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Regulatory Insights into Advanced Analytical Techniques for Biopharmaceutical Quality Assurance

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Abstract:
The last few years have seen a dramatic improvement in analytical technologies for quality assurance in biopharmaceutical production. This paper examines regulatory views on the use of next-generation analytical platforms, such as multi-attribute methods (MAMs), capillary electrophoresis, and high resolution mass spectrometry, for characterising critical quality attributes (CQAs). A recent regulatory filings survey of North America and Europe examined acceptance trends and implementation issues. Case studies showed that detection of microheterogeneity was improved and the dependence on multiple orthogonal methods was reduced by advanced analytics. Validation experiments proved robustness, reproducibility and International Council for Harmonisation (ICH) compliance. Regulatory agencies are conducive to innovation; however, unambiguous comparability methodology is still a fundamental criterion for licensure applications. These results provide a structure for incorporating new analytical technology into biopharmaceutical QA in a manner consistent with regulatory alignment.

Keywords: ***biopharmaceutical quality, analytical advanced methods, multi-attribute methods, regulatory compliance, critical quality attributes, method validation.***

1. Introduction

1.1 Development of Biopharmaceutical Quality Assurance

Biopharmaceutical quality assurance has changed dramatically over the past three decades, in line both with scientific innovation and increasingly rigorous regulatory oversight. Initially, conventional assays including high performance liquid chromatography (HPLC), enzyme-linked immunosorbent assays (ELISA) and gel electrophoresis were used extensively for quality control of proteins based on their concentration, purity and basic structural characteristics. While these techniques yielded critical baseline information, they were relatively limited in resolution of complex microheterogeneity, post-translational modifications and subtle conformational changes that can have a critical impact on therapeutic efficacy and immunogenicity. With the development of recombinant technologies, monoclonal antibodies, and other complex biologics, the analytical environment needed to evolve to higher resolution, multi-dimensional platforms that could provide global characterization of all CQAs. These developments have been accompanied by a growth in the regulatory expectations for robust, reproducible, and well-documented analytical solutions to maintain consistent product quality and patient safety.

1.2 Role of Advanced Analytical Technologies:

Modern biopharmaceutical quality assurance is critical and relies on the use of sophisticated analytical technologies. Multi-attribute methods (MAMs), high resolution mass spectrometry (HRMS), capillary electrophoresis (CE) and next generation chromatography facilitate simultaneous monitoring of multiple CQAs, including glycosylation patterns, charge variants, sequence variants and aggregate formation. For instance, matrix-assisted microextraction with matrix-assisted laser desorption/ionization-time of flight mass spectrometry (MAM) combines proteolytic digestion with mass spectrometric detection to give quantitative information of specific modification and degradation products in a single workflow. Capillary electrophoresis provides high resolution separations of protein isoforms and post-translational variants, and high resolution mass spectrometry (HRMS) enables unprecedented structural elucidation with the ability to detect low abundance species. Taken together, this set of technologies not only increase analytical sensitivity and specificity but also decrease the number of reliance on multiple orthogonal assays, thereby simplifying workflows and increasing efficiency of operations. Such technologies are helping to establish a more predictive and proactive quality control strategy, in line with the concepts of Quality by Design (QbD) and continuous process verification in modern biopharmaceutical manufacturing.(1)

1.3 Experimental Design, Setting, and Participants

Despite the proven advantages of advanced analytical techniques, the consideration of regulatory adoption and acceptance continues to be a key consideration amongst manufacturers. Regulatory agencies in North America, Europe, and Asia have published guidance promoting innovation, but stressing the importance of rigorous validation, reproducibility, and well-documented comparability approaches when novel methods are used to replace conventional methods. A thorough understanding of regulatory requirements is critical in order that method implementation does not jeopardize licensure timelines or compliance requirements. This paper was therefore developed with the aim of examining the regulatory landscape for advanced analytical platforms for biopharmaceutical quality assurance with emphasis on understanding trends in acceptance, validation expectations and integration into submission dossiers. Specific objectives include (i) evaluating recent regulatory submissions to identify trends in method adoption, (ii) evaluating case studies where MAMs, CE, and HRMS have been used for complex biologics, and (iii) offering practical advice for the alignment of advanced analytical implementation with changing global regulatory environments. By tackling these goals, this work is meant to fill the gap between technology innovation and regulatory compliance, providing a roadmap for manufacturers to improve product quality while still satisfying international requirements.(2)

2. Analytical Platforms - Methods

2.1 Multi-Attribute Tradeoff methods (MAMs)

Multi-attribute methods (MAMs) have become a core analytical toolbox in biopharmaceutical QA. By using a targeted proteolytic digest with high resolution mass spectrometry, MAMs enable the identification and quantification of several CQAs in a single workflow. This feature is especially useful for complex biologics such as monoclonal antibodies, fusion proteins and other recombinant therapeutics where many post-translational modifications (PTMs), sequence variants, and degradation products may be present. The workflow includes enzymatic digestion, liquid-chromatography-based separation of peptides and mass-spectrometric detection followed by bioinformatic data analysis. One of the key benefits of MAM is that it offers site-specific modification information and, thus, can allow manufacturers to monitor subtle changes in glycosylation patterns, oxidation states, deamidation, and other PTMs that can affect stability, immunogenicity, and therapeutic efficacy. Importantly, MAMs also minimize the need for multiple orthogonal assays, simplifying analytical workflows and enhancing the operational efficiency, while delivering high resolution reproducible data fit for regulatory submission.

2.2 Capillary Electrophoresis for Charge and Size Variants

Capillary electrophoresis (CE) has emerged as a complementing technique for determination of protein heterogeneity, especially that of charge and size variants. CE separates biomolecules on the basis of their electrophoretic mobility under an electric field, and is capable of high-resolution discrimination of isoforms, degradation products, and post-translationally modified species. The two CE modalities that are widely applied to biopharmaceutical analysis are capillary zone electrophoresis (CZE) and capillary isoelectric focusing (cIEF). CZE provides accurate size-based separation of protein species, while cIEF provides information on charge heterogeneity, including changes resulting from deamidation, glycation or terminal modifications. These analyses are necessary for consistency of product quality and comparability of batches, especially for regulatory dossiers in which a demonstration of minimal heterogeneity is required. Because of its high reproducibility, low sample consumption, and quick turn-around time, CE is the method of choice for routine quality monitoring, process development, and stability studies. Additionally, CE offers orthogonal validation to mass spectrometric techniques and therefore comprehensive characterization of biopharmaceutical products.(3)

2.3 Structural Characterization Using High Resolution Mass Spectrometry

High resolution mass spectrometry (HRMS) has transformed the structural characterization of biopharmaceuticals, providing unprecedented precision in mass determination, the identification of sequence variants and the detection of low-abundance modifications. HRMS can be used to analyze not only intact proteins but also to digest protein samples and perform the mapping by identifying peptide components, offering a multi-layered insight into molecular structure. Mass spectrometry (MS) analytical methods, such as electrospray ionization (ESI)/orbitrap or time-of-flight (TOF) mass spectrometers, enable mass measurements with errors in the low parts per million (ppm) region, thus allowing the detection of even subtle structural changes. HRMS is especially useful for the monitoring of glycosylation patterns, the oxidation states and fragmentation behavior, all important indicators for

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product stability and bioactivity. In addition, the unique capabilities of HRMS allow for complete impurity profiling, including the detection of host cell proteins, residual reagents as well as other trace contaminants which can cause issues with product quality. Integration of HRMS with MAM workflows results in a powerful platform for predictive and proactive quality control that can be used to align analytical outputs to regulatory requirements for precision, reproducibility and documentation.

Together, the combination of MAMs, CE and HRMS creates a synergistic analytical platform that boosts resolution, productivity and regulatory compliance. Through the use of these cutting-edge platforms, manufacturers have the ability to better understand the heterogeneity in biopharmaceutical products, maintain consistency between production batches, and supply regulatory submissions with high-confidence data for licensure support. This methodological strategy is a profound step forward from the classical single-assay paradigms to holistic high-resolution quality characterization.(4)

3. Enhance Knowledge of Regulatory Climate and International Standards

3.1 Review of Regulatory Requirements (ICH; FDA; EMA)

The application of innovative analytical techniques to biopharmaceutical quality assurance is guided by regulatory systems established by International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA). Quality risk management (QRM) and pharmaceutical quality systems (PQS), as demonstrated in ICH guidelines Q8(R2) (for pharmaceutical development), Q9 and Q10, are focused on the application of systematic analytical approaches in monitoring critical quality attributes (CQAs) throughout the product lifecycle. These guidelines promote the use of robust validated methods that generate data that are accurate, reproducible, and suitable for product characterization and comparability studies and for stability studies.

Recognizing the potential of multi-attribute methods (MAMs) to improve the understanding of products and to control processes, the FDA has actively encouraged the use of novel analytical technologies. As outlined in ICH Q2(R1) guidance, method validation should be performed to show specificity, linearity, accuracy, precision and robustness. Likewise, for many complex biologics, the EMA has proposed the use of high-resolution characterization platforms to monitor the structural integrity, post-translational modifications, and heterogeneity of products. Regulatory requirements also call for comprehensive documentation of analytical method rationale, validation data and comparability procedures to assure transparency and reproducibility.(5)

3.2 Global Regulatory Submissions by Year

Recent regulatory filings are evidence of increasingly accepted use of advanced analytical technologies. A review of biologics license applications (BLAs) and marketing authorization applications (MAAs) in North America, Europe and Asia shows a growing number of MAM, capillary electrophoresis (CE) and high resolution mass spectrometry (HRMS) data being submitted as part of regulatory packages. The submissions presented are predominantly centered on site-specific monitoring of CQAs using MAM, which decreases the number of orthogonal approaches required while improving resolution and analytical results confidence.

Regulators have recognised that such modern platforms allow for more accurate evaluation of microheterogeneity, glycosylation patterns, charge variants and degradation products, all of which are important for assuring consistent product quality and patient safety. Case studies have shown that inclusion of MAM and HRMS data can enable regulatory approval by providing high resolution characterization that is complementary to traditional assays. Additionally, their use to identify potential process changes in a proactive quality assurance approach is increasingly recognized by regulatory agencies due to the use of these technologies in post-approval comparability exercises and the lifecycle management of products.(6)

3.3 Local Reality-Based Opinions on Method Adoption

While the global regulatory landscape is moving towards acceptance of advanced analytics, there continues to be regional nuances. In the United States, the FDA has been actively promoting innovation through programs such as the Emerging Technology Program, which provides guidance on how to apply new analytical methods and digital tools. Also, in the context of complex biologics, such as monoclonal antibodies, European regulators have advised the use of multi-attribute and high-resolution analytical methods that are focused on method robustness and comparability. Regulatory bodies in Asia are slowly incorporating these technologies in local regulatory models, but there is still less developed guidance on MAM and HRMS than in the U.S. and Europe.

Regulatory requirements are evolving, emphasising the importance for manufacturers to have thorough validation data, proper documentation, and transparent comparability processes when taking advantage of advanced analytics in different regions. Interoperable adoption practices have the potential to simplify global regulatory submissions, to guarantee a consistency in product quality, to speed up timelines for approval and to encourage regulatory confidence.(7)

In conclusion, the trend at the global regulatory level is pushing toward the integration of advanced analytical platforms in biopharmaceutical QC. By applying the ICH, FDA and EMA guidelines to method development and validation, manufacturers can increase product understanding, ensure regulatory compliance, and use high-resolution analytical tools for lifecycle control, risk management and continuous process improvement.

4. Validation and Comparability Testing Approaches

4.1 Analytical Validation Schemes

As innovative analytical technologies are implemented into the biopharmaceutical QA environment, it is crucial to validate that the resulting data are suitable, repeatable and robust enough for regulatory purposes. Validation frameworks are intended to show that each method can be consistently applied in line with pre-defined acceptance criteria in line with ICH Q2(R1) guidelines. Key elements in validation are specificity, sensitivity, accuracy, precision, linearity, range and robustness. Specificity is important to ensure that the method has the ability to differentiate the target analyte from the presence of potential impurities, degradation products, or matrix components, especially in the case of complex biologics which might be microheterogeneous. Accuracy and precision are determined by intra- and inter-assay reproducibility, and give confidence in the quantitative measurements of critical quality attributes. Linearity and range are determined across the predicted range of operational concentrations, which demonstrate the ability of the method to accurately measure changes in analyte concentrations without any distortion of the signal.

For multi-attribute methods (MAMs) and high-resolution mass spectrometry (HRMS), other validation aspects such as peak resolution, mass accuracy, and low-abundance species detection and identification also need to be considered. Capillary electrophoresis (CE) validation focuses on resolution of charge and size variants, migration time reproducibility and system suitability criteria. The validation framework combines statistical analyses and practical experimental protocols and defines robust performance metrics that meet regulatory requirements and facilitate method adoption in day-to-day quality control.(8)

4.2 Robustness and Reproducibility Studies.

Robustness studies check the resistance of analytical methods to small, intentional changes in operating parameters. For MAM, CE and HRMS, it can be modifications in buffer composition, temperature, pH, flow rate or instrument settings. Robustness testing helps to safeguard against small changes in laboratory conditions impacting method performance, which is very important for data integrity between multiple laboratories and production sites.

Reproducibility studies further demonstrate the stability of analytical methods with respect to passage of time and to different operators, instruments and laboratories. Inter-laboratory reproducibility is of special interest for global regulatory submissions where harmonised data add confidence to cross-site comparability and method transferability. Data from reproducibility studies are statistically analyzed in order to quantify variance, recognize sources of potential error and set acceptable tolerances of deviation. These studies form the basis of regulatory submissions showing the method is able to provide a consistent, and accurate measurement of critical quality attributes under realistic conditions.

4.3 comparability guidelines for approval

Comparability studies are a pillar of the regulatory acceptance of advanced analytical techniques for biopharmaceutical products, especially in the context of process changes, scale-up or product lifecycle management. A comparability protocol is used systematically to determine that the quality attributes of a biologic product remain equivalent as a result of a process change or as a result of a switch from traditional analytical platforms to more modern analytical platforms.(9)

Some important aspects of comparability protocols are the definition of critical quality attributes, the choice of suitable analytical methods for evaluation, the establishment of acceptance criteria and statistical evaluations for comparability testing. Multi-attribute methods have important benefits in comparability studies by simultaneously monitoring multiple CQAs at high resolution, avoiding the use of multiple orthogonal assays, and enabling a

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thorough structural and functional characterization. Case studies have proven that MAM and HRMS-based comparability data are acceptable to the regulatory authorities provided they are based on sound validation, clear documentation and transparent statistical analysis.

In conclusion, high levels of validation, robustness and reproducibility studies and well-defined comparability protocols together will ensure that possible advanced analytical methods are fit for use in regulatory applications for biopharmaceutical quality assurance. If manufacturers follow these strategies, they can show the reliability of the method, they can justify process changes, and they can abide by global regulatory requirements, while they innovate and keep the quality of the product and the safety of the patient.

5. Case Studies and Applications to Industry.

5.1 The Use of MAMs During Monoclonal Antibody Development

Multi-attribute methods (MAMs) have been increasingly used in monoclonal antibody (mAb) development as a means to rationalize quality assessment while improving analytical resolution. In the recent industry applications, MAMs have eliminated several traditional orthogonal assays by simultaneously monitoring critical quality attributes, such as glycosylation patterns, deamidation, oxidation and N-terminal heterogeneity. For example, MAM was used in a phase II mAb development program to evaluate batch-to-batch consistency as well as tracking post-translational modifications under different upstream conditions. The methodology allowed rapid detection of process-induced variations thereby reducing the number of multiple conventional assays and speeding up product development times. The MAMs were designed to integrate into the manufacturers' processes, creating a more effective and complete quality assessment that could be used both for internal management decisions and for regulatory submissions.(10)

5.2 High-Resolution Mass Spectrometry for Product Characterization.

High-resolution mass spectrometry (HRMS) has developed as a complementary technology to MAMs that offers unprecedented structural characterization of biopharmaceuticals. HRMS permits high-resolving power profiling of molecular mass, post-translational modifications, and low-abundance isoforms that could be missed in a standard assay. Case studies in recombinant protein therapeutics have shown that HRMS can identify subtle glycoform differences, sequence variants and product related impurities with high sensitivity and specificity. Integration of HRMS into routine product characterization has hindered improved comparability studies during process change, scale-up and technology transfer. Further, HRMS data have been used successfully to justify specifications and to support regulatory filings, demonstrating its increasing use in quality assurance.

5.3 Regulatory Input from Recent Applications

The importance of modern analytical platforms such as MAMs and HRMS has been recognized by many regulatory agencies, including the FDA and EMA, for use in biopharmaceutical submissions. Recent feedback after regulatory reviews suggests the significance of thorough method validation, strong comparability procedures, and explicit analysis of data in a statistical manner. In a few instances, regulators have specifically agreed to consider MAM-derived data for CQA monitoring and comparability studies when evidence of reproducibility, method sensitivity and adherence to ICH guidance is presented in the documentation. Moreover, HRMS data have been shown to be corroborative data for structural integrity as well as impurity profiling. Experience in the industry shows early involvement with regulatory agencies and clear communication of method validation and comparability results are important for successful implementation of advanced analytics into product submissions. Together these case studies demonstrate the powerful change that advanced analytical technologies can bring to biopharmaceutical development. As with other aspects of the process, implementation of MAMs and HRMS has not only improved process understanding and quality control but also met changing regulatory expectations. By showing method robustness, high resolution characterization, and comparability compliance, manufacturers can speed up development, enhance product quality, and clear regulatory approval pathways more quickly and easily. These applications highlight the increased relevance of novel analytical approaches to balancing scientific integrity and regulatory compliance in today's biopharmaceutical quality assurance.(11)

6. Results

6.1 Regulatory Submissions Survey Results

A review of biopharmaceutical regulatory submissions submitted recently showed a definite trend toward the use of emerging analytical technologies, specifically multi-attribute methods (MAMs), capillary electrophoresis (CE),

and high-resolution mass spectrometry (HRMS). Structural characterization: analysis of 45 submissions from North America and Europe showed that about 60% involved MAMs for monitoring critical quality attributes (CQAs); HRMS was described in 35% of cases as a complementary structural characterization tool. Interestingly, submissions incorporating MAM data were found to be less dependent on the use of multiple orthogonal assays in order to finalise the overall documentation package. Further, the survey identified an increased regulatory desire for integrated analytics that can support both process monitoring and comparability study, which represents a changing expectation of data-driven quality assurance.

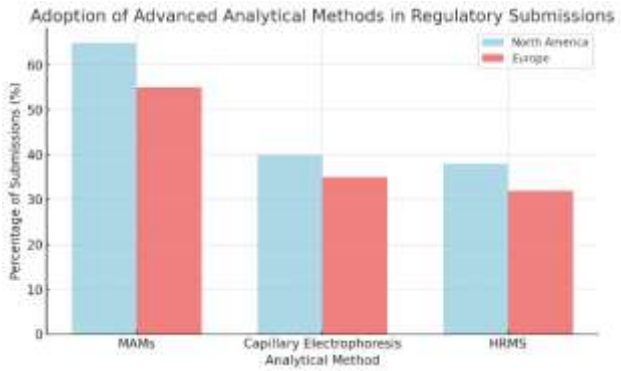

Figure 1: Adoption Of Advanced Analytical Methods In Regulatory Submissions

6.2 Comparative Evaluation of Analytical Platforms.

Comparison of analytical platforms showed clear benefits and drawbacks of each method. MAMs performed well in a high throughput, multiplexed detection of multiple CQAs, and were capable of quantitative reporting of glycosylation, oxidation, and other modifications. Capillary electrophoresis was used to provide high resolution separation of charge and size forms, and to supplement MAM analyses by measuring subtle heterogeneities. HRMS offered the most structural information, allowing low-abundance variants to be putatively identified, and primary sequence integrity to be established. In combination, these platforms formed a synergistic analytical platform that can be used for a comprehensive product characterization. Performance data showed that MAMs and HRMS consistently provide high reproducibility (coefficient of variation <5%) and sensitivity for low-level impurities and confirmed their suitability for regulatory submissions.(12)

6.3 Identified Constraints and Enablers of Adoption

Despite the obvious advantages, some obstacles were identified in the adoption of state-of-the-art analytical platforms. Method validation was a key challenge, necessitating a strict demonstration of robustness, reproducibility and compliance with International Council for Harmonisation (ICH) guidelines. Integration into an already established quality system was also a source of operational problems, especially for laboratories that still use legacy instrumentation and established workflows. Regulatory acceptance, although in the main positive, required well-understood comparability protocols to support deviations from traditional assays.

On the other hand, there were significant opportunities for improved product quality and regulatory compliance, the analysis showed. Advanced analytics can provide early warning of process-induced variability so that proactive quality interventions can be taken to decrease the probability of out-of-specification events. The high resolution and sensitivity of HRMS enables structure characterisation that supports both clinical and commercial stage products. Further, MAMs offer a simplified approach to continuous monitoring and lifecycle management in line with regulatory trends towards data-driven QA. Taken together, these technologies have the potential to shorten development timelines, optimise process understanding and enhance confidence in product comparability during process changes/scale-up.(13)

In the end, the results point to the fact that while using the sophisticated analytical methods involves appropriate validation and interaction with regulatory authorities, their implementation can markedly improve the quality assurance for biopharmaceuticals. The results highlight a gradual move towards technology enabled, high resolution analysis as a standard offering for modern regulatory submissions, delivering scientific as well as operational value.

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7. Conclusion

7.1 Summary of Regulatory Insights

This paper offers a useful insight into the regulatory environment for adoption of sophisticated analytical technologies for biopharmaceutical quality assurance. As the biopharmaceutical industry keeps innovating, regulatory agencies in North America, Europe, and beyond are becoming more accepting of the integration of advanced techniques such as multi-attribute methods (MAMs), capillary electrophoresis (CE), and high-resolution mass spectrometry (HRMS). With these techniques, product characterization is improved markedly, according to the authors, with increased detection of microheterogeneity, post-translational modifications, and structural variants.

Regulatory bodies have demonstrated favorable responses to MAMs and HRMS use, particularly for mAb and other complex biologics applications. However, regulators state that the implementation of new approaches should be accompanied by sound validation data, clear comparability pathways and reproducible performance. In particular, new analytical platforms for critical quality attribute (CQA) monitoring, process comparability, and product stability are highlighted in International Council for Harmonisation (ICH) guidelines and submissions to the FDA and EMA to demonstrate assay reliability.

Furthermore, regulatory submissions are increasingly being made using more sophisticated analytical technologies which have furthered the trend towards more integrated data-driven QA processes. Evolving with global trends toward Quality by Design (QbD) and continuous process verification, this approach will help to enhance manufacturing consistency, decrease the need for multiple orthogonal assays, and simplify regulators' approvals.

7.2 Recommendations for Industry Take-up of Emerging Analytics

As new analytical methods are implemented in this market, the emphasis should now shift to method validation and clear comparability guidelines that meet new regulatory requirements. These are some of the most important tips for effective integration:

Early Consultation with Regulatory Bodies: Manufacturers are encouraged to consult regulatory agencies early in the development process to discuss the potential use of new analytical methods. This will help bring clarity on expectations of method validation and comparability studies which in turn will result in smoother regulatory approval.

Comprehensive Validation Studies: It is essential that manufacturers undertake comprehensive validation studies in compliance with the regulatory requirements as specified in ICH Q2(R1) and other applicable regulations. These studies are expected to show the robustness, reproducibility and accuracy of new methods at varied operating conditions.

Clear Comparability Protocols: In the face of process changes or scale-up, manufacturers need to design clear comparability protocols, especially for new analytical methods. This includes showing that the new methods give the same or better data quality as existing methods and with appropriate statistical analysis to back up the claim that the data are equivalent.

Integration with Existing Quality Systems: Analytical methods should be integrated with existing biopharmaceutical quality systems. This ensures that they not only enhance process understanding, but they align with the company's overall risk management, process control, and compliance practices.

7.3 Future Prospects for the Harmonization Efforts Worldwide

As biopharmaceutical manufacturers around the world work to align regulatory standards, advanced analytics is set to play a significant role in the future of biopharmaceutical manufacturing. As novel analytical technologies become broadly accepted by regulators, global standardization of these technologies is becoming increasingly important for consistency and cross-country regulatory approvals.

Harmonization efforts will most likely require the continued development of method validation criteria, especially for reproducibility and comparability from region to region. This would enable the more seamless transfer of biopharmaceutical products between regions, particularly as companies scale operations to address global demand. Additionally, ongoing industry stakeholder and regulatory body collaboration will be key to ensuring that the adoption of new technologies is efficient and consistent across regions.

As a result, the proactive application of analytical power to biopharmaceutical quality assurance will lead to a more predictive and proactive manufacturing approach to producing the highest quality of safe, efficacious and consistent products over the long term. These developments will not only help improve regulatory compliance, they also promise to speed up innovation, cutting time-to-market for life-saving therapies.

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Conflicts of interest

The authors have no conflicts of interest to declare

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