

A transformation in the pharmaceutical industry has occurred in the past few decades due to the advancement of biologics as therapeutic agents. What is less often discussed is a similar shift in companies that support this industry. The more complex biotherapeutics become, the more sophisticated methods the analytical development laboratories require to analyze these new modalities. Governed by regulatory agencies including the FDA and EMA, the characterization requirements for a biologic are provided as guidelines with flexibility.

The International Council of Harmonisation (ICH) brings together pharmaceutical companies and regulators to discuss the critical technical details of new drug registrations. Stemming from these meetings, the ICH Q6B document is a standard document outlining the analytical criteria required for biological products. Embedded in these guidelines are chromatography and mass spectrometry (MS) techniques that can be employed for biotherapeutics characterization. As mentioned before, the companies that support the pharmaceutical industry, including analytical solution providers, are constantly evolving to keep up with the high level of scrutiny necessary for emerging modalities.

Phenomenex and sister company, SCIEX, are two prime examples of solution providers that are evolving along with the pharmaceutical industry to support the trend toward biologic drug products. Next month, our teams will be near two biotech hubs, San Francisco and San Diego, to present some recent developments to support the biopharmaceutical industry in their analytical development.

**Registration is open and can be found here:**

<https://info.sciex.com/Biotherapeutics-Seminar-Series-2019>

From Phenomenex, Dr. Michael McGinley and Brian Rivera will be presenting on our latest advances in native protein and oligonucleotide analysis by chromatographic methods. Take a quick look into what you can expect from their presentations:

### **Native Protein Analysis**

Analytical development scientists are constantly looking for new ways to analyze proteins with the most detail but least experimentation as possible. While some chromatographic methods are emerging to leverage advances in mass spectrometry, such as multi-attribute methods, scientists still have to run the gamut of chromatography techniques to fully characterize biopharmaceuticals protein including, at minimum, size exclusion chromatography, ion exchange chromatography, peptide mapping, intact and subunit analysis, and N-glycan analysis. A recent trend in the field is to look at proteins in their native, non-denatured state combined with MS. Deemed native MS, there are inherent challenges due to the salt content in the chromatographic mobile phase required to keep the protein in the native state. Moreover, from a chromatography standpoint, the mobile phase must be suitable to provide acceptable separation of aggregated from monomeric protein. In March, our team will discuss these challenges and provide some guidance for researchers to consider when native MS techniques on our bioZen columns.

## Oligonucleotide Analysis by SPE

Synthetic oligonucleotides in the biopharmaceutical industry is gaining more attention in recent years. During the development of these therapeutics, DMPK laboratories are required extract these therapeutics from biological matrices including plasma and serum, to assess their pharmacokinetic (PK) information. This task is especially challenging with oligonucleotides compared to their small molecule counterparts, and even proteins, due to their much lower concentration. Traditional methods to perform this analysis are complex, laborious and time consuming. In recent years, Phenomenex developed a solution to address these issues and created Clarity OTX. This tool to perform oligonucleotide extraction from biological matrices quickly emerged as the most efficient method on the market. In March, our team will discuss the development of Clarity OTX and provide technique considerations for analytical scientists interested in using this method.

Don't forget to register for this seminar series "Powerful Analytical Solutions for Biotherapeutics Development & QC", as they could be coming to a city near you!

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