

Designing for the Realities of Clinical Practice

Integrating End-User Perspectives into Medical Device Development

Tanis Morris · Klim-Loc Medical · PDA Universe of Pre-Filled Syringes and Injection Devices 2026 · Abstract #2467470

REAL PEOPLE.
REAL ENVIRONMENTS.
BETTER DEVICES.

Better Device Design Begins with Clinical Reality

Healthcare professionals work in complex environments shaped by time constraints, confined workspaces, interruptions, established workflows, and varying levels of experience. Because they encounter these conditions firsthand, they are often the first to recognize limitations in existing tools and processes. In some cases, that clinical insight becomes the starting point for innovation.

An initial observation, however, must be examined beyond the experience of a single clinician or setting. Human factors engineering provides the bridge between an identified clinical problem and a broadly applicable design response. By studying representative users, workflows, environments, and potential risks, design teams can determine whether the original insight reflects a wider need and translate it into meaningful design requirements.

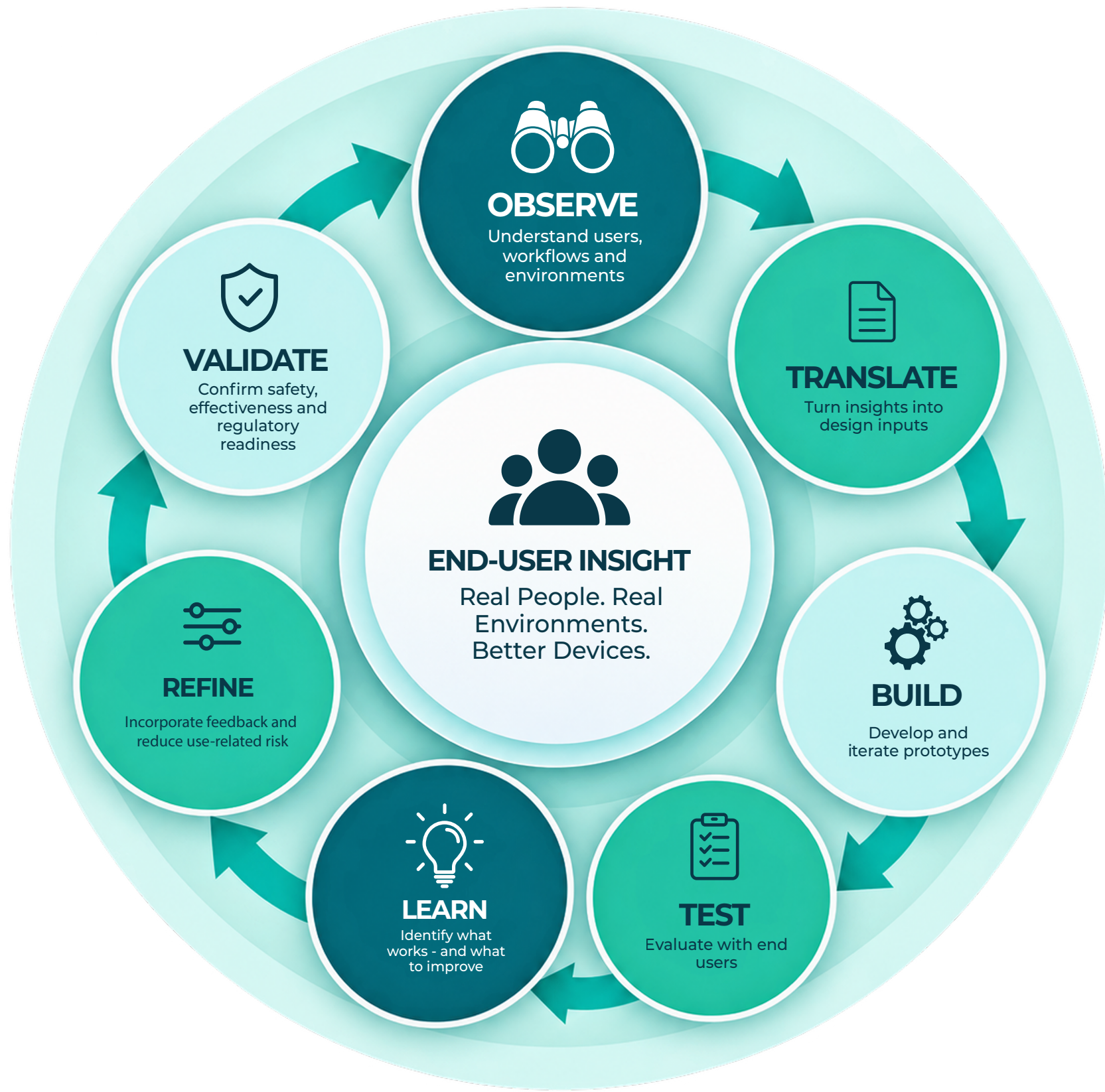
Those requirements can then guide technical development, formative evaluation, and refinement throughout the product lifecycle. By keeping the original clinical need connected to each decision that follows, teams can make better-informed changes while meaningful improvements are still possible, supporting devices that are more intuitive, responsive to clinical needs, and aligned with the people who will ultimately use them.

From Observation to Design Input

Representative users are identified early, and their workflows are observed in the environments where the device will be utilized: in the operating room, on the battlefield, or at a patient's bedside, to name a few. Clinical realities such as lighting, gloves, interruptions, time pressure, and workflow constraints are then translated into defined design considerations and anticipated use-related risks. These insights guide early development, ensuring that decisions are grounded in real-world use rather than assumption.

As the product evolves, formative evaluations put prototypes in users' hands, providing direct feedback that refines each iteration. Multidisciplinary review among engineers, clinicians, regulatory specialists, and usability professionals ensures that what is learned from users is translated into actionable design inputs and carried forward through validation.

End-User Insight Across the Development Lifecycle



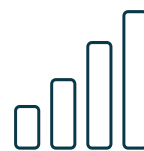
Learning Objectives



Translate clinical observations into actionable design inputs



Incorporate user needs, workflows, and environments across development



Apply iterative human factors evaluation to reduce use-related risk



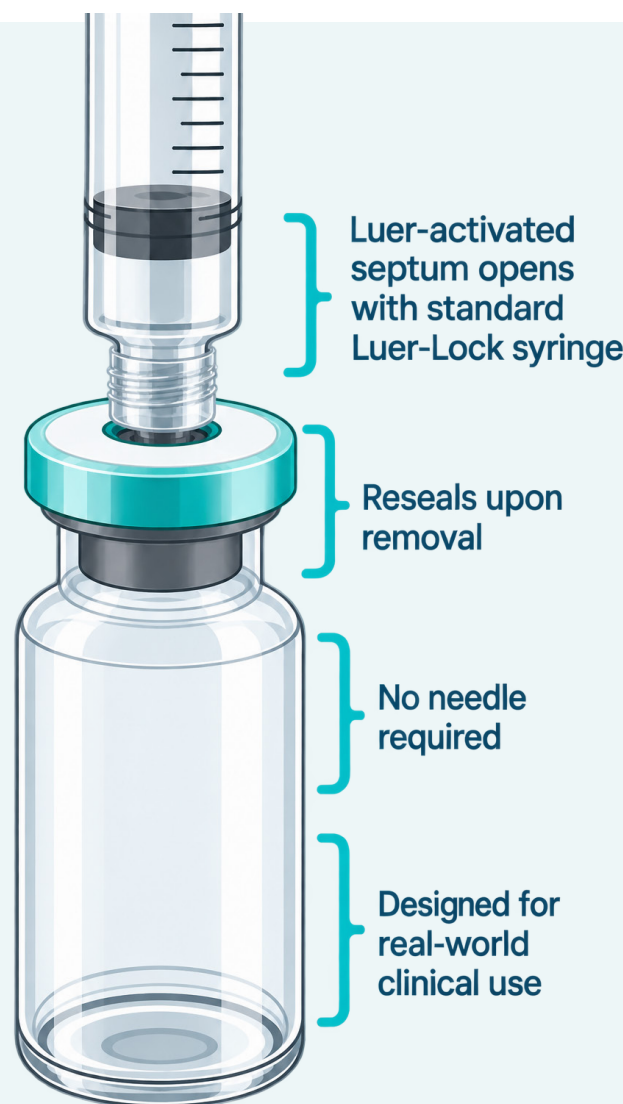
Leverage multidisciplinary collaboration for safer, more effective devices

Case Illustration: A Needle-Free Vial Container Closure System

These principles are illustrated through the development of a needle-free injectable pharmaceutical packaging and delivery platform featuring a vial closure with a Luer-activated septum. The septum opens when a Luer-Lock syringe is threaded onto the closure and reseals upon removal, eliminating the need for a needle during vial access.

The concept originated in the field, where its inventor, a helicopter flight paramedic, repeatedly encountered the risks and workflow challenges associated with needle-based medication preparation in high-pressure environments. That firsthand experience helped define the problem the technology was designed to solve.

Formative evaluation with clinical end users has since informed product development ahead of verification and validation, with end-user insight continuing to guide the platform toward regulatory submission.



Lessons Learned

The earlier clinicians are brought into the process, the more opportunity there is to identify what engineering requirements alone may not reveal. Workflow constraints, environmental factors, and unexpected patterns of use can surface through formative evaluation while there is still time to respond. Although drawn from a single platform, these lessons apply broadly to medical device and combination product development.

Beyond the Checkpoint

Human factors is most powerful when it helps shape a product from the beginning, as opposed to evaluating a device after its fundamental design has already been established. When clinical observation, representative users, and formative evidence are incorporated from the outset, teams can identify needs and use-related risks while there is still an opportunity to respond. The result is not only a device that performs as intended, but one developed with a deeper understanding of how, where, and by whom it will actually be used. The broader lesson is simple:

the earlier we understand the people and environments a technology must serve, the better equipped we are to design for them.

Scan for more on the Klim-Loc needle-free vial container closure system, or to connect with our team.

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