

MASS SPECTROMETRY INNOVATION: IYKYK

By: Singota Solutions

Singota® Solutions is a CDMO located in Bloomington, Indiana, USA that specializes in Parenteral, Early Phase Drug Development and Aseptic Filling projects.

When it comes to drug development, there are two kinds of people: those who know the power of mass spectrometry and those who are about to have their minds blown. For those in the know, mass spec is the unsung hero of early-phase and small-batch drug development—a marvel of science that can identify impurities, confirm molecular stability, and make method transfers feel like a breeze. At Singota Solutions, we've just leveled up our analytical game with the Agilent 1290 Infinity II Bio-inert uHPLC system paired with the XT Single Quad Mass Spectrometer.

Trust us, if you know, you know. If you don't? Buckle up—this is about to get technical.

Why Mass Spectrometry Matters in Drug Development

In the intricate world of drug development, precision is everything. For small molecules and peptides, even the tiniest impurity or degradation product can spell trouble for stability, safety, or efficacy. Mass spectrometry has emerged as a cornerstone of modern analytical chemistry, providing unparalleled insight into molecular structure, mass, and purity. Unlike traditional analytical methods, mass spec doesn't just tell you what's there—it shows you the molecular landscape, offering a high-resolution view of related substances and potential impurities.

For small-batch and early-phase development, where quantities are limited, and timelines are tight, the ability to generate high-resolution mass data is a game-changer. The XT Single Quad Mass Spectrometer at Singota Solutions can handle it all, from small molecules to large peptides, with precision that rivals a Swiss watch. This capability is especially critical during stability studies, where unexpected peaks can emerge over time. Mass spec doesn't just detect these anomalies; it helps identify them, providing a clearer understanding of a drug substance's behavior.

The Agilent 1290 Infinity II: The Perfect Pairing

Mass spectrometry is only as good as the system that feeds it, which is where the Agilent 1290 Infinity II Bio-inert uHPLC system shines. This state-of-the-art chromatography platform ensures that samples arrive at the mass spectrometer in peak condition, separating complex mixtures with high precision and reproducibility. At Singota, the 1290 Infinity II is a workhorse for method development and transfer, ensuring seamless integration with external laboratory methods.

One standout feature of the system is its ability to compensate for subtle differences when methods are transferred from other HPLC platforms. Analytical method transfers can be notoriously tricky, often requiring adjustments to maintain consistency. The software powering the Agilent 1290 mitigates these issues, enabling seamless transitions and reliable results. This is a boon for CDMOs managing complex pipelines with diverse client needs—saving time, resources, and a few headaches along the way.

Expanding the Analytical Horizon

For early-phase clients, where every bit of data counts, the addition of mass spectrometry services means more robust decision-making. The XT Single Quad Mass Spectrometer enables deeper insights into API purity, degradation pathways, and the impact of formulation on molecular stability. This translates to fewer surprises during later development stages, reducing the risk of costly delays or failed studies.

Furthermore, Singota's system is uniquely suited to support challenging method transfer projects. Whether the methodology comes from another lab or another continent, the combination of HPLC and mass spec ensures reproducibility and accuracy. These tools aren't just advancing our analytical capabilities; they're pushing the boundaries of what's possible in small-batch and early-phase drug development.

Conclusion: A Mass Spec Masterclass

Mass spectrometry isn't just another tool in the drug development toolbox—it's the MVP. At Singota Solutions, we're thrilled to offer this cutting-edge capability, empowering our clients to tackle complex analytical challenges with confidence. Whether it's identifying a rogue peak, transferring a tricky method, or unlocking new insights into molecular stability, the Agilent 1290 Infinity II and XT Single Quad Mass Spectrometer are rewriting the rules of early-phase development.

So, are you part of the "IYKYK" crowd yet? If not, there's no better time to get acquainted with mass spectrometry's transformative potential. Because in the fast-paced world of drug development, staying ahead of the curve isn't optional—it's essential. Stay tuned for more insights from the Singota team, and if you're ready to make mass spec magic happen for your next project, you know where to find us.



Singota Solutions is a US based CDMO in Bloomington, Indiana. Singota specializes in formulation development and aseptic fill finish for injectable projects. Once a formulation is established, Singota utilizes state of the art robotic filling technology and focuses on smaller batch size requirements. For more information, visit Singota.com to explore how Singota has established itself as a one-stop solution for all your developmental needs.

Contact solutions@singota.com to schedule a meeting with our business development team to further discuss your current or future projects.