INTRODUCTION
The application of mass spectrometry techniques in late development and QC environments has shown significant advantages in monitoring critical quality attributes (CQAs) at the molecular level, which provides an in-depth understanding of the biopharmaceutical production process and facilitates the implementation of the principles of Quality by Design (QbD) for the process, stability and formulation studies. Here, we demonstrate the applicability of high-performance liquid chromatography (HPLC) for attribute monitoring at both the peptide and subunit levels using an MS platform capable of operating under the compliance requirements of late development and QC environments. A comprehensive workflow for monitoring of domain-specific CQAs, whereas peptide-mapping provides more precise site-specific information.

METHODS
NIST mAbs were treated by H2O2, and then IdeS. Trastuzumab samples were treated with alkaline under conditions that minimized sample disturbance and fast separations displays advantages in throughput for monitoring subunit analysis with. Sample Preparation: the molecular level, which provides an in-depth understanding of the process, stability and formulation studies. Here, we demonstrate the applicability of high-performance liquid chromatography (HPLC) for attribute monitoring at both the peptide and subunit levels using an MS platform capable of operating under the compliance requirements of late development and QC environments. A comprehensive workflow for monitoring of domain-specific CQAs, whereas peptide-mapping provides more precise site-specific information.

RESULTS
The UNIFI accurate mass screening workflow enabled targeted multiattribute monitoring, providing rapid qualitative and quantitative assessment of changes in the sample. The workflow was automated, allowing for rapid screening and subsequent targeted analysis for component ranges (C).

CONCLUSION
• Subunit and Peptide-based analysis both facilitate multiple attribute monitoring assays
• The UNIFI-based platform demonstrated all elements required of systems deployed for Characterization, GMP Development and QbD/Lot Release
• Common platform for characterization and attribute-monitoring for efficient tech transfer
• Support both subunit and peptide MM
• Automation of extraction, processing, and reporting of data
• Compliant architecture ensuring full data integrity

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A COMPLIANT READY HIGH RESOLUTION LCMS PLATFORM
MONITORING CRITICAL QUALITY ATTRIBUTES OF MONOCLONAL ANTIBODIES AT SUBUNIT AND PEPTIDE LEVEL USING A COMPLIANT READY HIGH RESOLUTION LCMS PLATFORM

MOONING CRITICAL QUALITY attributes of monoclonal antibodies at subunit and peptide level using a compliant ready high resolution LCMS platform

Monitoring Product Attributes using Subunit Mass Workflow

Monitoring Product Attributes using Accurate Mass Screening Workflow

Monitoring Product Attributes using Peptide Mapping Workflow

Monitoring Product Attributes using Glycopeptide Profiling Monitoring

Monitoring Product Attributes using New Peak Detection & Identification

Monitoring Product Attributes using Deamidated Peptide Monitoring

Monitoring Product Attributes using Oxidized Peptide Monitoring

Monitoring Product Attributes using Glyceropeptide Profiles Monitoring

Monitoring Product Attributes using Glycoconjugate Workflow

Monitoring Product Attributes using Univariate Data Analysis

Monitoring Product Attributes using Multivariate Data Analysis

Monitoring Product Attributes using Attribute Centric Reporting

Monitoring Product Attributes using GxP Development and QC/Lot Release.