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Editorial

Advances in the Pharmaceutical and Biotechnology Industry: From Manufacturing to Ethics, Analytics, and Access †

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† Dedicated to the memory of Professor Dr. Ecevit Bilgili (1974–2024), co-founder and first Editor-in-Chief of *Journal of Pharmaceutical and BioTech Industry*.

The pharmaceutical and biotechnology industries are experiencing rapid and multidimensional evolution, driven by advances in chemistry, biologics, data analytics, formulation, as well as regulatory and ethical frameworks. These developments are reshaping how pharmaceutical products are designed, manufactured, evaluated, and delivered to patients. This Special Issue of the *Journal of Pharmaceutical and BioTech Industry* gathers eight contributions that collectively reflect the breadth and depth of contemporary research and practice across the pharmaceutical and biotechnology landscape.

The articles included in this Special Issue span fundamental physicochemical investigations, innovative manufacturing and process monitoring strategies, artificial-intelligence-enabled quality control, bioprocess optimization, ethical governance in global health research, and real-world analyses of drug utilization and expenditure. Together, the articles highlight the increasingly interdisciplinary nature of pharmaceutical and biotechnological innovation.

1. Advances in Biopharmaceutical Manufacturing and Process Monitoring

Biologics now represent a substantial and growing proportion of new pharmaceutical approvals, placing increasing pressure on manufacturing capacity, process robustness, and product stability. Addressing these challenges, Koynov et al. present a precipitation-based approach for producing solid formulations of therapeutic monoclonal antibodies as an alternative to conventional lyophilization. Their work demonstrates that the co-precipitation of proteins with excipients using organic solvents can preserve protein integrity while potentially reducing processing time, manufacturing costs, and exposure to freezing-induced stresses. The study provides a compelling example of how alternative solidification strategies may complement or replace established technologies in biologics manufacturing.

Process robustness and real-time monitoring are equally critical in biopharmaceutical production. Marathe et al. conducted a comprehensive study on the development and implementation of multivariate statistical process monitoring models for monoclonal antibody manufacturing. By incorporating in silico data with historical manufacturing datasets, the authors illustrate how advanced multivariate analytics can improve early fault detection, enhance process understanding, and support preventative interventions. The work underscores the growing importance of digitalization and data-driven decision-making in modern pharmaceutical manufacturing.

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2. Artificial Intelligence and Quality Control in Solid Dosage Forms

Despite the rise of biologics, solid oral dosage forms remain central to pharmaceutical therapy. Ensuring their quality and consistency is therefore of continued importance. Freiermuth et al. addressed the limitations associated with traditional visual inspection of tablet surface defects by introducing a quantitative and automated methodology that combines convolutional neural network-based object detection with deterministic computer vision approaches. Their method enables the precise identification and classification of surface defects such as sticking, picking, chipping, and abrasion, offering improved sensitivity and reproducibility over manual inspection. This contribution highlights the growing role of artificial intelligence in pharmaceutical quality control and process development.

3. Physicochemical Characterization Supporting Formulation Development

Fundamental physicochemical data remain essential for rational formulation and process design. Delgado et al. performed a detailed investigation of the solubility and apparent specific volume of sodium sulfadiazine in ethanol–water mixtures for different temperatures. Using established thermodynamic models, including Jouyban–Acree-based correlations, the authors offer valuable insights into cosolvency effects and volumetric behavior. These findings are directly relevant to preformulation studies, purification processes, and the development of liquid dosage forms, reinforcing the importance of systematic physicochemical characterization in pharmaceutical research.

4. Natural Products, Fermentation, and Nanoscale Formulation Strategies

The search for safer, more sustainable, and pharmaceutically acceptable excipients and processes is a growing priority. Ozsoysal and Bilgili comprehensively reviewed non-traditional natural stabilizers used in drug nanosuspensions. Their analysis covers stabilization mechanisms, formulation performance, pharmaceutical acceptability, and safety considerations, with comparisons to conventional synthetic stabilizers, where available. The review serves as a valuable resource for formulators seeking alternative stabilization strategies aligned with evolving regulatory and sustainability expectations.

In a related application-focused study, Ghosh and Bhattacharya described the development of FERMENZA®, a patented bioactive fermented product designed for cosmeceutical applications. Using a quality-by-design framework, the authors demonstrate that fermentation enhances the antioxidant, antimicrobial, and phenolic contents compared with those achieved with conventional extraction methods. Their findings highlight fermentation as a scalable, cost-effective bioprocess capable of improving bioactive availability while minimizing synthetic excipients, with potential relevance beyond cosmeceuticals.

5. Ethics, Access, and Health Economics

Importantly, scientific innovation must be coupled with ethical oversight and equitable access to its benefits. Rägo and Sawyer addressed ethical governance in clinical trials and health research conducted in Africa. Their opinion article examines calls for Africa-specific research ethics frameworks and emphasizes the continued relevance of internationally harmonized principles, such as the Declaration of Helsinki and CIOMS guidelines. The authors argue that the improved implementation and enforcement of existing frameworks could offer a more effective, less fragmented approach to protecting research participants while supporting responsible innovation.

Economic considerations were further explored by Alqahtani et al., who analyzed the utilization, expenditure, and pricing trends of nonbiologic and biologic disease-modifying antirheumatic drugs within U.S. Medicaid programs over more than three decades. Their

findings reveal a marked shift toward biologic therapies, accompanied by substantial increases in healthcare spending, highlighting ongoing challenges in affordability, sustainability, and access. The study provides important real-world evidence to inform policy discussions surrounding biosimilars and cost-containment strategies.

6. Conclusions

The contributions assembled in this Special Issue reflect the dynamic and interconnected nature of the pharmaceutical and biotechnology industries. By addressing challenges spanning molecular formulation and nanoscale stabilization to digital manufacturing, ethical governance, and health economics, these articles collectively underscore the need for integrated, multidisciplinary approaches.

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Conflicts of Interest: The author declares no conflicts of interest.

List of Contributions

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