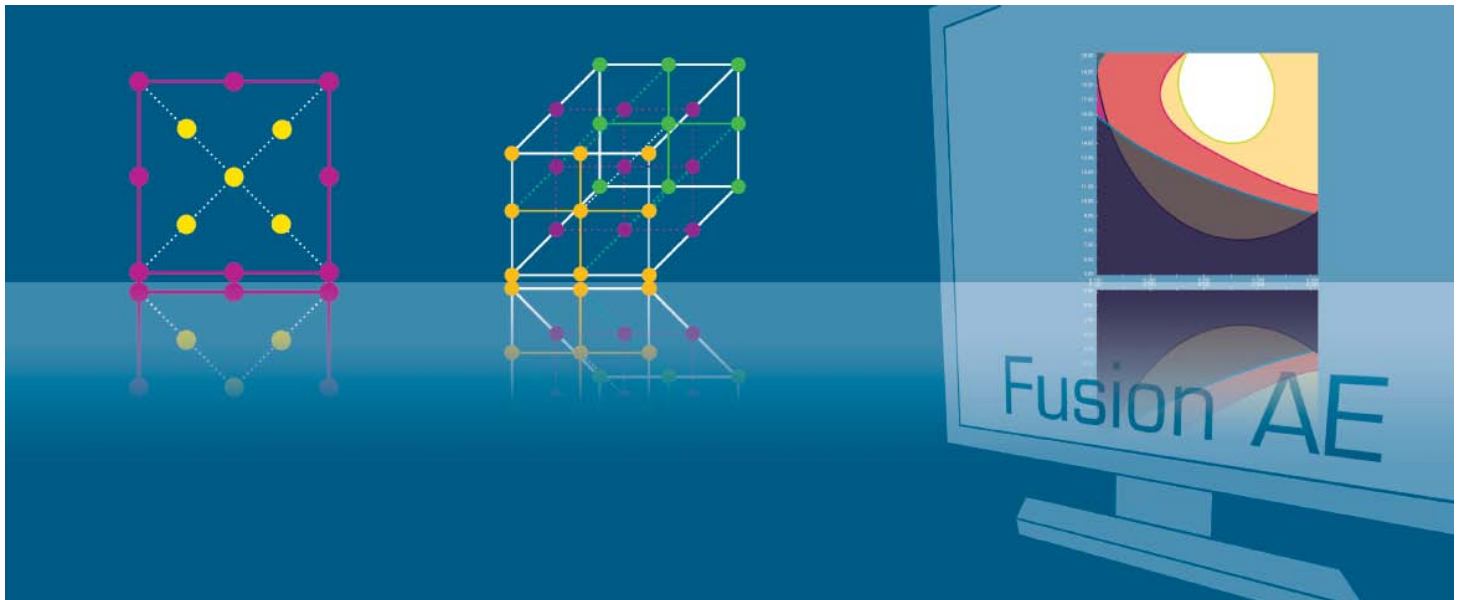# Fusion AE™
Fusion Product Development


S-Matrix®

Multiple Experiment Design Types

Fusion Product Development (**FPD**) incorporating a systematic QbD approach, Fusion AE automatically constructs the experimental region and selects the most efficient experimental design. Alternative design types and settings are accessed via a user-interactive Design Wizard.

Available design types include: Full and Fractional Factorial, Plackett-Burman, Box-Behnken, Central Composite, Star, Mixed Level, and Model-robust Algorithm designs.

Designs .can be exported directly to an MS Excel Workbook, or in a variety of file formats, including Comma- or Tab-delimited files, HTML, or XML. Export can include all response data sets.
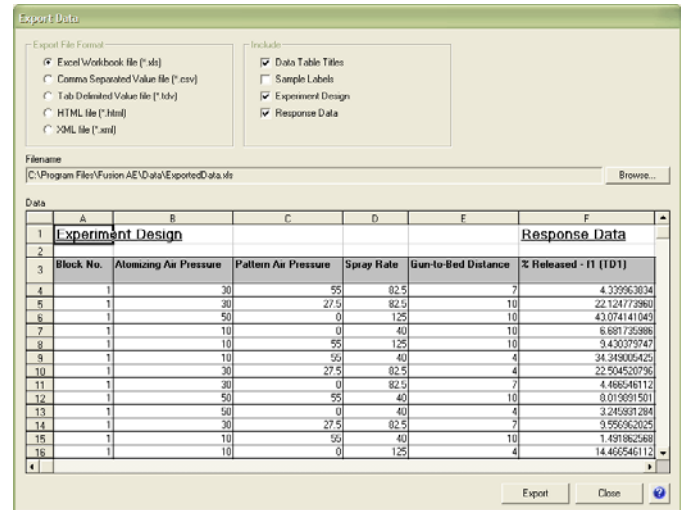
Automated LC Testing and Data Capture

FPD creates coordinated LC Testing Designs, such as for dissolution testing, that it directly exports to Chromatography Data Systems (CDS).

Export automatically builds the sequence (or sample set) in the CDS, adds the appropriate standards injections, and attaches the LC Assay Method so that the sequence is ready to execute in full walk-away mode.
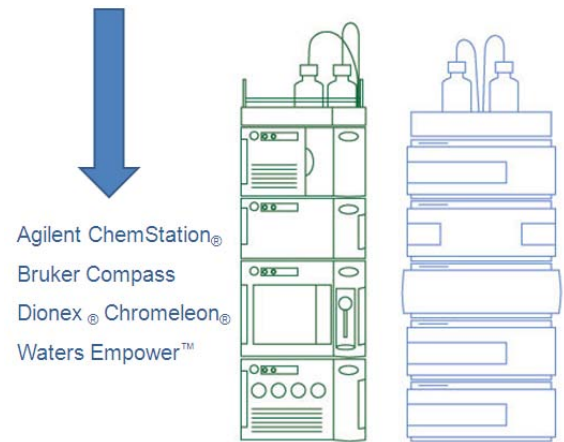
Easily Handles Complex Response Data

FPD also automatically imports all chromatographic results from the CDS.

FPD translates test repeat data into statistically analyzable data, including non-normally distributed data.

FPD manages and graphs time-series (profile) response data, including reference standard data, and derives analyzable curve fit metrics such as f1 and f2 results.

Agilent ChemStation®
Bruker Compass
Dionex ® Chromeleon®
Waters Empower™
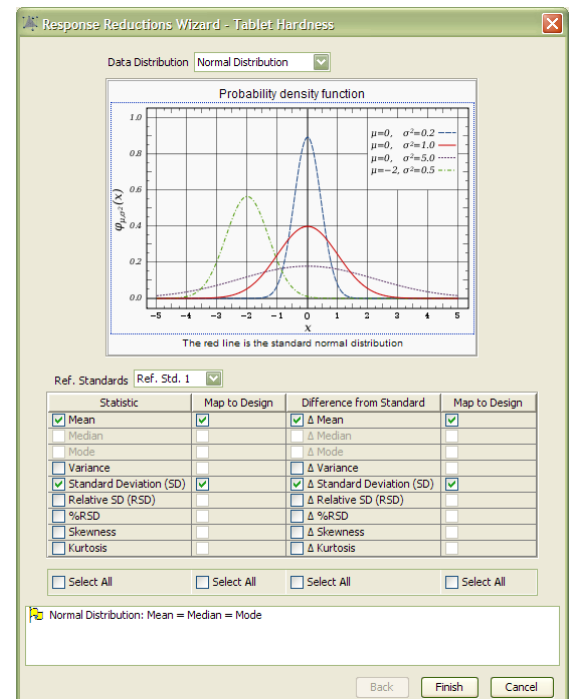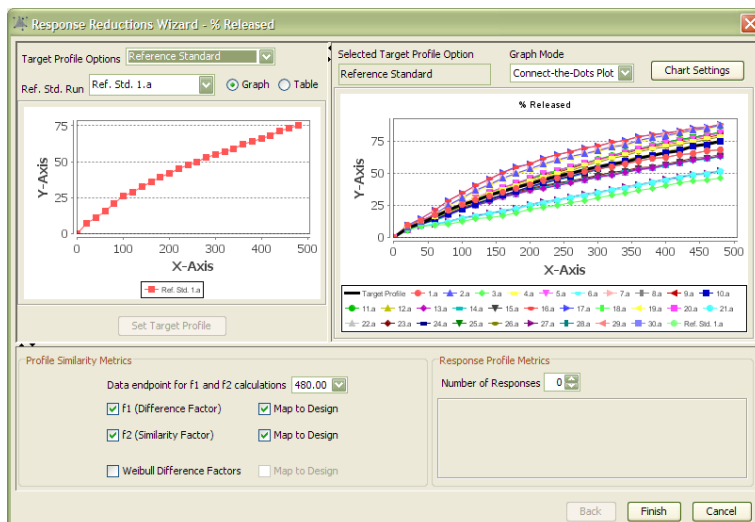
Visualize All Study Factor Effects

Fusion AE can accurately model linear additive effects, interaction effects, and complex higher-order effects.

Response surface plots show the combined effects of Critical Mixture and Process Parameters on key Critical Quality Attributes (response data sets).

Color gradation represents the magnitude of critical parameter effects with curvature indicating the nature of the effects.

Fusion AE automatically analyses all response data, and identifies regions, where formulations and processes will optimally perform.

3D Response Surface Plots
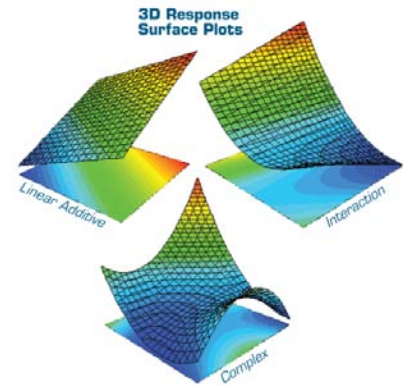
Optimize Formulations/Processes for Mean Performance and Robustness

FPD brings a new QbD-based methodology to formulation and process development. Regulatory guidances state that a best-practices approach should address robustness formulation and process development. Therefore, a critical feature of **FPD** is the patented Robustness Simulator™ technology (U.S. Patent No. 7,606,685 B2), which integrates automatically computed robustness metrics for all Critical Quality Attributes (CQA) studied, into formulation and process development experiments. This novel methodology automates a best-practices approach in which the formulation or process can be rapidly developed and simultaneously optimized for mean performance and robustness.
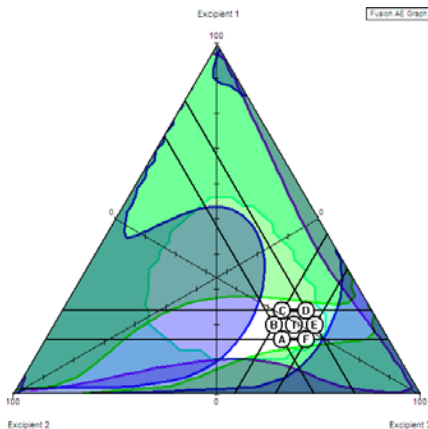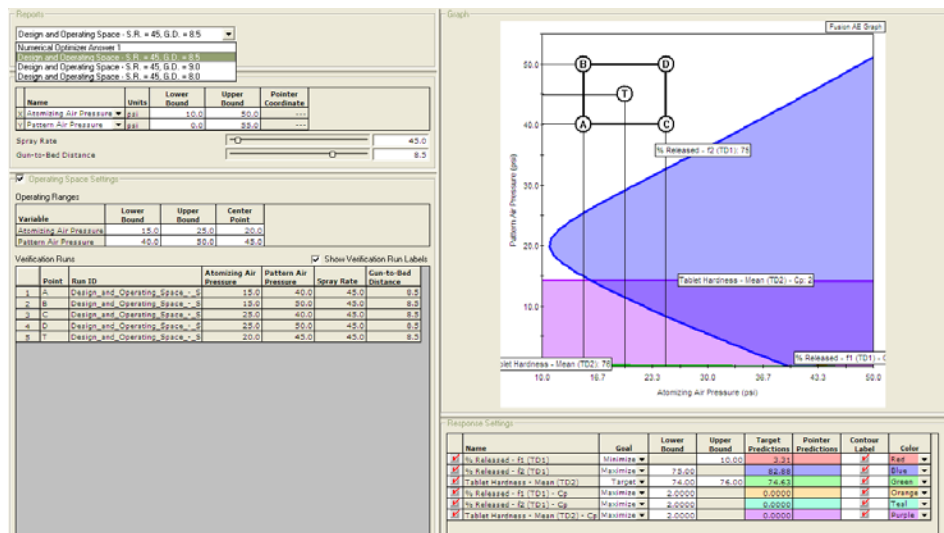
Color-coded response maps define the QbD Knowledge and Design Spaces. Users can predict and display best and most robust conditions.

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 report. You can create any number of design space graphs, with each graph containing a representation of the design space for different level setting combinations of critical parameters.

Fusion Product Development – Science at it's Best

- Scales from workstation to a network or Citrix environment
- Designed for cGXP and 21 CFR Part 11 environments
- Contains an integrated Workflow Management System

S-Matrix®

S-Matrix 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. For the Pharmaceutical and Biotechnology industries, S-Matrix's Fusion AE platform automates and redefines experimentation in Analytical R&D, Chemical and Process R&D, Formulation, and Product R&D.

Fusion AE™ Automated Experimentation Software 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.

■ **Dissolution Method Development – Coming in 2012***

Run dissolution method development experiments on apparatus from multiple vendors. Create coordinated dissolution testing designs for LC built as ready to run in the CDS. Automatically capture LC results and map to the dissolution study for instant analysis, graphing, and optimization.

■ **Fusion Inhaler Testing**

Calculate and collate particle size distribution results, and generate reports according to USP 601 and Ph.Eur. 2.9.18.

■ **Respiratory Drug Product Development – Coming in 2012***

The integration of QbD drug formulation and device design development with Fusion Inhaler Testing's automated Sampling Plan generation and reconstruction in the chromatography data systems and calculation of particle size distribution results according to USP 601 and Ph.Eur. 2.9.18

■ **Fusion Pro***

Combine advanced Data Mining with customizable, state-of-the-art Design of Experiments capabilities.

       * - includes patented Robustness Simulator™, and design space and operating space visualization graphics and reporting.

Support

Sales: 800-336-8428 or 707-441-0404
Technical: 800-336-8428 or 707-441-0406, Weekdays 8AM-5PM, PST
E-mail: support@smatrix.com
FAX: 707-441-0410

Workshops and Training

S-Matrix offers a wide range of workshops as well as training programs for installed systems. Interactive workshops review of current technologies, general principals of DOE and QbD, as well as S-Matrix products. Workshop listings can be found on www.smatrix.com. Hands-on training programs are tailored to suit your experimental requirements. Training includes experiment strategies, design of experiments, data analysis, graphical visualization, and product and process optimization.

To arrange a customized workshop or training program at your location for five to ten participants, call 707-441-0404.