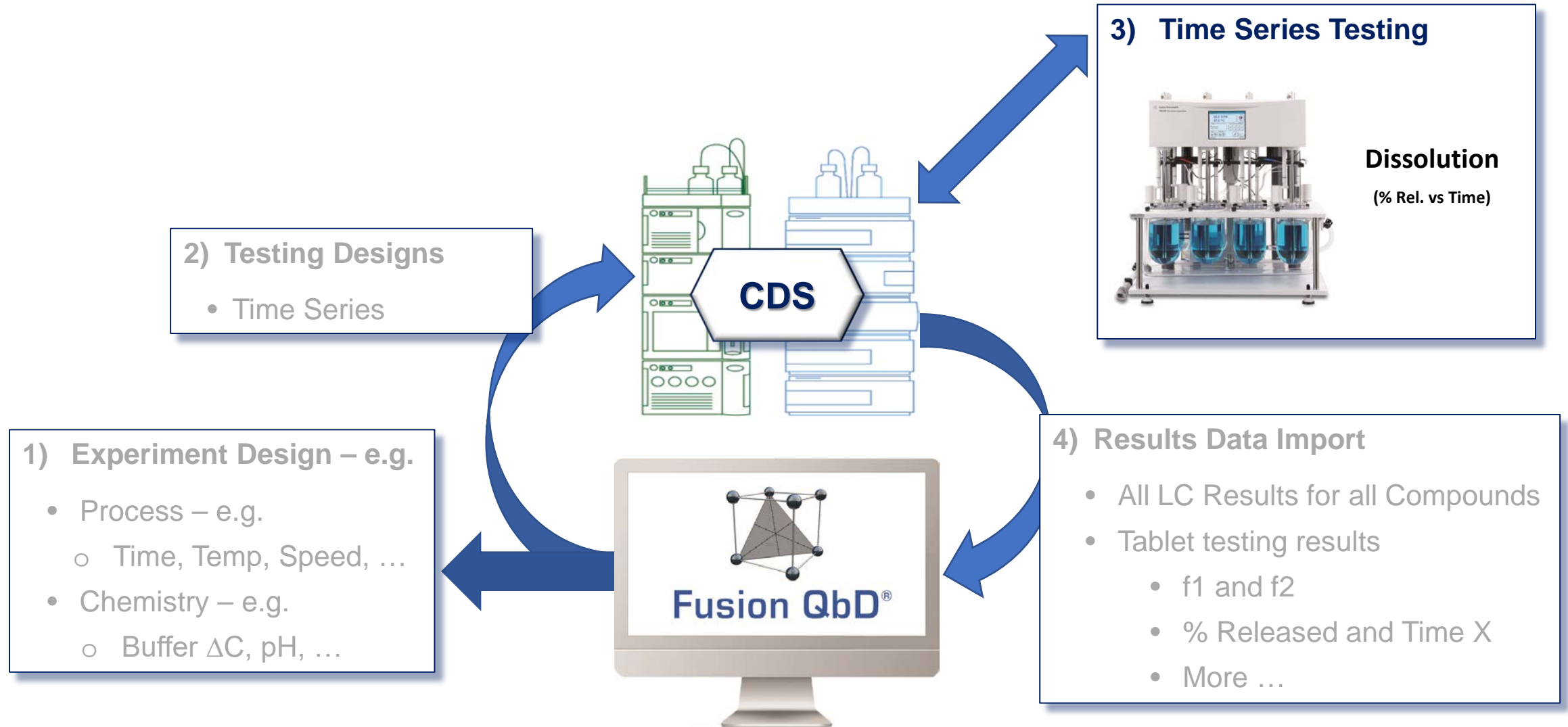
- Fusion Reporter
- Audit Log Reporter

Response Name:
 Response Units:
 Lower Limit
 Upper Limit
 Testing Design Type:

	A	B	C	D	E	F	G	H	I	J	K	L	M	N
	Run No.	t - 0.00	t - 60.00	t - 120.00	t - 180.00	t - 240.00	t - 300.00	t - 360.00	t - 420.00	t - 480.00	t - 540.00	t - 600.00	t - 660.00	t - 720.00
1	1.a													
2	1.b													
3	1.c													
4	2.a													
5	2.b													
6	2.c													
7	3.a													
8	3.b													
9	3.c													
10	4.a													
11	4.b													
12	4.c													
13	5.a													
14	5.b													
15	5.c													
16	6.a													
17	6.b													
18	6.c													
19	7.a													
20	7.b													
21	7.c													
22	8.a													
23	8.b													
24	8.c													
25	9.a													

The template is automatically replicated to support CDS auto-import of all your desired results for all compounds.

Dissolution Experiment Dataflow



Automatically Export Ready-to-Run Testing Design to the CDS

Export

Bracketing

Strategy: Bracketing - Overlap

<None Selected>
 Bracketing - Overlap
 Bracketing - NonOverlap
 Grand Average
 Calibration and Check Standards
 Multi-level Bracketing - Overlap
 No. of Standards per Bracket: 1

Bracketing Scheme - first two brackets

```

  1 Std - 1.a
  2
  3
  4 Bracket
  5
  6 Std - 1.b
  7
  8
  9
  10 Bracket
  Std - 1.c
  
```

No. of Injections within Brackets: 5

<< Back Next >>

Select Project and Method Sets

Select Project

- FIT
- FMD Tutorial - 9_9_0
- FMV - A_L_R
- Internal Development
- RD1 - Demo Screening Expt
- RD2 - Demo Optimization Expt
- Test
 - FDS_1_Named_Peaks
 - RD2 - Opt - 9_9_0 - Named Peak
 - RD2 - Opt - FMD 9_9_0
 - RD2_990_No_SS
 - RD2_990_No_SS_Named_Peak
 - Screening BOA Confirmation
 - Tip of the Week

Method Set

Acquity_UPC2
 ADL_H_Class_AutoBlend_Plus
 ADL_H_Class_QDa_PDA
 ADL_H_Class_QDa_PDA_Fusion
 Agilent 6890 GC
 Agilent_Infinity_IL_1
 Alliance 1
 Demo Alliance Shutdown Method
 Demo_H_Class Shutdown Method

Enable Shutdown Method

ADL_H_Class_AutoBlend_Plus
 ADL_H_Class_QDa_PDA
 ADL_H_Class_QDa_PDA_Fusion
 Agilent 6890 GC
 Agilent_Infinity_IL_1
 Alliance 1
 Demo Alliance Shutdown Method
 Demo_H_Class Shutdown Method

User Types (logged in as 'Owner')

Owner

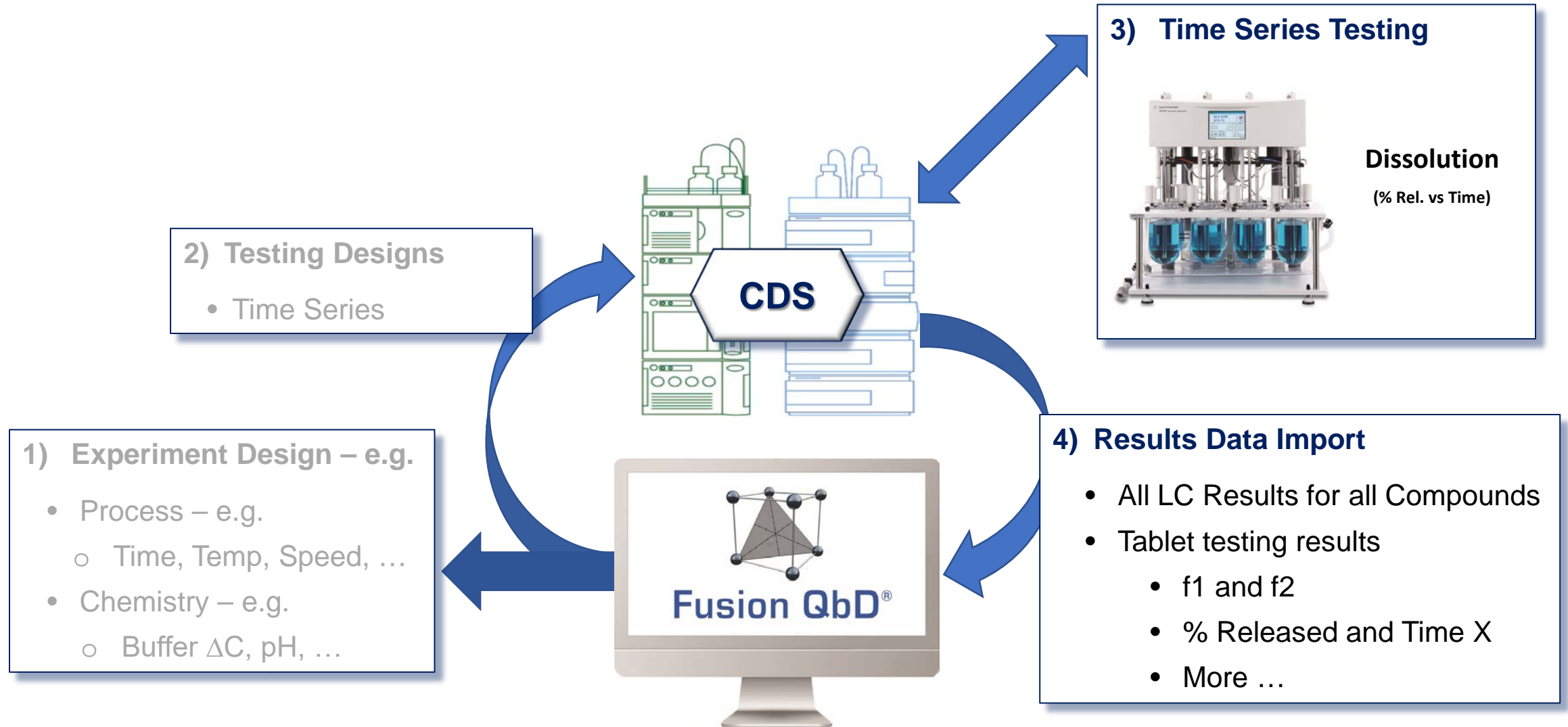
Ready

IMPORTANT: Be sure the selected template method has the correct structure and properties required for the experiment design you are exporting. Refer to the on-line Help for detailed information on these requirements.

<< Back Next >> Cancel

**Bi-directional
 Auditing
 Assures Data
 Traceability
 and Integrity!**

Dissolution Experiment Dataflow



Automatically Import All Required Results Data from CDS

Select a Project and Result Set

Select Project

Find Filter Reset

- Projects
 - Customers
 - Distributors
 - S-Matrix
 - ADL
 - FIT
 - FMD Tutorial - 9_9_0
 - FMV - A_L_R
 - Internal Development
 - Agilent DAD Test
 - FMD - New Tutorial
 - Forced Degradation Study 1
 - PT Dev - Non-Ionizing Peaks
 - RD1 Screening Confirmation
 - RD1_New-1_Traditional-Acquity
 - RD2_Large_Data_Set
 - Replicate Study - PeakTracker
 - RD1 - Demo Screening Expt
 - RD2 - Demo Optimization Expt
 - Test
 - Tip of the Week

Select Result Set(s)

Result Set Name	ResultSetID	Date	Sample Set
RD2 Optimization	1009	2/19/2019 7:23:52 PM EST	RD2 Optimizati

Fetch Selected Result Sets

Select Processed Channel:

PDA Ch1 225nm@4.8nm, Time offset by 0.020 mins.

Result(s) for Import

Sample	ResultID	Date	Type	Channel ID
1	1422	2/19/2019 7:56:43 PM	LC	1007
10	1378	2/19/2019 7:43:08 PM	LC	1169
11	1380	2/19/2019 7:44:13 PM	LC	1178
12	1382	2/19/2019 7:44:53 PM	LC	1187
13	1384	2/19/2019 7:45:20 PM	LC	1196
14	1386	2/19/2019 7:45:47 PM	LC	1205
15	1388	2/19/2019 7:46:04 PM	LC	1214
16	1225	2/19/2019 7:24:36 PM	LC	1223
17	1390	2/19/2019 7:47:44 PM	LC	1232
18	1392	2/19/2019 7:48:06 PM	LC	1241
19	1394	2/19/2019 7:48:42 PM	LC	1250
2	1364	2/19/2019 7:36:34 PM	LC	1097
20	1396	2/19/2019 7:49:11 PM	LC	1259
21	1398	2/19/2019 7:49:28 PM	LC	1268
22	1400	2/19/2019 7:50:01 PM	LC	1277
23	1402	2/19/2019 7:50:33 PM	LC	1286
24	1404	2/19/2019 7:50:59 PM	LC	1295
25	1406	2/19/2019 7:51:48 PM	LC	1304
26	1408	2/19/2019 7:52:15 PM	LC	1313
27	1410	2/19/2019 7:52:46 PM	LC	1322
28	1412	2/19/2019 7:53:02 PM	LC	1331

User Types (logged in as 'Owner')

Owner

Ready

Next >> Cancel ?

**Bi-directional
Auditing
Assures Data
Traceability
and Integrity!**

Time Series – Multiple Time Point Tests per Run

Fusion Product Development - Fusion Product Development Tutorial - Part 2 - 990 SR2b.smae

File Edit Activity Tools Window Help

Create Testing Design
 Delete Testing Design
 Create Response
 Edit Response
 Delete Response
 Response Reductions
 Export
 Import Responses

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

Response Name: API - % Released Response Units: % Lower Limit: Upper Limit: Testing Design Type: Time Series View Testing Design

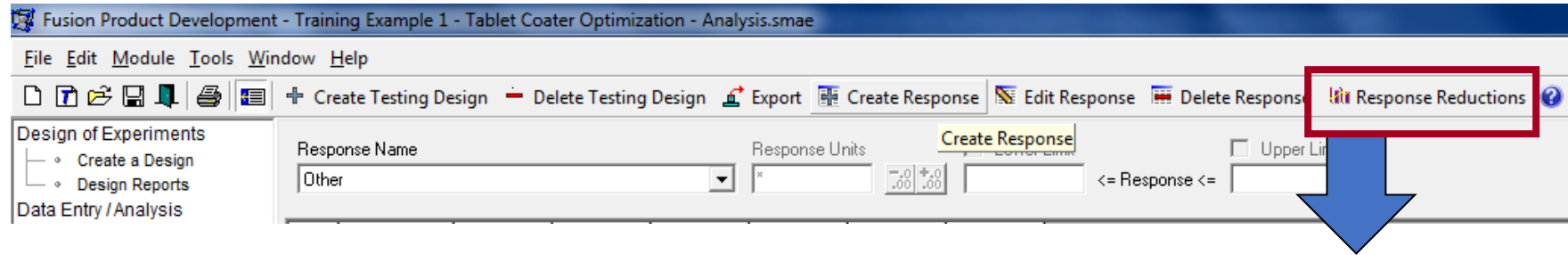
	A Run No.	B t - 0.00	C t - 60.00	D t - 120.00	E t - 180.00	F t - 240.00	G t - 300.00	H t - 360.00	I t - 420.00	J t - 480.00	K t - 540.00	L t - 600.00	M t - 660.00	N t - 720.00
1	1.a	0.00	13.40	21.35	29.55	35.50	41.45	46.50	51.50	55.55	59.35	62.50	65.60	68.45
2	1.b	0.00	13.60	21.55	29.65	35.45	41.45	46.45	51.65	55.60	59.60	62.55	65.45	68.55
3	1.c	0.00	13.50	21.60	29.30	35.55	41.60	46.55	51.35	55.35	59.55	62.45	65.45	68.50
4	2.a	0.00	12.20	24.65	36.70	45.95	53.65	60.65	65.55	71.00	75.55	79.50	84.00	87.60
5	2.b	0.00	12.15	24.80	36.35	46.25	53.35	60.50	65.45	70.80	75.40	79.80	84.05	87.60
6	2.c	0.00	12.25	25.25	36.45	46.10	53.50	60.35	65.50	70.90	75.25	79.50	83.95	87.30
7	3.a	0.00	8.60	10.55	14.45	17.25	21.65	25.05	28.60	32.75	36.35	40.40	43.95	46.75
8	3.b	0.00	8.45	10.10	14.20	17.05	21.80	25.00	28.75	32.70	36.35	40.30	44.20	46.40
9	3.c	0.00	8.45	10.55	14.25	17.30	21.95	25.25	28.75	32.65	36.50	40.50	43.85	46.65
10	4.a	0.00	11.50	21.05	30.70	39.90	48.55	56.80	64.65	72.10	79.15	85.80	92.00	97.75
11	4.b	0.00	11.40	21.15	30.30	39.80	48.45	56.70	64.55	72.00	79.05	85.70	91.90	97.55
12	4.c	0.00	11.30	21.10	30.50	39.70	48.30	56.60	64.45	71.90	78.95	85.60	91.80	97.30
13	5.a	0.00	10.95	21.50	31.05	40.20	48.85	57.10	64.95	72.40	79.45	86.10	92.30	98.05
14	5.b	0.00	10.85	21.70	31.00	40.10	48.75	57.00	64.85	72.30	79.35	86.00	92.20	97.95
15	5.c	0.00	10.90	21.40	30.95	40.00	48.65	56.90	64.75	72.20	79.25	85.90	92.10	97.85

	A Run No.	B t - 0.00	C t - 60.00	D t - 120.00	E t - 180.00
1	1	0.00	13.50	21.50	29.50
2	2	0.00	12.20	24.90	36.50
3	3	0.00	8.50	10.40	14.30
4	4	0.00	11.40	21.10	30.50
5	5	0.00	10.90	21.50	31.00
6	6	0.00	9.10	12.50	17.30
7	7	0.00	12.40	25.10	36.70
8	8	0.00	13.40	21.40	29.40
9	9	0.00	12.10	21.70	31.00
10	10	0.00	10.30	18.60	26.00
11	11	0.00	10.20	20.50	29.90
12	12	0.00	11.40	19.90	27.90
13	13	0.00	10.60	17.60	25.20
14	14	0.00	10.10	17.10	25.00

Experiment Design Tablet Physical Property Tests (1) **Dissolution Testing (2)**

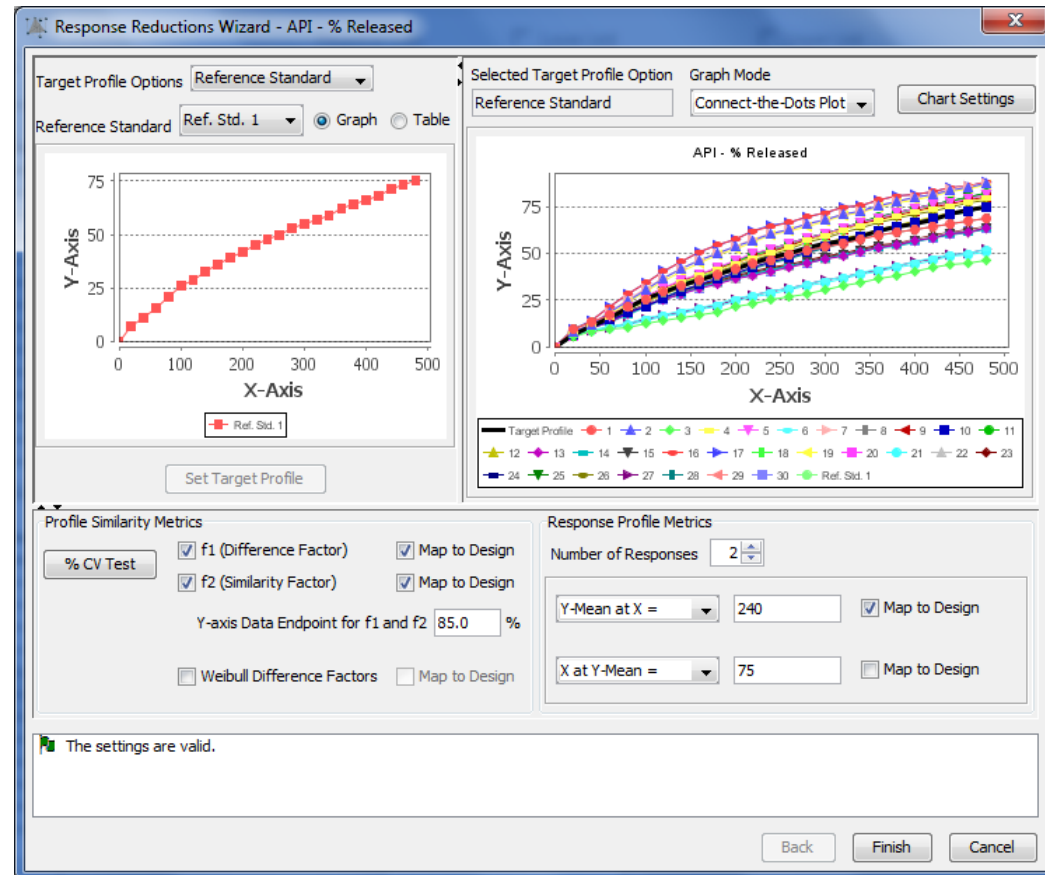
Ready

Automatically Generates Average Response Curves (Profiles) from Individual Test Repeats for each Run. For example, results from multiple dissolution vessels.



Coordinated Response Reductions:

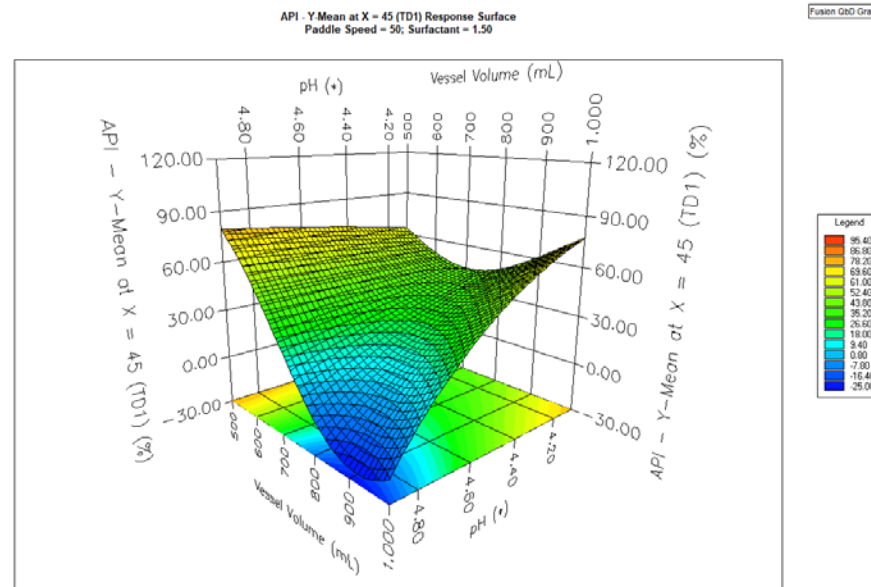
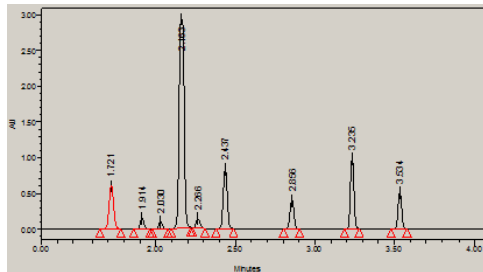
- Handles test repeat data
- Computes average profiles
- Computes f1 & f2 curve fit metrics
- Computes sensitive Weibull curve fit metrics
- Computes additional profile response metrics



Automated Import and 1-Click Modeling

Multivariate DOE Study – goal is characterizing all significant effects of the study parameters on all Critical Quality Attributes (CQAs)

Run	Std. Dev.	# of Std. Dev.	Label	Sample Name	Line	Function	Method Set / Report Method	Label Reference	Processing	Run Time (minutes)	Data Start (minutes)	Test Ng. (minutes)	Column Position	Auto. Adjusts	Sample Ngs	Clones
1						Condition Column	Testfile per 001_001			8.75	0.00	0.00	No Change			
2						Condition Column	Testfile per 001_001			8.75	0.00	0.00	No Change			
3						Equilibrat	Testfile per 001_001			3.00	0.00	7.00	No Change			
4	1	0.0	1	001-001-000	Blank 1	Injekt Samples	Testfile per 001_001	Normal		10.00	0.00	1.00			1.00000	1.00000
5						Condition Column	Testfile per 001_001			8.75	0.00	0.00	No Change			
6						Equilibrat	Testfile per 001_001			3.00	0.00	0.00	No Change			
7	2	0.0	1	001-001-001	1 x 1 x 1	Injekt Samples	Testfile per 001_001	Normal		10.00	0.00	1.00			1.00000	1.00000
8						Condition Column	Testfile per 001_002			8.75	0.00	0.00	No Change			
9						Equilibrat	Testfile per 001_002			3.00	0.00	0.00	No Change			
10	2	0.0	1	001-001-002	2 x 1 x 1	Injekt Samples	Testfile per 001_002	Normal		10.00	0.00	1.00			1.00000	1.00000
11						Condition Column	Testfile per 001_002			8.75	0.00	0.00	No Change			
12						Equilibrat	Testfile per 001_002			3.00	0.00	0.00	No Change			
13	2	0.0	1	001-001-003	3 x 1 x 1	Injekt Samples	Testfile per 001_003	Normal		10.00	0.00	1.00			1.00000	1.00000
14						Condition Column	Testfile per 001_003			8.75	0.00	0.00	No Change			
15						Equilibrat	Testfile per 001_003			3.00	0.00	0.00	No Change			
16	2	0.0	1	001-001-004	3 x 1 x 1	Injekt Samples	Testfile per 001_004	Normal		10.00	0.00	1.00			1.00000	1.00000
17						Condition Column	Testfile per 001_004			8.75	0.00	0.00	No Change			
18						Equilibrat	Testfile per 001_004			3.00	0.00	0.00	No Change			
19	2	0.0	1	001-001-005	3 x 1 x 1	Injekt Samples	Testfile per 001_005	Normal		10.00	0.00	1.00			1.00000	1.00000
20						Condition Column	Testfile per 001_005			8.75	0.00	0.00	No Change			
21						Equilibrat	Testfile per 001_005			3.00	0.00	0.00	No Change			
22	2	0.0	1	001-001-006	3 x 1 x 1	Injekt Samples	Testfile per 001_006	Normal		10.00	0.00	1.00			1.00000	1.00000
23						Condition Column	Testfile per 001_006			8.75	0.00	0.00	No Change			
24						Equilibrat	Testfile per 001_006			3.00	0.00	0.00	No Change			



$$CQA = 9.3 + 4.2(pH) - 5.4(Surf.)^2 + 12.7(pH*Surf.) + 1.3(Vol.*Speed) + 1.6[(\Delta pH)^2(Surf.)] + \dots$$

Linear Effect

Pure Curvature Effect

Interaction Effects

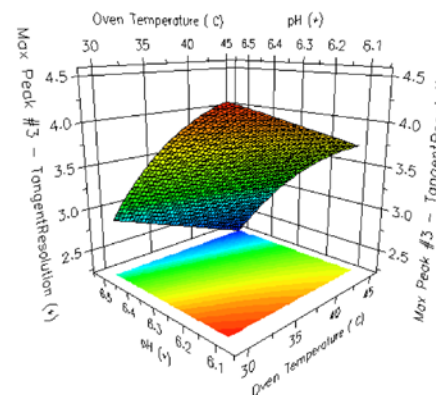
Complex Effect

Example of a Resolution Model Eqn.

- Peak 3 resolution

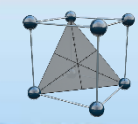
$$R = 3.0607 + 0.4109(\text{GT}) - 0.3367(\text{Temp}) - 0.7772(\text{pH}) - 0.2013(\text{pH})^2$$

Example of a Resolution Model Eqn. Predicted Response



✓ Regulatory Acceptance of Fusion QbD

John F. Kauffman, Ph.D. and Daniel J. Mans, Ph.D., “*Experimental Design and Modeling to Improve HPLC Method Performance for Small Molecules*”, FDA Division of Pharmaceutical Analysis, CASSS CMC Strategy Forum Europe 2015



Regulatory Acceptance of Monte Carlo Simulation Approach

Monte Carlo Robustness Simulation

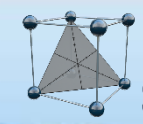
“Statistical treatments (e.g., **Monte Carlo simulations**) can help evaluate the effects of uncertainty.”

Points to Consider for Design Space – A Regulatory Perspective, Elaine Morefield, Ph.D., 2012 Annual Meeting, AAPS.

Statistical Robustness Metrics

The FDA has stated that accepted process capability indexes such as **C_p , C_{pk} , C_{pm} , and C_{pkm}** are also part of the QbD toolset.

US FDA, Quality by Design: Objectives, Benefits, and Challenges, Lawrence X. Yu, Ph.D., 2012 Annual Meeting, AAPS.



Regulatory Acceptance of Monte Carlo Simulation Approach

3. Process Capability

Process capability refers to the performance of the process when it is operating under statistical control. Two capability indices are usually computed: C_p and C_{pk} in a similar way as was described with P_p and P_{pk} . However, C_p measures the **potential** capability in the process, if the process was centred, while C_{pk} measures the actual capability in a process which is off-centre or biased. If a process is centred, then $C_p = C_{pk}$.

$$C_{pk} = \min \left[\frac{U - \bar{X}}{3S_w}, \frac{\bar{X} - L}{3S_w} \right] \quad (1.5)$$

The critical thing to note is that whilst the formulae for P_{pk} and C_{pk} look very similar, the standard deviation used to calculate the reference interval for C_{pk} is not S_t but S_w .

S_w is the within batch standard deviation (called the within sub group standard deviation in ISO) not the overall process standard deviation. It is usually estimated from a Shewhart mean and range control chart using the formula

Robustness Simulator
✕

C_p

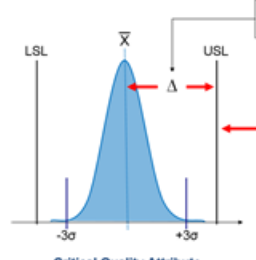
C_{pk} Use C_p when both of the conditions below apply to the response.

1. The response has a defined maximum allowable amount of variation.
2. The response has symmetrical **lower** and **upper** specification limits.

C_{pm}

C_{pkm}

C_p – Symmetrical Specification Limits Relative to a Mean Result

$$C_p = \frac{USL - LSL}{6\sigma}$$


IMPORTANT:

The distance from a given mean performance result to the **relative** specification limits.

Response Settings

Include Additional Error

Enabled	Response	Robustness Index	Specification Limit Delta (±)	LSL
<input checked="" type="checkbox"/>	API - f1 (TD1)	Cpk		
<input checked="" type="checkbox"/>	API - f2 (TD1)	Cpk		50.
<input checked="" type="checkbox"/>	API - Y-Mean at X = 15 (TD1)	Cpk		
<input checked="" type="checkbox"/>	API - Y-Mean at X = 30 (TD1)	Cpk		
<input checked="" type="checkbox"/>	API - Y-Mean at X = 45 (TD1)	Cpk		

Select All Select None Restore

The settings are valid.

Cpk

Cpkm

Variance

%RSD

1 Std.Dev.

2 Std.Dev.

3 Std.Dev.

4 Std.Dev.

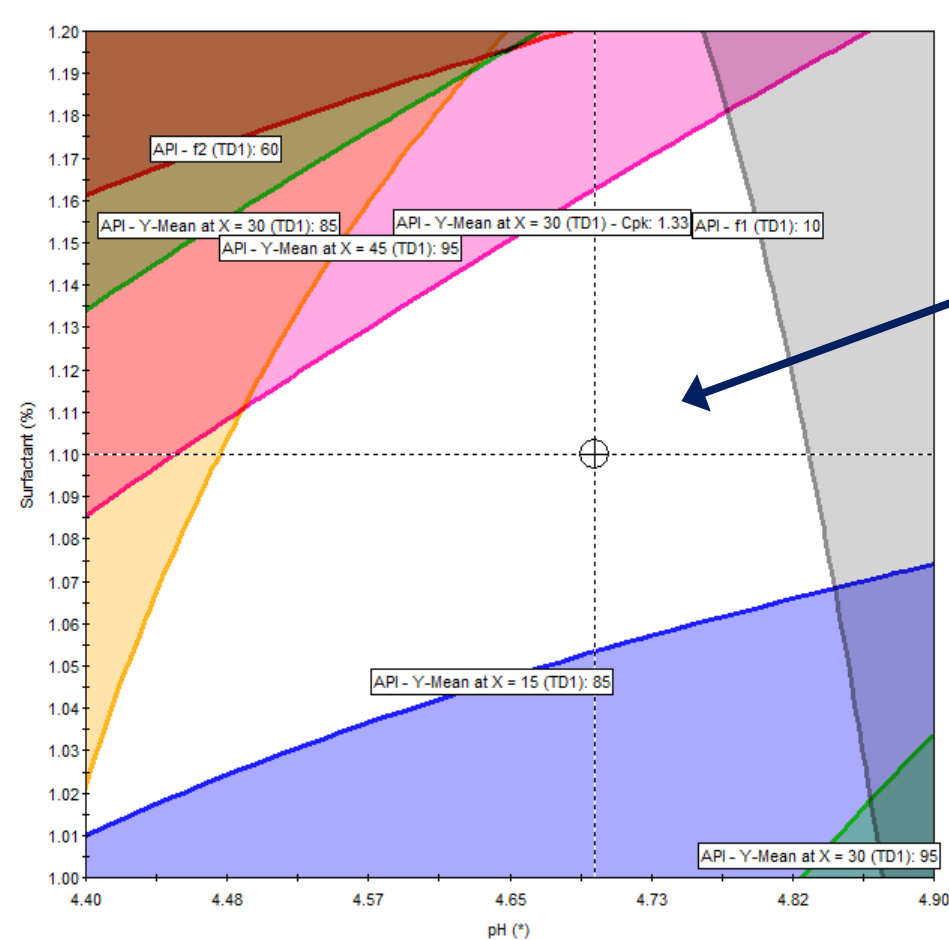
Built-in Robustness Metrics

Select correct metric (index) for each response (CQA).

Define edge of failure.

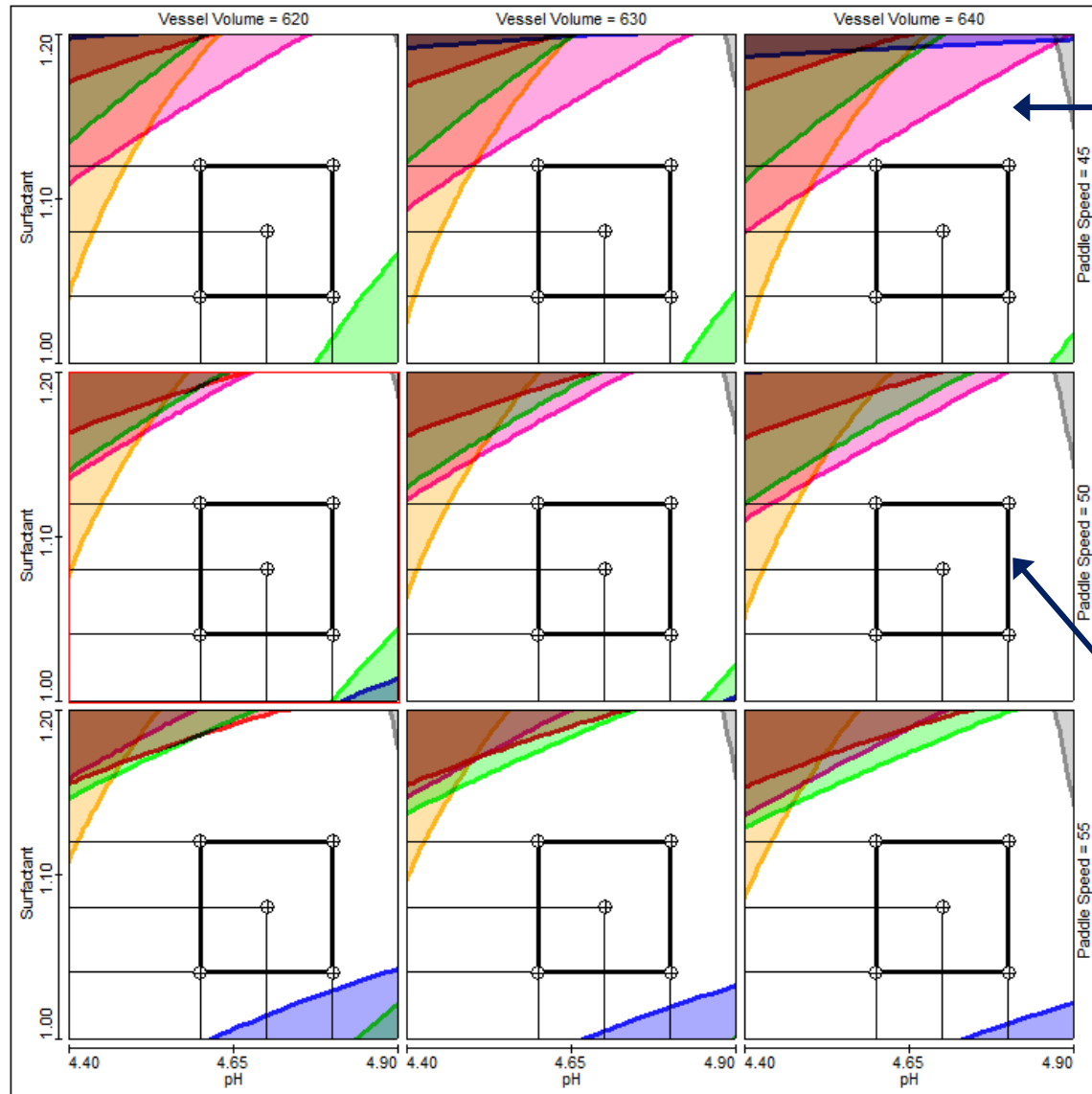
Multi-response Overlay Graph

Below is the *Final Robust Design Space* in which methods meet or exceed all critical **mean performance** and **robustness** goals simultaneously.



UNshaded Region in the graph is the Robust Design Space

MODR Trellis Graph – 4 Study Factors



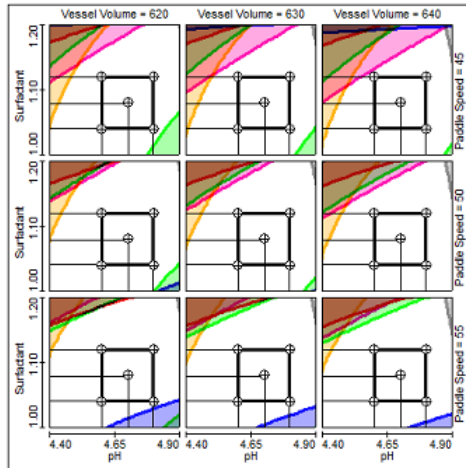
Unshaded Region in the graphs in combination with the Lower & Upper Bounds Of the Trellis Factors represent the 4-Factor **Method Operable Design Region (MODR)**.

Rectangle represents the independently adjustable ranges of Buffer pH and Organic Level within the MODR.

Name: Administrator
 Company: S-Matrix Corporation
 Project: Project 1
 Date: 20 AUG 2021 14:25:39 PDT [UTC-07:00]



Robust Design Space Trellis



Response Variable Goals

Name	Units	Goal	Color	Lower Bound	Upper Bound
API - f1 (TD1)	%	Minimize	Gray		15.00
API - f2 (TD1)	%	Maximize	Red	60.00	
API - Y-Mean at X = 15 (TD1)	%	Target	Blue	75.00	88.00
API - Y-Mean at X = 30 (TD1)	%	Target	Green	85.00	95.00
API - Y-Mean at X = 45 (TD1)	%	Maximize	Orange	94.00	
API - Y-Mean at X = 60 (TD1)	%	Maximize	Teal	53.67	
API - f1 (TD1) - Cpk		Maximize	Purple	1.33	
API - f2 (TD1) - Cpk		Maximize	Light Green	1.33	
API - Y-Mean at X = 15 (TD1) - Cpk		Maximize	Sky	1.33	
API - Y-Mean at X = 30 (TD1) - Cpk		Maximize	Fuchsia	1.00	
API - Y-Mean at X = 45 (TD1) - Cpk		Maximize	Gray	1.33	

Independently Adjustable Ranges Rectangle Settings

Axis	Name	Units	Lower Bound	Upper Bound	Centerpoint
X	pH	°	4.60	4.80	4.70
Y	Surfactant	%	1.04	1.12	1.08

1 of 3

Report Output in Multiple Formats

- MS Excel



- MS Word

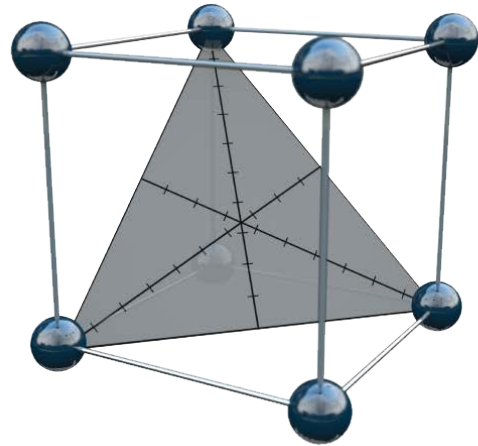


- PDF



- ...

End of Presentation



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