DFM Guidelines For Early Combination Product Design

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By Bill Welch
CTO, Phillips-Medisize

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Twenty-first century medical device manufacturers are faced with high-tech challenges. With the move toward a self-administered healthcare system, medical devices must be smaller and smarter to make them easier to use by patients and caregivers. Making a "smarter" device means transitioning from conventional mechanical systems to integrating electronics into the device. The success of this product development has to be an integrated process to ensure that the final device gets to market on time with the quality and cost expectations that the manufacturer has established.

Having an integrated product development process combining Human-Centered Design (HCD) principles with a Design for Manufacturing (DFM) philosophy will help ensure product adoption and compliance, predictable processing, overall product quality improvement, cycle time reduction, risk mitigation, and stakeholder satisfaction while also potentially limiting product recalls. If DFM is not implemented correctly, the cost of doing business becomes much higher for any manufacturer. That fact was confirmed by a study conducted by AdvaMed a few years ago. The study noted that during a 10-year period the number and complexity of medical technologies increased, but the total number of recalls remained the same. What's interesting about this study is that a leading manufacturer of implants had estimated 2.1 million patients received its products over a decade, and only .03% had to have their implants removed due to product defects. While that percentage may seem low, it still equates to at least 630 patients! This one incident placed a heavy burden on the entire healthcare system — especially for the patients.

There have been a number of DFM-related recalls in the last few years, including the one related to GE's Giraffe and Panda T-Piece Resuscitation Systems. In October 2012, GE initiated the recall on 223 units citing in an Urgent Medical Device Correction letter sent to its customers that it was recalling these infant resuscitation systems because the oxygen and air-wall inlet fittings or labels were possibly reversed during assembly. This could potentially invert the desired ratio of air to oxygen. Even though GE hasn't commented on the total cost of this recall, these products can range anywhere from a few thousand dollars to more than $20,000 per unit.

Another example of failed manufacturing-related recalls was Zimmer Spine's PEEK Ardis Inserter. Zimmer initiated a voluntary recall of 315 units in December of 2012 after realizing the Inserter may break when excessive lateral force or off-axis force was applied to it. If failed, the patient may experience severe damage to their spinal chord, blood loss, and possible nerve injury. Although DFM principles are not a complete fail-safe method, the implementation of them will help reduce some of these risks.

Create A Cultural Mindset

DFM and DFA are the pillars of any robust development process, and a sound DFM/DFA philosophy should be a cultural mindset, becoming ingrained in every stage of development. While HCD focuses on the user's experience, DFM and DFA home

in on manufacturing quality, cost, and risk. DFM ensures the system will work as intended while DFA ensures that the components are correctly assembled. Both are necessary to get a quality product to market.[1]

Applying these principles can prevent most design issues. Designers, engineers, and manufacturing representatives must collaborate early and often to create designs that meet targeted quality and cost objectives. Because most of the product cost (as well as quality and risk) is driven by decisions early in the design cycle, the product development team must include expertise in DFM for the intended manufacturing processes.[1]

The culture should support the belief that DFM must be applied across the product development process by a fully engaged multidisciplinary team including manufacturing representatives. Early manufacturing involvement not only brings DFM expertise to the product development team, it also promotes concurrent early learning and buy-in by the manufacturing team, reducing lead time and risk.[2]

DFM forms the backbone of the assembly process — regardless of the planned level of automation — because the process capability at the component level is necessary to reduce variation in the assembly process. DFA is done concurrently with product design, with quality, cost, and risk of the assembly in mind. At the component level, this includes the addition of features to include part handling, positioning, and orientation in the assembly or subassembly. Component-level DFA ensures that a mistake-proofing plan is established, which is necessary to reduce variation in the assembly process. Additional benefits are gained by concurrent DFM/DFA throughout the product development process, for example, to reduce part count and eliminate high-risk assembly operations.[3]

10 Guidelines To DFM and DFA

Successful DFM/DFA needs to be an underlying philosophy truly integrated into the product development process. The following are some basic guidelines to help ensure a successful program, although this should not be viewed as a checklist to be completed on the individual components after the drug delivery mechanism design is nearly complete:

1. Ensure component-level DFM is applied to provide a stable and capable supply to the assembly process.
2. Simplify the design and reduce the number of components, using techniques such as multi-material molding for plastic components.

[1] Welch, Bill and Jeremy Odegard. Human-centric design at the heart of product development, WorldPharma, http://www.worldpharmaceuticals.net/contractors/contract-manufacturing/phillips-medisize/, accessed Dec. 2, 2015.
[2] Welch, Bill. The human touch: Phillips-Medisize explain the key to success, Medical Plastics News, May 14, 2015, http://www.medicalplasticsnews.com/news/the-human-touch/, accessed Dec. 2, 2015.
[3] Welch, Bill. Scalable Automation for Drug Delivery Devices, Phillips-Medisize

3. Standardize and use common components and materials, both within and across drug delivery device assemblies, to minimize tooling, validation, and supply chain management costs.

4. Ensure component-level DFA is applied for stable and capable orientation, handling, and placement.

5. Minimize the use of fasteners, flexible components, interconnections, and adhesive/lubricant dispensing operations.

6. Design mistake-proofing, part presence checking, in-line quality controls, and segregation of failed or rejected components, into the assembly process starting with initial builds.

7. Design for robust assembly by minimizing complex orientations and axis of assembly, beginning with components that have suitable "lead-in" taper and location features.

8. Manage final assembly cost and risk by strategic selection of subassemblies and modules in the assembly process, and ensuring high-value components and subassemblies are known to be of acceptable quality before integration into the next build level.

9. Design for flexible assembly to minimize time and cost associated with equipment, validation, and change-overs:

    a. Design components to use the same or similar bowl feeding, pallets, or other methods to introduce to the base flexible assembly line.

    b. Design components and assembly sequence to use the same or similar assembly and joining methods already included in the base flexible assembly line.

    c. Develop a standard set of product requirements to be subsequently inspected or tested on the base flexible assembly line.

10. Design for high-speed, automated assembly:

    a. Use components that can be fed without tangling. In the case of springs, consider making the springs as part of the device assembly process.

    b. Pre-orient the components when presented to the line to reduce cycle time.

    c. Integrate finished device handling, packaging, and palletization into device assembly and facility planning because high-volume devices require purpose-built infrastructure beyond the assembly equipment itself.

Although an understanding of the DFM guidelines for the intended manufacturing processes is key at the component level, the greatest benefit comes from looking beyond

component-level DFM/DFA to find system- or subsystem level solutions that enhance device performance while meeting human factors, quality, cost, and risk requirements.

Scale-Up Using a Device Manufacturing Concept

Scalability for drug delivery devices begins with concurrent engineering via DFM/DFA and development of a device manufacturing concept. Scalability is the process of developing the manufacturing scale from the initial low-volume methods to the desired end-state volumes. In the case of a specialized, niche drug delivery device, this may mean progressing from low-volume, 3D-printed components assembled by skilled technicians to an assembly process conducted by a trained operator. In the case of a commonly used drug delivery device, this typically means developing processes to support first engineering builds, then clinical supply, and finally a fully automated or high-speed automation process, supported first by developmental, single-cavity tooling and then incrementally higher multi-cavity tools.[3]

Although related to scalability, flexibility has its own definition as it relates to two concepts[3]:

1. The ability to reuse assembly equipment modules when progressing from one scale level to the next, in order to prove-out initial assembly concepts at lower scale and save time and cost by leveraging that same equipment.

2. The ability to use all or most of an entire base flexible assembly line to produce multiple, similar devices. In the case of pens and auto-injectors, this typically means matching up a device product platform with an assembly platform, with changes being primarily in the components presented to the line following a controlled line clearance and changeover process.

Scalability considerations must be looked at concurrently with product development as part of a device manufacturing concept. This is a device-specific plan to scale component and assembly production capabilities to a desired end-state, typically with iterations for both components and assembly to meet engineering, clinical, and commercial volume demand.[3]

A well-constructed device manufacturing concept will not only consider the volume, costs, and timing of device needs but also the regulatory requirements, risks, and geographic considerations with each iteration of the scale-up plan. It provides clearly structured, modularly designed assembly lines which can be extended at any time, allowing fast retooling times. Essentially, the device manufacturing concept provides the “road map” to progress from initial, limited-control engineering builds to the validated end-stage scale, meeting all quality system and regulatory requirements.[3]

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Core to the device manufacturing concept is a strong assembly systems foundation[3]:

- Early manual builds need to establish the assembly sequence, component orientation, and assembly operations that will be carried forward to subsequent scaling iterations.
- Proper manual assembly is an enabler for a higher level of automation.
- Collect and analyze reject data to reduce variation with each subsequent scaling iteration. It is imperative to ensure proof-of-concept has been achieved for each process before making further scaling investment.

Summary

Next-generation medical devices will be undoubtedly smaller and smarter. But to achieve such designs, improve patient adherence, and limit risk of product recalls manufacturers will need to follow DFM and DFA principles aimed at creating more usable, intuitive, and desirable devices for patients.[4]

Bill Welch is the CTO of Phillips Medisize and manages all product development, manufacturing, and engineering responsibilities for their drug delivery device business. For questions Bill can be reached at bill.welch@phillipsmedisize.com.

[4] Welch, Bill. Human-Centered Design and Inhalation Device Development, Phillips-Medisize.