Systems Engineering for Complex Portable Medical Device Development

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March 2015

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Introduction

As the demand for complex, portable medical devices continues to grow, reducing risk and increasing efficiency during the development of these products should be paramount. Taking a systems-engineering (SE) approach to development provides a holistic, organized, and deliberate method for identifying as well as reducing both patient and business risks early in the process. Furthermore, it facilitates efficient progression throughout the entire product development life cycle.

Systems Engineering Explained

The latest auto-injectors, pen injectors, inhalers, and insulin pumps on the market reflect the relentless industry-wide drive toward smarter, smaller, more-portable medical devices. To ensure reliability and repeatability, however, such complex devices demand a greater number of requirements, as well as more testing and validation during their development than do the larger, simpler devices of previous decades. In turn, they also carry with them greater technical and schedule risk.

Applying systems engineering to the development of today's complex medical devices addresses the whole device system and determines the following features:

- All subsystems (a discrete selection of components that work together to perform a function) that make up the full system
- Each subsystem-to-subsystem dependency
- All of the rules that will need to be drawn up in order for the subsystems to work together, or integrate
- The order in which those rules will be drawn up so that subsystem integration occurs correctly

This approach differs from the traditional linear product development approach, typically in that it breaks the whole product idea into subsystems and—beyond simply establishing requirements for those subsystems—devises an order in which each subsystem must be defined. It also determines which dependencies between subsystems are needed for proper operation.

Systems engineering requires both subsystem-specific engineers and the overall systems engineer, who focuses on establishing the requirements for the interactions and integration of the subsystems—that is, what makes the whole system work together.

Systems Engineering Step by Step

To kick off the SE process for a complex, portable medical device, the user and stakeholder needs must first be determined by the client (the device company), then communicated to the product development (PD) team. Once the PD team has a firm grasp of what the client wants, the team members will typically brainstorm ways in which those wishes can be fulfilled.

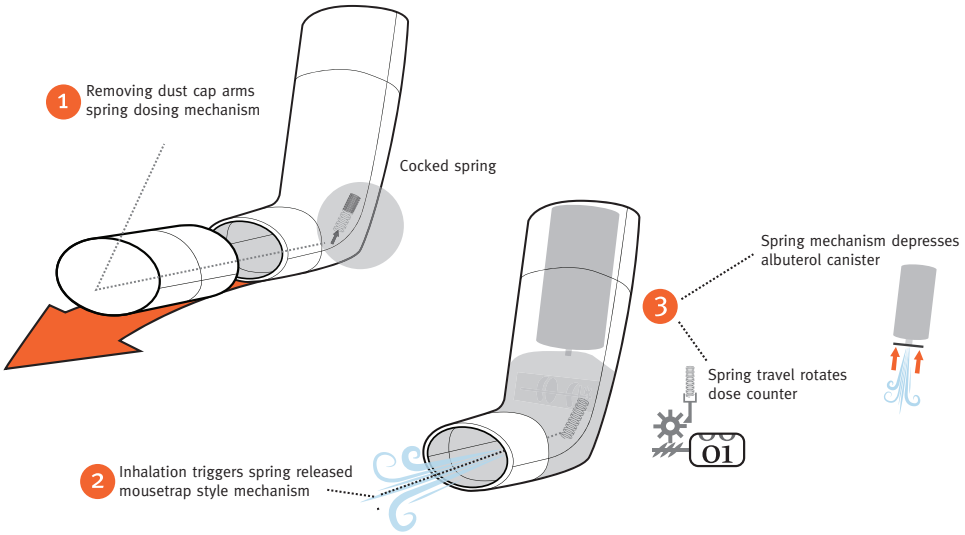
Next up after brainstorming are the following crucial steps:

1. Defining subsystems that will work together to make up the whole device system.
2. Creating a subsystem architecture and depicting it as a flow chart that shows the links between the subsystems.
3. Prioritizing the subsystems, which is the keystone of the SE approach: For which subsystem will requirements be defined: First? Second? Third? This ordering of study and activity enables efficient movement through the PD process. "Locking down" the priority-one subsystem will lead to the definition of requirements for the priority-two subsystem, and so on. Concepts can be generated for each subsystem and then tested against each other or with subsystems that have been thoroughly characterized and defined.
4. Developing subsystem-level requirements for the device concepts (performed by the engineering teams) and concurrently developing system-level requirements (done by the systems engineer) with an eye to subsystem integration.
5. Integrating the "locked down" or successful subsystems: Once subsystems A and B, for instance, are complete and functional, development of a prototype of an integrated subsystem AB can be initiated. As integration occurs, product development moves from meeting requirements to creating actual specifications.

Systems Engineering Illustrated: Developing an Automatic-Dosing Inhaler Product

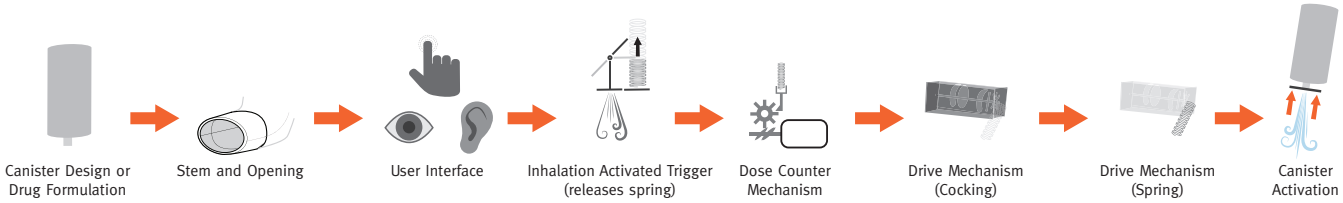
The SE approach can be illustrated using a hypothetical complex portable medical device: an automatic-dosing albuterol inhaler, which represents an upgrade of the traditional manually dosed albuterol inhaler. This mechanical upgrade features automatic dosing triggered by the user's inhalation, as well as, a dose counter that tracks the number of doses that have been administered.

In early brainstorming, the team decided the order of operation would occur as follows:



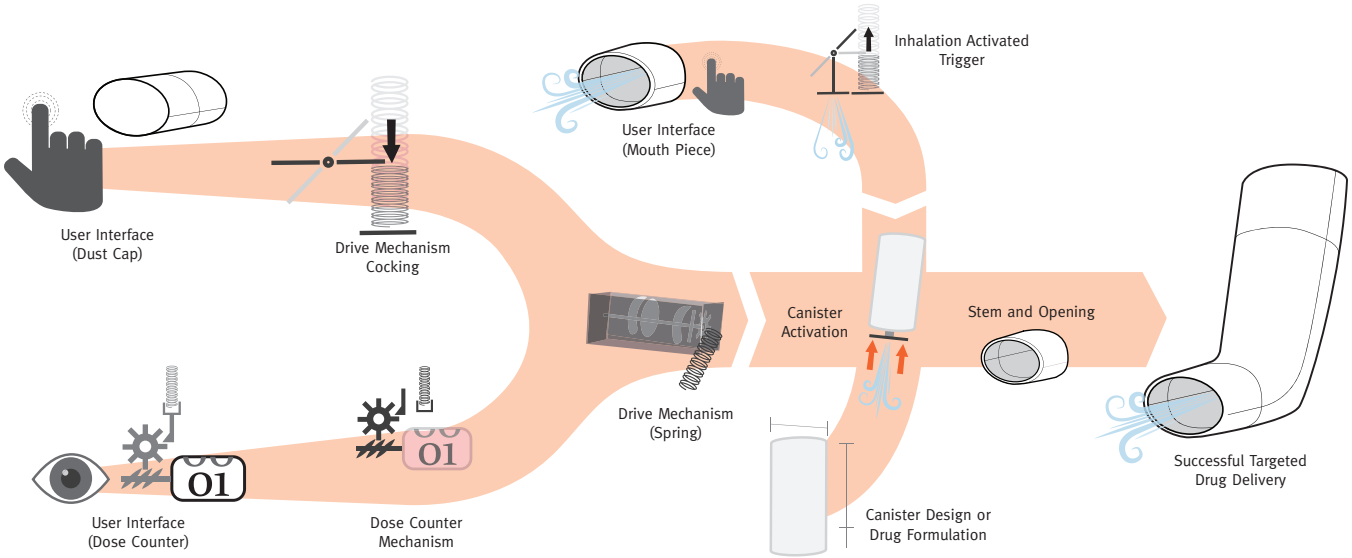
Several subsystems are present in the entire device, including canister design and drug formulation, user interface, drive-mechanism cocking, drive mechanism (spring), stem and opening, canister activation, dose-counter mechanism, and an inhalation-activated trigger. Rather than jumping right to the creation of a total-product concept that incorporates all of these subsystems at once—thereby making it difficult to define what is critical about each subsystem and its components—the SE approach first establishes the individual subsystems, determines the links between them, prioritizes those links, defines and tests in a logical order, and then finally, integrates the subsystems.

The following diagram depicts the links that have been established between the subsystems of the hypothetical automatic-dosing inhaler, along with how the links have been prioritized:



As is illustrated in the above diagram, the PD team has determined that defining the requirements for the canister design and drug formulation are the most important, followed by the stem and opening from which the drug will exit the canister. These two subsystems and their interaction can then be studied on their own, independent of other variables, such as the drive mechanism. Subsystems 1 and 2 are used to define the requirements for Subsystems 3, 4, and 5.

Finally, the diagram below illustrates the structured, deliberate manner in which integration of the inhaler's subsystems occurs.



Advantages of Systems Engineering

While adopting a SE approach to product development does not totally eliminate development risk, it does reduce risk significantly. By defining each subsystem and specifying the order in which those subsystems must be characterized, troubleshooting during subsystem integration becomes more efficient and straightforward. Engineering teams can work backward through the system, if needed, to determine where gaps may have occurred.

Patients, ultimately will benefit from a product that does not cause harm and that functions as intended while the manufacturer will benefit from a timely product launch. “Learn early and inexpensively” is a useful mantra here: By focusing on subsystem- and system-level requirements during the proof-of-concept phase, the team will set up a solid foundation for the more-expensive development work that follows.

Understanding and Trusting Systems Engineering’s Value

Although SE for complex portable medical devices demands a greater expense up front, it is well worth it in the long run. A less-seasoned medical device manufacturer that has no experience with problematic late-stage PD issues, for example, may not immediately understand the value of the SE approach. However, medical device makers are urged to have faith that the additional up-front costs required by SE will pay off in reduced risk, more timely development schedules, and greater efficiency.

Medical device makers that understand SEs high value should listen carefully to the language potential vendors use. Such SE terms as subsystem, integration, subsystem interactions, and system-level requirements and specifications indicate that the vendor’s SE approach is sound and credible. Additionally, when asked about how it approaches proof of concept, the vendor should be able to explain that its engineers work out the functional aspects of the device in question “on the bench” first, rather than jumping straight to a fully integrated product concept.

Systems Engineering for Today’s – and Tomorrow’s – Smaller, Smarter, More Portable More Complex Medical Devices

Healthcare products continue to shrink, feature greater connectivity, and grow ever more complex. These trends are not going away, and the SE approach to product development is the best choice for firms creating these devices. Medical device manufacturers can stay current and competitive by taking the SE approach to product development for reduced user, patient, product, financial, and schedule risk in addition to improved PD life cycle efficiency. Those who don’t, may find themselves falling behind.

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