

## **Transparency and Open Communication Are Key to Contract Manufacturing Relationship**

Joseph Lee, President, Xeridiam



Joseph Lee, President of [Xeridiam](#) [1], was a part of the staff written article, “[Not All Contract Manufacturers Are Created Equal](#) [2].” He took time to present a full array of responses that were not able to be included in the article, so they are presented here.

**Q:** *What are the primary reasons on OEM will seek out a contract manufacturer?*

**Lee:** The primary reason for an OEM to seek out a CM remains cost. CMs have proven their ability to reduce total device costs and are now expanding their expertise to address total supply chain cost reduction. Other primary reasons OEMs seek out CMs is for quality and reliability. CMs must maintain a current and proven quality system and must be compliant with increasing supplier controls. OEMs demand reliability from their CMs so they can manage thin as possible inventory investments.

**Q:** *How do medical device contract manufacturers stand out from their competition?*

**Lee:** Over the past several years CMs have been expanding services to OEMs beyond standard manufacturing. CMs stand out from the competition by offering a variety of services and creating product innovation. It’s not uncommon for the OEM to rely on the CM to perform a range of services including packaging, sterilization,

validation, and testing, including regulatory assistance. Also, CMs stand out by innovating product features and designs. Those CMs who can help OEMs bring new product features and technologies to market faster help the OEM gain market share in competitive markets.

**Q:** *Are there still concerns from the OEM regarding IP when working with a contract manufacturer?*

**Lee:** OEMs are protective of IP and the issue remains a concern especially when dealing with CMs with offshoring operations or partnerships in countries where IP is traditionally not well protected. Xeridiam maintains all manufacturing and development services based in the U.S., which provides a higher degree of confidence that IP will have appropriate protections and reduces customers concerns.

**Q:** *How has the OEM/CM relationship changed in the medical device manufacturing industry over the past five to ten years?*

**Lee:** The nature of the relationships between the two has changed. With the rapid growth of outsourcing and the increase in regulatory scrutiny, OEMs are much more reliant on CMs than they were five or 10 years ago. There is much more sharing of information, integration of systems, and transparency in costs. As a result, the best relationships are structured more as a partnership.

**Q:** *What misconception do OEMs have in working with a contract manufacturer?*

**Lee:** At times, OEMs don't fully examine the effect to their CMs when they change SOPs or elements of their quality systems. These changes may have major impacts on the way business is conducted between the two parties if not considered and planned up front. It would not be uncommon to cause a supply interruption or unintended regulatory consequences.

**Q:** *How do you ensure clear lines of communication with a partner OEM?*

**Lee:** As a practice, Xeridiam establishes regular business reviews with our OEM partners in which mutual goals and metrics that were established are reviewed and any changes to long and short term tactics are planned. Individual responsibilities at both companies are identified and documented in agreements so that clear expectations are in place.

**Q:** *How do you earn the trust of an OEM who has been "burned" by another contract manufacturer?*

**Lee:** Transparency and open communication are keys to good customer relationships, particularly for OEMs that have been "burned" by another contract manufacturer. Xeridiam informs the customer upfront of expected tasks, milestones, challenges, timing and costs. Once the OEM has selected Xeridiam, there are regularly scheduled project updates, typically on a weekly basis, to discuss progress, challenges and timeline. It's rare for any project to go exactly as planned, so communicating the deviations as quickly as possible is crucial to building trust.

**Q:** *How can a contract manufacturer be a valuable ally when it comes to the validation process for a medical device?*

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**Lee:** Often, the contract manufacturer is the expert of the technical aspects regarding the manufacturing process that directly impacts product performance and functionality. Furthermore, many contract manufacturers have in house test equipment that may not be readily available in house by the OEM. If the OEM and contract manufacturer form a strategic partnership and share design/process risk assessments, responsibilities throughout the verification and validation process can be shared: resulting in a more appropriate and robust verification and validation process.

**Q:** *Any thoughts/comments on contract manufacturing or another related area that you would like to share with medical device manufacturers to aid them?*

**Lee:** A practice of problem solving with an OEM and presenting solutions in a timely manner is a great practice to provide support in this industry. Also, CMs can drive a significant amount of value to medical device of OEMs when the business relationship is structured as a partnership as opposed to transactional only. CMs can be a valuable partner in reducing cost, bringing innovation to market faster, responding to unforeseen demand changes and providing additional outsourced services.

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## **Links:**

[1] <http://www.xeridiem.com/>

[2] <http://www.mdtmag.com/articles/2013/08/not-all-contract-manufacturers-are-created-equal#.UnAJ8JzAaQw>