

# Fusion Pro

QbD-aligned DOE Software for  
Formulation & Process Development



# Fusion Pro®

## Quality by Design aligned Design of Experiments Software!

If you are wondering where to start when implementing Quality by Design (QbD), **Fusion Pro** is the answer you've been looking for. With automated experimental design selection, automated data analysis and modeling, integrated Monte Carlo robustness simulation, and comprehensive reporting, **Fusion Pro** is the perfect place to start your QbD journey.

### Key Benefits

- Translates QbD Guidances into Usable Tools
- Quantifies and Manages Risk
- Automated DOE Built In!
- Designed for Working Scientists  
(although statisticians are welcome!)

### Example Applications

- Formulations
- Tableting / Tablet Coating
- Synthetic Chemistry
- Process or Device Development
- Manufacturing

Systematic, logical workflow, easy to use and understand, **Fusion Pro** is perfect for all your development activities, from defining the "Experimental Region" through to reporting the Robust Design Space and Proven Acceptable Ranges.

### The Experimental Region

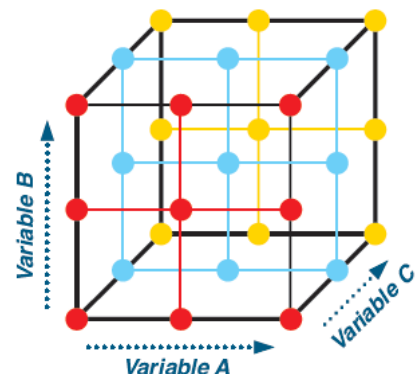
Your journey begins here. **Fusion Pro** allows you to define multiple variables (potential Critical Process Parameters) and the ranges over which you wish to study them. It is these that will ultimately define your Knowledge Space.

One key benefit of **Fusion Pro** is that you do not need to have a statistics degree to use it! Based on the variables entered in the simple Experiment Setup template, **Fusion Pro** automatically selects the most efficient design for modeling your data, including the higher order models required to visualize complex interaction effects usually responsible for a lack of Robustness.

### Experimental Design

Design of Experiments (DOE) best practices are always adhered to, ensuring that the appropriate number of repeats, center points, and degrees of freedom are used. Designs (the list of experiments to be run) can be exported in a variety of file formats, including MS Excel, Comma or Tab-delimited files, HTML, or XML.

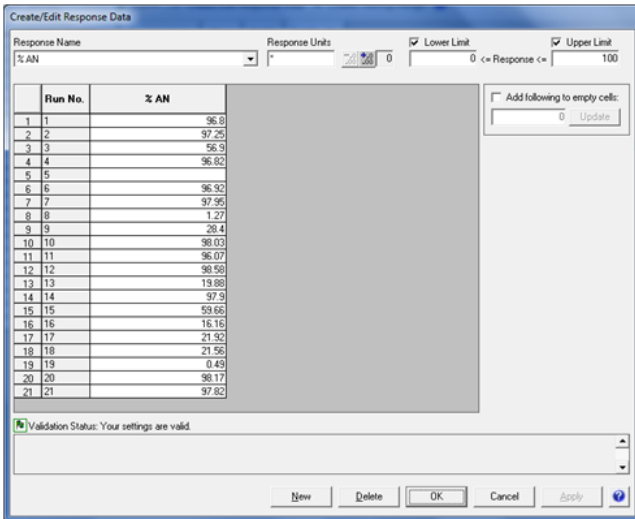
In addition, you can build templates using the "user Interactive" design mode. This enables full control over the choice of design and all associated design structure settings. Available design types include: Full & Fractional Factorial, Plackett-Burman, Box-Behnken, Central Composite, Star, Mixed Level, and advanced Algorithm (Letter Optimality) designs.



## Data Management and Processing

Any study is likely to require data from a range of measurement systems for each experiment run (trial) to determine the necessary Critical Quality Attribute results. These tests can provide simple **one-run-one-result** data, or they can include **multiple test results per experiment run**. **Fusion Pro** supports these types of data.

### Direct Data Entry



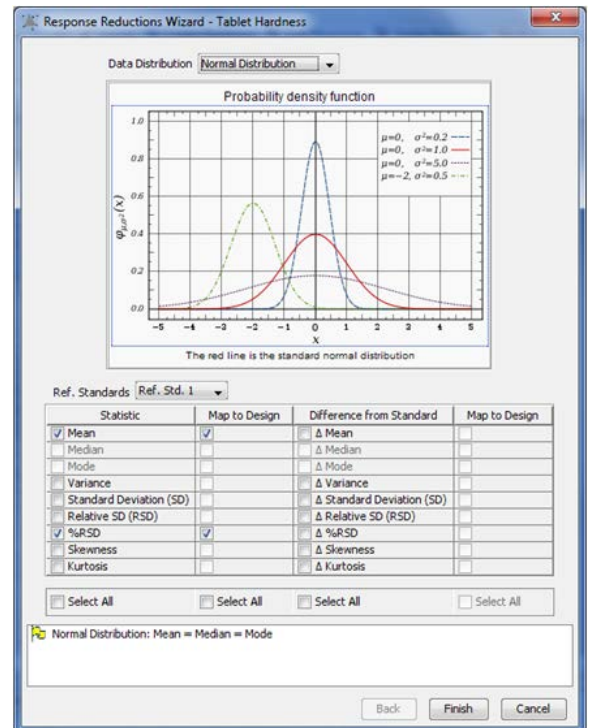
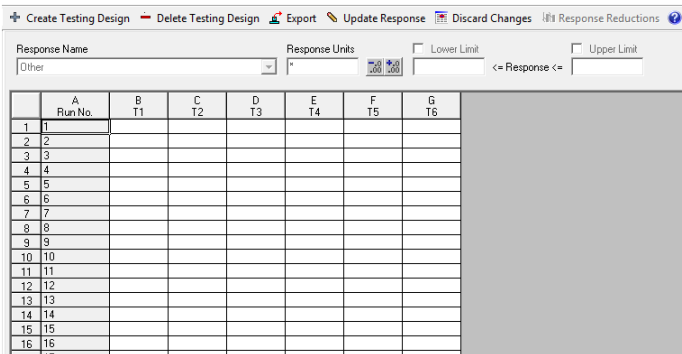
You can directly enter responses consisting of only one measurement per run (no test repeats) as analysis-ready data sets.

For each response you can also enter any limits associated with the test measurement – for example, % Released data for which the measurement cannot exceed 100%. **Fusion Pro** will automatically accommodate this critical feature of the response data in its automated data analysis and modeling.

### Testing Plans

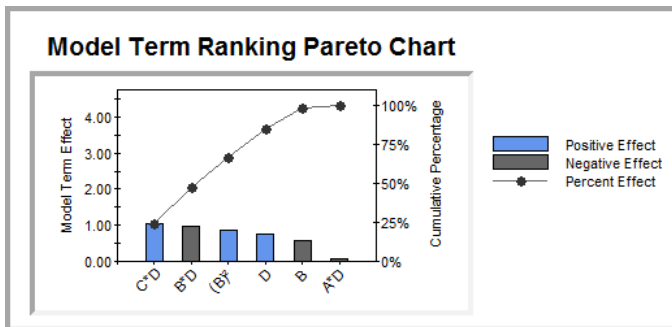
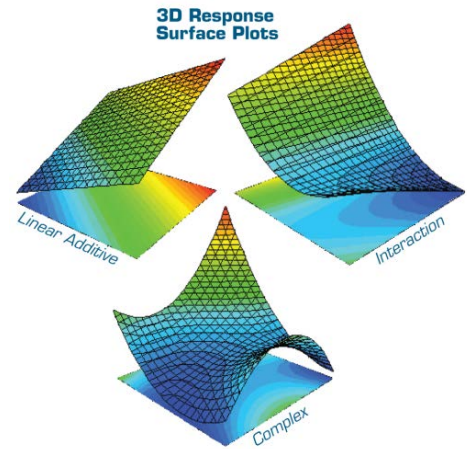
Create Testing Plans for response data which consists of multiple test repeats per experiment run (test replicates).

**Fusion Pro** will automatically translate your test repeat data into any statistical result you want to analyze, such as Mean, Variance, Std. Dev., % RSD, etc. And **Fusion Pro** can handle non-normally distributed test data.



## Knowledge Space

With your rationalized experimental data mapped to the design, the data analysis can begin. With a click of a button **FPD** will perform your multi-variant analysis and build the empirical models describing the relationships between your potential Critical Process Parameters (CPPs) and Critical Quality Attributes (CQAs). These are displayed as readily interpretable Response Surfaces, contour plots and effects plots ensuring you acquire "formulation and process understanding".



Pareto Ranking charts allow you to see which study variables should be treated as Critical Process Parameters.

Analysis Summary and Detail Reports define the quality of your experimental data, allowing you to have confidence in the models generated.

## Quantification of Risk — Process Robustness

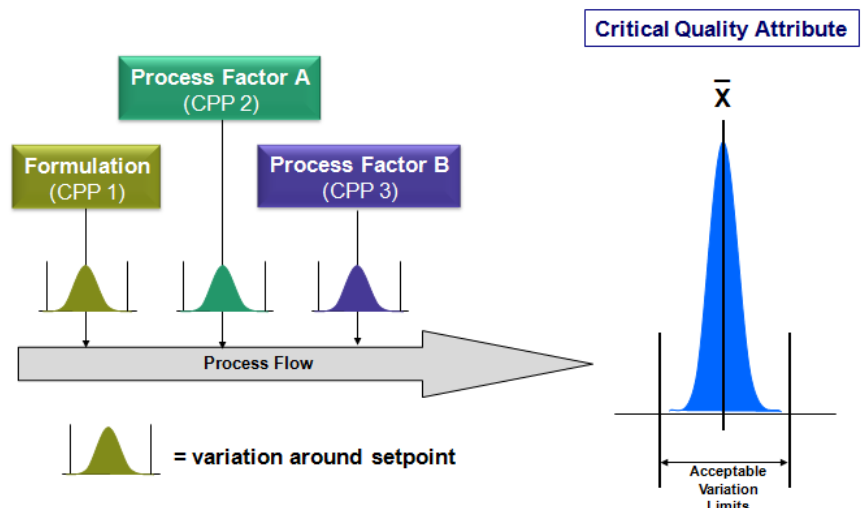
*"Ability of a process to tolerate variability of materials and changes of the process and equipment without negative impact on quality"*

ICH Q8(R2) - Guidance for Industry, Pharmaceutical Development, August, 2009

**Fusion Pro's** patented Robustness Simulator™ technology (U.S. Patent No. 7,606,685 B2) allows you to quantify risk. Enter expected variation in your Critical Process Parameters (CPPs) and allowable variation limits for your Critical Quality Attributes (CQAs).

**Fusion Pro** will automatically compute and model Robustness metrics (Process Capability metrics – e.g.  $C_p$ ,  $C_{pk}$ ), enabling you to characterize Robustness and incorporate that characterization into your Knowledge Space and Design Space.

This powerful capability allows you to visualize and optimize your formulation and process for both mean performance and robustness, representing a complete best-practices approach.



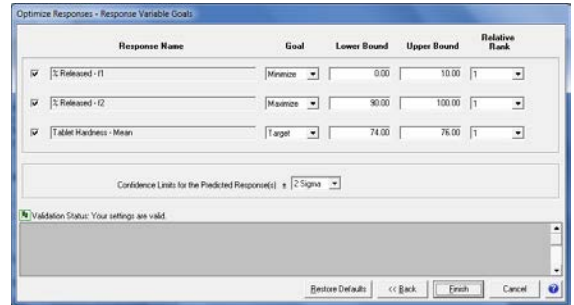
# Design Space

"The multidimensional combination and interaction of input variables (e.g., material attributes) and process parameters that have been demonstrated to provide assurance of quality"

ICH Q8(R2) - Guidance for Industry, Pharmaceutical Development, August, 2009

## Best Overall Answer

With your Knowledge Space established, **Fusion Pro's** powerful Numerical Best Answer Search tool allows you to search for the conditions that meet all your required Critical Quality Attribute goals. Results are produced and displayed in concise tabular and graphical report formats.



### Variable Settings

Variable	Level Setting
Atomizing Air Pressure	19.9
Pattern Air Pressure	55.0
Spray Rate	40.0
Gun Distance	8.1

Numerical Best Answer Search reporting displays the "Best Result" level setting of each experiment variable, and also reports the level settings of all key factors maintained constant for the experiment.

### Predicted Results

Response	Goal	Predicted Result	Desirability	-2 Sigma Conf. Limit	+2 Sigma Conf. Limit
Tablet Hardness - Mean (TD1)	75.00	74.99	0.9907	74.85	75.13
API - % Released - f1 (TD2)	Minimize	0.45	0.9553	0.18	1.04
API - % Released - f2 (TD2)	Maximize	92.20	0.8049	89.59	94.80

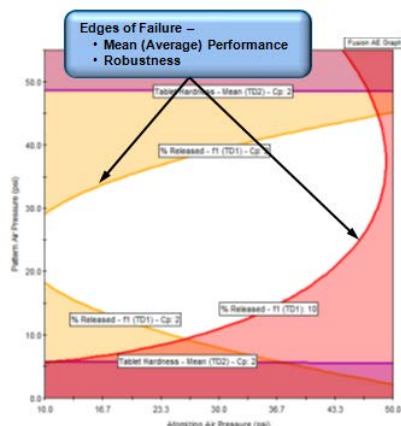
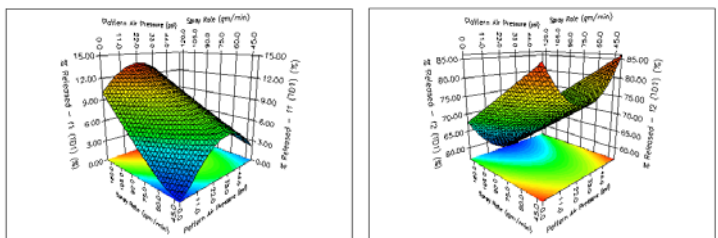
Cumulative Desirability Target = 1.0000  
 Cumulative Desirability Result = 0.9141

Best Answer Search reporting includes the model-predicted result for each included response (CQA), along with the prediction confidence interval limits, and the "Overall Desirability" of the results relative to all your goals.

## Acceptable Performance Region

The Acceptable Performance Region Search tool translates *Knowledge Space* understanding into a visualized composite region in which all response (CQA) quality and performance goals are simultaneously met for two study factors within their ranges.

## Knowledge Space Visualization



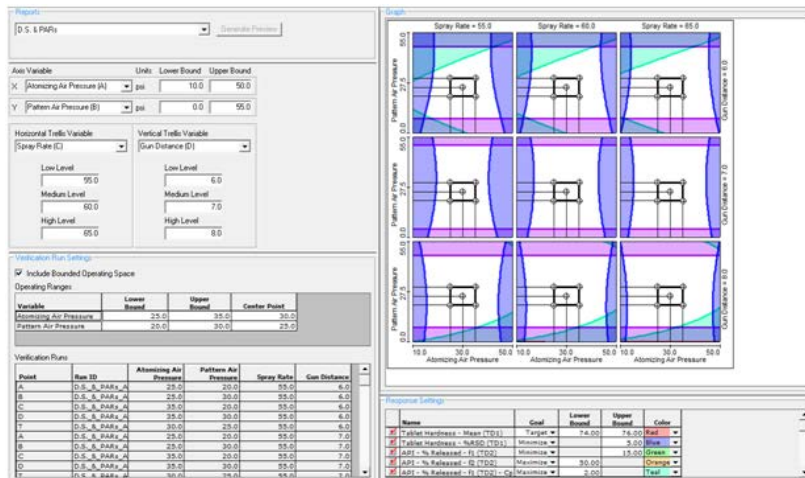
## Acceptable Performance Region Visualization

Search tool assigns a color to each response, and then uses the color to shade the region of unacceptable performance for the response. The **UN-shaded** region thus represents the region of acceptable performance for the response. As many responses as desired can be included in a graph, so that the un-shaded region represents the proposed Design Space for all included responses.

# Visualize Formulation/Process Design Space and Operating Space

Color-coded response maps define the QbD Knowledge and Design Spaces. Users can predict and display best and most robust conditions.

**Fusion Pro** enables you to scribe the Quality-by-Design (QbD) “operating space” – the specified optimal conditions and the control limits of the critical parameters being studied – on the Design Space graphs. The specified conditions and limits which define the operating space are automatically added to the output reports.



## Scalable From Walk-up System to Global Enterprise Solution

### Fusion Pro

Simple, standalone system without the overhead of the Regulatory Compliance and Workflow Management Systems

### Fusion Product Development - Workstation

- Full implementation at the workstation level
- Full 21 CFR 11 Compliance Support Toolset / Full Workflow Management System
- Data Exchange with Chromatography Data Software

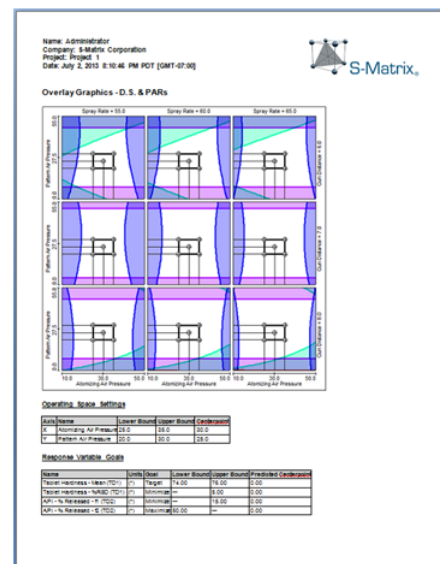
### Fusion Product Development - Network

Small to large networks – Certified Citrix Ready (Metaframe and XenApp)



## Fusion Product Development — Science at its best!

- walks the scientist through the QbD maze
- ensures QbD "best practices" are followed
- automates design selection, data transfer and analysis, optimization, and reporting
- outputs reports in a variety of file formats, including MS Word, HTML, and PDF
- scales from a single PC to corporate networks, supporting VMware and Citrix environments
- designed for cGXP and 21 CFR Part 11 environments



# S-Matrix Software Products and Support

S-Matrix Corporation develops advanced Design of Experiment based-software that automates R&D experimental work according to Quality-by-Design principles and methodologies. S-Matrix's Fusion QbD platform automates and redefines experimentation in Analytical R&D, Chemical and Process R&D, Formulation, and Product R&D.

## Fusion QbD Software System Product Suite

### ■ Fusion LC Method Development

Rapidly develop and optimize robust LC methods on instruments from multiple vendors.

### ■ Fusion LC Method Validation

Meet regulatory guidelines with a best-practices approach toward LC method validation with comprehensive reporting.

### ■ Fusion Inhaler Testing

Create sampling plans, export and import data from your CDS via validated data exchange and calculate particle size distribution results, and generate reports according to USP 601, Ph.Eur. 2.9.18, and ISO 27427.

### ■ Fusion Product Development / Fusion Pro

The perfect QbD software for formulation & product development – automated experimental design selection, sophisticated analysis tools, including automated modeling and simulation, comprehensive reporting, with a full 21 CFR 11 compliance toolset.

## Sales and Support

Sales: Tel: 800-336-8428 (Outside the USA: 707-441-0406). Email: [Sales@smatrix.com](mailto:Sales@smatrix.com)  
Customer Support: Tel: 707-441-0407. Fax: 707-441-0410. Email: [Support@smatrix.com](mailto:Support@smatrix.com)

## On-site and Web Training

S-Matrix offers on-site training programs for installed systems. Training includes experiment strategies, experimental design (DOE), data analysis, graphical visualization and ranking of effects, numerical and graphical optimization, and QbD Reporting.

S-Matrix also offers interactive web training which covers software features and operation, along with general principles of DOE and QbD. Web training programs can be tailored to suit your individual focus and information requirements.

To arrange an on-site or web-based training program, call 707-441-0406.

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