

Technology Showcase

MASTERING PRODUCT TRANSFER FOR A RANGE OF INJECTABLES

For injectable drug products, quality is often associated with formulation development and final filling operations. However, an equally critical phase occurs between these stages – product transfer. The movement of a product from one processing step to the next can have a significant impact on consistency, uniformity and overall product integrity. As formulations become more complex, transfer operations must be designed to accommodate a wide range of physical and processing characteristics while maintaining product quality throughout manufacturing.

THE HIDDEN COMPLEXITY OF PRODUCT TRANSFER

Different formulations can place very different demands on manufacturing systems. Fully understanding those demands is critical for success. A transfer strategy that works effectively for a water-like solution may not be suitable for a highly



Figure 1: Highly viscous APIs, suspensions and water-like solutions all present different challenges and technical requirements when it comes to product transfer.

viscous product or a suspension prone to rapid settling (Figure 1). As a result, transfer technologies must be carefully aligned with product-specific requirements. The ultimate objective is to maintain molecular fidelity while delivering the product consistently and efficiently throughout the manufacturing process.

A TOOLBOX FOR DIVERSE PRODUCT CHALLENGES

A variety of transfer approaches can be employed depending on the characteristics of the product in question (Table 1). Peristaltic pumping technologies are commonly used for standard solutions, transferring products to a surge vessel before gravity feeding them to downstream operations. Sterile applied nitrogen may also be incorporated as part of the transfer process. For products requiring greater force, positive displacement technologies can provide an effective solution for both sterile and non-sterile applications. Extremely viscous products may require piston-driven transfer systems that use piston-and-cylinder technology.

“A TRANSFER STRATEGY THAT WORKS EFFECTIVELY FOR A WATER-LIKE SOLUTION MAY NOT BE SUITABLE FOR A HIGHLY VISCOUS PRODUCT OR A SUSPENSION PRONE TO RAPID SETTLING. AS A RESULT, TRANSFER TECHNOLOGIES MUST BE CAREFULLY ALIGNED WITH PRODUCT-SPECIFIC REQUIREMENTS.”

Product Type or Challenge	Transfer Solution
Standard solutions	Peristaltic pumping with surge vessel and gravity feed
Oxygen-sensitive formulations	Sterile applied nitrogen
Applications requiring controlled movement	Positive displacement systems
Extremely viscous products	Piston-and-cylinder technology
Formulation-specific challenges	Custom transfer solutions

Table 1: Product transfer technology overview.

Suspension Behaviour	Product Transfer Strategy
Settling occurs over hours	Continuous mixing within the vessel
Settling occurs within minutes	Recirculation loop extending towards downstream processing equipment
Product concentration variability is a concern	Active suspension management strategy

Table 2: Suspension management approaches.

KEEPING SUSPENSIONS UNIFORM FROM START TO FINISH

Suspension-based products introduce another level of complexity to transfer operations. Unlike true solutions, suspensions can change over time as particles settle, creating the potential for product variability during manufacturing. Continuous mixing and recirculation strategies can help to maintain product homogeneity throughout processing (Table 2).

THE ROLE OF MIXING AND RECIRCULATION

For suspensions that remain stable for several hours before settling, continuous mixing within the vessel can help maintain product homogeneity. Products that settle within minutes may require recirculation systems extending towards downstream processing equipment to maintain homogeneity.

“UNLIKE TRUE SOLUTIONS, SUSPENSIONS CAN CHANGE OVER TIME AS PARTICLES SETTLE, CREATING THE POTENTIAL FOR PRODUCT VARIABILITY DURING MANUFACTURING.”

DESIGNING TRANSFER PROCESSES AROUND PRODUCT COMPLEXITY

Process developers understand that there is no universal solution for product transfer. The success of a transfer depends on selecting the appropriate combination of transfer technologies, mixing capabilities and recirculation strategies to address the specific characteristics of each formulation.

DOWNSTREAM CHALLENGES BEYOND PRODUCT TRANSFER

While product transfer lays the foundation for successful product handling, it represents only the first step in the overall manufacturing journey. Downstream filling operations introduce the next set of challenges, particularly for complex or sensitive products. Considerations such as oxygen, lighting and bubble control, temperature management, plunger-position accuracy, shear sensitivity and the management of highly viscous formulations become increasingly important when developing a robust end-to-end product handling and filling process that maintains product quality through to final container closure.

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