Right First Time: Automated System Suitability through Deep Query Dashboards

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Summary

Integrated Framework for System Suitability
Combines automated dashboards and advanced visualization tools to ensure LC-MS instrument readiness and data confidence.

Automation Enhances Efficiency and Compliance
Real-time monitoring via Protein Metrics' Byosphere platform reduces manual intervention, accelerates troubleshooting, and supports regulatory data integrity.

Proactive Validation Improves Data Quality
Early detection of anomalies mitigates risks in biotherapeutic characterization, ensuring reproducibility and robust decision-making in development pipelines.

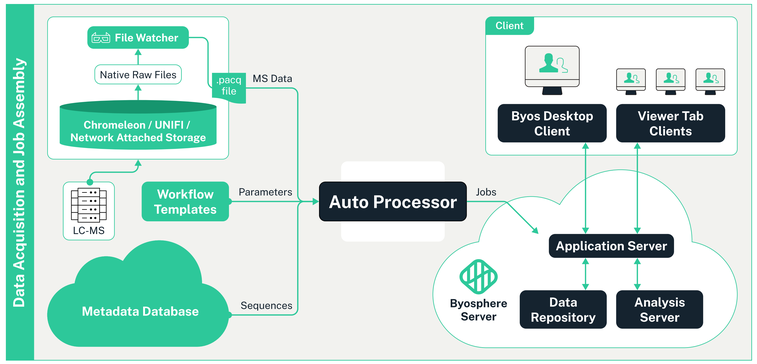
Introduction

Reliable LC-MS data generation for biotherapeutic characterization requires rigorous system suitability assessment before analysis. This work introduces an integrated framework using automated dashboards and visualization tools to ensure instrument readiness and data confidence. Suitability protocols monitor critical indicators such as retention time stability, mass accuracy, peptide digest quality, and chemical quality attributes (CQAs) like oxidation and deamidation, enabling early detection of deviations. Leveraging Protein Metrics' Byosphere platform, automated processing and dashboarding provide real-time evaluation across instruments and workflows. Browser-based access supports global review, while Deep Query dashboards streamline anomaly investigation and root cause analysis, reducing downtime and manual intervention.

This approach improves reproducibility, mitigates risks from inaccurate quantitation or incomplete peptide coverage, and supports regulatory compliance through automated reporting. Case studies show enhanced efficiency and data quality via early anomaly detection and corrective action. Routine implementation strengthens confidence in results, enabling robust biotherapeutic characterization and informed decision-making. Combining system suitability with automation and visualization ensures high-quality, reproducible LC-MS data in modern analytical environments.

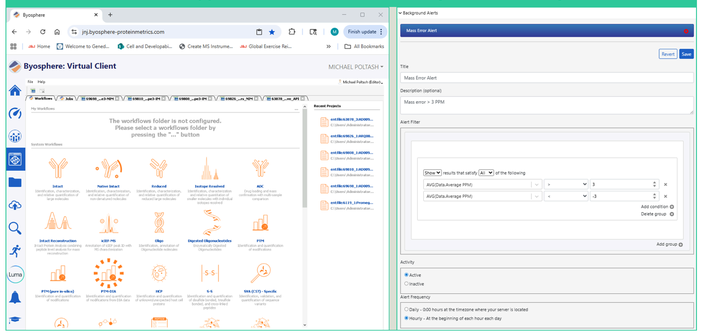
Intact Mass	Reduced Mass	Deglycosylated Intact Mass	Native SEC-MS	Peptide Mapping
• Molecular weight confirmation	• Molecular weight confirmation	• Molecular weight confirmation	• Aggregation	• Trypsin and Chymotrypsin digests
• Clipping	• Glycoform characterization	• Glycation	• Noncovalent interactions	• Sequence variant analysis
• Covalent modifications	• Clipping	• Clipping	• Excess chain expression	• PTM characterization
	• PTM characterization	• Proline amidation		• Sequence confirmation
		• Covalent modifications		• Contamination

Automated Cloud-Based Data Processing & Analysis



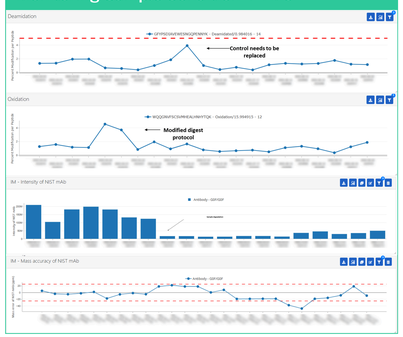
Globally Accessible & Notifications

Browser-based Client App with email notifications for system suitability dashboards

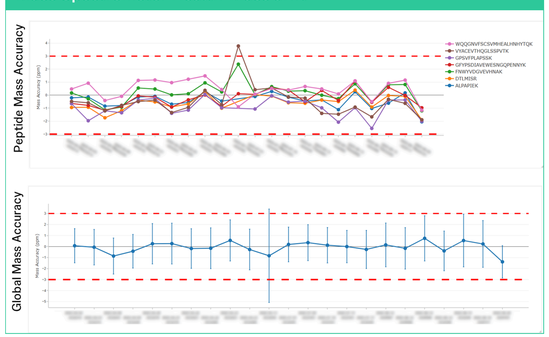


Evaluate System Suitability Controls Earlier-Automation allows us to shift the paradigm

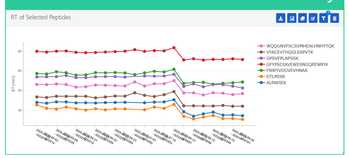
Monitoring Sample Condition- PTMs



Mass Spectrometer Health-Mass drift



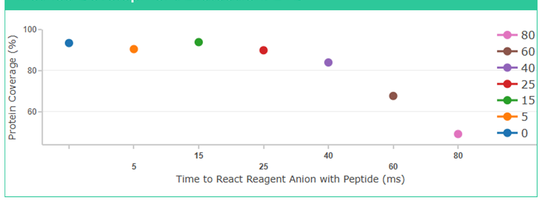
HPLC Health-Retention Time Consistency



Monitoring Sample Preparation-Digest efficiency evaluation

Beyond Quality Control

Method Development Evaluation: ETD



Cross-Platform Comparability