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Short communication

Continuous manufacturing in pharmaceutical industry with focus on semisolid dosage forms

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Background

Pharmaceutical manufacturing has traditionally been based on batch production, which involves sequential processing steps and intermediate testing. Although this method ensures compliance with regulatory requirements, it is associated with longer production cycles, increased variability, and higher operational costs. In contrast, continuous manufacturing integrates all unit operations into a single, uninterrupted process that enables streamlined production and improved efficiency (Helal et al., 2019).

Over the past decade, continuous manufacturing has gained significant attention due to advances in automation, digitalization, and real-time process monitoring. Regulatory agencies such as FDA and ICH strongly support its implementation as part of modern pharmaceutical development strategies.

The approach aligns with key quality concepts such as Quality by Design (QbD), where product quality is built into the process, and Process Analytical Technology (PAT), which enables real-time monitoring of critical parameters. As a result, continuous manufacturing is increasingly recognized as a transformative technology capable of improving product quality, reducing costs, and enhancing manufacturing flexibility (Fisher et al., 2022).

Continuous manufacturing and PAT for semisolid dosage forms

The present study is based on an extensive review of scientific literature, regulatory guidelines and industrial practices related to continuous pharmaceutical manufacturing. Key regulatory documents, including ICH Q7, Q8, Q9, Q10 and Q13, were analyzed to understand requirements for quality management, process validation and control strategies. A comparative analysis between batch and continuous manufacturing systems was performed, focusing on process efficiency, variability and product quality. Special attention was given to semisolid dosage forms such as creams, ointments and gels, as they require precise control of process parameters.

Critical process parameters (CPPs) such as temperature, mixing speed, pressure, and particle size distribution were evaluated in relation to critical quality attributes (CQAs). The role of Process Analytical Technology (PAT) tools, including Raman spectroscopy and near-infrared spectroscopy, was also assessed as a key enabler for real-time process monitoring and control (Jelsch et al., 2021).

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Advantages and challenges of continuous manufacturing

The analysis indicates that continuous manufacturing provides multiple advantages over traditional batch production. One of the most important benefits is improved process efficiency, achieved through elimination of intermediate storage and reduction of production time. Continuous systems allow direct transfer of material between unit operations, minimizing the risk of degradation and contamination. In addition, real-time monitoring of process parameters enables rapid detection of deviations and immediate corrective actions. This is particularly important for maintaining consistent product quality. The implementation of PAT tools allows non-destructive, inline analysis of product characteristics, providing deeper process understanding.

In the case of semisolid dosage forms, parameters such as mixing efficiency, temperature control and homogeneity significantly affect product performance (Burcham et al., 2018).

Continuous manufacturing improves control over these parameters, resulting in better consistency and reduced variability. However, challenges remain, including the need for advanced equipment, robust control systems, and validated cleaning procedures to prevent cross-contamination. From an economic perspective, continuous manufacturing reduces material waste, lowers energy consumption and minimizes storage requirements. It also offers greater flexibility, allowing manufacturers to adjust production rates according to market demand. Overall, continuous manufacturing represents a highly efficient and reliable alternative to batch production, especially when combined with modern quality systems such as QbD and Quality Risk Management (Helal et al., 2019).

Conclusion

Continuous manufacturing is a modern and innovative approach that significantly enhances pharmaceutical production processes. By integrating real-time monitoring, advanced control strategies, and robust quality systems, it ensures consistent product quality and improved operational efficiency. Its application in semisolid dosage forms demonstrates strong potential, particularly in achieving better homogeneity and process stability. Despite existing challenges related to implementation and regulatory adaptation, continuous manufacturing is expected to play a key role in the future of pharmaceutical production. Further development of automation technologies and data-driven control systems will support its broader adoption and contribute to more efficient and sustainable manufacturing practices.

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