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Key Features Unique to Fusion QbD

- Full 21 CFR 11 Compliance Support
  - Note – some companies market a private logon as full compliance support. However, this is only one of dozens of requirements for full e-signature and e-record compliance.
  - Fusion QbD supports ALL Part 11 e-signature and e-record compliance requirements.

- Cross-platform Compliance with Chromatography Data Software (CDS)
  - Full bi-directional compliance support maintained between Fusion QbD and the Chromatography Data Software (CDS).
  - Support includes full audit trail support with Fusion QbD and the CDS for all data exchanges.
  - Fusion QbD only allows CDS data exchanges to be executed by CDS-authenticated users!

- Integrated Project Management System for Advanced Data Integrity and Security
  - Create projects, associate users with projects, and define a secure external data repository!
  - Only project-associated users can access project data.
  - Project data cannot be saved outside of the secure data repository.
  - External data repository can be coupled to the customers backup/archiving system.

- 100% Aligned with Analytical Quality by Design (AQbD) Principles and Best Practices
  - Fusion QbD supports all current regulatory and industry guidances, including ICH Q2(R2) and Q14, USP <1210> and <1220>, and EP 11.6.
  - Fusion QbD contains guidance-recommended Tolerance and Prediction Interval metrics which combine Accuracy (Bias) and Precision into a single, more sensitive method performance metric.
  - Fusion QbD modeling and analytics can define and visualize both the Method Operable Design Region (MODR) and the Established Conditions to meet regulatory requirements.

- Full Bi-directional CDS Automation
  - Constructs the experiment in the CDS for turnkey experimentation.
  - Eliminates the need for manually constructing experiment sequences, methods, standards, and testing protocols in the CDS.
  - Eliminates manual time, effort, and transcription errors associated with results data capture from the CDS.
  - Chromatographic results can easily be combined with results from other platforms (e.g., dissolution, hardness, friability, etc.) for multi-response optimization.

- Expert DoE System – *Automated Modes for Working Scientists*
  - Critical DoE Flexibility – not just 2 or 3 specific factors, but any combination of factors needed in any given study based on your risk assessment.
  - Automated (1-click) DoE design selection/generation based on the user's defined variables and level of the study. User-interactive data modeling mode for DoE expert users.

- Full Support for Chemistry System Screening (Method Scouting)
  - You only need basic integration – no labor intensive and error-prone peak tracking is required.
  - Flexible Trend Response engine lets you define meaningful metrics of method performance metrics such as number of separated peaks, number of resolved peaks, number of peaks with good peak shape, main peak resolution, first peak retention or K-Prime, and number of peaks with acceptable S/N ratio.
  - Trend Response metrics such as peak/valley ratio and retention time deltas (RTDs) can also be used to support screening for large molecules such as mAbs. These metrics can also be used in Fusion QbD method optimization studies.
  - Fusion QbD automatically extracts all your defined Trend Response metrics from each experiment chromatogram for automated data modeling.

- Automated Peak Tracking for Method Optimization
  - Fusion QbD can track peaks using traditional peak results such as retention, area, and height.
  - Fusion QbD can utilize UV Spectra data to augment traditional peak results to support peak tracking when UV spectra data are available.
  - Fusion QbD can utilize MS Spectra data for peak tracking when MS spectra data are available.

    Fusion QbD uses extremely advanced algorithms to create a unique fingerprint for each peak based on multiple spectra data analytics. This results in hyper-accurate peak tracking, including deconvolution of co-eluted peaks.

- Method Optimization with Flexible, Advanced Chromatographic Data Modeling
  - Hyper-accurate retention-based resolution modeling – unsurpassed predictive precision of both separation and peak shape!
  - Predicts resolution of each individual peak under any method conditions as well as generic prediction of resolution of least-resolved peak pair.
  - Proven predictive accuracy and precision for all separation modes and classes of molecule.
    - RP, NP, HILIC, HIC, IEX, SEC, SFC.
    - Small Molecule, Intact Protein (e.g. mAbs), Chiral, Oligonucleotides, Polysaccharides, Peptides, etc.
  - Fusion QbD is not limited to hard-wired models which can accommodate only a few specific study factors. Fusion QbD can model all important effects of any study factors in any combination for any important result data set.
  - Fusion QbD does not rely exclusively, or principally, on modeling retention versus slope – which most often drives you to a risky multi-segment gradient answer.
  - Accurately models ALL important method effects for any chromatographic result – including additive, interaction, curvature, and nonlinear effects.
  - Automated (1-click) data modeling – state-of-the-art, statistically defensible and aligned with best practices. User-interactive data modeling mode for DoE expert users.
  - Fusion QbD lets you link ALL modeled performance characteristics to identify best overall method and visualize method performance throughout the experimental region.

- Correct Robustness Estimation and Modeling
  - Only Fusion QbD provides a complete implementation of Monte Carlo robustness simulation to establish robustness performance for all included performance metrics throughout the entire experimental region. No additional experimental data are required!

    This unique approach enables you to accurately locate 1) the most robust method for all included performance metrics, and 2) the exact locations of the edges of failure for each performance metric – not only for average performance, but also for robustness.

    This knowledge directly translates into your Analytical Control Strategy (ACS) for:

    - re-qualifying instruments for use with the protocol.
    - monitoring performance.
    - Effectively identifying the root causes before obtaining Out-of-Specification (OOS) results.
  - Other software only uses limited models directly to predict performance of a given candidate method or process.

    However, all these models can only predict the average performance of a given set of conditions – they cannot directly predict robustness.

- Full Support for Complex Experimental Strategies:
  - **Replication Strategy Study** – defines 1) the component contributions of sample preparation error and injection error to the Total Analytical Error, and 2) the optimum preparation-x-injection replication scheme to meet all method performance requirements specified in the Analytical Target Profile.
  - **Forced Degradation Studies** – complete experimental design, CDS automation, peak tracking, and composite chromatogram generation for data modeling, method performance optimization, and chromatogram simulation and visualization.
  - **Sample Preparation Studies** – automated construction of testing protocols in the CDS and automated CDS results retrieval, and automated modeling and robustness simulation to define the optimum preparation protocol and eliminate unnecessary and error-prone steps.
  - **Dissolution Studies** – automated construction of testing protocols in the CDS and automated CDS results retrieval, automated handling of time-series data (multiple tie points per experiment run), including multi-vessel test repeats, automated generation of release profile curves and extraction of user-definable critical profile metrics for data modeling.