

Standing Out from the Crowd with Your Reputation

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Mike Nowaczyk, Vice President of Operations, for [SMC Ltd.](#) [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 an OEM will seek out a contract manufacturer?*

Nowaczyk: There are several reason why an OEM would seek out a contract manufacturer:

- When the OEM doesn't have the technology available to build it internally
- When they are out of capacity with their own equipment or with personnel
- An OEM may be looking for a lower cost solution, or to get to market faster

We have seen all of these scenarios with the Medical OEMs we work with.

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

Nowaczyk: Companies stand out in this industry by providing outstanding service levels, having a good value proposition, offering low cost alternatives within and outside U.S., providing quick time-to-market solutions, having superior supply chain management with robust systems in place for managing third tier suppliers, and ultimately making the commitments they promised. Of course, having a depth of resources, both personnel and equipment that can help the OEM achieve their overall manufacturing objectives. In my opinion, the best way to really stand out from the competition is to have an outstanding reputation in the marketplace.

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

Nowaczyk: This is a good question to ask if OEMs are using outside U.S. contract manufacturing. With certain countries, I believe the IP question remains a huge concern for OEMs. However since SMC's facilities, even international locations, are all U.S. based and owned, we haven't seen this as a concern with the OEMs we work with. Of course Non-Disclosure Agreements (NDA) are one way to help protect the IP and another is a no-show practice when touring facilities so others (clients) cannot see what is being done.

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

Nowaczyk: More outsourcing is being done inclusive of complete devices, which demands that the contract manufacturer having strong FDA compliance knowledge. This is what the customer has come to expect and they depend on the contract manufacturer to provide consistent highly reliable products that are in compliance. In some cases, they are also looking for their contract manufacturer to manage sterilization service and provide distribution to their customers.

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

Nowaczyk: That every request outside of producing product will be met without a service charge. That the contract manufacturer has design related experience when it comes to knowing and meeting the user needs of their finished device. Or that the contract manufacturer will be able to deliver to unforeseen market forecasts.

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

Nowaczyk: Setting expectations for both sides up-front and appointing a point person on each end to work together on projects during the development stage goes a long way in establishing strong communications from the start. Also by having face-to-face relationships at various levels within both organizations ensures that all levels are expectations are being communicated. Depending on their roles, each person at the customer will expect something different than the other. That's why it's so important at all levels and functions to know the customer and set expectations up-front, and calibrate often to ensure that both are being satisfied.

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

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Published on Medical Design Technology (<http://www.mdtmag.com>)

Nowaczyk: Open discussion of expectations on both sides, frequent communication, and addressing any issues quickly will help to build trust. Of course the ultimate trust builder is delivering on commitments and consistently walking the talk of what you showed and promised.

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

Nowaczyk: To be valued as an ally in validation, you must first be knowledgeable in understanding what process needs to be validated and what process parameters need to be part of the validation. Having robust validations that prevent variation of the product to the customer, and managing the process consistently through standard work ensures that the product will always meet the validated process. This will be a great benefit so the customer can always defend audits from the regulatory bodies.

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