



# ***Fusion QbD***

## ***Fusion Process Development Module***

**S-Matrix Corporation**  
**[www.smatrix.com](http://www.smatrix.com)**

# Key Benefits of Fusion Process Development

**Supports All Install Environments (Citrix Ready Certified)**



**Full 21 CFR Part 11 Compliance Support**



**Flexible, Automated (1-Click) Design**



**Full LC Testing Automation**



**Simplifies Handling of Complex Data**



**Integrated Monte Carlo Robustness**



**Full QbD Reporting**



## Example Applications

- Tablet Coating Optimization
- Tablet Excipient Formulation and Process Optimization

## Example Workflows

- Sample Preparation Method Development
- Dissolution Method Development
- Respiratory Drug Development

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# Supports All Install Environments

## Install Environment

## FPD

Standalone (Workstation)



Network (Enterprise)



Citrix Ready Certified



Fully Qualifiable for GXP Environments\*



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

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## How Fusion Process Development Assures Compliance

### Required Features

### FPD

Full integration of **all e-record** and **all e-signature** features and functions required to support full 21 CFR 11 compliance.



Integrated Project Management System.



Full audit trail, including all data exchanges with the CDS.



## Why Compliance is Important!

### FDA Statement Regarding Robustness Done During Method Development\* –

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!

What CDS Project  
did this data come  
from?



Who entered this  
data – was the  
data modified?

Filter Options

Date

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 ?

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# Flexible Experiment Design – Easy Setup

**Experiment Setup**

Experiment Type: Optimization

Mixture Variable Settings

No. of Mixture Variables: 4

Units: %      Mixture Amount: 100.00

Mixture Variable	State	Lower Bound	Upper Bound
Starch	Variable	2.00	25.00
Lactose	Variable	2.00	25.00
MCC	Variable	2.00	25.00
DPI-90	Constant	75.00	---

Process Variable Settings

No. of Process Variables: 1

Split-plot Design (restriction on randomization)

Name	Units	Type	Lower Bound	Upper Bound
Compaction Force	kN	Continuous	9.88	20.35

State

Variable  
 Constant

## Formulation (Mixture) Studies

Simply Enter:

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

## Process Development Studies

Simply Enter:


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

## Combined Mixture-Process Studies

Enables you to characterize interactions between the two!

## Automated DOE Wizard Selects and Generates the Right Design for you!

Name: Administrator  
 Company: S-Matrix Corporation  
 Project: Project 1  
 Date: May 10, 2011 12:10:33 PM PDT [GMT-07:00]



**Experiment Design - Pan Coater Process Optimization**

Experiment Design Matrix

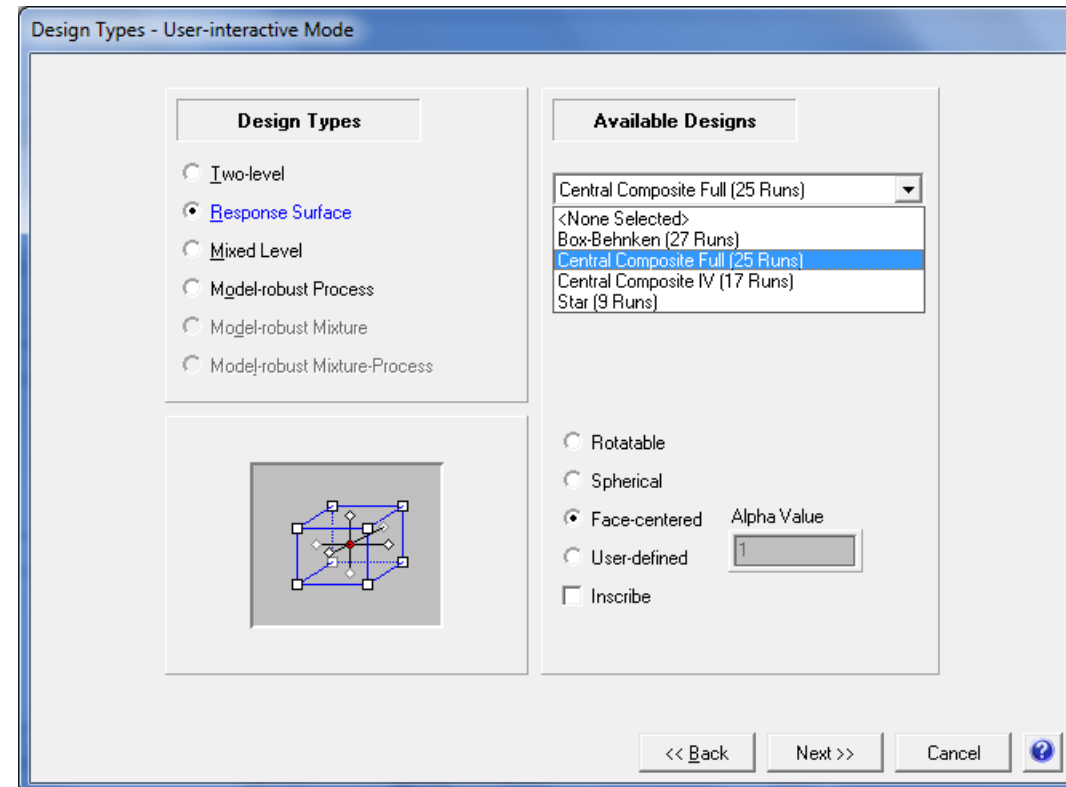
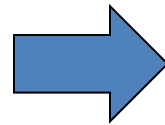
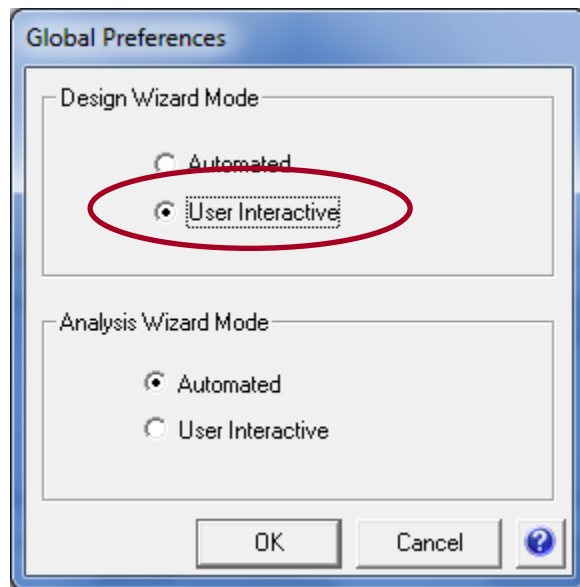
Run No.	Block No.	Atomizing Air Pressure (psi)	Pattern Air Pressure (psi)	Spray Rate (gm/min)	Gun-to-Bed Distance (inches)
1	1	30.0	55.0	82.5	7.0
2	1	30.0	27.5	82.5	10.0
3	1	50.0	0.0	125.0	10.0
4	1	10.0	0.0	40.0	10.0
5	1	10.0	55.0	125.0	10.0
6	1	10.0	55.0	40.0	4.0
7	1	30.0	27.5	82.5	4.0
8	1	30.0	0.0	82.5	7.0
9	1	50.0	55.0	40.0	10.0
10	1	50.0	0.0	40.0	4.0
11	1	30.0	27.5	82.5	7.0
12	1	10.0	55.0	40.0	10.0
13	1	10.0	0.0	125.0	4.0
14	1	50.0	55.0	40.0	4.0
15	1	10.0	0.0	40.0	4.0
16	1	10.0	0.0	125.0	10.0
17	1	50.0	55.0	125.0	10.0
18	1	50.0	27.5	82.5	7.0
19	1	50.0	0.0	40.0	10.0
20	1	30.0	27.5	82.5	7.0

### Automated Design Logic Accounts for:

- **Stage of the Work**  
(Screening or Optimization)
- **Number of Variables**
- **Types of Variables**
  - Continuous Numeric
  - Discrete Numeric
    - # of defined levels
  - Categorical (Non-numeric)
    - # of defined levels

# User Interactive Design Wizard Mode

- DOE Expert Users
- Users Following an SOP



## Can Accept Designs and Results from Other Software

Fusion Product Development - Untitled1

File Edit Activity Tools Window Help

Edit Run No. Labels Matrix Master Create/Edit Response Data Show/Hide Responses Create Testing Design Export Sort Grid

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

	Run No.	Modified Starch	Stearic Acid	MCC	Mixing Speed	Mixing Time
1	1	0	50	50	200	1.5
2	2	0	50	50	100	3
3	3	100	0	0	200	1.5
4	4	0	100	0	200	3
5	5	0	0	100	100	3
6	6	16.67	66.67	16.66	175	3
7	7	50	0	50	100	3
8	8	50	50	0	200	3
9	9	0	100	0	100	3
10	10	0	100	0	100	3
11	11	100	0	0	100	3
12	12	50	0	50	200	3
13	13	100	0	0	100	3
14	14	66.67	16.67	16.66	175	3
15	15	16.67	66.67	16.66	125	3
16	16	33.33	33.33	33.34	150	1.5

Context Menu:

- Cut
- Copy
- Paste
- Set Response Precision...
- Delete All Responses
- Remove Row
- Redimension Matrix**



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## Standards Protocol Setup Wizard

Export Options

Select Export Type

Export To Chromatography Data System

Export to File

OK Cancel

Export

Bracketing

Strategy: Bracketing - Overlap Clear Reset

Bracketing Settings

No. of Standards per Bracket: 2

No. of Injections within Brackets: 5

Bracketing Scheme - first two brackets

Bracket

Std - 1.a  
1.alt - 0.00  
1.b.t - 0.00  
1.c.t - 0.00

2.alt - 0.00  
2.b.t - 0.00  
2.c.t - 0.00

Std - 1.b

3.alt - 0.00  
3.b.t - 0.00  
3.c.t - 0.00

4.alt - 0.00  
4.b.t - 0.00  
4.c.t - 0.00

Std - 1.c

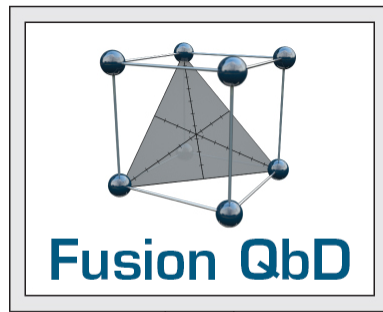
Bracket

<< Back Next >> Finish

Select your standards protocol – Standard injections are automatically included in the testing sequence exported to the CDS.



# Export Testing Design Sequences to the CDS



Generates QbD-aligned  
DOE Experiment

Automatically Builds  
Testing Sequence as  
Ready-to-Run

Fusion QbD automatically builds testing sequences in your CDS which can include your standard injection protocol for all test data which will be generated by LC testing.

### Chromatography Data Software (CDS)

Vial	Inj Vol (uL)	# of Injs	Label	SampleName	Level	Function	Method Set / Report Method	Label Reference	Processing	Run Time (Minutes)	Data Start (Minutes)	Next Inj. Delay (Minutes)	Column Position	Auto Additions	SampleWeight	Dilution
1						Condition Column				6.70	0.00	0.00	No Change			
2						Condition Column	Text Mix pH 001_017			0.10	0.00	0.00	No Change			
3						Equilibrate	Text Mix pH 001_017			3.00	0.00	7.95	No Change			
4	1	2.0	1	Unk-000-000	Blank - 1	Inject Samples	Text Mix pH 001_017		Normal	10.50	0.00	1.50			1.00000	1.00000
5						Condition Column	Text Mix pH 001_001			0.10	0.00	0.00	No Change			
6						Equilibrate	Text Mix pH 001_001			3.00	0.00	0.00	No Change			
7	2	2.0	1	Unk-001-001	1.a.1.a	Inject Samples	Text Mix pH 001_001		Normal	10.50	0.00	1.50			1.00000	1.00000
8						Condition Column	Text Mix pH 001_002			0.10	0.00	0.00	No Change			
9						Equilibrate	Text Mix pH 001_002			3.00	0.00	0.00	No Change			
10	2	2.0	1	Unk-001-002	2.a.1.a	Inject Samples	Text Mix pH 001_002		Normal	10.50	0.00	1.50			1.00000	1.00000
11						Condition Column				6.70	0.00	0.00	No Change			
12						Condition Column	Text Mix pH 001_003			0.10	0.00	0.00	No Change			
13						Equilibrate	Text Mix pH 001_003			3.00	0.00	0.00	No Change			
14	2	2.0	1	Unk-001-003	3.a.1.a	Inject Samples	Text Mix pH 001_003		Normal	10.50	0.00	1.50			1.00000	1.00000
15						Condition Column				6.70	0.00	0.00	No Change			
16						Condition Column	Text Mix pH 001_004			0.10	0.00	0.00	No Change			
17						Equilibrate	Text Mix pH 001_004			3.00	0.00	0.00	No Change			
18	2	2.0	1	Unk-001-004	4.a.1.a	Inject Samples	Text Mix pH 001_004		Normal	10.50	0.00	1.50			1.00000	1.00000
19						Condition Column	Text Mix pH 001_005			0.10	0.00	0.00	No Change			
20						Equilibrate	Text Mix pH 001_005			3.00	0.00	0.00	No Change			
21	2	2.0	1	Unk-001-005	5.a.1.a	Inject Samples	Text Mix pH 001_005		Normal	10.50	0.00	1.50			1.00000	1.00000
22						Condition Column				6.70	0.00	0.00	No Change			
23						Condition Column	Text Mix pH 001_006			0.10	0.00	0.00	No Change			
24						Equilibrate	Text Mix pH 001_006			3.00	0.00	0.00	No Change			

**Automated, Audited Data Exchange Preserves Data Integrity**

# 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

User Types (logged in as 'Owner')

Owner

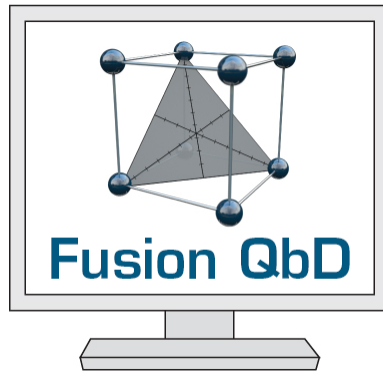
Ready

Next >> Cancel ?

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

# Import All Required Results Data from CDS



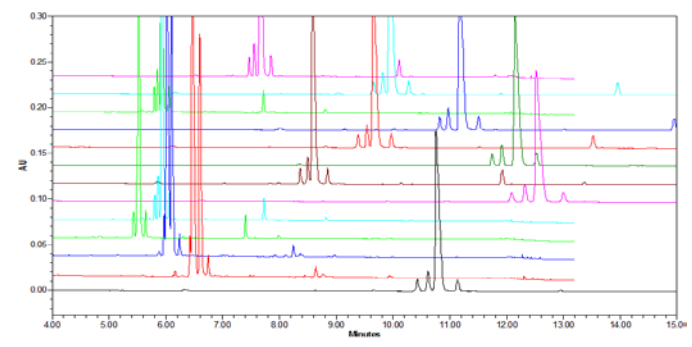
Fusion QbD automatically imports all important test results from the CDS for all compounds.

## Chromatography Data Software (CDS)

Run No.	Run Name	Label	Sample Name	Lot	Injection	Method Set / Report Method	Label	Processing	Run Time (minutes)	Data Start (minutes)	Wait In Delay (minutes)	Column Position	Auto Injections	Sampling(s)	Dilution
1						Condition Column			8.70	0.00	0.00	No Change			
2						Condition Column	Test file pH 01_017		0.10	0.00	0.00	No Change			
3						Equilibr	Test file pH 01_017		3.00	0.00	0.00	No Change			
4	1	2.0	1	UN-005-000	Batch-1	Inject Samples	Test file pH 01_017	Normal	10.00	0.00	1.00	No Change		1.00000	1.00000
5						Condition Column	Test file pH 01_017		0.10	0.00	0.00	No Change			
6						Equilibr	Test file pH 01_017		3.00	0.00	0.00	No Change			
7	2	2.0	1	UN-001-001	1 a 1 a	Inject Samples	Test file pH 01_017	Normal	10.00	0.00	1.00	No Change		1.00000	1.00000
8						Condition Column	Test file pH 01_022		0.10	0.00	0.00	No Change			
9						Equilibr	Test file pH 01_022		3.00	0.00	0.00	No Change			
10	2	2.0	1	UN-001-002	2 a 1 a	Inject Samples	Test file pH 01_022	Normal	10.00	0.00	1.00	No Change		1.00000	1.00000
11						Condition Column	Test file pH 01_023		0.10	0.00	0.00	No Change			
12						Equilibr	Test file pH 01_023		3.00	0.00	0.00	No Change			
13	2	2.0	1	UN-001-003	3 a 1 a	Inject Samples	Test file pH 01_023	Normal	10.00	0.00	1.00	No Change		1.00000	1.00000
14						Condition Column	Test file pH 01_024		0.10	0.00	0.00	No Change			
15						Equilibr	Test file pH 01_024		3.00	0.00	0.00	No Change			
16	2	2.0	1	UN-001-004	4 a 1 a	Inject Samples	Test file pH 01_024	Normal	10.00	0.00	1.00	No Change		1.00000	1.00000
17						Condition Column	Test file pH 01_025		0.10	0.00	0.00	No Change			
18						Equilibr	Test file pH 01_025		3.00	0.00	0.00	No Change			
19	2	2.0	1	UN-001-005	5 a 1 a	Inject Samples	Test file pH 01_025	Normal	10.00	0.00	1.00	No Change		1.00000	1.00000
20						Condition Column	Test file pH 01_026		0.10	0.00	0.00	No Change			
21						Equilibr	Test file pH 01_026		3.00	0.00	0.00	No Change			
22	2	2.0	1	UN-001-006	6 a 1 a	Inject Samples	Test file pH 01_026	Normal	10.00	0.00	1.00	No Change		1.00000	1.00000
23						Condition Column	Test file pH 01_026		0.10	0.00	0.00	No Change			
24						Equilibr	Test file pH 01_026		3.00	0.00	0.00	No Change			

Automatically Retrieve All Chromatogram Results Data

Automated analysis, graphing, and reporting.  
Report formats: RTF, DOC, HTML, PDF, XLSX, XML



**Automated, Audited Data Exchange Preserves Data Integrity**

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Full 21 CFR Part 11 Compliance Support



Flexible, Automated (1-Click) Design



Full LC Testing Automation



**Simplifies Handling of Complex Data**



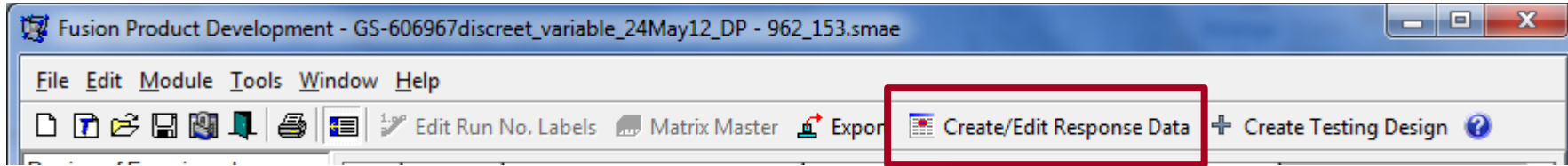
Integrated Monte Carlo Robustness



Full QbD Reporting



# Simple Data Entry – One Test Result Per Trial



Responses consisting of only one measurement per run (no test repeats) can be entered directly.

Create/Edit Response Data

Response Name: Example Response    Response Units: Units    Lower Limit: 0    Upper Limit: 100

0 <= Response <= 100

Run No.	Example Response
1	
2	
3	
4	
5	
6	
7	
8	
9	
10	
11	
12	
13	
14	
15	
16	
17	
18	
19	
20	
21	
22	

Add following to empty cells: 0    Update





Validation Status: Your settings are valid.

New    Delete    OK    Close    Apply

# Simple Data Entry – One Test Result Per Run

Fusion Product Development - Temporary File.smae

File Edit Activity Tools Window Help


 Edit Run No. Labels  Matrix Master  Create/Edit Response Data  Show/Hide

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

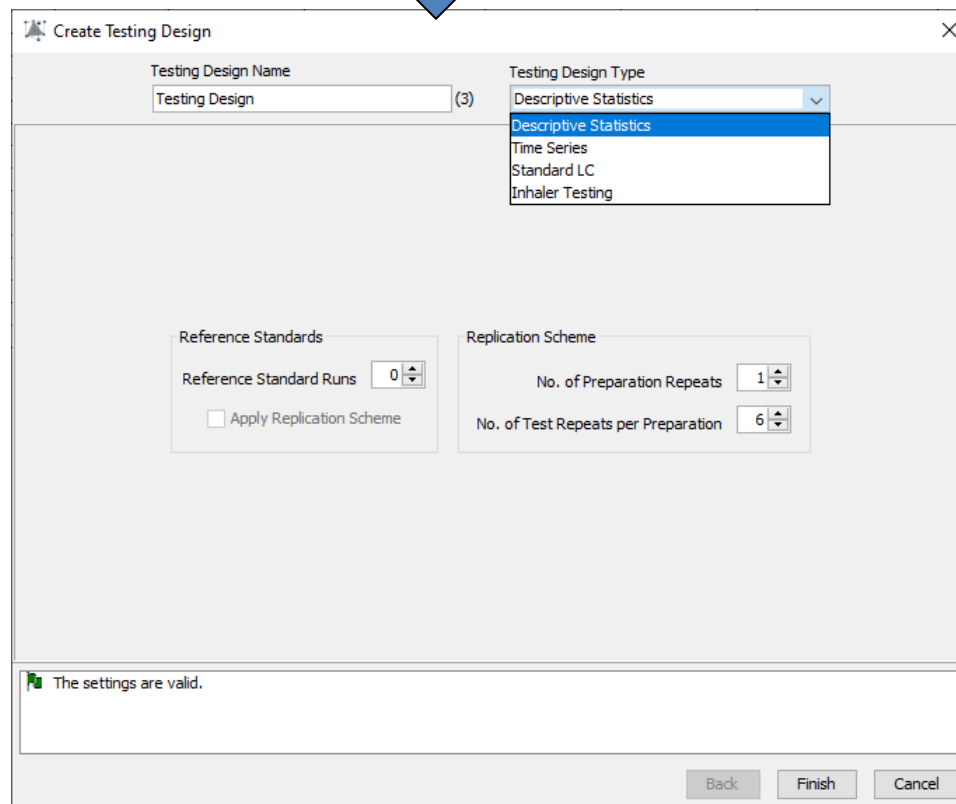
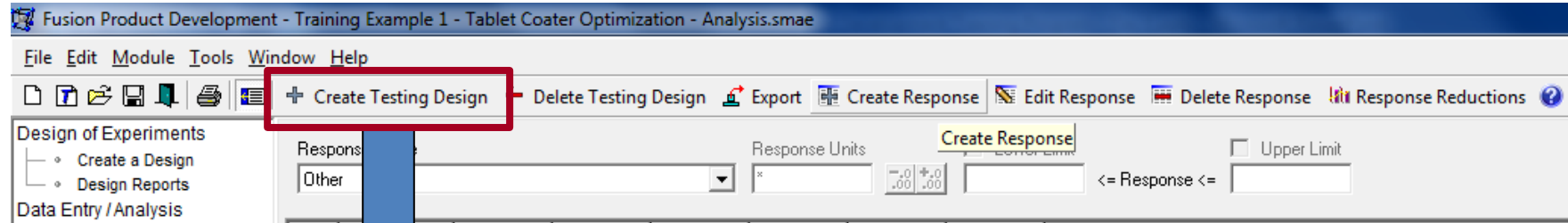
Reporting Toolkit

- Fusion Reporter
- Audit Log Reporter

	Run No.	Starch	Lactose	MCC	C_Force	Example Response
1	1	11.5	2	11.5	20.35	
2	2	2	11.5	11.5	15.12	
3	3	2	21	2	15.12	
4	4	2	2	21	20.35	
5	5	2	11.5	11.5	20.35	
6	6	5.17	14.67	5.16	17.73	
7	7	2	2	21	15.12	
8	8	2	2	21	9.88	
9	9	21	2	2	9.88	
10	10	11.5	11.5	2	15.12	
11	11	21	2	2	9.88	
12	12	5.17	5.17	14.66	12.5	
13	13	21	2	2	15.12	
14	14	14.67	5.17	5.16	12.5	
15	15	2	21	2	9.88	
16	16	21	2	2	20.35	
17	17	11.5	11.5	2	20.35	
18	18	2	11.5	11.5	9.88	
19	19	8.33	8.33	8.34	15.12	
20	20	2	21	2	20.35	
21	21	2	21	2	9.88	
22	22	8.33	8.33	8.34	15.12	
23	23	11.5	2	11.5	15.12	
24	24	2	2	21	9.88	
25	25	5.17	5.17	14.66	17.73	
26	26	11.5	2	11.5	9.88	
27	27	14.67	5.17	5.16	17.73	
28	28	11.5	11.5	2	9.88	

Placeholder  
for Direct  
Data Entry



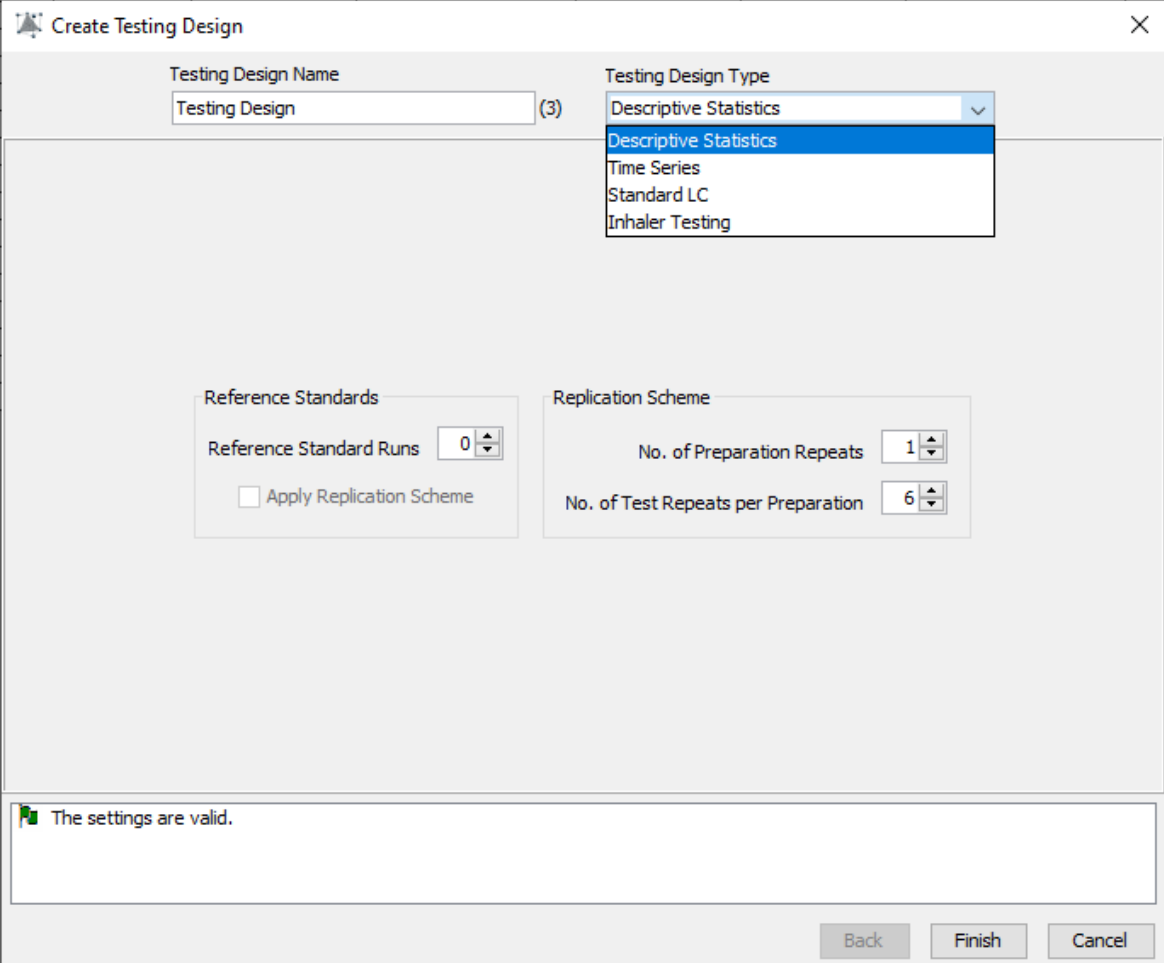


All Raw Test Results Data  
from All Platforms Entered,  
Managed, Converted to  
Modelable Data, and Audited  
in One Fusion QbD  
Experiment Workbook File.

## Handle Complex Data Simply and Easily!

### Testing Design Setup Modes

- **Descriptive Statistics**  
Multiple test results per run.
- **Time Series**  
Testing at multiple time points per run.
- **Standard LC**  
Testing at multiple time points per run.
- **Inhaler Testing**  
Respiratory drug test results.



Testing Design Name: Testing Design (3)

Testing Design Type: Descriptive Statistics (selected)

Reference Standards: Reference Standard Runs: 0,  Apply Replication Scheme

Replication Scheme: No. of Preparation Repeats: 1, No. of Test Repeats per Preparation: 6

The settings are valid.

Buttons: Back, Finish, Cancel



# Descriptive Statistics Testing – Multiple Test Repeats per Run

Create Testing Design

Testing Design Name: Testing Design (3)

Testing Design Type: Descriptive Statistics

Reference Standards

Reference Standard Runs: 0

Apply Replication Scheme

Replication Scheme

No. of Preparation Repeats: 1

No. of Test Repeats per Preparation: 6

The settings are valid.

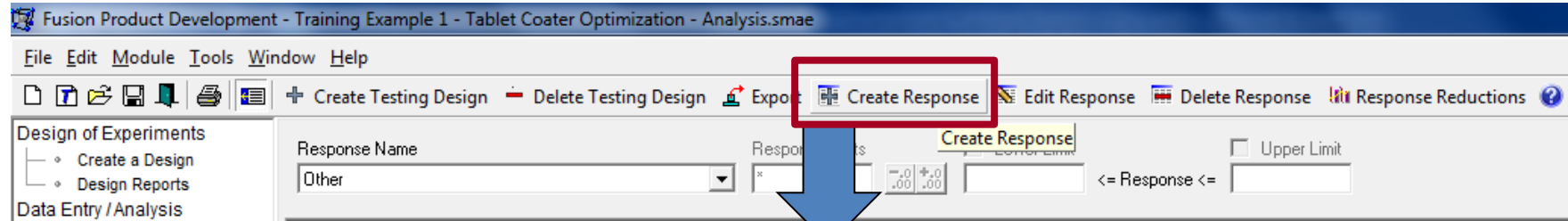
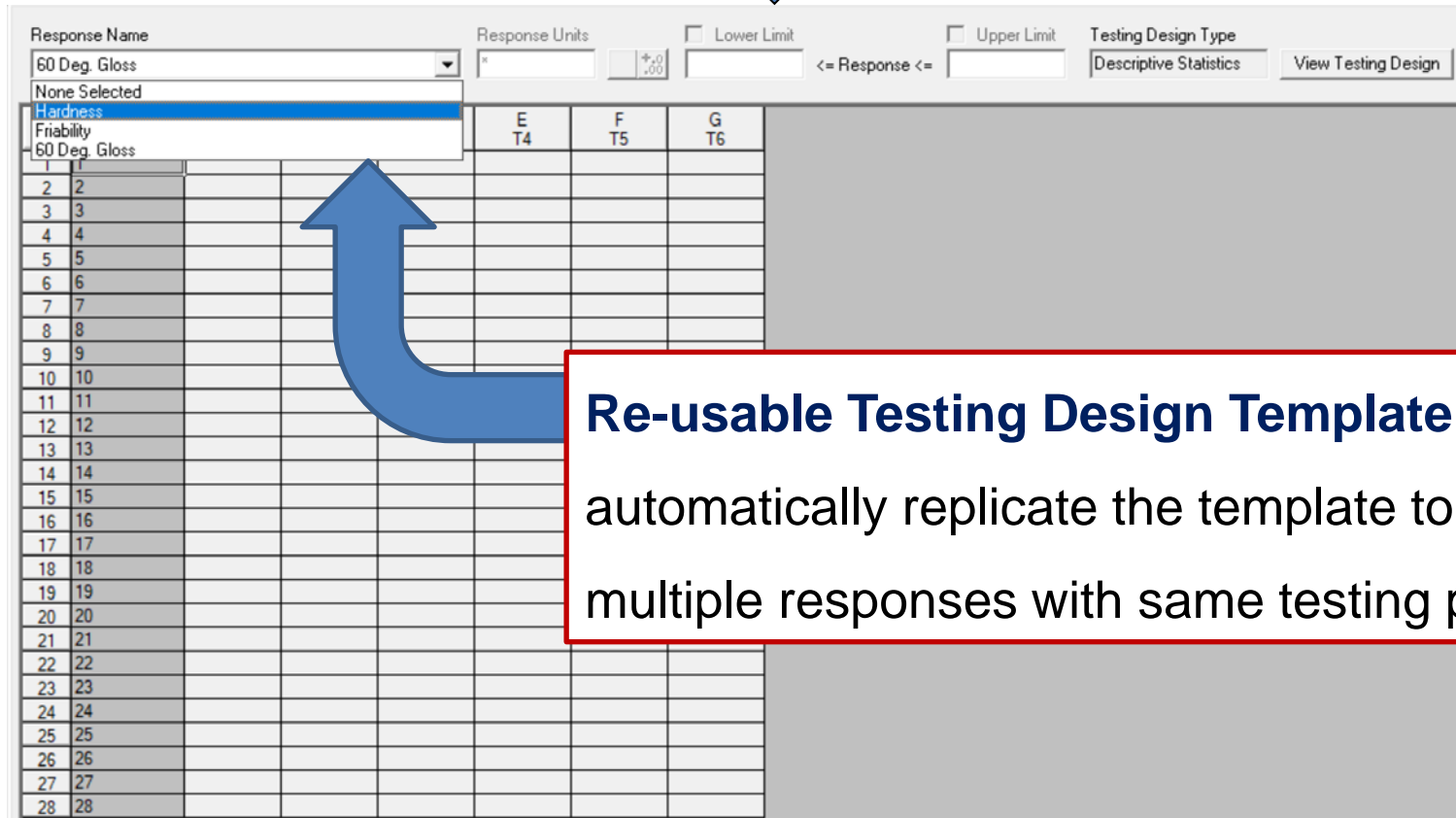
Back Finish Cancel

## Example Protocol –

Test six (6) tablets for physical properties:

- Hardness
- Friability
- Gloss
- ...

# Descriptive Statistics – Testing Template

Response Name: 60 Deg. Gloss

Response Units: \*

Lower Limit:

Upper Limit:

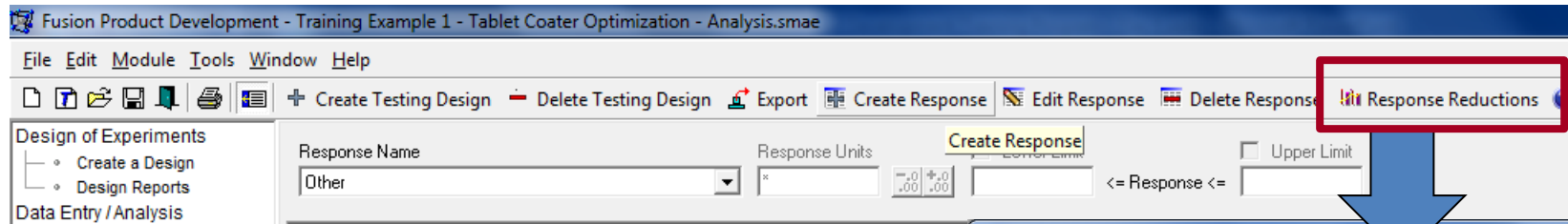
Testing Design Type: Descriptive Statistics

View Testing Design

		E	F	G
		T4	T5	T6
1	1			
2	2			
3	3			
4	4			
5	5			
6	6			
7	7			
8	8			
9	9			
10	10			
11	11			
12	12			
13	13			
14	14			
15	15			
16	16			
17	17			
18	18			
19	19			
20	20			
21	21			
22	22			
23	23			
24	24			
25	25			
26	26			
27	27			
28	28			

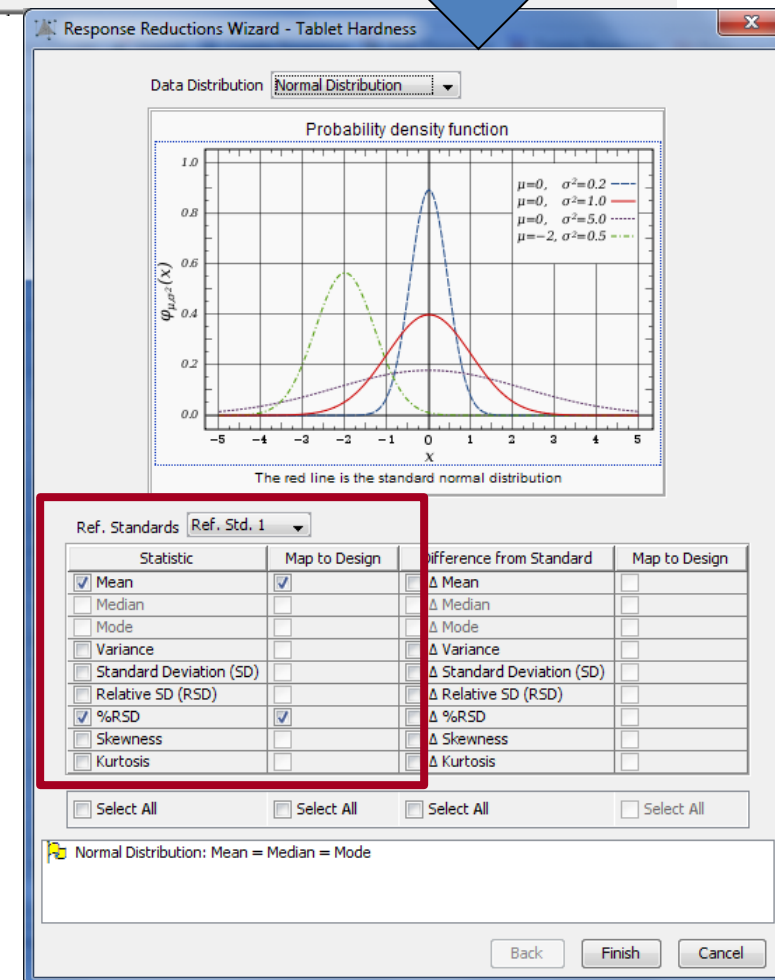
**Re-usable Testing Design Template –**  
 automatically replicate the template to add  
 multiple responses with same testing protocol.

# Descriptive Statistics – Automated Response Generation



## Automated Response Reductions:

- Handles test repeat data
- Handles non-normally distributed data
- Computes descriptive statistics responses  
E.g., Mean, Variance, Std. Dev., % RSD
- Computes differences of all statistics from a reference standard
- Maps all computed responses to the experimental design for analysis



# Descriptive Statistics – Automated Response Generation

Fusion Product Development - Tablet Formulation and Process Optimization - New Analysis - 990.smae

File Edit Activity Tools Window Help

Edit Run No. Labels Matrix Master Create/Edit Response Data

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

	Run No.	Starch	Lactose	MCC	C_Force	Friability
1	1	11.5	2	11.5	20.35	0.28
2	2	2	11.5	11.5	15.12	1.02
3	3	2	21	2	15.12	0.75
4	4	2	2	21	20.35	0.38
5	5	2	11.5	11.5	20.35	0.37
6	6	5.17	14.67	5.16	17.73	0.49
7	7	2	2	21	15.12	0.95
8	8	2	2	21	9.88	2.44
9	9	21	2	2	9.88	1.48
10	10	11.5	11.5	2	15.12	0.65
11	11	21	2	2	9.88	1.54
12	12	5.17	5.17	14.66	12.5	1.33
13	13	21	2	2	15.12	0.56
14	14	14.67	5.17	5.16	12.5	1.03
15	15	2	21	2	9.88	1.57
16	16	21	2	2	20.35	0.21
17	17	11.5	11.5	2	20.35	0.27
18	18	2	11.5	11.5	9.88	1.97
19	19	8.33	8.33	8.34	15.12	0.73
20	20	2	21	2	20.35	0.34
21	21	2	21	2	9.88	
22	22	8.33	8.33	8.34	15.12	0.75
23	23	11.5	2	11.5	15.12	0.74
24	24	2	2	21	9.88	2.44
25	25	5.17	5.17	14.66	17.73	0.53
26	26	11.5	2	11.5	9.88	1.94
27	27	14.67	5.17	5.16	17.73	0.41
28	28	11.5	11.5	2	9.88	1.55

Automatically  
Computes your  
Selected Results  
and Transfers  
them to the Main  
Grid for Instant  
Analysis

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: Inhaler Testing

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

# Time Series – Testing Template

## 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.

# 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									79.35
11	4.b	0.00	11.40	21.15	30.30									79.55
12	4.c	0.00	11.30	21.10	30.50									79.30
13	5.a	0.00	10.95	21.50	31.05									81.40
14	5.b	0.00	10.85	21.70	31.00									81.25
15	5.c	0.00	10.90	21.90	30.95									81.25

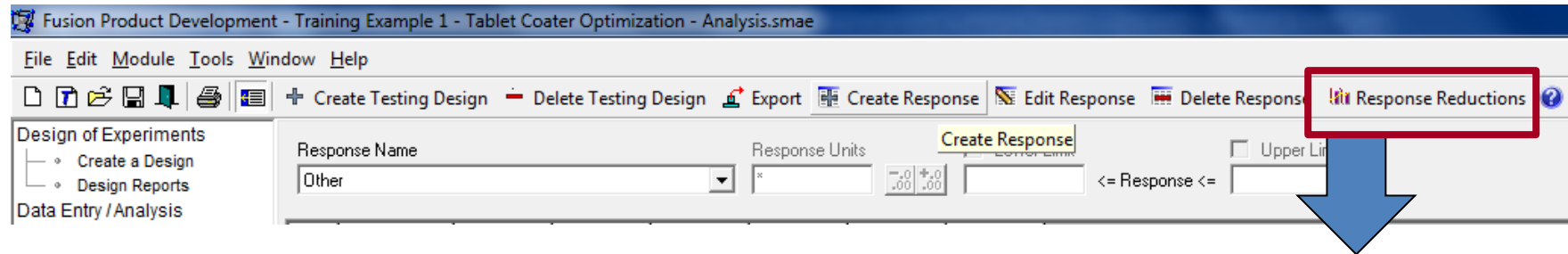
  

	A Run No.	B t - 0.00	C t - 60.00	D t - 120.00	E t - 180.00
1	1	0.00	13.50	21.50	29.50
2	2	0.00	12.20	24.90	36.50
3	3	0.00	8.50	10.40	14.30
4	4	0.00	11.40	21.10	30.50
5	5	0.00	10.90	21.50	31.00
6	6	0.00	9.10	12.50	17.30
7	7	0.00	12.40	25.10	36.70
8	8	0.00	13.40	21.40	29.40
9	9	0.00	12.10	21.70	31.00
10	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)**

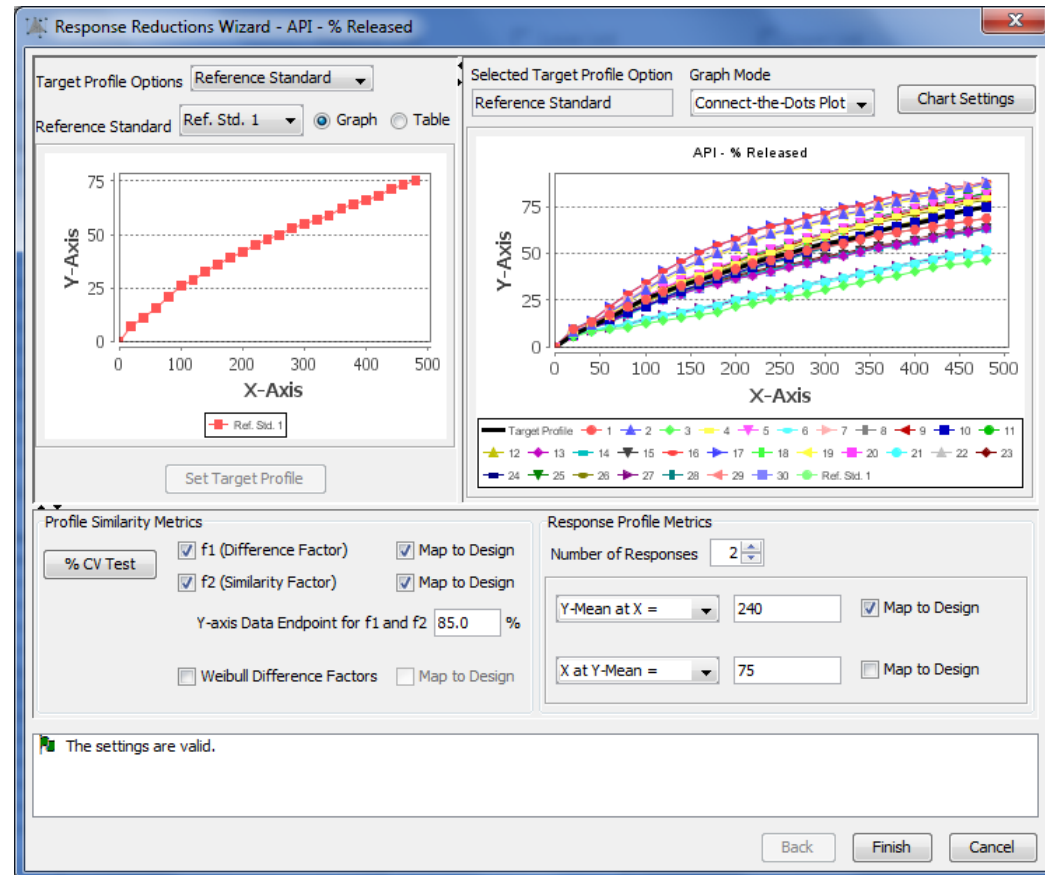
Ready

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



## Coordinated Response Reductions:

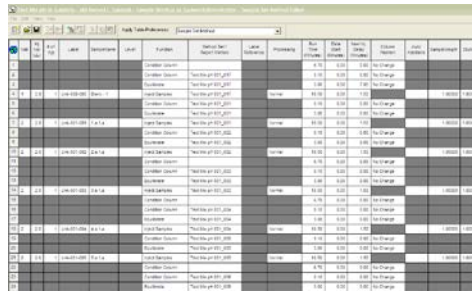
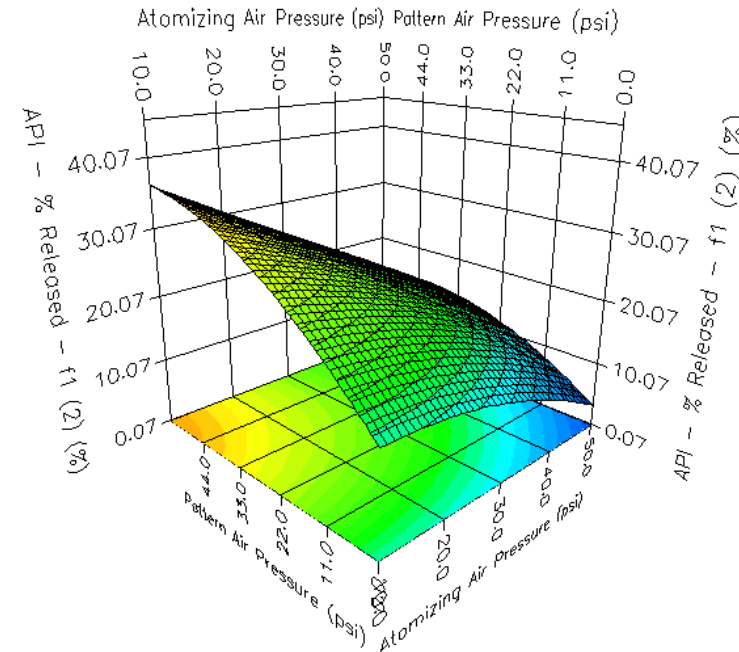
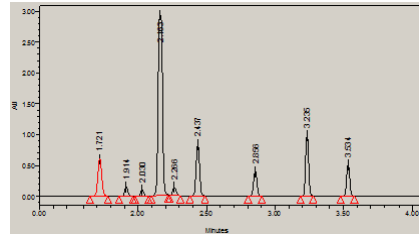
- Handles test repeat data
- Computes average profiles
- Computes f1 & f2 curve fit metrics
- Computes sensitive Weibull curve fit metrics
- Computes additional profile response metrics





# 1-Click Modeling Turns Data into Knowledge

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

$$CQA = 9.3 + 4.2(AAP) - 5.4(PAP)^2 + 12.7(AAP*PFP) + 1.3(PAP*CP) + 1.6[(G.D.)^2*CP] + \dots$$

Linear Effect

Curvature Effect

Interaction Effects

Complex Effect

# Key Benefits of Fusion Process Development

Supports All Install Environments (Citrix Ready Certified)



Full 21 CFR Part 11 Compliance Support



Flexible, Automated (1-Click) Design and Analysis



Full LC Testing Automation



Simplifies Handling of Complex Data



**Integrated Monte Carlo Robustness**



Full QbD Reporting



## 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.

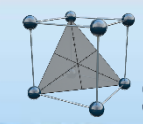
## 3. Process Capability

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

$C_p$   
  $C_{pk}$   
  $C_{pm}$

Use  $C_{pm}$  when **both** of the conditions below apply to the response:

- The response goal is **Target**.

Lower and upper specification limits are **symmetrical** (equal distance from the target).

**$C_{pm}$  – Symmetrical Specification Limits with Target**

$$C_{pm} = \frac{USL - LSL}{6\sqrt{\sigma^2 + (\bar{x} - T)^2}}$$

Specification Limit Delta ( $\pm$  Distance from Target to Edge of Failure)

IMPORTANT: The numerical distance from the Target value to a Specification Limit.

Critical Quality Attribute

Include Additional Error  
 Model Error  E

Enabled	Response	Robustness Index	Specification Limit Delta ( $\pm$ )	LSL	USL	Target
<input checked="" type="checkbox"/>	API 1 - %L.C.-(1_1)	Cpm	1.000			
<input checked="" type="checkbox"/>	API 2 - %L.C.-(1_2)	Cpm	1.000			

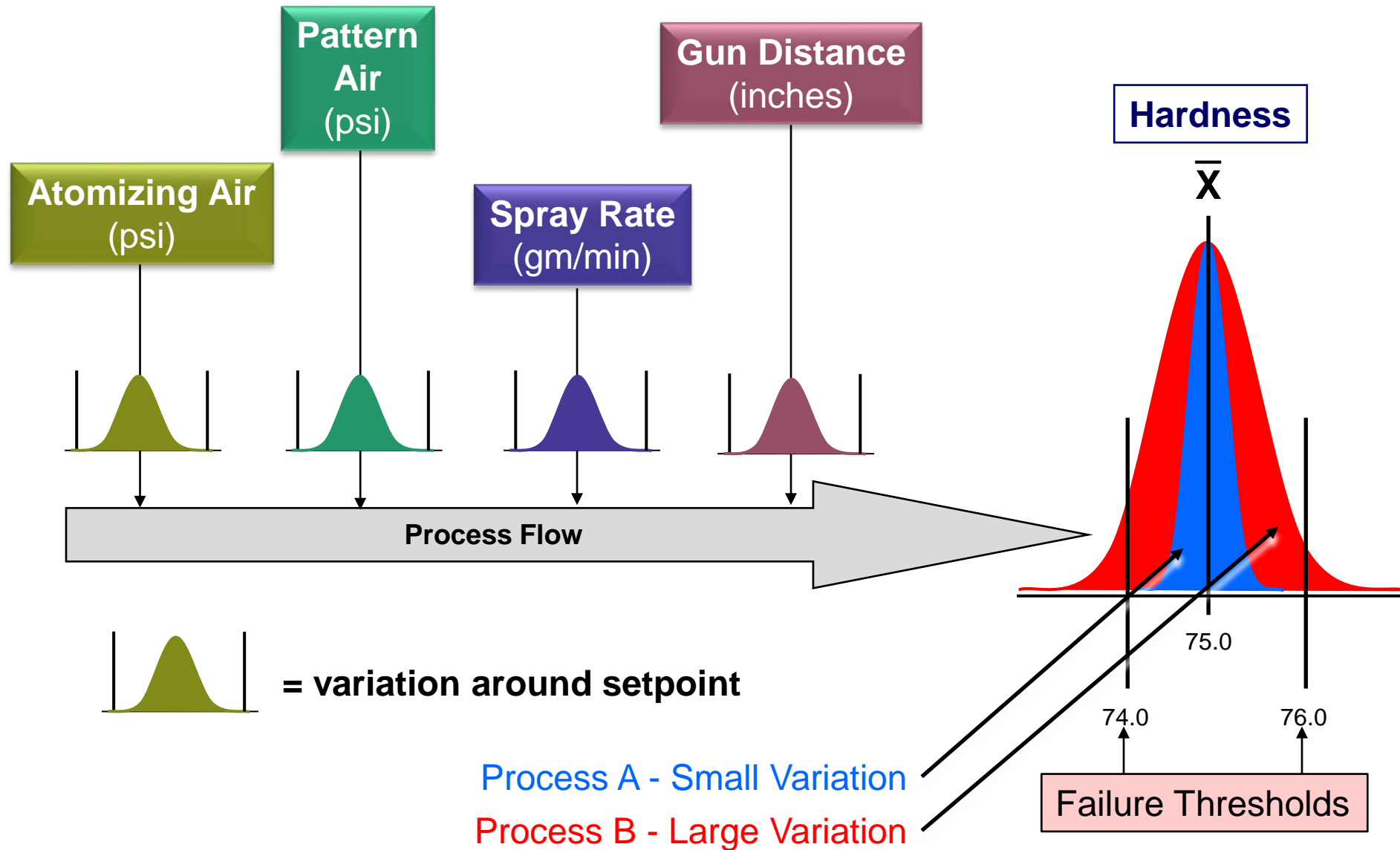
The settings are valid.

Fully Automated  
In-silico  
Monte Carlo  
Robustness  
Simulation

**Built-in Robustness Metrics – Simply:**

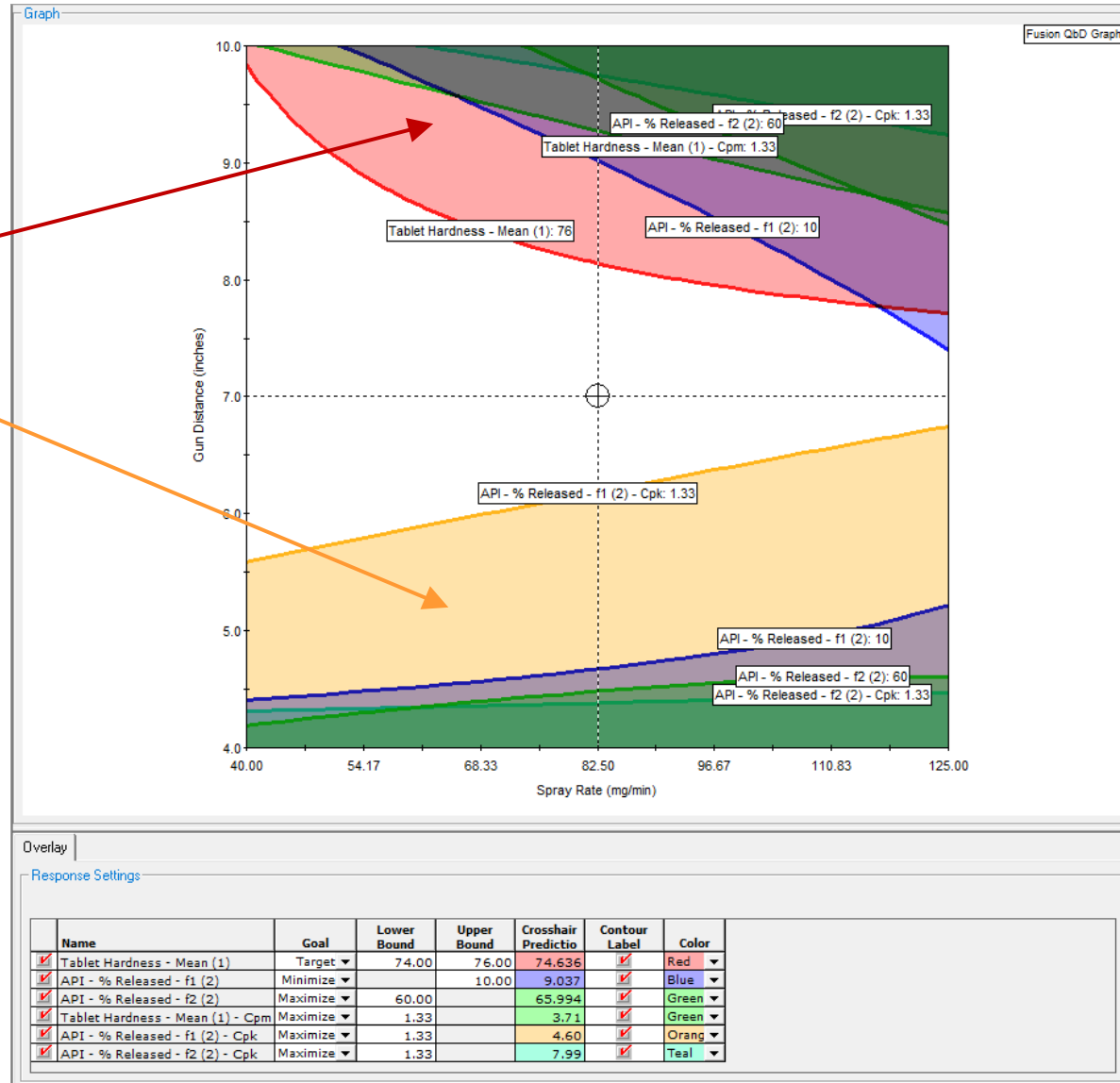
1. Select the metric for the failure mode of your response (CQA).
2. Define the failure limit(s).

# Robustness Simulation – Performance Variation in 10,000 Runs



Region of Failure – Mean Hardness

Region of Failure – % Rel. Robustness



# Key Benefits of Fusion Process Development

Supports All Install Environments (Citrix Ready Certified)



Full 21 CFR Part 11 Compliance Support



Flexible, Automated (1-Click) Design



Full LC Testing Automation



Simplifies Handling of Complex Data



Integrated Monte Carlo Robustness



**Full QbD Reporting**





## ICH Q8(R2) – Page 22

### C. Presentations of Design Space

**Example 1:** Response graphs for dissolution are depicted as a surface plot (Figure 1a) and a contour plot (Figure 1b). Parameters 1 and 2 are factors of a granulation operation that affect the dissolution rate of a tablet (e.g., excipient attribute, water amount, granule size.)

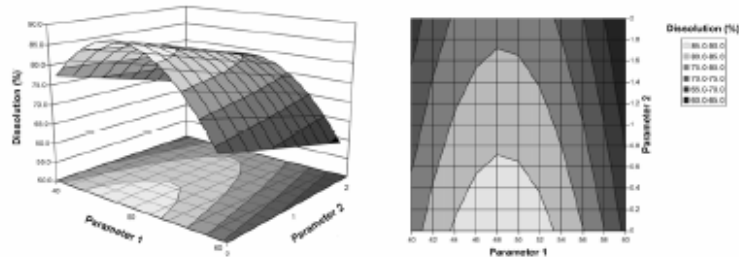


Figure 1a: Response surface plot of dissolution as a function of two parameters of a granulation operation. Dissolution above 80% is desired.

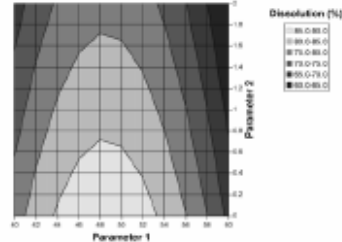


Figure 1b: Contour plot of dissolution from example 1a.

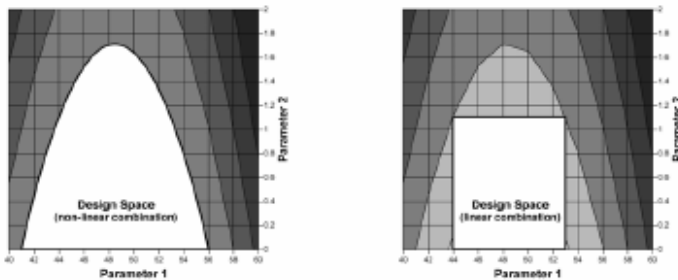


Figure 1c: Design space for granulation parameters, defined by a nonlinear combination of their ranges, that delivers satisfactory dissolution (i.e., >80%).

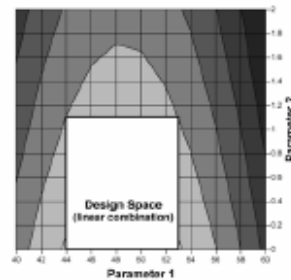


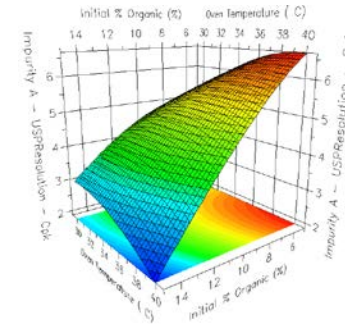
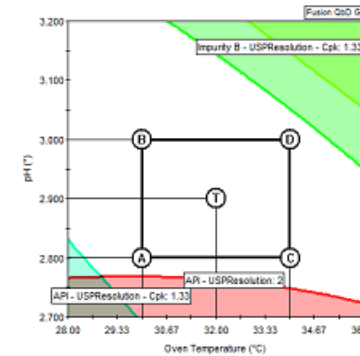
Figure 1d: Design space for granulation parameters, defined by a linear combination of their ranges, that delivers satisfactory dissolution (i.e., >80%).

## Fusion QbD

Name: Administrator  
Company: S-Matrix  
Project: Project 1  
Date: October 29, 2015 6:31:03 PM PDT [GMT-07:00]



### D.S. + PARs - 10% Organic



### Proven Acceptable Range Settings

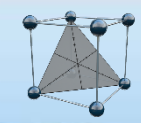
Axis	Name	Units	Lower Bound	Upper Bound	Centerpoint
X	Oven Temperature	°C	30.00	34.00	32.00
Y	pH	-	2.800	3.000	2.900

### Response Variable Goals

Name	Units	Goal	Lower Bound	Upper Bound	Color	Predicted Centerpoint
API - USPResolution	(*)	Maximize	2.00		Red	2.48
Impurity A - USPResolution	(*)	Maximize	2.00		Blue	3.88
Impurity B - USPResolution	(*)	Maximize	2.00		Green	2.39
API - USP Tailing	(*)	Target	0.90	1.10	Orange	1.01
API - USPResolution - Cpk	(*)	Maximize	1.33		Teal	3.88
Impurity A - USPResolution - Cpk	(*)	Maximize	1.33		Purple	6.44
Impurity B - USPResolution - Cpk	(*)	Maximize	1.33		Light	4.88
API - USP Tailing - Cpm	(*)	Maximize	1.33		Sky	5.40

### Graph Variable Settings

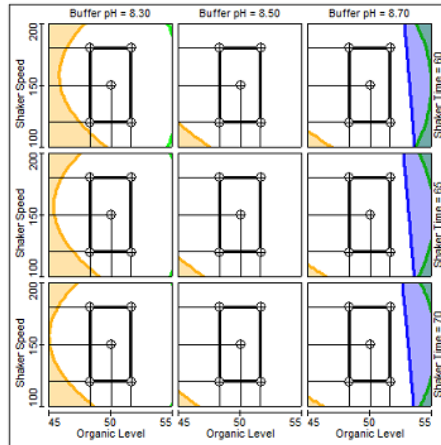
Name	Units	Graph Setting	Range/Level(s)
Oven Temperature (°C)	X Axis Variable		28.00 ⇐ Oven Temperature ⇐ 36.00
pH	Y Axis Variable		2.700 ⇐ pH ⇐ 3.200
Initial % Organic (%)	Constant		8.7



Name: Administrator  
 Company: S-Matrix  
 Project: API Assay Method (User Defined)  
 Date: 21 JUL 2020 07:35:03 PDT [UTC-07:00]



## Robust Design Space Trellis



### Response Variable Goals

Name	Units	Goal	Color	Lower Bound	Upper Bound
API 1 - %L.C.-(1_1)	-	Target	Red	97.50	99.50
API 2 - %L.C.-(1_2)	-	Target	Blue	98.70	100.70
API 1 - %L.C.-(1_1) - Cpm		Maximize	Orange	1.33	
API 2 - %L.C.-(1_2) - Cpm		Maximize	Green	1.33	

### Proven Acceptable Range Settings

Axis	Name	Units	Lower Bound	Upper Bound	Centerpoint
X	Organic Level	%	48	52	50
Y	Shaker Speed	rpm	120	180	150

### Trellis Variable Settings

Series	Variable Name	Units	Low	Middle	High
Horizontal	Buffer pH	-	8.30	8.50	8.70
Vertical	Shaker Time	min	60	66	70

### Graph Variable Goals

Name	Units	Graph Setting	Range/Level(s)
Organic Level	%	X Axis Variable	45 <= Organic Level <= 55
Sonication Time	min	Constant	0
Shaker Speed	rpm	Y Axis Variable	100 <= Shaker Speed <= 200
Buffer pH	-	Horizontal Trellis Levels	8.30, 8.50, 8.70
Shaker Time	min	Vertical Trellis Levels	60, 66, 70

### Experiment Variables for Robustness Simulator

Included	Variable Name	Units	Maximum Expected Variation (+/- 3 Sigma Value)
Yes	Buffer pH	-	0.20
Yes	Organic Level	%	2
No	Sonication Time	min	
Yes	Shaker Speed	rpm	5
Yes	Shaker Time	min	2

### Responses for Robustness Simulator

Response Name	Robustness Index	Specification Limit (+/- distance from target)	LSL	USL	Target	Additional Error	Additional Error Amount (+/- 3 Sigma Value)
API 1 - %L.C.-(1_1)	Cpm	1.00	---	---	98.50	None	None
API 2 - %L.C.-(1_2)	Cpm	1.00	---	---	99.70	None	None

### Report Settings

Setting	Value
Report Name	Robust Design Space Trellis
Action	Report Created
Report Type	Trellis Graph
Graph Category	Process
Include PARs	Checked
Include Verification Runs	Unchecked
Include Verification Runs in Report	Unchecked

Reports can be output in a variety of file formats:

PDF / MS Word / HTML / TXT / XLSX

# Example Applications

**Tablet Coating Optimization**

**Tablet Excipient Formulation and Process Optimization**

# Example 1 – Tablet Coater Optimization

## Tablet Coater Processes Optimization Study

**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	Lower Bound	Upper Bound
Atomizing Air Pressure	psi	Continuous	10.0	50.0
Pattern Air Pressure	psi	Continuous	0.0	55.0
Spray Rate	mg/min	Continuous	40.0	125.0
Gun Distance	inches	Continuous	4.0	10.0

State

Variable

Constant

# 4-Factor Trellis – Mean Performance and Robustness

**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

**Reports**

Final Design Space + PARs

Axis Variable	Units	Lower Bound	Upper Bound
X Atomizing Air Pressure (A)	psi	10.0	50.0
Y Pattern Air Pressure (B)	psi	0.0	55.0

**Horizontal Trellis Variable**

Spray Rate (C)

	mg/min
Low	40.0
Middle	50.0
High	60.0

**Vertical Trellis Variable**

Gun Distance (D)

	inches
Low	6.0
Middle	7.0
High	8.0

**Verification Run Settings**

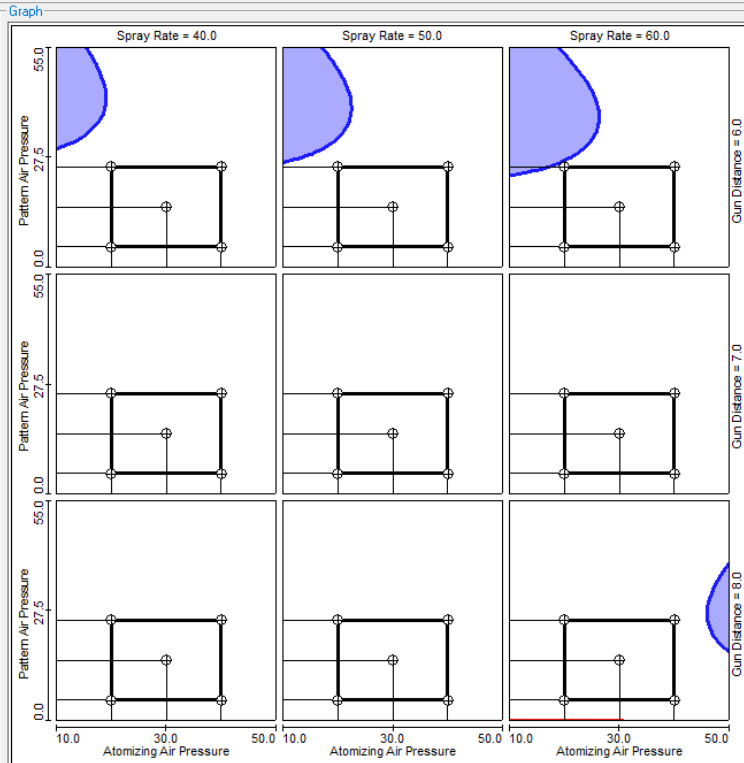
Include Independently Adjustable Ranges Rectangle

Variable	Lower Bound	Upper Bound	Center Point	Pointer Coordinate
Atomizing Air Pressure	20.0	40.0	30.0	
Pattern Air Pressure	5.0	25.0	15.0	

Include Verification Runs

Validation Status: Your settings are valid.

**Graph**

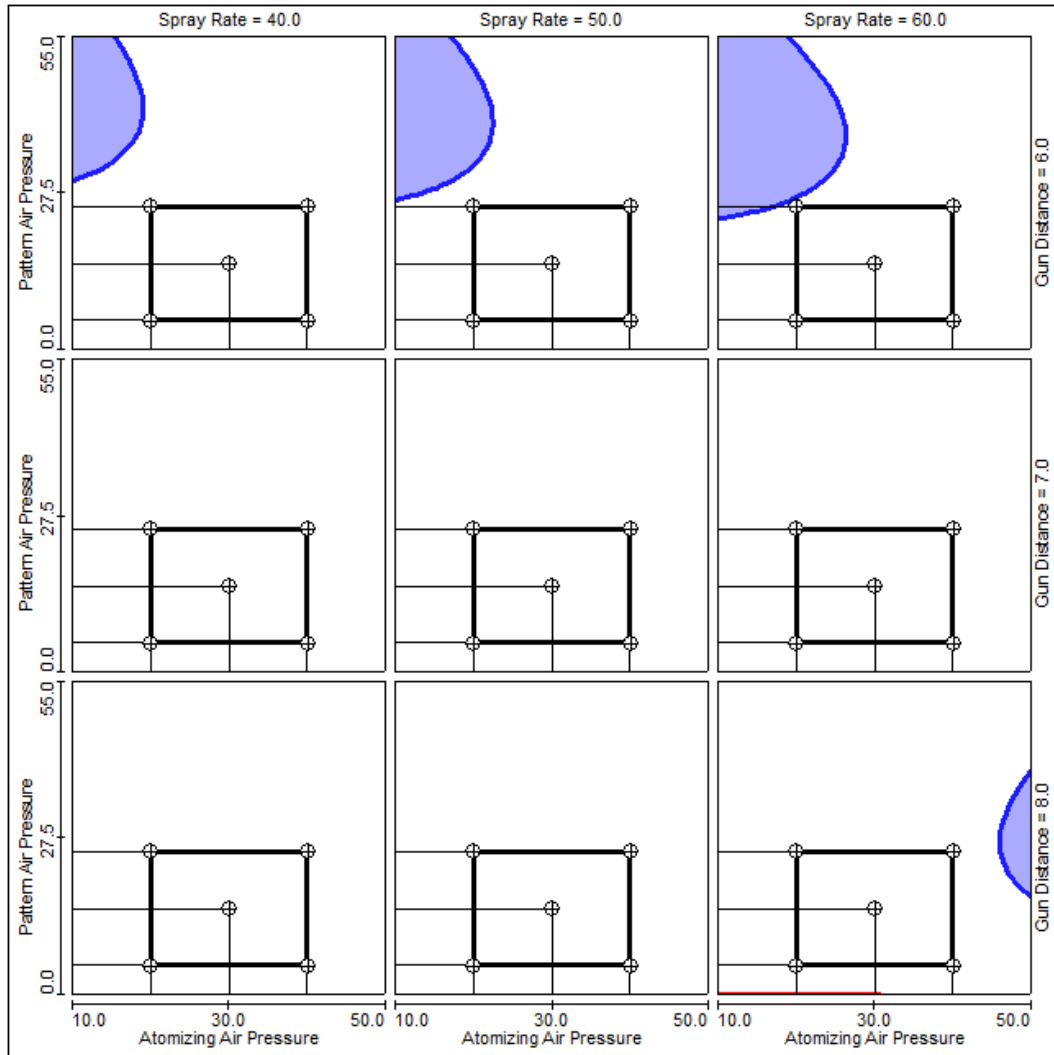


**Overlay**

**Response Settings**

Name	Goal	Lower Bound	Upper Bound	Color
Tablet Hardness - Mean (1)	Target	74.00	76.00	Red
API - % Released - f1 (2)	Minimize		10.00	Blue
API - % Released - f2 (2)	Maximize	60.00		Green
Tablet Hardness - Mean (1) - Cpm	Maximize	1.33		Orange
API - % Released - f1 (2) - Cpk	Maximize	1.33		Teal
API - % Released - f2 (2) - Cpk	Maximize	1.33		Purple

# 4-Factor Trellis – Mean Performance and Robustness



## Independently Adjustable Ranges

Variable	Lower Bound	Upper Bound	Center Point
Atomizing Air Pressure	20.0	40.0	30.0
Pattern Air Pressure	5.0	25.0	15.0

Spray Rate	40	60	50
Gun Distance	6	8	7

# Example 2 – Tablet Excipient Formulation and Critical Process Factor Optimization

## Formulation + Processes Optimization Study

**Experiment Setup**

Experiment Type: Optimization

Mixture Variable Settings

No. of Mixture Variables: 4

Units: %      Mixture Amount: 100.00

Mixture Variable	State	Lower Bound	Upper Bound
Starch	Variable	2.00	25.00
Lactose	Variable	2.00	25.00
MCC	Variable	2.00	25.00
DPI-90	Constant	75.00	---

Process Variable Settings

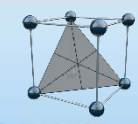
No. of Process Variables: 1

Split-plot Design (restriction on randomization)

Name	Units	Type	Lower Bound	Upper Bound
Compaction Force	kN	Continuous	9.88	20.35

State

Variable  
 Constant



Create Report  
  Update Report  
  Delete Report  
  Restore Report  
  Robustness Simulator  
  Export

**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

---

**Reports**  
 Robust Design Space  
 View as Report    Show Ternary Axis Lines

**Graph Settings**

Name	Units	Lower Bound	Upper Bound	Pointer Coordinate
X1 Starch	%	1.00	25.00	4.00
X2 Lactose	%	1.00	25.00	7.00
X3 MCC	%	1.00	25.00	16.00

  
 C\_Force

---

**Verification Run Settings**  
 Include Independently Adjustable Ranges Rectangle   Mixture Amount:  %

Variable	Lower Bound	Upper Bound	Center Point	Pointer Coordinate
Starch	2.00	6.00	4.00	4.00
Lactose	5.00	9.00	7.00	7.00
MCC	14.00	18.00	16.00	16.00

Include Verification Runs    Include Verification Runs in Report  
 Show Verification Run Labels    Include Prediction Chromatograms in Report

Point	Run ID	Starch	Lactose	MCC	C_Force
A	Robust_Design_Space_A	2.00	9.00	16.00	18.0
B	Robust_Design_Space_B	4.00	9.00	14.00	18.0
C	Robust_Design_Space_C	6.00	7.00	14.00	18.0
D	Robust_Design_Space_D	6.00	5.00	16.00	18.0
E	Robust_Design_Space_E	4.00	5.00	18.00	18.0
F	Robust_Design_Space_F	2.00	7.00	18.00	18.0
T	Robust_Design_Space_T	4.00	7.00	16.00	18.0
Crosshair	Robust_Design_Space_Cross	4.00	7.00	16.00	18.0

Validation Status: Your settings are valid.

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**Graph**  
 Fusion QbD Graph

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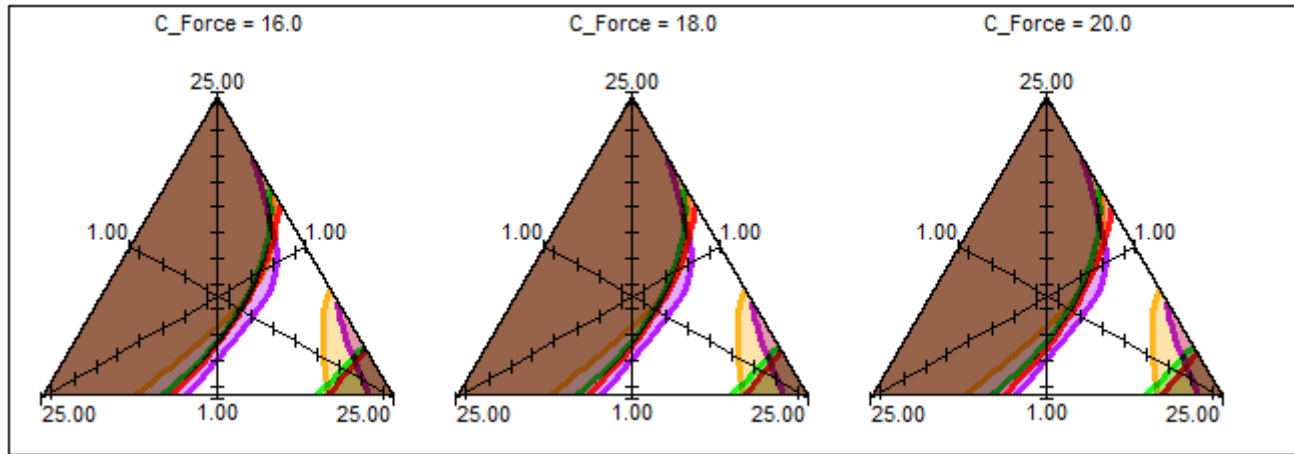
**Overlay**  
**Response Settings**

Name	Goal	Lower Bound	Upper Bound	Crosshair Prediction	Contour Label	Color
<input checked="" type="checkbox"/> %Released @ 30 min.	Target	8.00	12.00	10.230		Green
<input checked="" type="checkbox"/> %Released @ 60 min.	Target	23.00	27.00	25.049		Red
<input checked="" type="checkbox"/> Friability	Minimize	1.751	2.00	1.589		Blue
<input checked="" type="checkbox"/> %Released @ 30 min. - Cpm	Maximize	1.33	4.147	4.147		Purple
<input checked="" type="checkbox"/> %Released @ 60 min. - Cpm	Maximize	1.33	1.682	1.682		Orange
<input checked="" type="checkbox"/> Friability - Cpk	Maximize	1.33	5.897	10.648		Teal

Ready modified



# 4-Factor Trellis – Mean Performance and Robustness



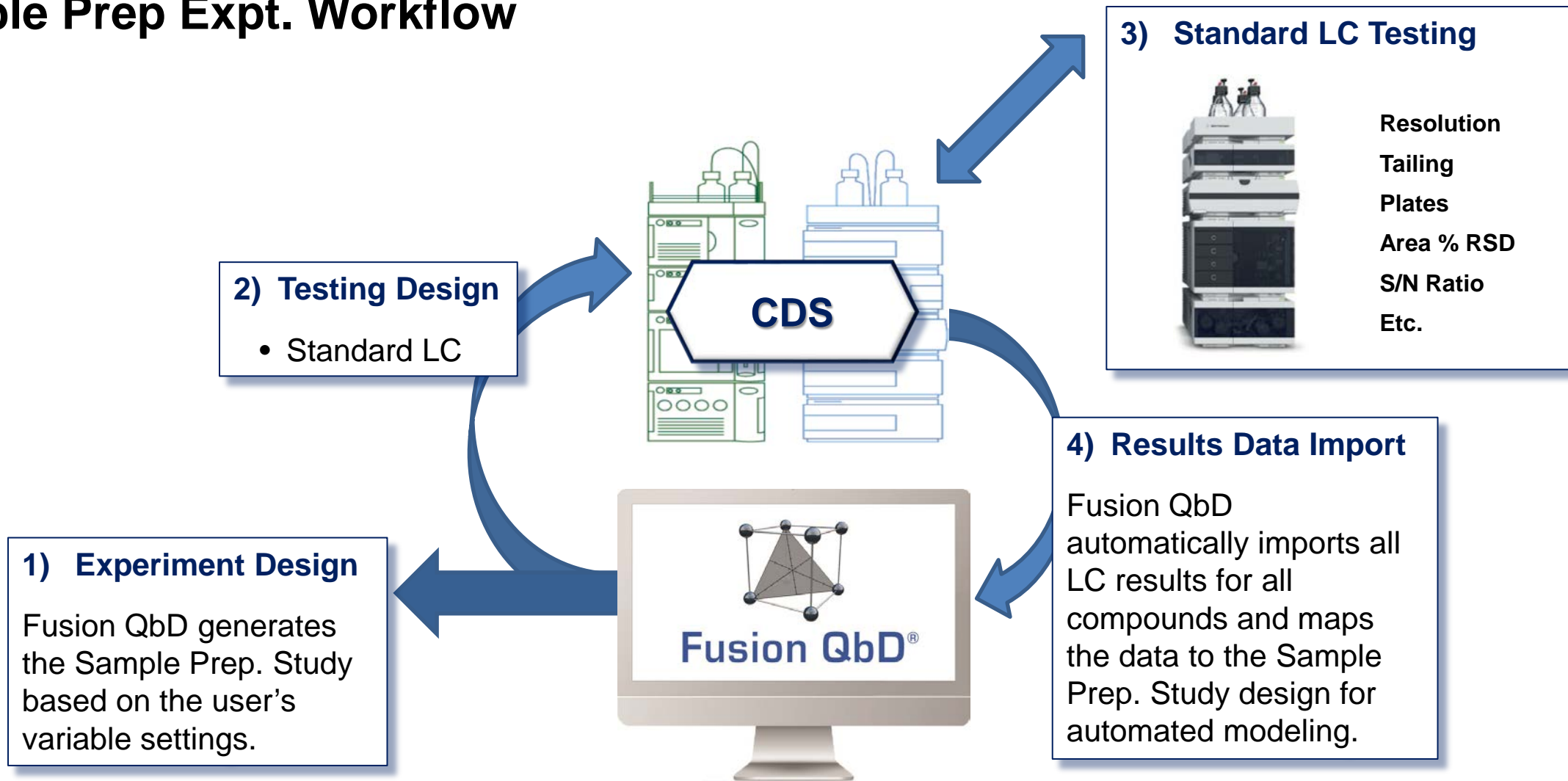
## Independently Adjustable Ranges

Variable	Lower Bound	Upper Bound	Center Point
Starch	2.00	6.00	4.00
Lactose	5.00	9.00	7.00
MCC	14.00	18.00	16.00
Compaction Force	16	20	18

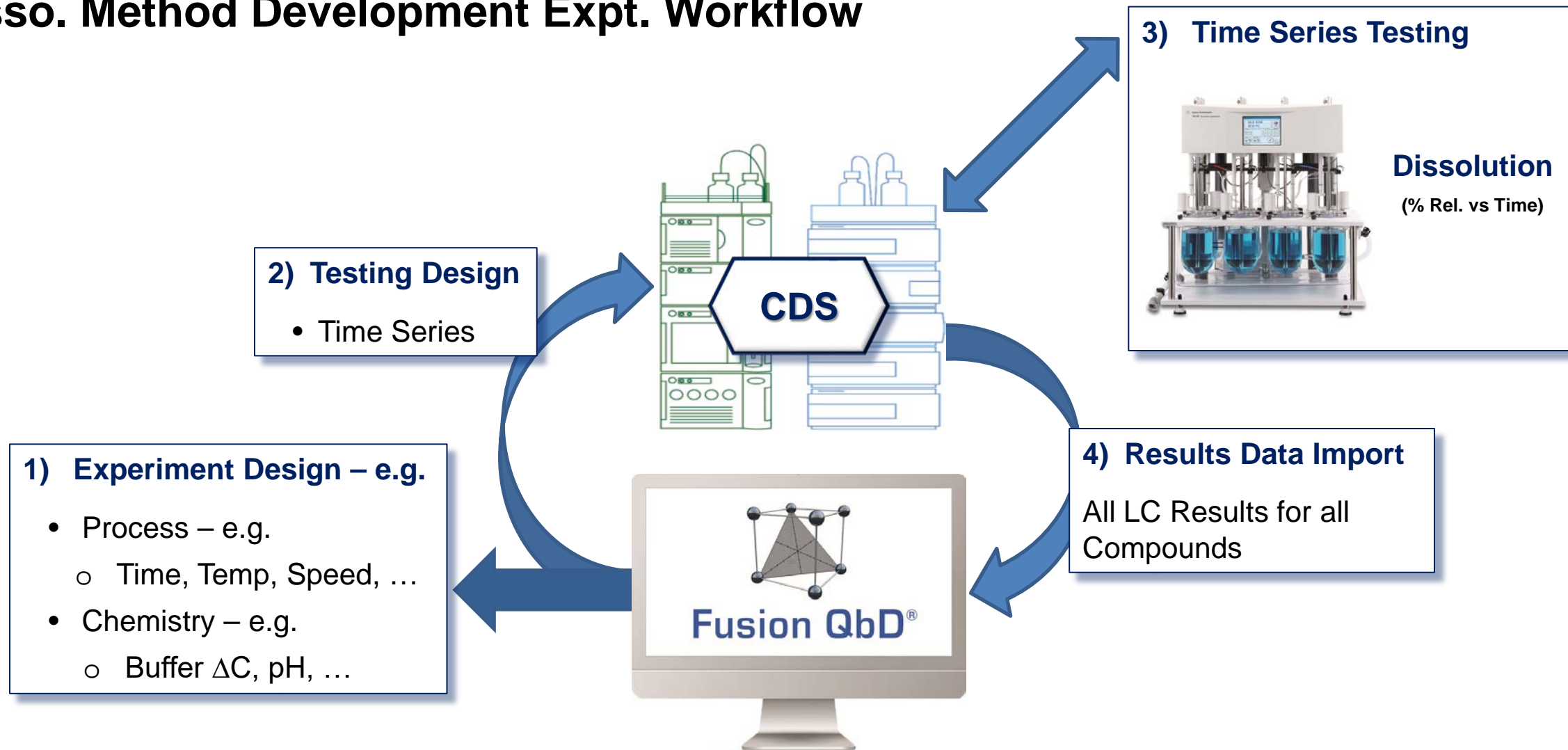
# Example Workflows

- **Sample Preparation Method Development**
- **Dissolution Method Development**
- **Respiratory Drug Development**

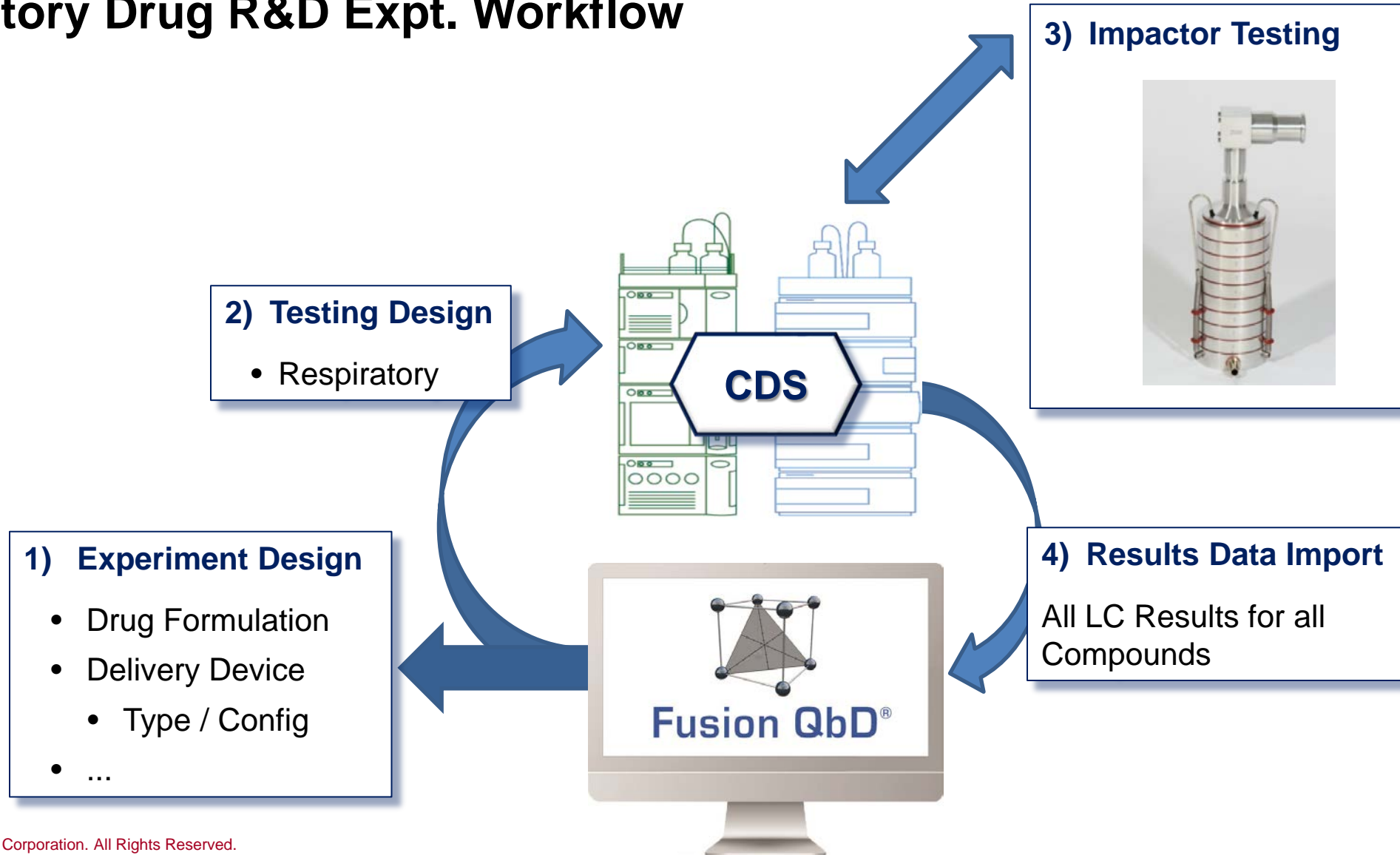
## Sample Prep Expt. Workflow



## Disso. Method Development Expt. Workflow

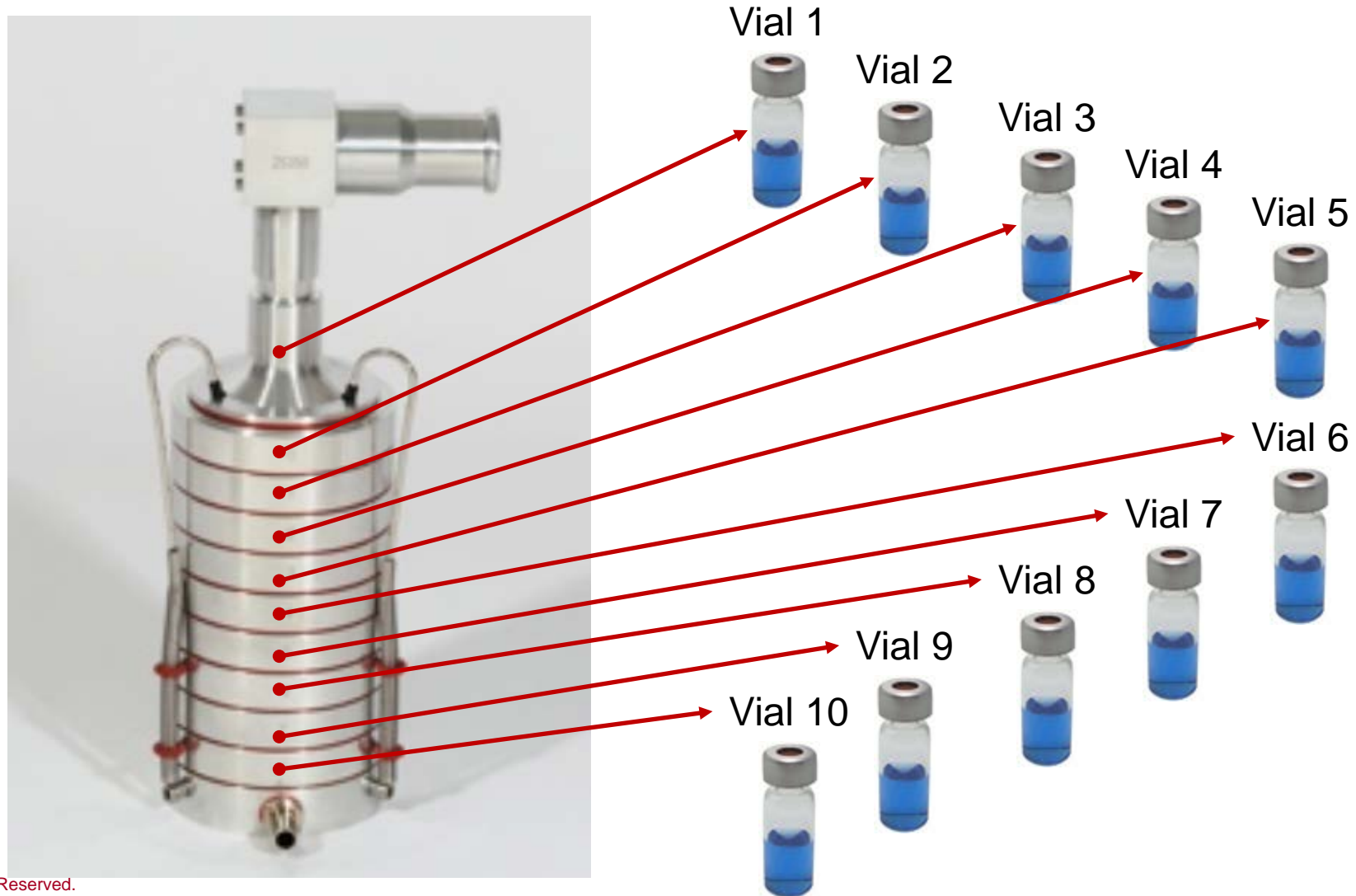


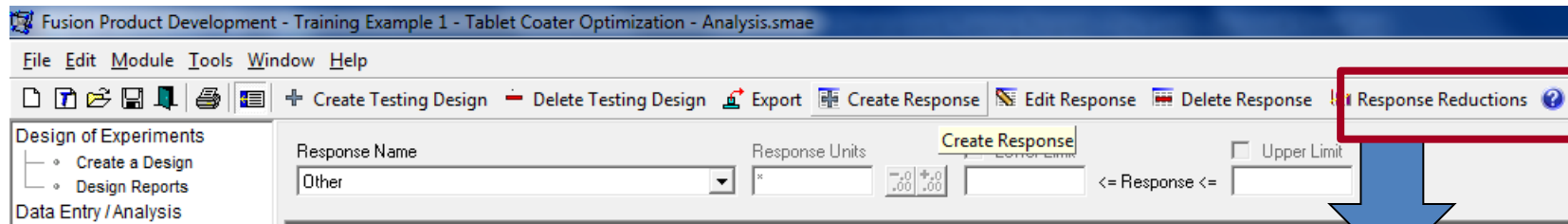
## Respiratory Drug R&D Expt. Workflow



# FPD – Respiratory Drug R&D

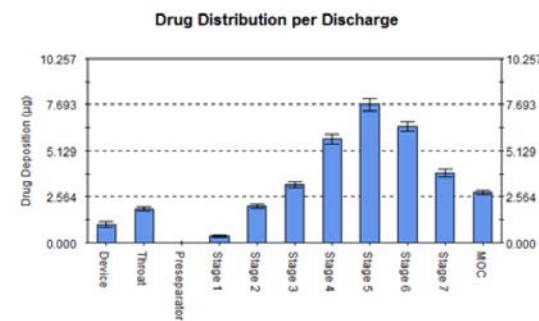
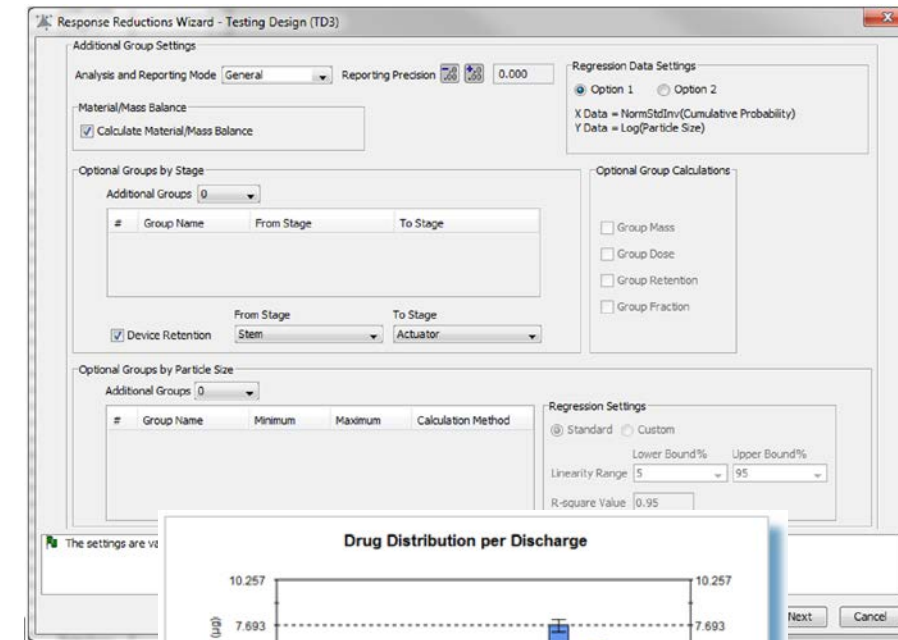
## LC Testing Demand for Each Experiment Run



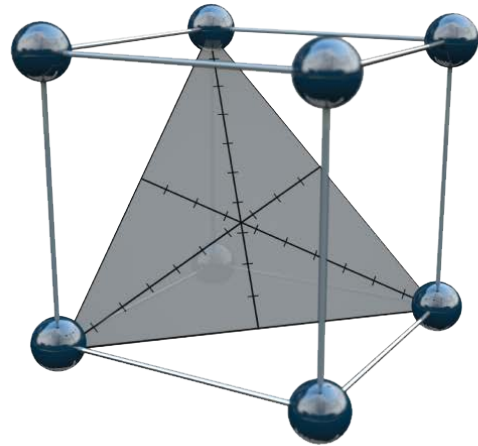


## Coordinated Response Reductions:

- Mass Median Aerodynamic Diameter (MMAD)
- Geometric Standard Deviation (GSD)
- Fine Particle Dose (FPD)
- Fine Particle Fraction (FPF)
- Total Dose and Emitted Dose
- Interpolation and Regression Calc Options
- Data Grouping Options
- ...



# *End of Presentation*



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