S-Matrix®

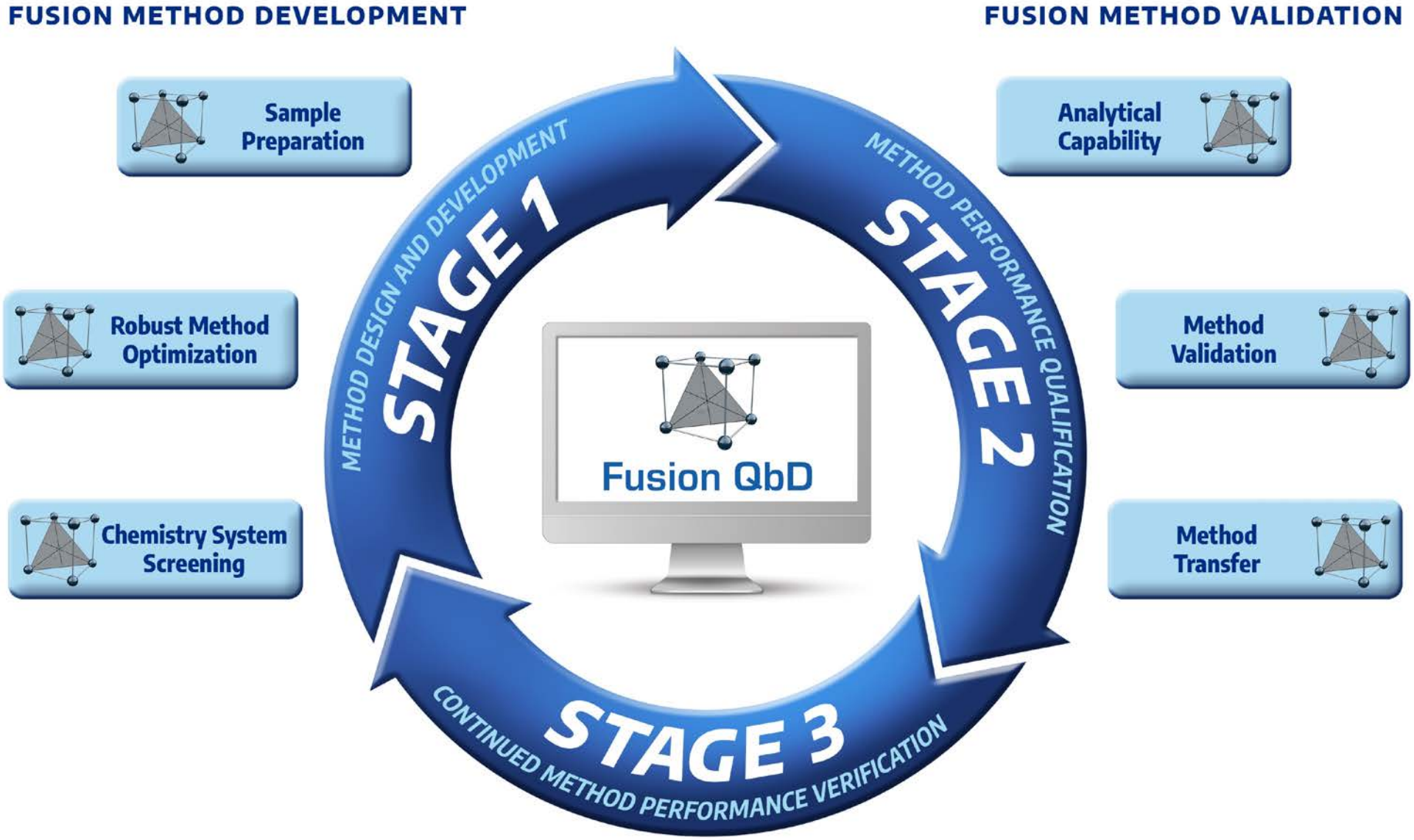
Fusion QbD

Advanced QbD Software for Analytical Method Validation and Transfer

S-Matrix Corporation

www.smatrix.com

A Complete Solution for APLM Stages 1 and 2



A Complete Solution for APLM Stage 2

METHOD VALIDATION MODULE

- Full Validation Experiment Suite
- Instant Analysis and Reporting
- Advanced Method Transfer Support
- Meets all Regulatory Requirements

All the Critical QbD Capabilities You Need

Critical QbD Capability	FMV
Supports All Install Environments (Citrix Certified)	✓
Full 21 CFR Part 11 Compliance Support	✓
Complete Method Validation Experiment Suite	✓
Simple Experiment Workflows	✓
Full LC Experiment Automation	✓
USP 1210> Tolerance and Prediction Interval Metrics	✓

- Analytical Capability
- Accuracy and Repeatability
- Analytical Method Transfer

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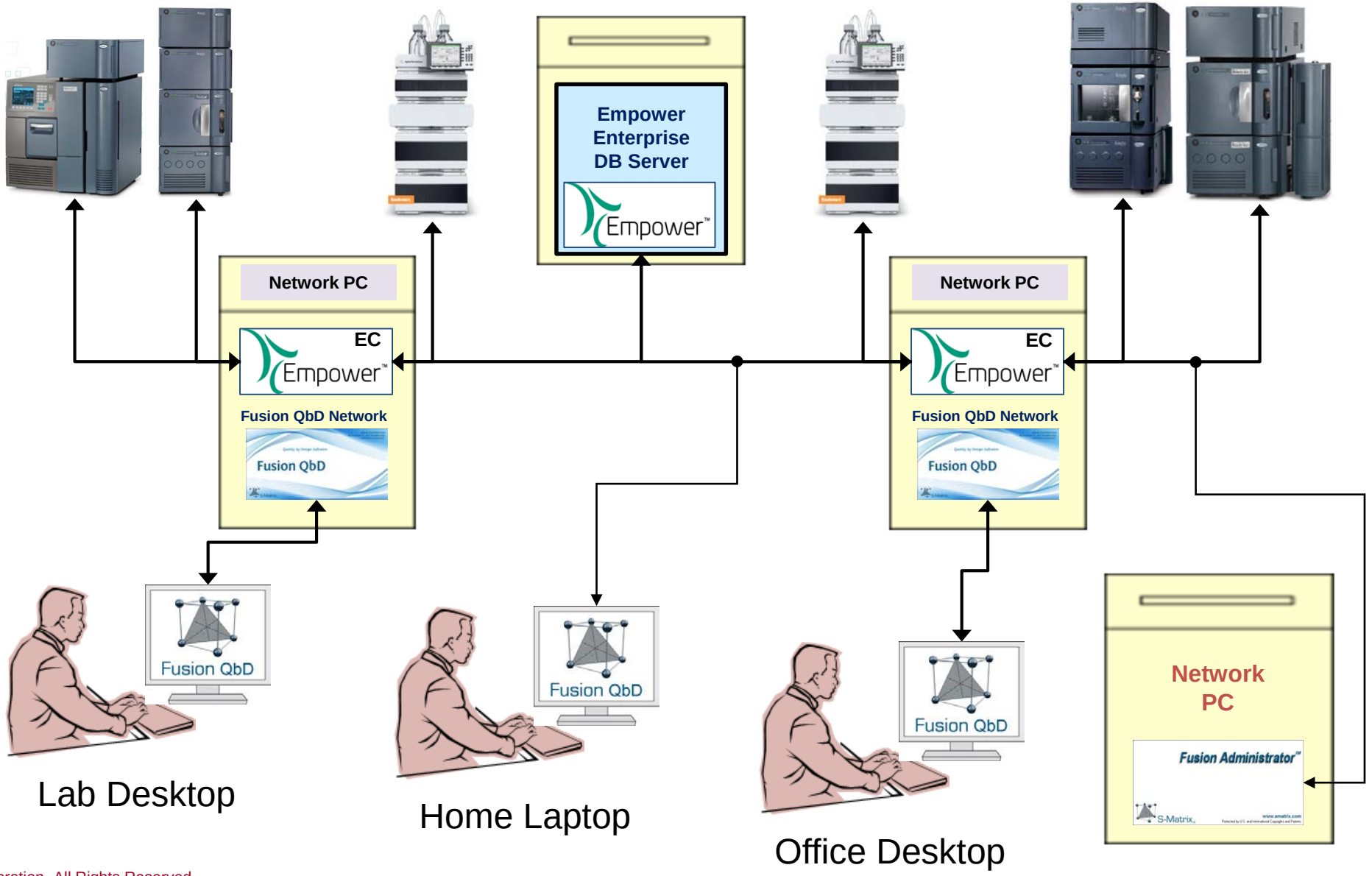
- Analytical Method Transfer

Supports All Install Environments

Install Environment	FMV
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.

Example Network Deployment



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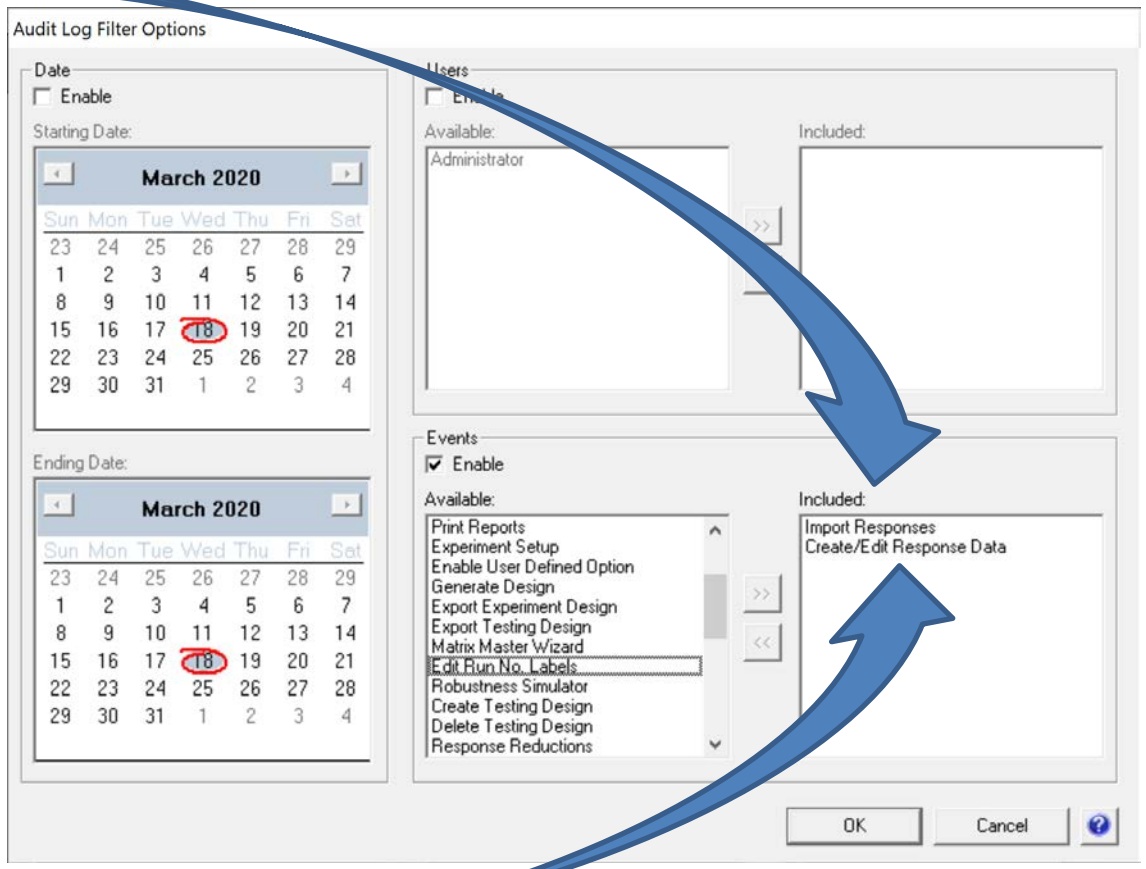
Full Part 11 Compliance Support

Full Support for 21 CFR 11 Compliance	FMV
Full integration of all e-record and all e-signature features and functions required to support full 21 CFR 11 compliance.	✓
Integrated Workflow Management and Secure Project Management Systems.	✓
Full audit trail, including bi-directional auditing of all data exchanges with the CDS.	✓

Why Audit Trail is Important!

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

Who imported this data – was the data modified?



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- Analytical Capability
- Accuracy and Repeatability
- Analytical Method Transfer

Complete Method Validation Experiment Suite

- Analytical Capability*
- Specificity
- Filter Validation
- Sample Solution Stability
- Accuracy*
- Linearity & Range
- Repeatability*
- Accuracy / Linearity / Repeatability*

  [Combined as per ICH Q2(R1)]
- LOQ*, LOD*
- Intermediate Precision and Reproducibility
- Validation Robustness – LC
- Validation Robustness – Non-LC

  [e.g. Sample Preparation, Dissolution]
- Method Transfer Study Support*

* – integration of USP <1210> Tolerance & Prediction Intervals]

All the Critical QbD Capabilities You Need

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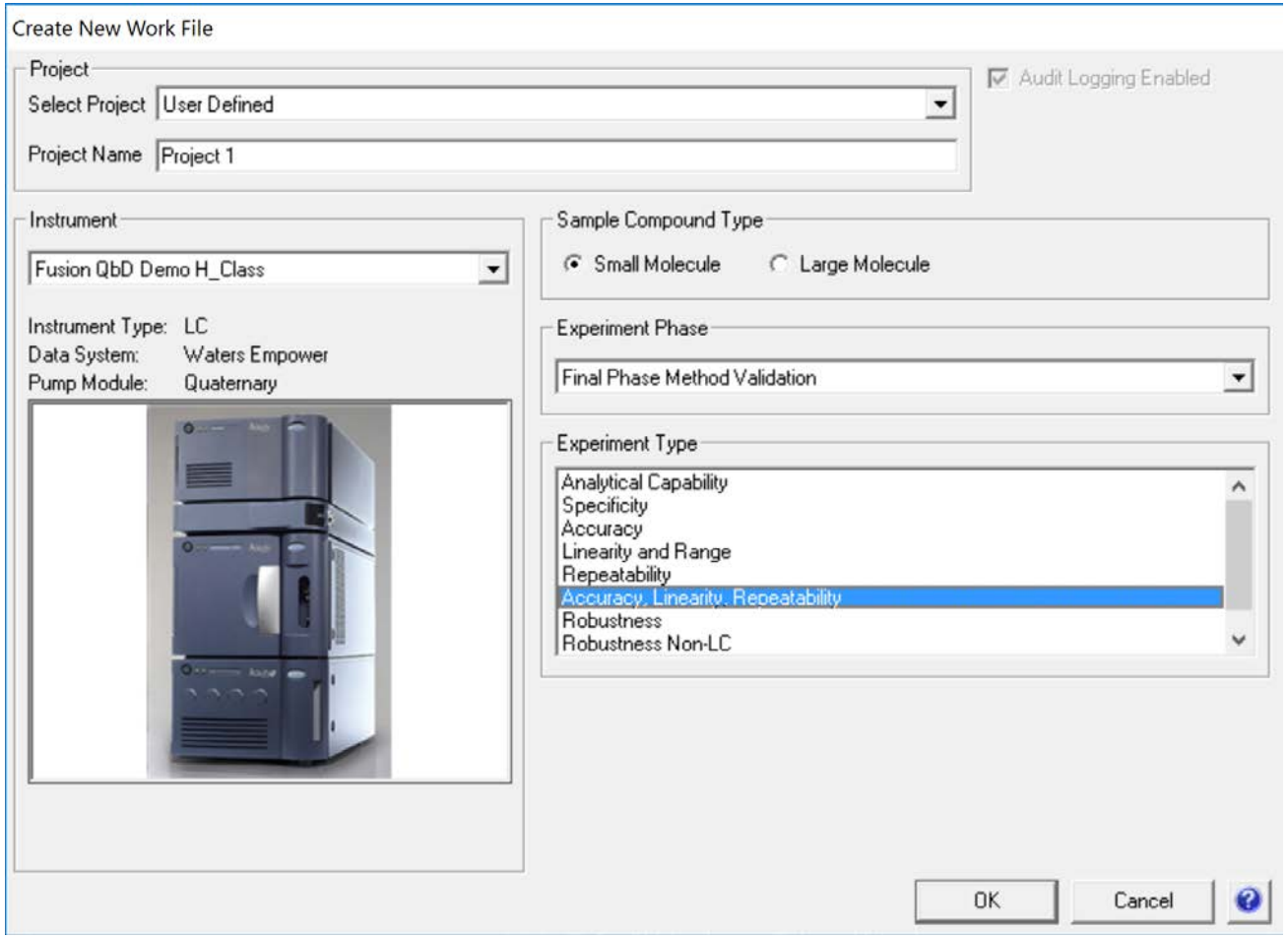
- Analytical Capability
- Accuracy and Repeatability
- Analytical Method Transfer

Simple Workflow with Complete QbD Reporting

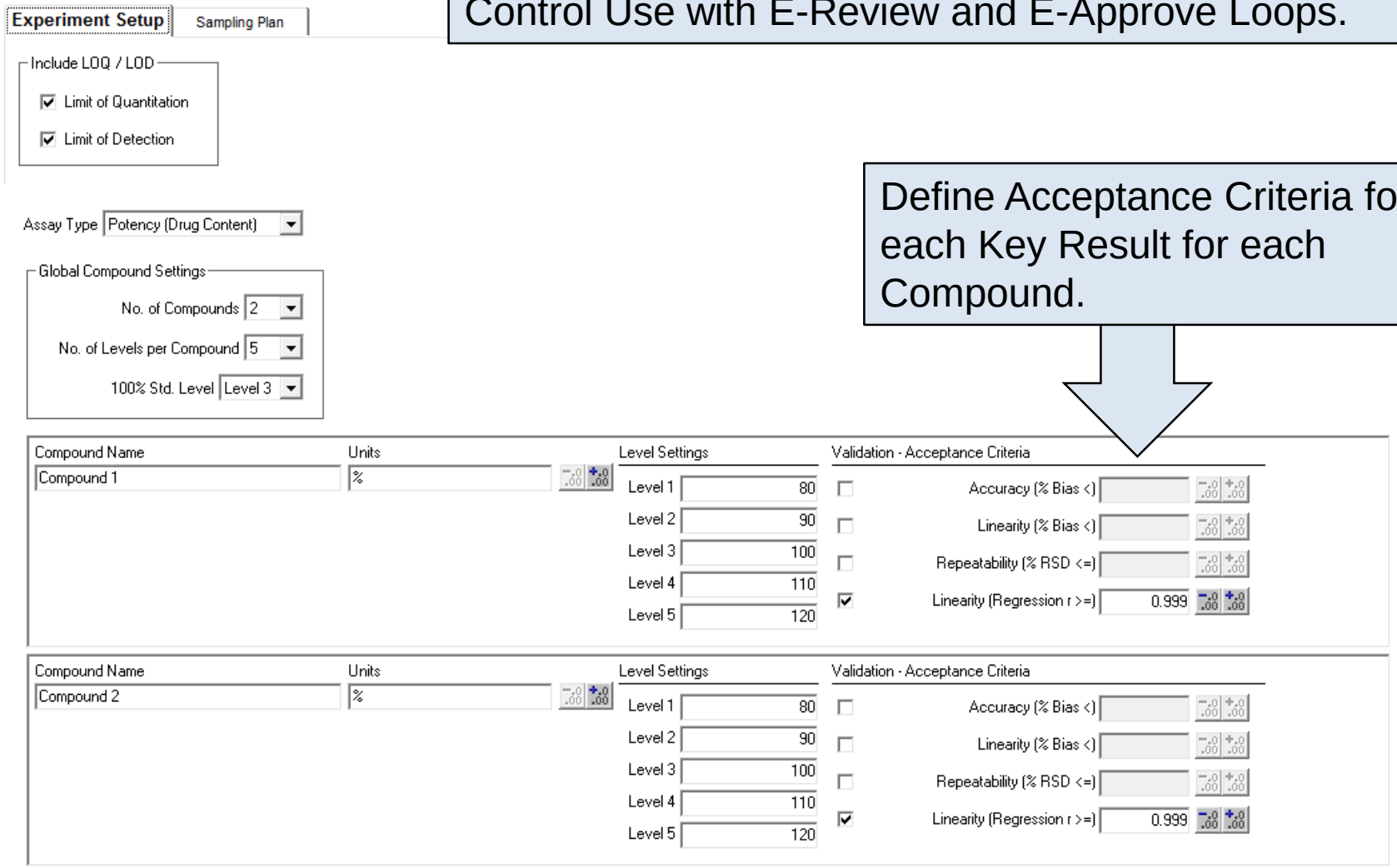
Example: Accuracy / Linearity / Repeatability – Combined Experiment



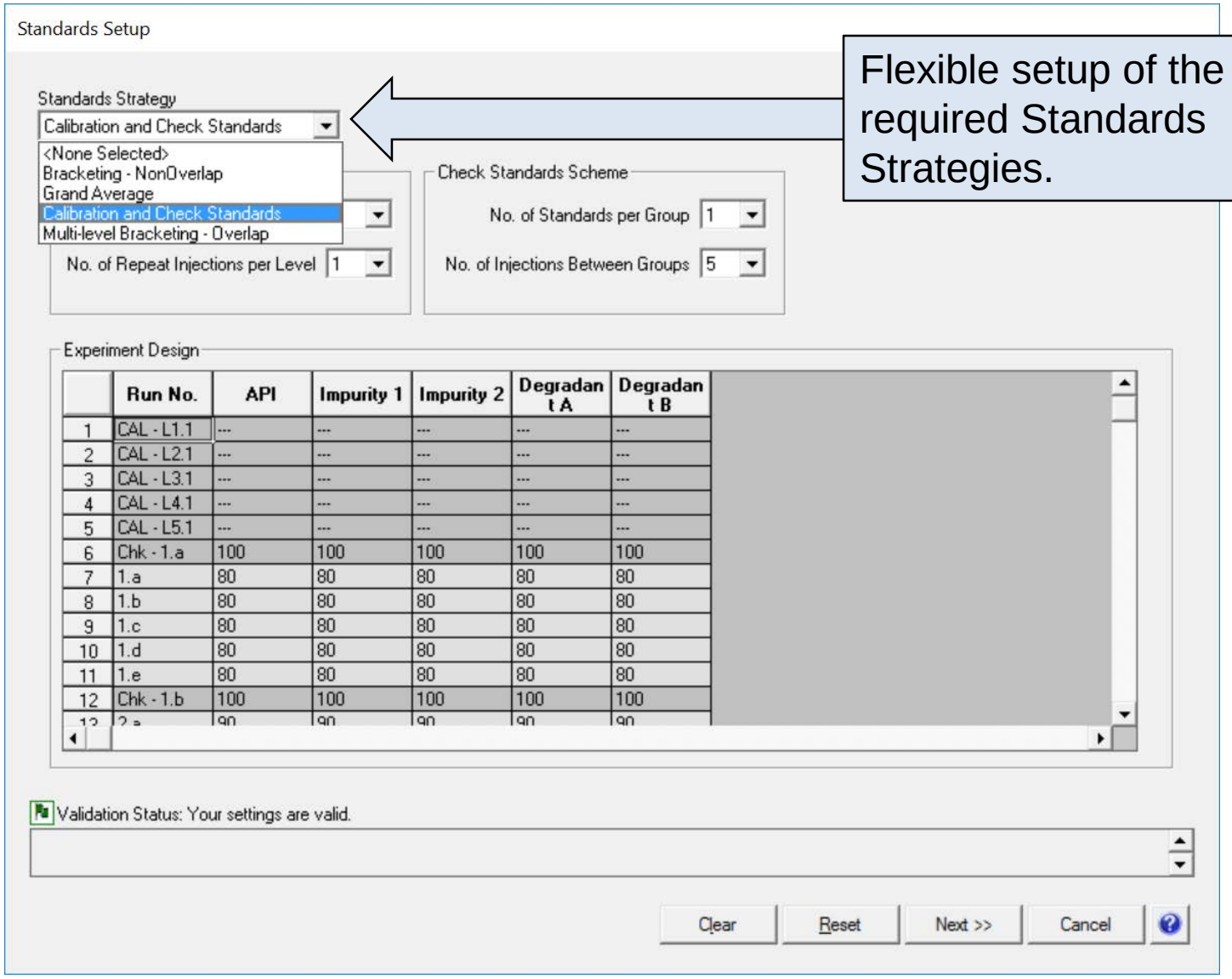
1. Simple Experiment Setup Template

Create and Maintain Templates.
Control Use with E-Review and E-Approve Loops.

Define Acceptance Criteria for each Key Result for each Compound.

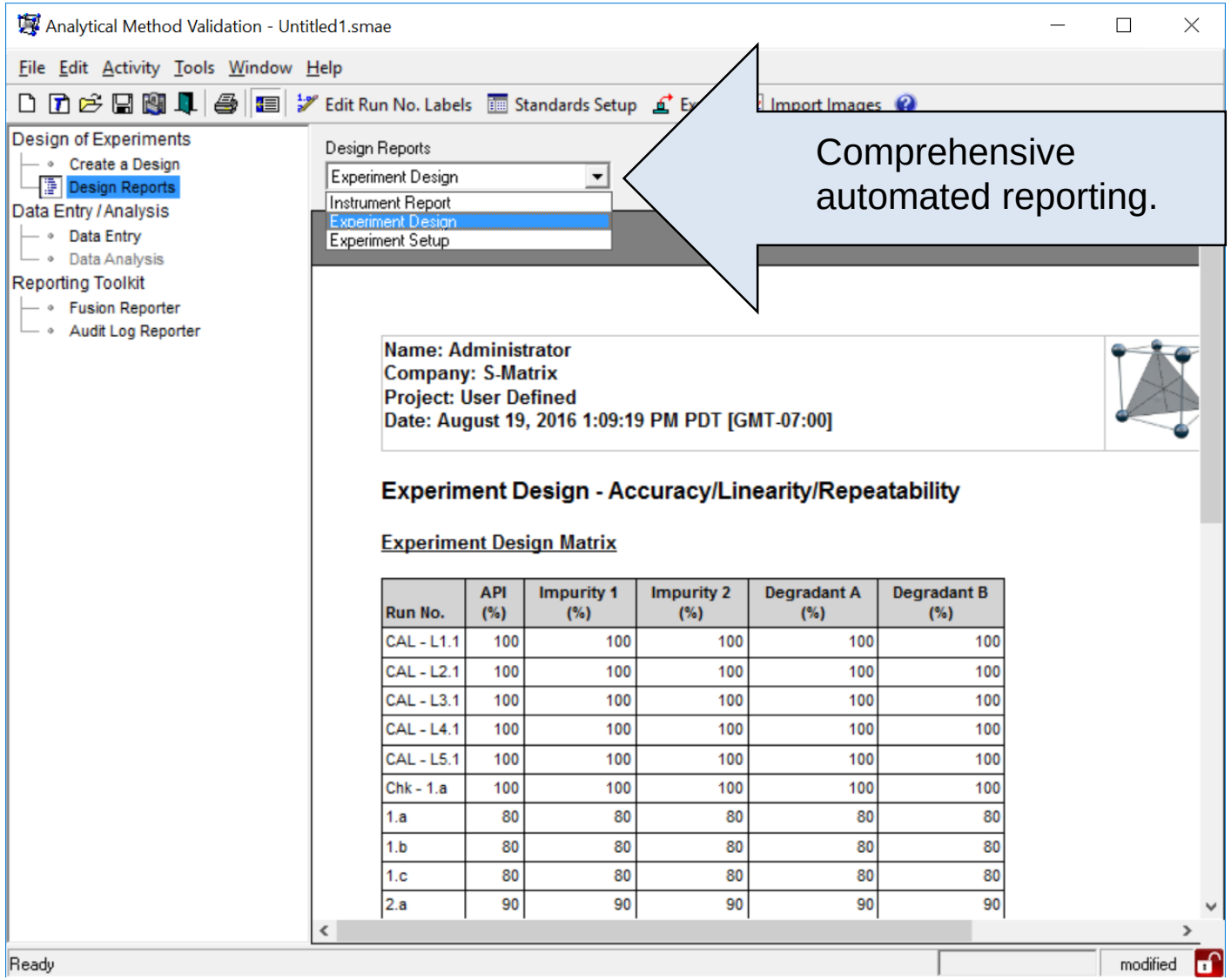


2. Standards Setup Options

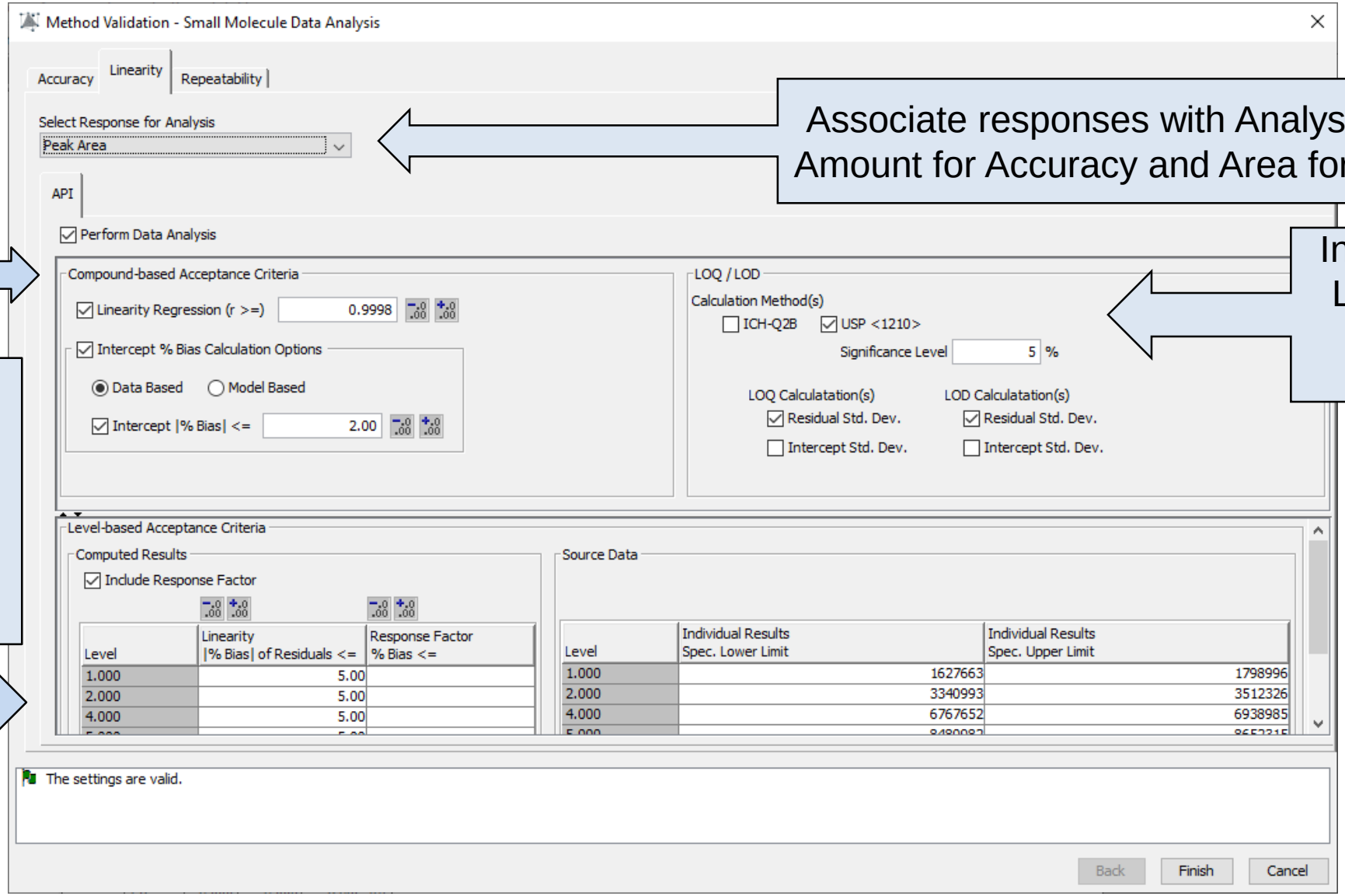


Flexible setup of the required Standards Strategies.

3. Auto-generated Experiment Design



4. Analysis Wizard for CDS Imported Results



Associate responses with Analyses – e.g. Amount for Accuracy and Area for Linearity

Include LOQ and LOD and select Calculation Method(s)

Set Global and Level-specific Acceptance Criteria, including Spec Limits for Data

5. Instant Analysis, Graphing, and Reporting

Name: Administrator
Company: S-Matrix Corporation
Project: Project 1
Date: October 13, 2012 3:51:17 PM PDT (GMT-07:00)

Linearity and Range Report: API - Amount (mg)

Linearity and Range Data Table

Run No.	Target API (mg)	Actual Amount (mg)	API - Amount
1.a	1.000	1.009	1.091
1.b	1.000	1.01	1.092
1.c	1.000	1.012	1.103
2.a	2.000	1.995	2.109
2.b	2.000	1.99	2.099
2.c	2.000	2.004	2.049
3.a	4.000	3.999	4.119
3.b	4.000	4	4.097
3.c	4.000	3.997	4.099
4.a	5.000	5.005	5.107
4.b	5.000	4.992	5.094
4.c	5.000	5.009	5.065
5.a	6.000	6.004	5.93
5.b	6.000	6.009	5.939
5.c	6.000	5.997	6.007

General Regression Statistics Table

Regression Statistic Name	Statistic Value	Pass / Fail
r	0.9997	Pass
R Square	0.9993	---
Adj. R Square	0.9993	---
Residual MSE	0.00059	---
Standard Error (s)	0.02592	---
+/- 95% C.I.	0.11001	---
Intercept % Bias	2.09	---
Observations	15	---

Acceptance Criterion - Regression r: > 0.9990

Regression ANOVA Statistics Table

Source of Variation	Sum of Squares	Degrees of Freedom	Mean Square	F-Ratio	P-Value
Regression	49.92199	1	49.92199	19213.2599	< 0.0001
Residual	0.03371	13	0.00259	---	---
Total	49.95570	14	---	---	---

Regression Coefficients Table

Variable Name	Coefficient Value	Coefficient Standard Error	Coefficient t Statistic	P-Value	Lower 95% Confidence Limit	Upper 95% Confidence Limit
Intercept	0.12532	0.02679	4.6800	0.0005	0.06735	0.18730
API	0.98021	0.00709	138.6119	< 0.0001	0.96799	0.99554

Natural Variable Model

API - Amount (pred) = 0.12532 + (0.98021 x API)

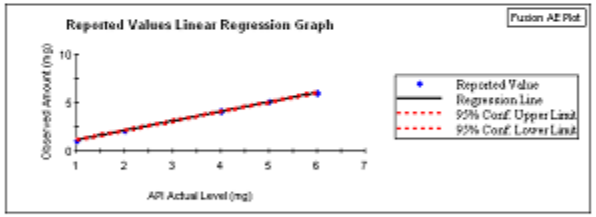
Range

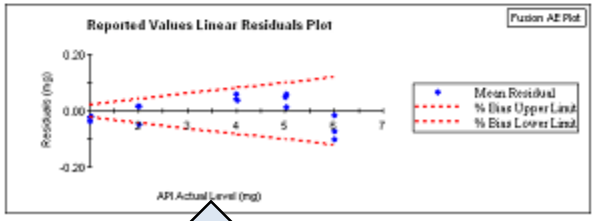
1.009 <= API <= 5.997

Residuals Table

Actual API - Amount (mg)	Predicted API - Amount	Observed API - Amount	Residuals	%Bias of Residuals	%Bias Pass / Fail
1.009	1.11149	1.091	-0.02049	-2.04	Fail
1.01	1.11257	1.092	-0.02057	-2.60	Fail
1.012	1.12059	1.103	-0.01739	-1.71	Pass
1.995	2.09983	2.109	0.01917	0.96	Pass
1.99	2.09181	2.099	0.01709	0.86	Pass
2.004	2.09399	2.049	-0.04799	-2.39	Fail
3.999	4.03921	4.119	0.08179	1.53	Pass
4	4.03917	4.097	0.03683	0.97	Pass
3.997	4.03523	4.099	0.04376	1.10	Pass
5.005	5.04930	5.107	0.06070	1.21	Pass
4.992	5.03952	5.094	0.05048	1.01	Pass
5.009	5.05304	5.065	0.01479	0.30	Pass
6.004	6.03853	5.930	-0.09853	-1.64	Pass
6.009	6.03722	5.939	-0.07192	-1.19	Pass
5.997	6.02162	6.007	-0.01462	-0.24	Pass

Acceptance Criterion: |% Bias| < 2% for each concentration tested.





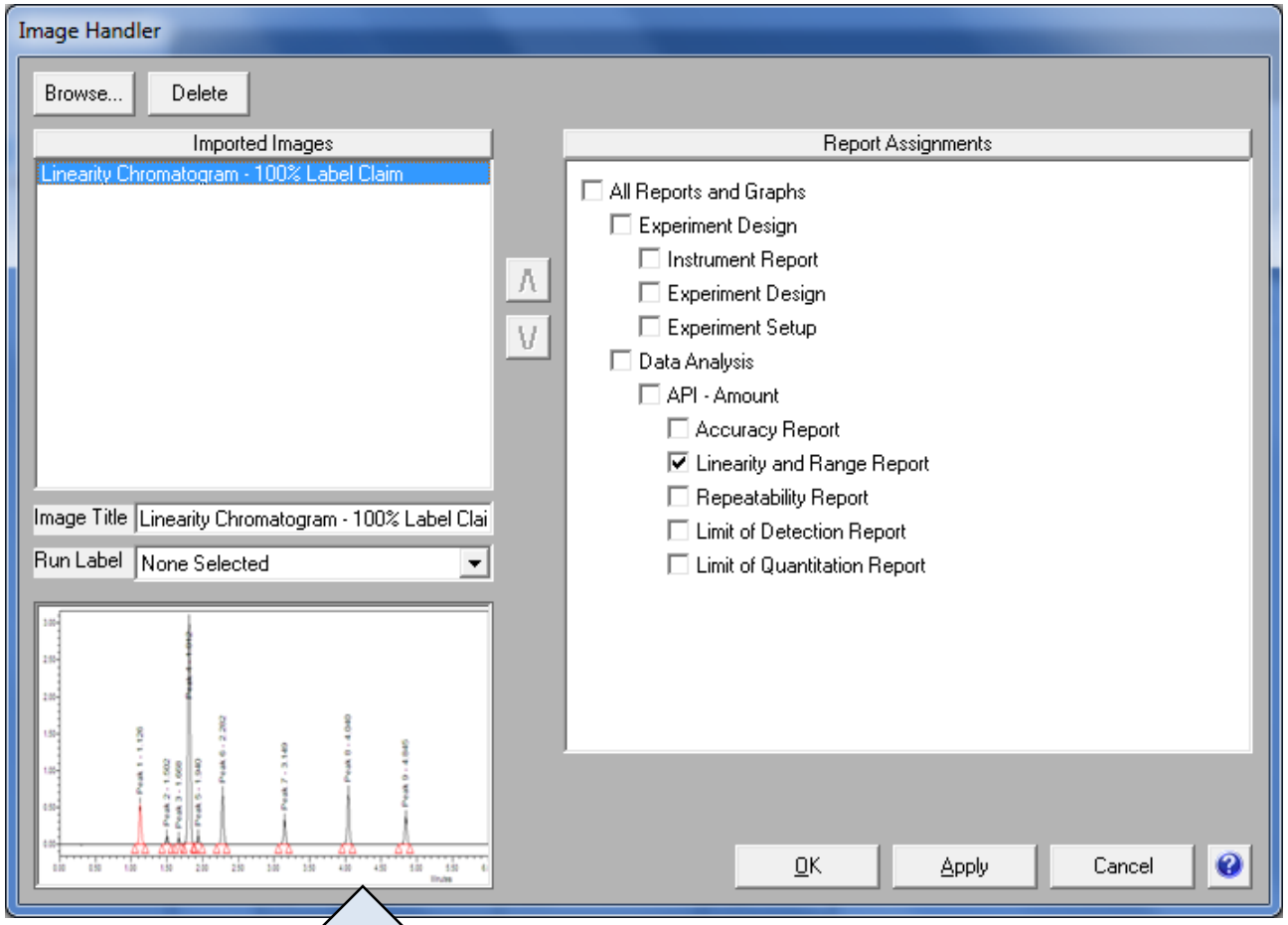
Fusion QbD instantly creates formal reports with all required tables and graphs.

5. Instant Analysis, Graphing, and Reporting

ICH Q2(R1):

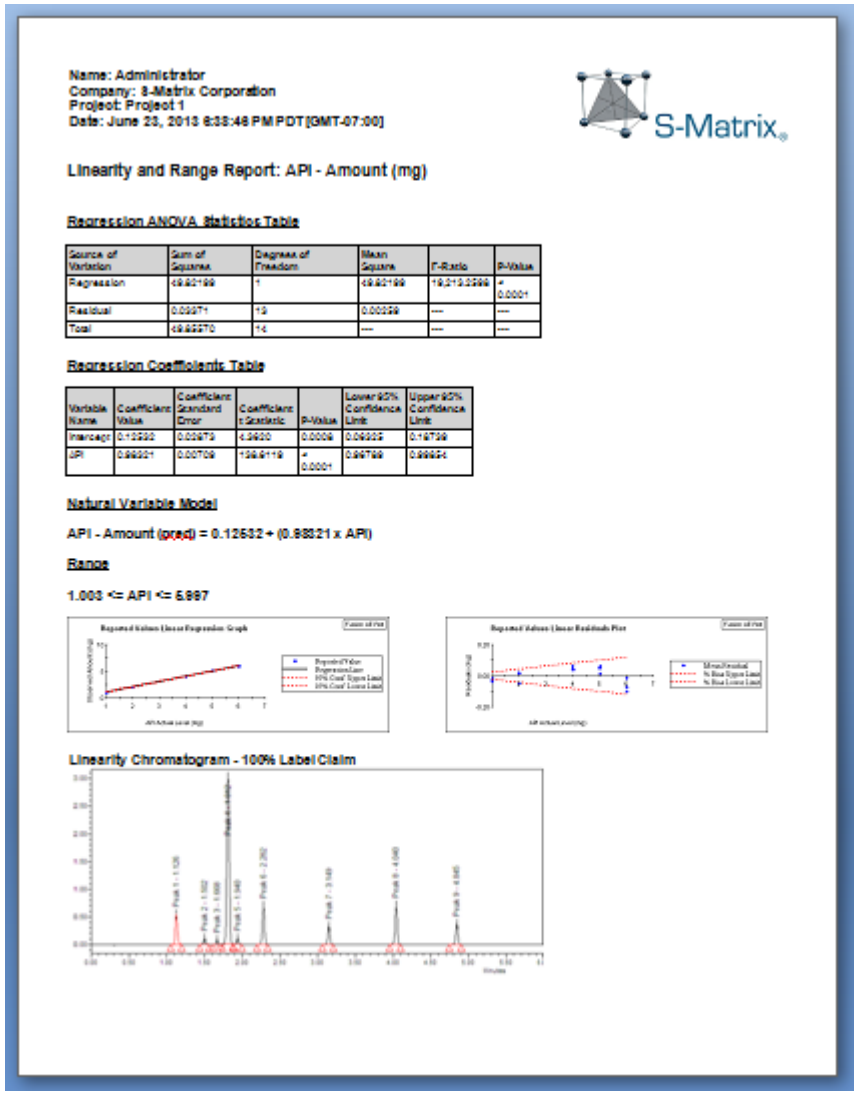
For chromatographic procedures, representative chromatograms should be used to demonstrate specificity, and individual components should be appropriately labeled.

If DL is determined based on visual evaluation or based on signal-to-noise ratio, the presentation of the relevant chromatograms is considered acceptable for justification.



Reports can be augmented with images of relevant chromatograms.

5. Instant Analysis, Graphing, and Reporting



Name: Administrator
Company: S-Matrix Corporation
Project: Project 1
Date: June 23, 2013 8:33:48 PM PDT [GMT-07:00]

S-Matrix

Linearity and Range Report: API - Amount (mg)

Regression ANOVA Statistics Table

Source of Variation	Sum of Squares	Degrees of Freedom	Mean Square	F-Ratio	P-Value
Regression	49.82199	1	49.82199	19,210.5396	< 0.0001
Residual	0.03971	13	0.00306	---	---
Total	49.86170	14	---	---	---

Regression Coefficients Table

Variable Name	Coefficient Value	Coefficient Standard Error	Coefficient t-Statistic	P-Value	Lower 95% Confidence Limit	Upper 95% Confidence Limit
Intercept	0.12532	0.03973	4.3920	0.0008	0.04333	0.19730
API	0.98321	0.00709	138.6119	< 0.0001	0.96789	0.99854

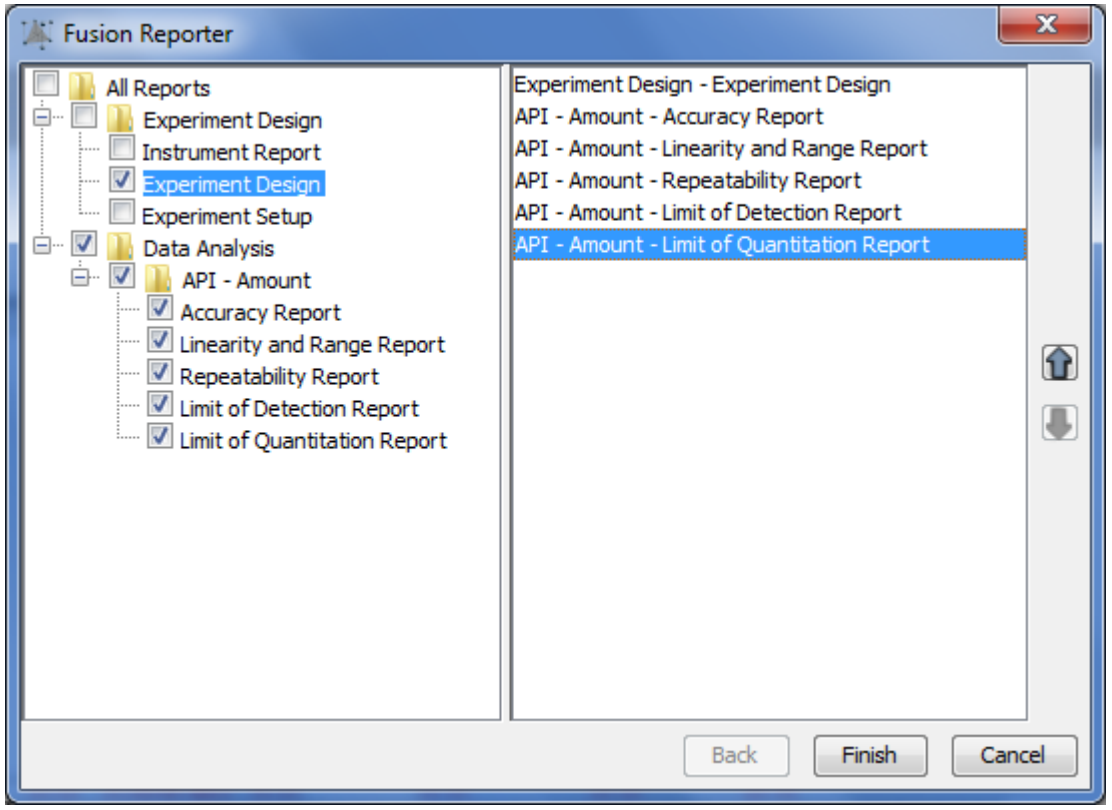
Natural Variable Model

API - Amount (pred) = 0.12532 + (0.98321 x API)

Range

1.003 <= API <= 5.997

Linearity Chromatogram - 100% Label Claim



Reports meet all output format requirements:

.TXT / .RTF / .DOC / .PDF / .HTML / XLSX

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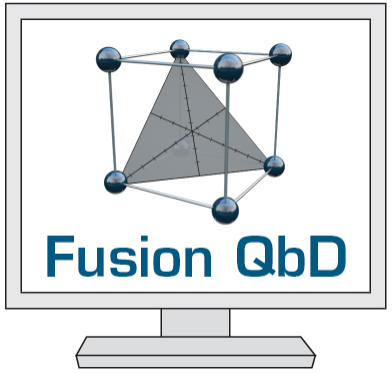
- Analytical Capability
- Accuracy and Repeatability
- Analytical Method Transfer

Automated Experiment Workflow

Steps 1 and 2

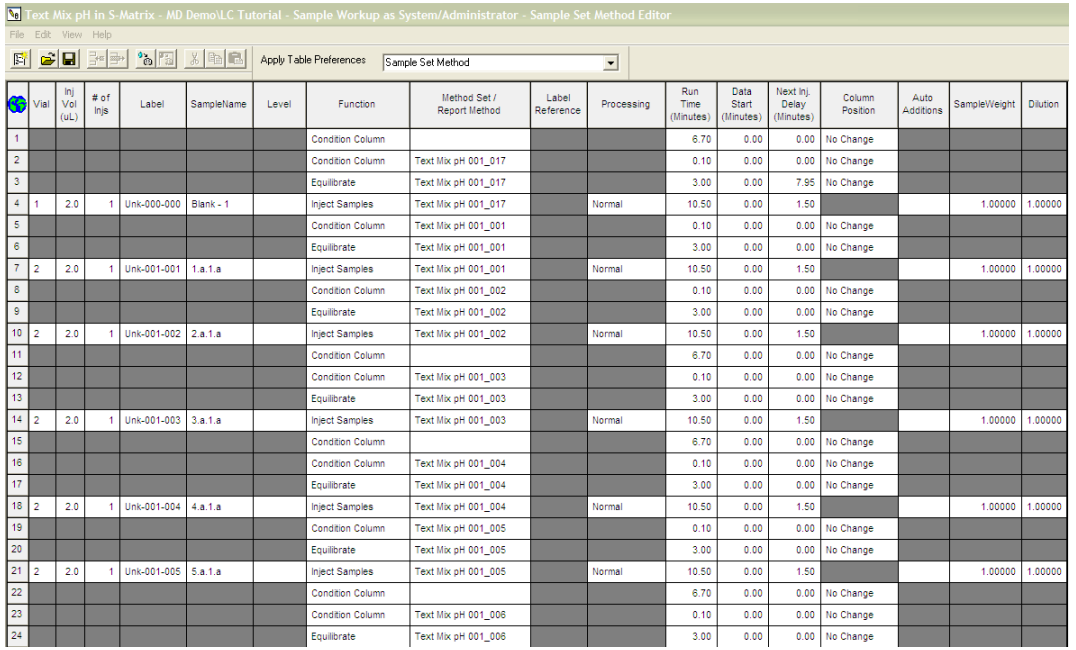


Generates Selected Validation Experiment

Automatically Builds Sequence with Standards Protocol and Assigns Method

Step 3

Chromatography Data Software (CDS)


Text Mix pH in S-Matrix - MD Demo\LC Tutorial - Sample Workup as System/Administrator - Sample Set Method Editor

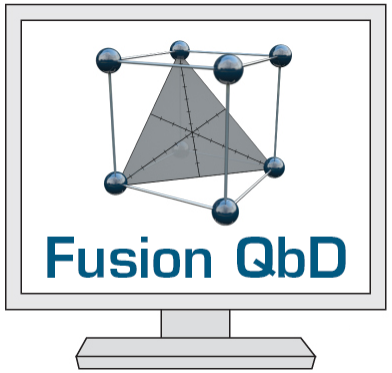
File Edit View Help

Apply Table Preferences: Sample Set Method

	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

Automated Experiment Workflow



Step 4

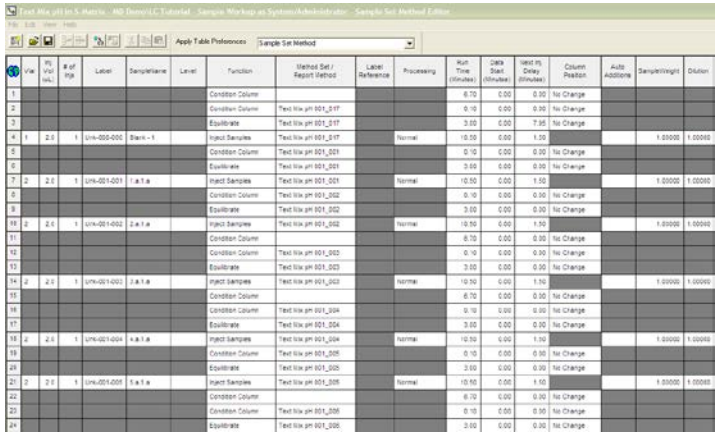
Automatically Retrieve All Chromatogram Results Data

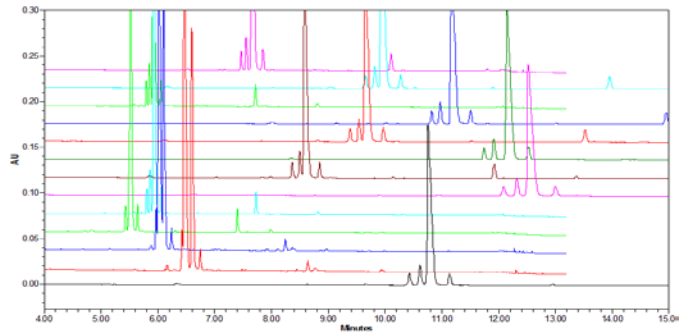
Step 5

Automated analysis, graphing, and reporting.

Multiple Report Formats: RTF, DOC, HTML, PDF, XLSX

Chromatography Data Software (CDS)





Automated, Audited Data Exchange Preserves Data Integrity

Fusion QbD Experiment Automation Platforms

Empower™

- ✓ Solvent Selection Valves
- ✓ Column Switching Valves

Alliance HPLC

Acquity Binary

Acquity H-Class

Acquity Arc

Acquity UPC²

Fusion QbD Experiment Automation Platforms

OpenLab – ChemStation Edition

CHROMELEON 7.2

Empower™

- ✓ 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 Experiment Automation Platforms

- ✓ Solvent Selection Valves
- ✓ Column Switching Valves

UltiMate LCs

Vanquish Horizon And Flex LCs

All the Critical QbD Capabilities You Need

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- **Analytical Capability**
- **Accuracy and Repeatability**
- **Analytical Method Transfer**

<1210> Statistical Tools for Procedure Validation

2. CONSIDERATIONS PRIOR TO VALIDATION

How many individual determinations will compose the reportable value, and how will they be aggregated?

- To answer this question, it is necessary to understand the contributors to the procedure variance and the ultimate purpose of the procedure. **Estimation of variance components** during pre-validation provides useful information for making this decision.

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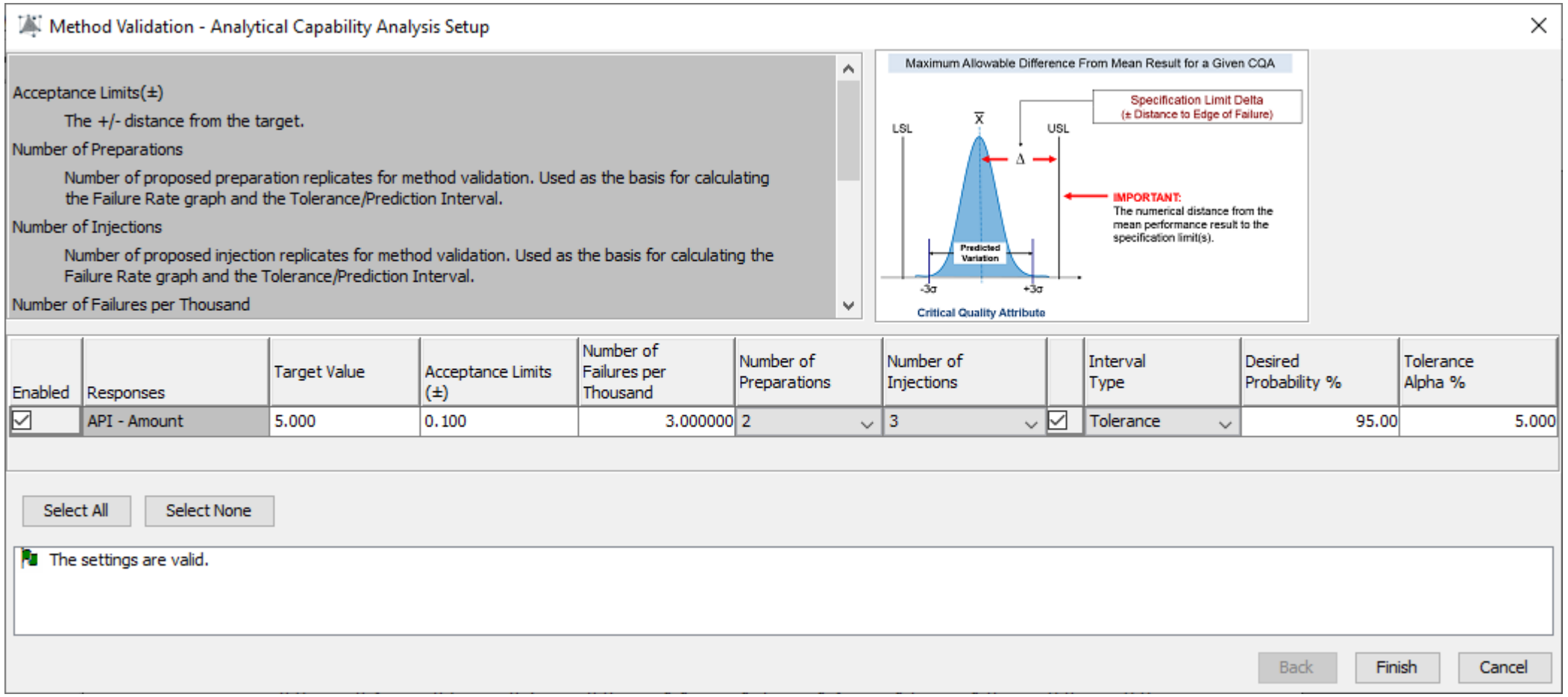
- **Analytical Capability**
- Accuracy and Repeatability
- Analytical Method Transfer

Analytical Capability Experiment

Define your Target (known value), Acceptance Limits, desired FPT upper limit, and your Method's Replication Scheme. You can also set your required LOC for the determination.



Analytical Capability Experiment

Fusion QbD reports the Components of Variation and the Corresponding % Contributions to method precision.

Analytical Capability Report: API - Amount (*)

ANOVA

Variable Name	Sum of Squares	Degrees of Freedom	Mean Square	F-ratio	P-value
Sample Preparation	0.055	4	0.014	7.9681	0.0005
Injection	0.035	20	0.002		
Overall	0.090	24			

Sample Preparation Bias

Sample Preparation Level	Mean Bias	Mean Bias Std. Dev.	Mean Bias DoF	Mean Bias t-statistic	P-value
P-1	-0.096	0.019	20	-5.169	0.0000
P-2	0.030	0.019	20	1.603	0.0623
P-3	-0.033	0.019	20	-1.778	0.0453
P-4	-0.035	0.019	20	-1.904	0.0357
P-5	0.028	0.019	20	1.530	0.0709

Between Variables Components of Variation

Variable Name	Variance	Standard Deviation	Degrees of Freedom	t-table Value	(+/-) 95% Confidence Limits	Error Contribution (%)
Sample Preparation	0.002	0.049	4	2.7764	0.13	58.22
Injection	0.002	0.042	20	2.0860	0.08	41.78

Fusion QbD also reports the Analytical Capability and Failures Per Thousand Results for any Proposed Replication Scheme.

Cp/Failures per Thousand Results

Observed Result:
Cp = 0.8623
No. of Failures per Thousand = 9.7873

No. of Injections		No. of Preparations									
		1	2	3	4	5	6	7	8	9	10
1	Cp	0.5179	0.7324	0.8970	1.0358	1.1580	1.2686	1.3702	1.4648	1.5537	1.6377
	FPT	120.2620	28.0042	7.1229	1.8877	0.5125	0.1414	0.0395	0.0111	0.0031	0.0009
2	Cp	0.5823	0.8234	1.0085	1.1645	1.3020	1.4262	1.5405	1.6469	1.7468	1.8413
	FPT	80.6734	13.4986	2.4820	0.4766	0.0939	0.0188	0.0038	0.0008	0.0002	0.0000
3	Cp	0.609	0.8623	1.0561	1.2194	1.3634	1.4935	1.6132	1.7245	1.8291	1.9281
	FPT	67.378	9.6873	1.5340	0.2539	0.0431	0.0074	0.0013	0.0002	0.0000	0.0000
4	Cp	0.6250	0.8839	1.0825	1.2500	1.3975	1.5309	1.6535	1.7677	1.8749	1.9764
	FPT	60.8013	8.0120	1.1643	0.1769	0.0276	0.0044	0.0007	0.0001	0.0000	0.0000
5	Cp	0.6347	0.8976	1.0993	1.2694	1.4193	1.5547	1.6793	1.7952	1.9041	2.0071
	FPT	56.8940	7.0847	0.9736	0.1400	0.0206	0.0031	0.0005	0.0001	0.0000	0.0000
6	Cp	0.6415	0.9072	1.1110	1.2829	1.4343	1.5712	1.6971	1.8143	1.9244	2.0284
	FPT	54.3100	6.4996	0.8589	0.1187	0.0169	0.0024	0.0004	0.0001	0.0000	0.0000
7	Cp	0.6464	0.9142	1.1196	1.2928	1.4454	1.5834	1.7102	1.8283	1.9392	2.0441
	FPT	52.4759	6.0982	0.7828	0.1051	0.0145	0.0020	0.0003	0.0000	0.0000	0.0000
8	Cp	0.6502	0.9195	1.1262	1.3004	1.4539	1.5926	1.7202	1.8390	1.9506	2.0561
	FPT	51.1074	5.8062	0.7288	0.0957	0.0129	0.0018	0.0002	0.0000	0.0000	0.0000
9	Cp	0.6532	0.9237	1.1314	1.3064	1.4606	1.6000	1.7282	1.8475	1.9596	2.0656

Analytical Capability Experiment

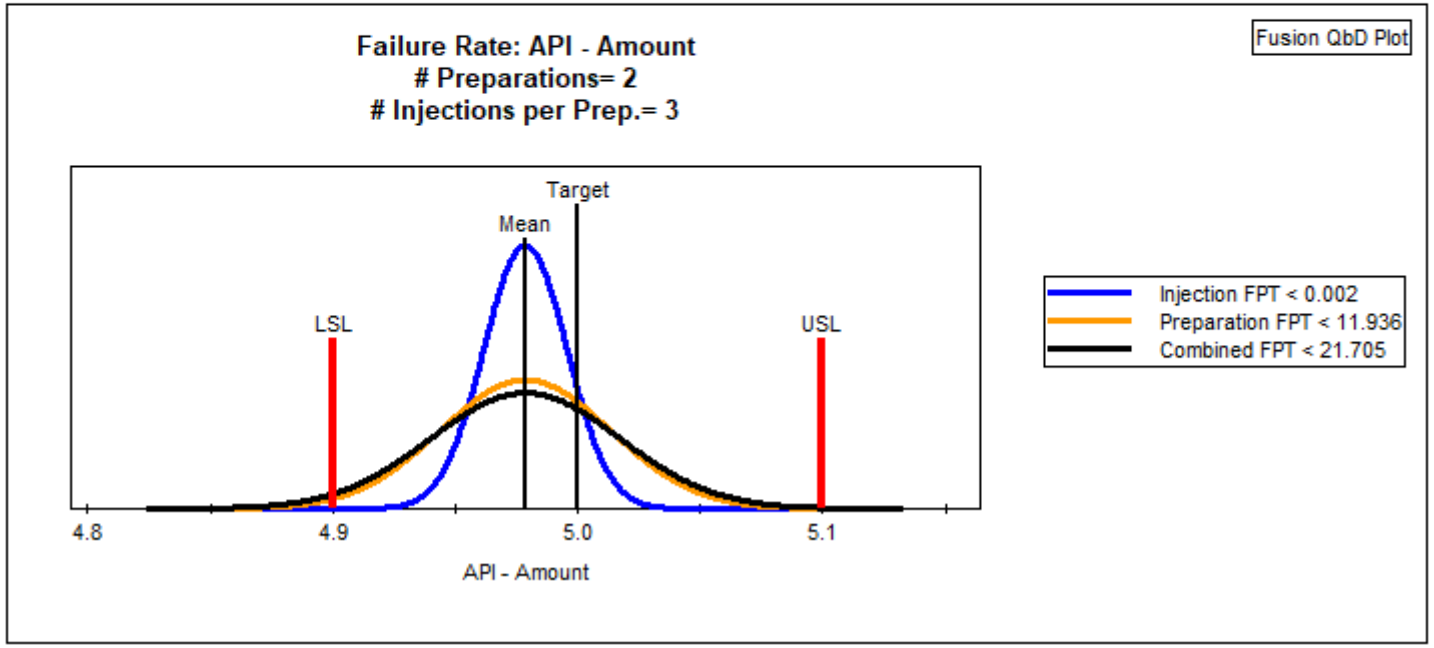
Fusion QbD also reports the <1210> Tolerance or Prediction Interval for your Replication Scheme.

Tolerance Interval

Interval Type	Computed Interval	Number of Preparations	Number of Injections
Acceptance Limits	4.900 <= 5.000 <= 5.100	2	3
Tolerance Interval	4.829 <= 4.979 <= 5.129		
Result			Fail

At least one of the Computed Interval bounds falls outside the Acceptance Limits.

Calculated Overall Mean: 4.979



All the Critical QbD Capabilities You Need

Critical QbD Capability	FMV
Supports All Install Environments (Citrix Certified)	✓
Full 21 CFR Part 11 Compliance Support	✓
Complete Method Validation Experiment Suite	✓
Simple Experiment Workflows	✓
Full LC Experiment Automation	✓
USP 1210> Tolerance and Prediction Interval Metrics	✓

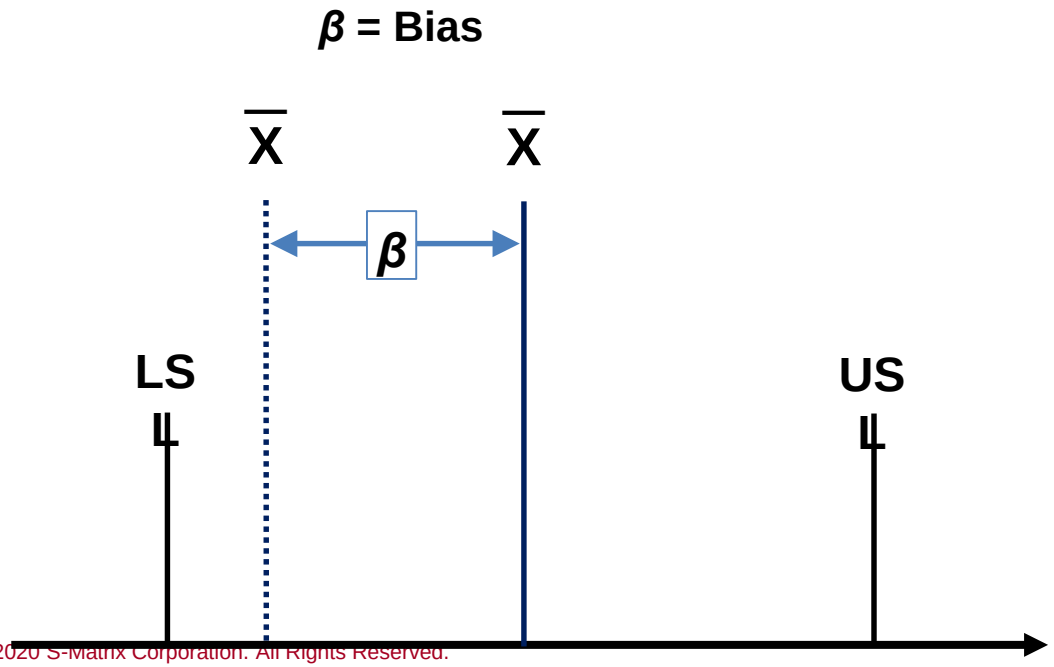
- Analytical Capability
- **Accuracy and Repeatability**
- Analytical Method Transfer

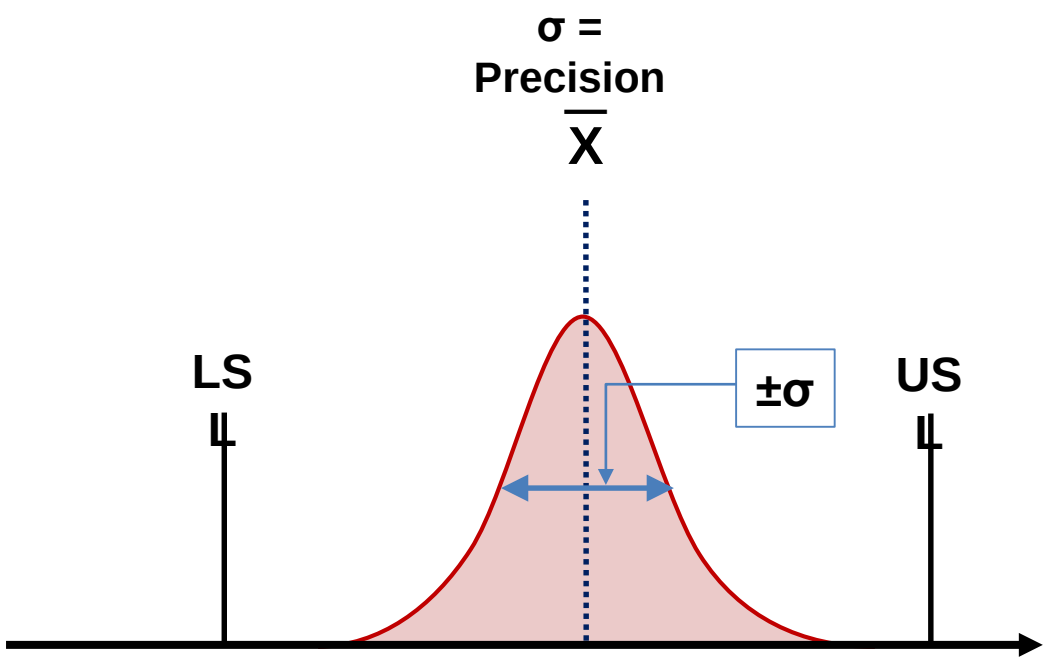
<1210> Statistical Tools for Procedure Validation

3. ACCURACY AND PRECISION

3.2 Combined Validation of Accuracy and Precision

The illustration below shows that the method will pass System Suitability performance for the Critical Process Parameter (CPP) being tested SST when Accuracy (***β* – bias estimate**) and Precision (**σ – variation estimate**) **are assessed independently (= High Risk Approach).**



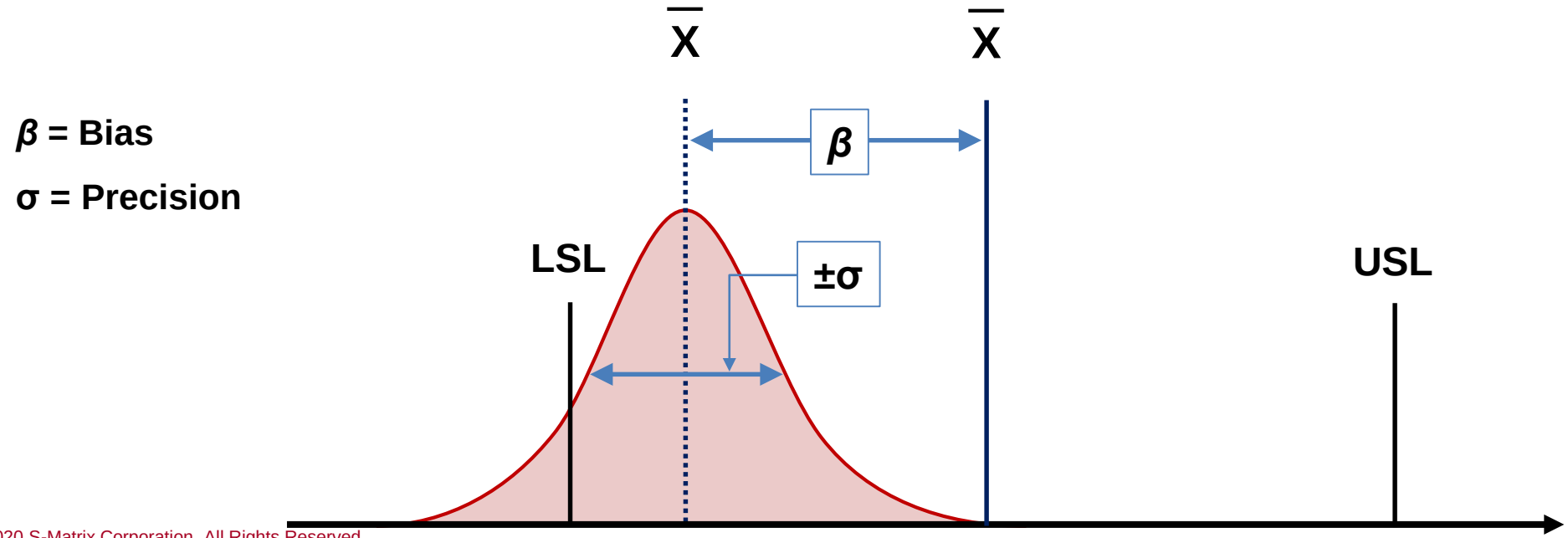


<1210> Statistical Tools for Procedure Validation

3. ACCURACY AND PRECISION

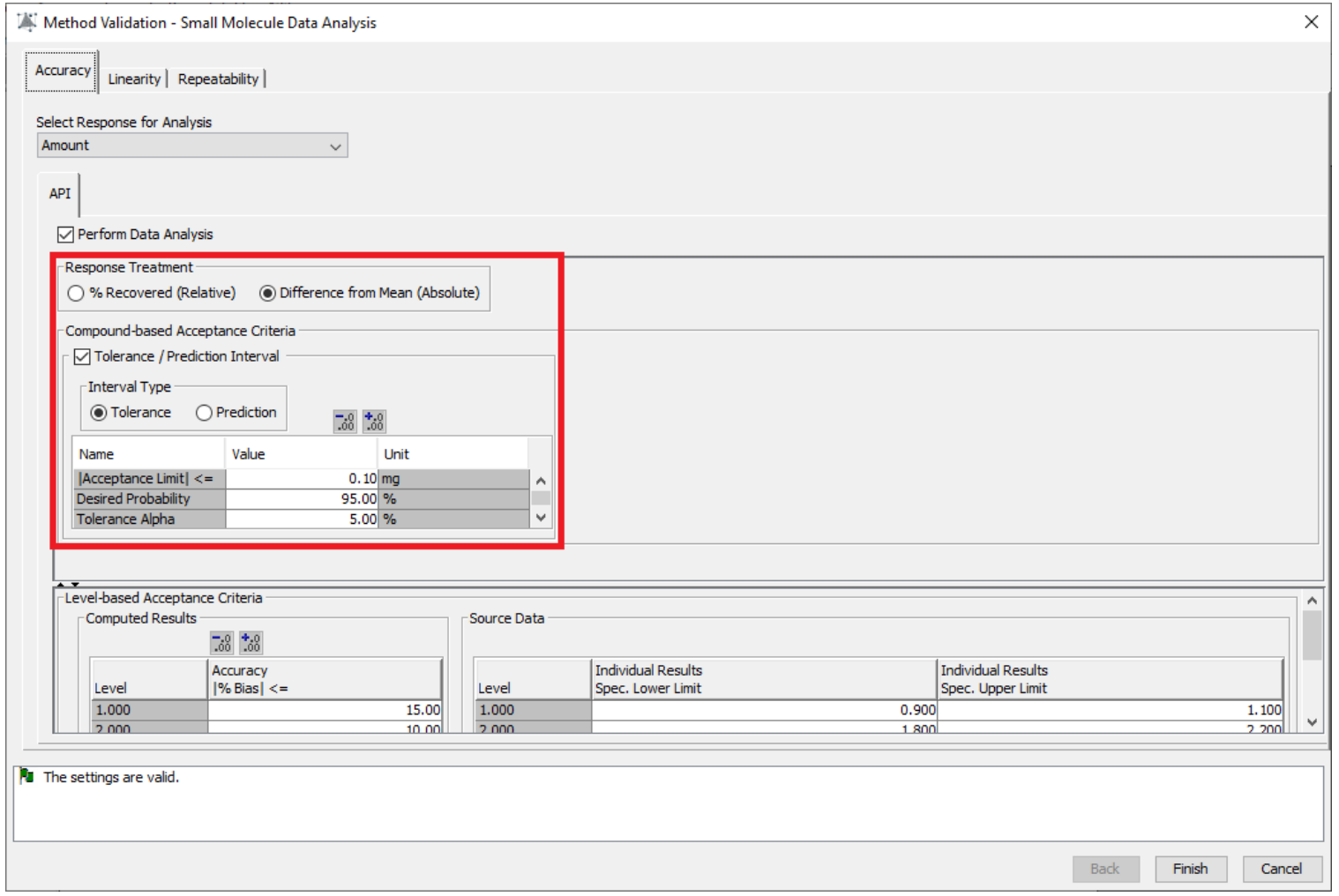
3.2 Combined Validation of Accuracy and Precision

However, as the illustration below shows – the method does not have acceptable System Suitability performance for the Critical Process Parameter (CPP) being tested when both Accuracy (*β* – bias estimation) and Precision (σ – variation estimation) **are assessed together (= Low Risk Approach).**



<1210> Metrics – Accuracy & Repeatability

Define your Acceptance Limits and required LOC for the determination.



<1210> Metrics – Accuracy & Repeatability

Fusion QbD Automatically Generates All Analysis Results and Graphs for Accuracy, Linearity, and Repeatability. Fusion QbD also reports the <1210> Tolerance or Prediction Analysis Results.

Tolerance Interval

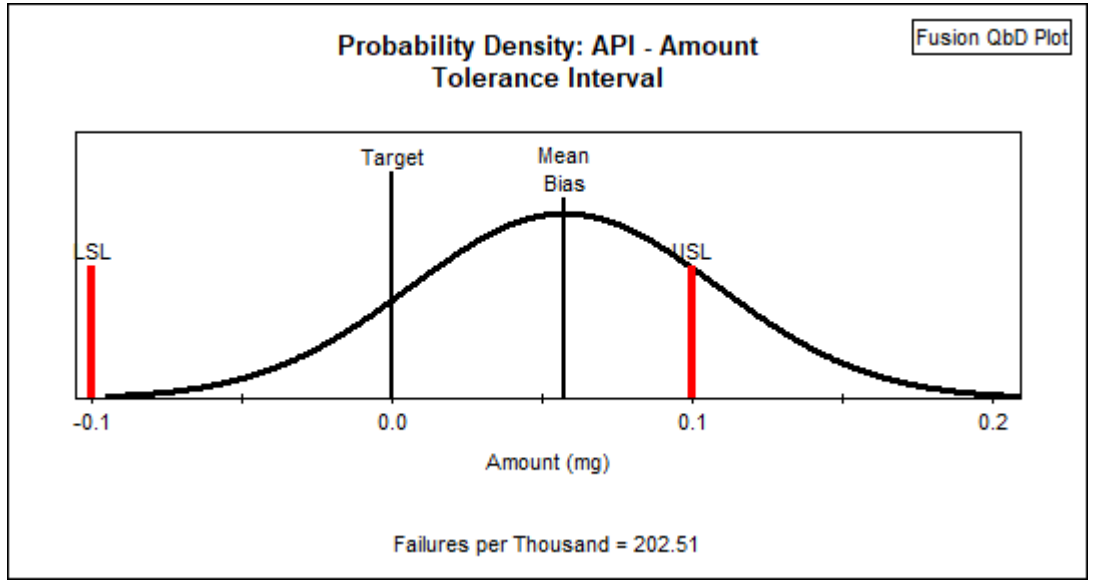
Name	Value
Acceptance Limits	-0.10 <= Target <= 0.10
Computed Interval	-0.04 <= Mean <= 0.16
Result	Fail

[Difference From Mean: Target = 0.00, Mean (Pooled) = 0.059]

At least one of the Computed Interval bounds falls outside the Specification Interval bounds.

Replicate Group Error Statistics

Replicate Group	Group Run No.	Observed Value	Group Std. Dev.	F-Ratio	P-Values
1	1.a 1.b 1.c	0.018 0.072 0.051	0.027	0.7366	0.5086
2	2.a 2.b 2.c	0.111 0.109 0.044	0.038	1.7550	0.2334
3	3.a 3.b 3.c	0.120 0.097 0.102	0.012	0.1267	0.8827
4	4.a 4.b 4.c	0.102 0.092 0.056	0.024	0.5602	0.5920
5	5.a 5.b 5.c	-0.074 -0.047 0.010	0.043	2.5143	0.1422



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Simple Experiment Workflows	✓
Full LC Experiment Automation	✓
USP 1210> Tolerance and Prediction Interval Metrics	✓

- Analytical Capability
- Accuracy and Repeatability
- **Analytical Method Transfer**

USP ⟨ 1224⟩ – Transfer of Analytical Procedures

Comparative Testing

Comparative testing requires the analysis of a predetermined number of samples of the same lot by both the sending and the receiving units. Other approaches may be valid, e.g., if the receiving unit meets a predetermined acceptance criterion for the recovery of an impurity in a spiked product. Such analysis is based on a preapproved transfer protocol that stipulates the details of the procedure, the samples that will be used, **and the predetermined acceptance criteria, including acceptable variability**. Meeting the predetermined acceptance criteria is necessary to assure that the receiving unit is qualified to run the procedure.

Analytical Method Transfer Example

Transferring Lab

Fusion QbD Sequence Execution

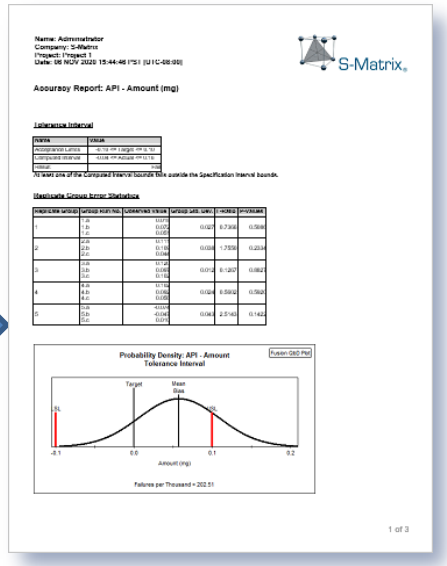
Fusion QbD Sequence Execution

Receiving Lab

Chromatography Data Software

ALR Design

Chromatogram Results Data



1. Fusion QbD – Exports Experiment to the CDS
   Ready-to Run sequence, methods, standards
2. Sequence is Run at Both Labs.
3. Fusion QbD – Imports Results for Instant, Complete Analysis and Reporting.

Accuracy
Linearity
Repeatability
Tolerance or
Prediction Interval
Pass/Fail Results

Key Benefits of FMV

1. **Consistency – Workflow and Reporting.**

   Work is standardized – done the same way every time. Reporting is standardized, complete, easy to communicate.

2. **Simplicity**

   Tremendous ease of use. Very brief learning curve. Clearly defined templatable workflows with built-in workflow management.

3. **Speed (Productivity)**

   Automation and simplified workflows dramatically increase productivity. Review process is minimized and simplified.

4. **Regulatory Alignment and Completeness**

   All required validation experiment types are supported. Reporting meets regulatory requirements. Reports can be attached to Project specific narrative documents.

Key Benefits of FMV

5. **Platform Independence**

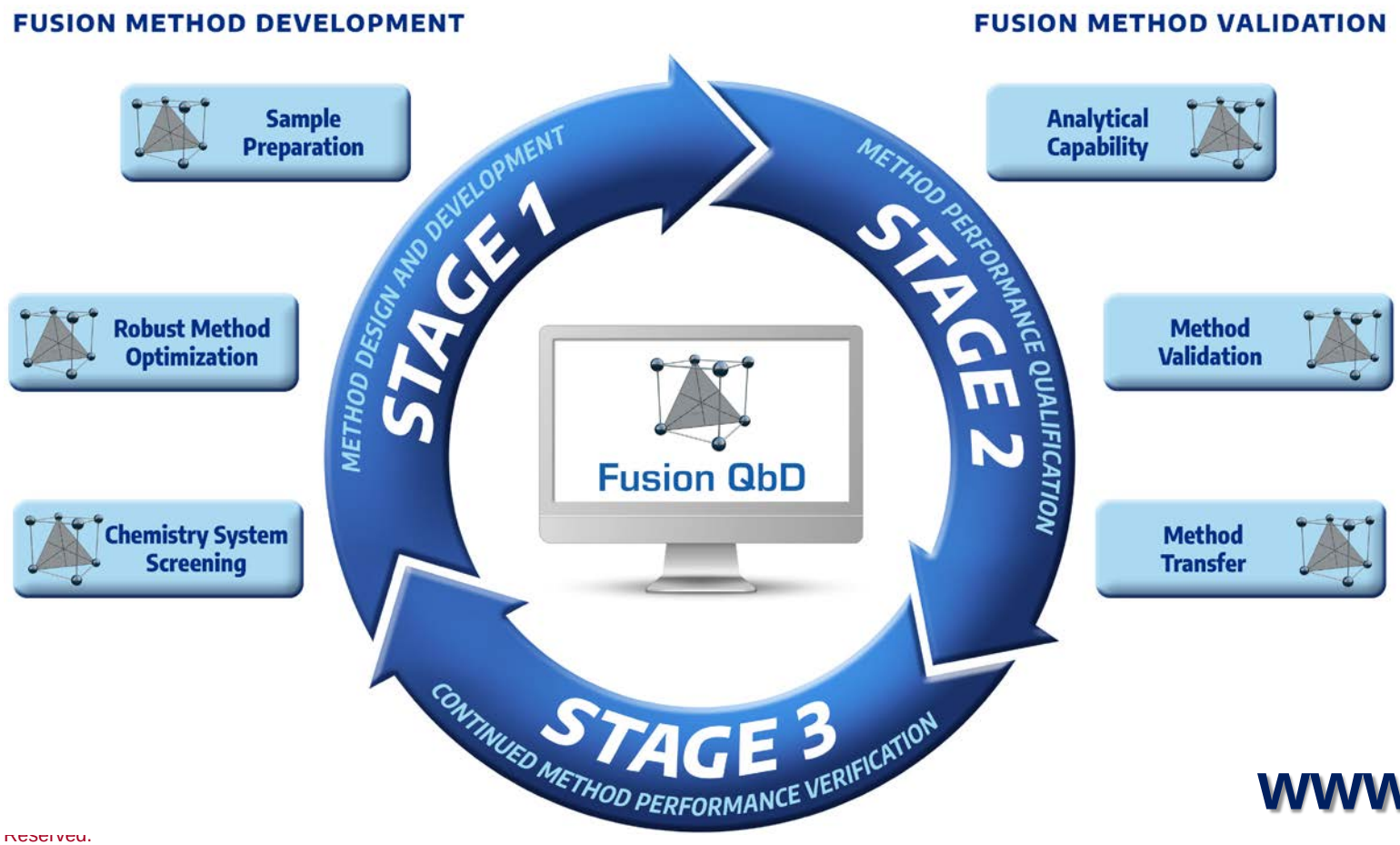
   Support for Empower, ChemStation, and Chromeleon means that the standardized workflows and reporting can be easily extended to users of other platforms at other sites or other companies (e.g. CMOs).

6. **Customer Support**

   Our support is top-rated worldwide. S-Matrix and our local distributors have a multi-year history of proven ability to meet all our customer's support needs.

End of Presentation

Fusion QbD — A Complete Solution for APLM Stages 1 and 2



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