

PRODUCT DEVELOPMENT INSIGHT**Exploring the Manufacture of Disposable Components**

Developing a manufacturing strategy early on can help OEMs to develop products at the lowest possible cost without compromising quality.

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The U.S. disposable medical supply industry is estimated to be worth \$55.4 billion, and U.S. demand for disposable medical supplies is forecast to increase 4.9% annually through 2011.¹

For example, disposable cartridges have many applications in point-of-care medical diagnostic devices. They provide sterile processing sites, prepackaged reagents, and onboard reference sample management. Single-use cartridges can also increase equipment reliability by replacing critical functions of the instrument each time the cartridge is replaced.

The plan to introduce such products commonly features setting a low price for the instrument, subsidized by the sale of the disposable devices. The cost to manufacture the cartridges becomes a key driver for the profit margin.

Disposables for use with medical devices are becoming more complex and are playing a more important role in the business model for diagnostic devices. This article discusses several tool sets that may help manufacturers efficiently plan and deliver disposable products to the point-of-care medical device market.

Three performance criteria can be assigned to the manufacture of disposables: quality, delivery, and cost. Each is important, but they may be prioritized differently during the life cycle of a product (see [Figure 1](#)). The next section describes a typical disposable product life cycle and the changing priorities that manufacturers often experience (and ideally anticipate).

Prototyping

Early prototyping is commonly the means used to verify functionality of the device design, and ideally, it establishes the process capability of the design. Once stable device performance is achieved, there is a logical reluctance to reverify the design with a different manufacturing process. Therefore, the early prototyping stage often defines the manufacturing technologies that will support the product throughout its life.

Prototypes need to be carefully manufactured with controlled processes. The outcomes of tests performed on a product's preliminary components will set the direction for the product. An essential activity in the prototyping stage is to support design development of the product through rapid turnaround of design iterations. Manufacturers must verify sensitivity and assay coefficient of variation (CV) in these designs to assess product development status. A common problem is that construction methods can affect performance variability. Hand-operated fixtures, for example, may contribute to inconsistent prototype assembly.

It is also important to recognize that the construction techniques established during prototyping will most likely be used when the product is in the high-volume manufacture stage. Validation of the product restricts subsequent changes, so it is important to select the appropriate high-volume process technologies early on.

When exploring fabrication process technologies, manufacturers should correlate the capability of the process to the needs of the disposable device. An example involves the use of pressure-sensitive adhesive-based laminated constructions to create channels with electrical contacts when an assay is sensitive to channel volume. Early estimates of the assembly variation would avoid designs in which the channel volume includes adhesive thickness. Estimating the contribution from the mechanical construction process to the assay process CV helps manufacturers select manufacturing technologies and design directions that lead to quality products at a low cost.

Establishing Product Quality

Point-of-care diagnostic devices commonly include fluidic features, such as multiple stored reagents, sample access features, and some form of electronic or optical measurement interface. Consistent product performance is dependent on managing all of the physical and chemical system features that strongly influence results. Many products also conduct biological or even molecular processes within a disposable device, which adds more opportunities for process variability.

Systematic development of the manufacturing techniques is essential to minimize problems that may arise as the time to market approaches. As the prototype design matures into pilot manufacture, the ability to consistently construct high-quality products is increasingly important. Pilot lots are used for clinical trials to verify product claims. Robust pilot-stage testing—particularly scoping batch-to-batch variability and identifying key acceptance criteria for sourced components—is the best insurance for minimizing problems in novel products.



Figure 1. (click to enlarge) A manufacturer's focus over a typical product life cycle.

The real challenges, however, arise once the manufacturer needs to produce consistent devices to meet demand. The flow of product requires new batches of raw materials and other incoming goods. At this point, extensive homework with respect to suppliers and sensitivity studies pays dividends. Manufacturers can focus on quality as they learn more about product nuances and track down sources of variability.

A sound manufacturing plan facilitates the delivery of quality products from day one on the market.

Product Launch and Scale-Up: Delivery

A successful product launch usually results in increased demand on the production system.

The production team may struggle to meet orders as new features of the product, its raw materials, and the surrounding processes are uncovered in the volume-manufacturing environment. Selection of techniques and materials that have been successfully implemented for other products can minimize unexpected problems. Every product has unique characteristics, however, and strong production resources are needed during this stage.



Figure 2. Automation for medium-scale assembly.

During production volume scale-up, additional production equipment is often needed (see Figure 2 for an example). The capital demand can be significant for small device companies, and additional calls for capital are difficult for such firms because the income stream for the product has only just commenced. Plans that account for equipment lead time and identify the trigger points for the capital demand should be created early in the product development process.

Mature Production: Cost

As the production process for a device matures, there often comes a time when production seems to be under control, back orders occur only during seasonal peaks, and there are only a few incidents that occur during the end-of-line testing. At that point, financial stakeholders may want to evaluate how production costs can be reduced.

Planning early in the product development process enables product cost to be predicted as volumes expand. The benefit of such early projection is understanding the key cost drivers for the product. These drivers can be addressed during the development process, but they cannot be changed once the product is mature. Sourcing options and supply contracts are crucial in determining how cost can be reduced, but such factors should be assessed early in the development stages.

Manufacturing Planning Process

Disposable manufacturability must also be addressed in early-stage development. The following tools create a robust plan that contributes to product success across the life cycle:

A design-for-manufacture review to explore competing component fabrication options.

A failure mode, effects, and criticality analysis (FMECA) of the design and the manufacturing process (see Figure 3).

The development of manufacturing system configurations that address the range of production volumes. Such configurations help to identify staffing and capital requirements for manufacture.

A product cost model that factors in material costs and manufacturing approaches to predict the cost of goods (see Figure 4).

A sensitivity analysis that assesses the level of uncertainty resulting from modeling.

The creation of a manufacturing strategy and capital plan to match the scale-up marketing plan.

Those tools are described in more detail below.

Product Design-for-Manufacture Review. As soon as disposable component functionality is achieved, the design team should perform a thorough product design review to challenge the existing design concepts and explore alternative paths for implementation. Alternative paths may include fabrication technology, interfaces to the instrumentation, reagent loading, and packaging approaches.

Process maps for alternative approaches can capture the inputs and outputs of the manufacturing process through to the final shipping configurations. Lean manufacturing concepts can positively influence the design. For example, by making variations between products as late as possible in the manufacturing process, more of the overall process will be common to all products. Therefore, manufacturers can reduce the cost of managing multiple products as well as increase flexibility and responsiveness to changing demand.

Design and Manufacturing Process Analysis. Once a design for the disposable component has been developed to a point at which components have been identified and fabrication and assembly techniques can be anticipated, an FMECA can be conducted. The analysis of the design and manufacturing process should be undertaken to:

Identify where the design of the product can be altered to eliminate potential manufacturing defects.

Actively monitor critical quality attributes in the manufacturing processes.

Identify controls on key raw materials.

Define bought-in component attributes.

These requirements can then be assigned to the product design, processing equipment functionality, and quality management system. Such action links the failure mode process into the formal design documentation.

Production-Line Configurations. There are software programs that can be used for this stage, but the intent of this section is to highlight that strategies exist to achieve scale-up from small volumes without compromising quality.

The assembly process can be further developed to incorporate quality-driven requirements.

Automation is initially focused on quality management functions. The quality-critical or inspection

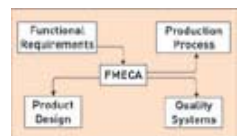


Figure 3. (click to enlarge) A risk-based design process.

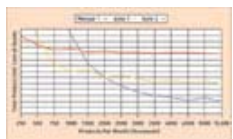


Figure 4. (click to enlarge) Cost-model scenarios for manual and automated processes.

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tasks need to be automated to achieve verifiable quality. Manual assembly processes between automated workstations can be used to minimize capital expenditure in the early stages (see [Figure 5](#)).

Flexible manning is a lean manufacturing strategy that helps manufacturers balance the labor in manual assembly to the demand. This strategy caters to steady increases in production from a low base with minimized capital cost and without any loss of operating efficiency.

When market predictions indicate the need for large production volumes, manufacturers can justify production system designs with integrated material handling and other automation. The challenge is to understand whether such automation is justified. Estimating the costs of an automated system allows comparison with less-automated options. The product cost delivered by automated systems can then be compared with that of manual processes to enable an informed decision to be made on the production volumes for which increased automation is justified.

Cost-of-Goods Analysis. Understanding the contribution of materials, labor, and capital commitment to the total cost of disposable components helps focus a company's development effort. Good product profiles for disposable components offer low capital establishment costs. Such profiles help OEMs develop a clearly defined route to lower costs through capital investment amortized over large volumes.



Figure 6. (click to enlarge) Example of a cost-of-goods analysis.

higher production volumes.

That type of model offers a powerful decision-making tool. It can be applied to issues such as country of manufacture, taking into consideration the different labor costs and duties as well as the freight and inventory considerations.

Sensitivity Analysis. The level of uncertainty that results from modeling can be assessed using a sensitivity analysis. For each input to the model, an estimate of the accuracy and likely variance is applied. Outputs of the analysis include confidence bands over the aggregated cost estimates as well as each component estimate's contribution to the uncertainty.

In [Figure 7](#), the cost uncertainty of one purchased component contributes nearly 25% to the total product cost uncertainty. Manufacturers can use this information to refine the cost model to greater confidence by obtaining quotes for a specific component, for example. Equally useful is the understanding that the several hundred other contributions to costs in this model do not stand out—suggesting that estimates for these items are adequate. This technique efficiently ensures an appropriate level of detail.



Figure 7. (click to enlarge) Sensitivity analysis for a disposable product.

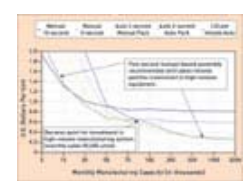


Figure 8. (click to enlarge) Comparative cost analysis used to set a manufacturing strategy.

systems need longer lead times. The development of an automated system, in parallel with initial production on a manually operated system, allows manufacturers to develop aggressive market launch plans.

As demand grows, additional high-volume systems can be replicated. Applying the marketing plan to the production equipment strategy creates a schedule for manufacturing capital demand. Applying the lead times for equipment construction also creates trigger points for the next investment in production capacity.

Conclusion

As the market for disposable components of medical devices expands at an increasing rate, an intense need emerges for products at the lowest possible cost with uncompromised quality. Best-in-class quality and cost is achieved through systematic processes that need to start early in the product development project.

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Reference

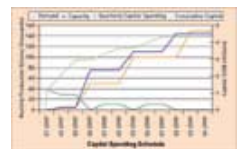


Figure 9. (click to enlarge) Example of a manufacturing capital demand schedule.

1. "Disposable Medical Supplies to 2011" (Cleveland: Freedonia Group, 2007).

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