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Under Review: Today's OEM/CMO Relationship

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Published February 3, 2016
Interviewee: Tim Bowe, CEO, Foliage, Inc.

Going back to the start of this millennium, industry veterans will recall an environment where medical device manufacturers (i.e., OEMs) were hesitant to enlist the services of contract manufacturing organizations (CMOs). The list of reasons for this was quite long, ranging from quality concerns to IP questions to communication issues. It seemed there was little interest in going outside to have tasks done that could possibly be done in-house, even if it wasn't a core competency of the OEM.

Fortunately, a new way of thinking about medical device CMOs has permeated the landscape and more medical device OEMs are establishing manufacturing partnerships with service providers to handle tasks from R&D all the way through to packaging and distribution. They are also looking to these CMOs to address other cost challenging areas, including supply chain management and regulatory procedures, in addition to more traditional tasks such as component fabrication, assembly, or full manufacturing.

Just as there was an array of reasons for the initial hesitance of OEMs to work with a CMO on medical device projects, there are just as many benefits today to justify such a venture. With this in mind, MPO sat down with Tim Bowe, CEO of both Foliage Inc. and Altran North America. Foliage is a product development/services provider to medical device manufacturers; the company does not manufacture devices directly. As part of its core services, however, the company works with clients to help optimize all phases of the product lifecycle, including transfer to manufacturing, as well as manufacturing optimization under the Altran brand.

The purpose of this discussion with Bowe was to investigate how the relationship between medical device OEM and CMO has changed, the primary reasons for this change, and where this relationship is today.

Sean Fenske: What's the status of the relationship between OEMs and CMOs in the medical device development space today?

Tim Bowe: Over the past few years, we have seen a very significant change in the device industry as cost pressure resulting from the ACA has increasingly forced fundamental changes within the industry. We see both a higher level of CMO utilization and a

stronger connection between the OEM and their CMO, including transitioning more responsibility for different phases of the lifecycle from the manufacturer to the CMO. This is especially prevalent in manufacturers with global distribution.

Fenske: How has this changed significantly from only five or ten years ago?

Bowe: The rate of change over the past few years has been breathtaking—due mostly to the passing of the ACA.

Fenske: Why has the medtech sector lagged behind other industries in the use of CMOs?

Bowe: The macroeconomics of the industry allowed for a less efficient supply chain. This is no longer the case. Another factor is volume. In many cases, device manufacturers held the opinion that they do not manufacture at a high enough volume to justify using CMOs. That attitude is changing, however, as device manufacturers look to cut full-time equivalent costs and take advantage of lower cost markets to accomplish manufacturing.

Fenske: What tasks are CMOs now being asked to handle that OEMs were primarily handling as recently as a couple years ago?

Bowe: The range of functions/tasks that we see both CMOs and product development companies take on is large and highly variable. Supply chain management related to manufactured products is most obvious. Other areas include various types of value engineering and obsolescence management. Some ID and product development tasks can also be more efficiently handled by CMOs. OEMs must be cautious, however, when utilizing a CMO for product design services because the core competency of these CMOs is often manufacturing, not design and development.

Fenske: What's driving the change here?

Bowe: In many ways, it is the rapidly changing cost competition in the industry that is causing the medical device industry to catch up with other industries in the adoption of CMOs. The breadth of the capabilities of CMOs, however, to offer the ability to improve efficiency and competitiveness is also a contributor. The CMO landscape has changed significantly over the past decade, leading to more sophisticated relationships between OEMs and CMOs.

Fenske: What are some examples of how CMOs are aiding in cost savings for OEMs?

Bowe: CMOs can provide a wide variety of cost advantages to OEMs. The specifics will vary dramatically depending on the relative strengths of the OEM and CMO. One large advantage is that most OEMs produce their products in comparatively low volume. This

low-volume/high-cost/high-margin combination was historically highly supportive of captive manufacturing. As the price point and margins have come under increasing pressure, CMOs can provide lower cost manufacturing options. And for OEMs requiring global product delivery, CMOs can offer lower transportation costs and more sophisticated knowledge of globally distributed supply chains.

Additionally, larger CMOs and product development companies can provide support in the area of design for manufacturing and cost/value engineering. Our experience in working with a broad cross section of OEMs is that this is an area of relative weakness and a source of significant margin improvements.

Further, we have seen a very significant rise in the number and size of companies that are more aggressively engaging with CMOs and product development companies to accelerate the development of increasingly complex product offerings. This is an area, however, where OEMs should exercise caution as most CMOs have stronger mechanical and electrical engineering skills than software. As systems become increasingly software centric, this is an area that OEMs should understand exactly what skills they are leveraging.

Fenske: How does working with a CMO help in terms of design innovation? What advantages are realized?

Bowe: This can be a double-edge sword. In areas of mechanical engineering and some electrical engineering, CMOs have well-developed skills and can offer services that provide not only cost advantages, but skills advantages as well. OEMs would do well to evaluate these possibilities. In other areas, such as systems and software engineering, CMO skills can be significantly behind product development companies that possess those skills and capabilities.

Properly utilized, CMOs combined with product development companies can provide the trifecta of lower costs, faster development, and more advanced capabilities. Clearly, a thorough evaluation of possible partnering options can provide a very important competitive advantage in the market.

Fenske: How are CMOs aiding in getting products to market faster?

Bowe: Some CMOs, and virtually all product development companies, have strong skills in ID as well as mechanical and electrical engineering. CMOs have the added advantage of strong experience with rapid transition to manufacturing and preparing a global supply chain. All of this can have a very positive impact in overall reduction of product introduction time. Depending on the level of systems and software complexity, working with a CMO can be very helpful. In other cases, working with a product development company with strong systems and software skills, as well as CMO integration skills, may provide even more advantages to medtech OEMs.

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Fenske: In what ways will the CMO/OEM relationship change in the coming years?

Bowe: We see a continued acceleration in the adoption of more expansive relationships with CMOs within the medical device industry. As product offerings become more software- and system-centric, we see more three-way partnering with CMOs, product development companies, and OEMs being leveraged as a core competitive advantage for OEMs.