

# Biotherapeutic Quantification eBook

Robust methods for accurate quantification in biological matrices at every stage of the process



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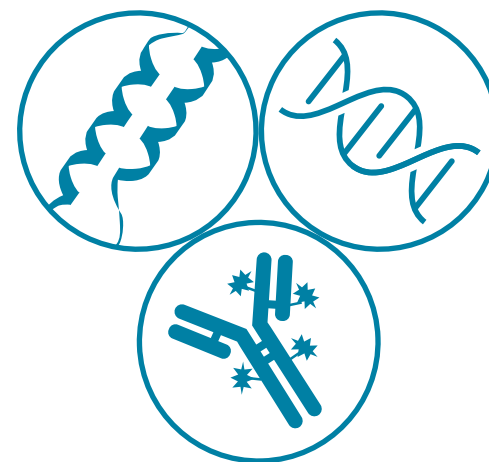
# Introduction

**Biotherapeutics offer novel and often revolutionary new treatments for diseases with unmet clinical needs. However, the development of this relatively new class of drugs is far from easy.**

**Successful biotherapeutic development requires robust methods for accurate quantification in biological matrices, at every stage of the process.**

The biotherapeutic discovery pipeline has expanded to encompass a wide range of modalities. Now, researchers are not only required to contend with challenges presented by monoclonal antibodies, but also by fusion proteins, antibody-drug conjugates, and oligonucleotides.

Different molecules raise different challenges, such as peptides with poor fragmentation efficiencies, oligonucleotide samples with high background interference, and large biomolecules that must be quantified intact.



## This eBook highlights:

- Techniques to overcome challenges in the development of biotherapeutic compounds
- How using LC-MS/MS offers you the sensitivity, linear dynamic range and selectivity you need to overcome biotherapeutic quantification challenges
- Market trends from around the world
- Demonstrations of robust SCIEX instruments handling complex and “dirty” biological samples

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# A Global Perspective



**Babburaj Kunnumal**

Senior Global Market  
Manager, Biopharma

**“Collaborating with our  
customers to bring life  
saving therapeutics to  
patients faster.”**

The biopharma industry has changed significantly over the past 25 years. Initially, many of the therapeutics coming through development were monoclonal antibodies (mAbs). Indeed, five of the top 10 best-selling drugs in 2017 were mAbs. Issues with efficacy, however, led to a new generation of biotherapeutics in the last decade, such as antibody-drug conjugates (ADCs), bispecific antibodies and fusion proteins. Very recently, there has been renewed interest in oligonucleotide-, mRNA- and cell-based therapies. While these types of molecules have been studied for their therapeutic potential, difficulties with stability and delivery reduced their ability to reach the market. Many of these problems have been resolved in the last few years, paving the way for increased new drug development in this area.

Conversations with customers reveal that current drug development pipelines contain many of these different types of biological molecules. This presents significant challenges for routine biotherapeutic quantitative analysis. Different types of molecules mean different demands for selectivity, specificity and dynamic range. Researchers need an array of different workflows that can be used for quantification, often in extremely challenging biological matrices, throughout different stages of clinical development. When working with customers, our focus is on delivering reliable solutions that can adequately address their needs for various types of biotherapeutics.

One area we are currently watching with interest is vaccine development. The field has shown a resurgence recently within the industry as pharma companies seek single vaccines that can be used to prevent multiple diseases. Significant investment is being made in this space by some of the largest global funding bodies. After many years on the backburner, the discovery side of vaccines is becoming profitable again. As the field develops further, researchers will need new, reliable methods for quantification, which SCIEX is poised to deliver.

Success in these areas are due to the reputable robustness, sensitivity and wide dynamic range offered by SCIEX CE and LC-MS instruments. As the interest in oligonucleotides increases for both therapeutic use and reagent manufacture, SCIEX will continue to work with customers to understand their challenges and deliver analytical solutions that help bring their important lead molecules through the drug development pipeline.

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