Innovation Phase Strategies to Ensure

A Smooth Transition from Concept to Production Design

Thomas James
Katie Goetz

key tech

Introduction

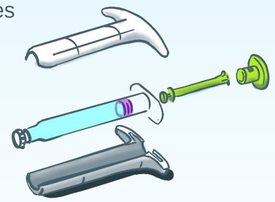
Transitioning from concept to production design in drug delivery devices demands careful planning and execution. This poster outlines strategies essential for this process, focusing on optimizing key technical parameters, understanding essential usability considerations, and aligning with primary container requirements. Collaboration with critical strategic partners ensures component performance and reliability, particularly in electromechanical devices. Beyond force specifications and injection stroke lengths, usability features such as secondary packaging and instructions for use are crucial to successful product presentation. By addressing these factors early, informed decisions can be made before the transfer-to-production phase. Micro case studies from customer programs demonstrate the scaffolding necessary to support this transition.

Medication Error Reduction Devices

Delivery Devices as Extensions of the Container

In medication error reduction devices, workflow errors often need revisions, but the primary container is locked due to CCI, E&L, and stability data. Instead of altering the container, modifying other device components—like housings or interfaces—can solve issues without disrupting validation.

Novel polymer-based containers further highlight the need for a systems approach to ensure compatibility and maintain device performance without disrupting validation.



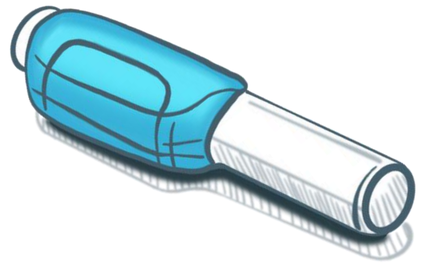
Dose Preparation and Delivery Devices

Device Exposure Design

When evaluating opportunities to improve the usability and functionality of a pharmaceutical system, observing the reactions of real users is a critical input. In these cases, Key Tech has employed an iterative approach to development, applying this strategy to an emergency-use reconstitution system and a combinatorial dose preparation system.

Tips to improve use study salience:

- Inclusion of secondary packaging in use studies enhances the study's realism.
- Mapping repeatable user touchpoints help drive placement of critical features
- Incorporate workspace aids users would typically have access to

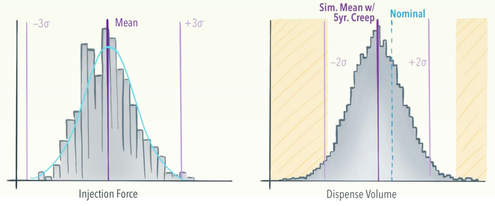


Cartridge-based Pen Injector

Technical De-Risking before Molding

Identifying and characterizing the areas of highest reliability risk is critical when evaluating the viability of a product concept.

To meet requirements for a lower injection time while retaining a small form factor, Key Tech created a "digital-twin," a custom simulation of the system that allowed for Monte Carlo analysis and predictive modeling of dose accuracy and injection endpoints. We complemented this with empirical subassembly testing with 3D-printed components and soft-tooled critical-to-quality parts. This phase streamlined development and lead to a quicker, more successful final molded design.

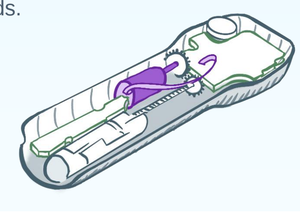


At-Home Electromechanical Injector

Early Supplier and Partner Engagement

Engaging critical component suppliers early allows for accurate supply projections and identification of relevant technical risks. Co-development with suppliers can address these risks, allowing for the exploration of early custom configurations if needed. Collaboration on an End-of-Life strategy is also essential, ensuring seamless transitions with drop-in component alternatives that do not compromise Critical-to-Quality functionalities.

Long-term, strategic usability partners provide a deeper understanding of patient populations and usage constraints, ensuring the device meets real-world needs.



Transfer Success

Build Outward From The Primary Container

Take a systems approach, with primary container requirements at the core. Like an assay in an IVD device, the primary container is the heart of the product and will impact all other design decisions.

Understand Essential Usability Considerations

Gain insights into essential usability considerations and iterative design cycles necessary to align product presentation with strategic vision, clinical need, and user expectations.

Optimize Key Parameters Before Production

Understand the importance of thoroughly exploring and optimizing key parameters to ensure robust feasibility and effectiveness before advancing to production design.

Engage Critical Partners Early

Recognize the value of early investment in strategic partnerships encompassing manufacturing, design, analysis, usability, regulatory, and packaging domains prior to transitioning to production phases.