

Trust in Manufacturing Has to be Earned

Treasa Springett, President, Donatelle



Treasa Springett, president of [Donatelle](#) [1], was a part of the staff written article, “[Not All Contract Manufacturers Are Created Equal](#) [2].” She 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?*

Springett: OEMs are under increasing pressure in today’s medical device environment - from reimbursement considerations to regulatory hurdles and global competition. Due to these pressures, they are seeking to make their organizations leaner and are refocusing their efforts on activities directly related to driving revenue for their organizations. As a result, OEMs seek a supply partner they can work collaboratively with and who has the vertically integrated capabilities to take their device from concept through production and market launch.

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

Springett: Supplier lists are shrinking as OEMs move toward working with a select group on their preferred supplier list. One of the distinctions Donatelle does to stand out from our competitors is to dedicate resources so we stay close to what is happening in our focus markets in order to understand trends and needs, and be prepared to help customers make their next move. We also work with many early stage and mid-size companies who are thinking about devices and the market in new ways. This challenges us to master new technologies and offer new services to those companies we partner with.

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

Springett: We do still hear customer concerns from time to time regarding sharing intellectual property; this is a valid concern for both parties in the relationship. Just as the OEM has concerns relating to the IP for their devices, the contract manufacturer has concerns relating to IP involved in a specific process used in the manufacturing of the device. From a legal standpoint, the appropriate nondisclosure agreements are put in place. Beyond this, it is a matter of having the controls and processes in place to ensure information is appropriately stored and viewed only by those working directly on that aspect of the project. When customers can see the appropriate controls are in place, they develop a level of trust and comfort in knowing their information and IP are secure.

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

Springett: There has been a shift over the past five to ten years of OEMs outsourcing more in an effort to better focus their resources. They are consolidating their supplier list while looking for an outsourcing partner who will help manage their entire supply chain. OEMs have begun to realize significant value in leveraging a single supplier that has all of the necessary capabilities to bring their device to market.

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

Springett: Some OEMs have the misconception that all contract manufacturers are equal. This is not the case. The OEM needs to take into consideration the manufacturing expertise of the contract manufacturer, such as: Can they achieve the difficult but strict dimensional requirements? If the contract manufacturer is using different facilities to manufacture various parts of a device, are all facilities following the same quality manual, and will it have an impact on time to market? OEMs should also ensure they are looking at a true apples-to-apples comparison when evaluating quotes from multiple contract manufacturers. The OEM needs to confirm upfront what is included in a quote and any additional expenses they may incur prior to program launch.

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

Springett: When Donatelle engages a partner OEM on a project, one of the things we do is assign a project leader to be the dedicated point of contact throughout the entire project. This person acts as a single interface between the customers' development team and our team of engineering managers and supporting engineers. A key aspect of the initial engagement on a project is ensuring scope and project intent are clearly defined and understood by both parties. Furthermore, the project leader will hold regular update meetings and define necessary follow-up actions to ensure project success. Customers appreciate and value having a single point of contact to coordinate every aspect of their project.

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

Springett: You've hit it on the head exactly - trust has to be "earned." Trust is something that can only come over time, through building a relationship. Initially, it

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begins with the basics of understanding and meeting the needs of the OEM and providing strong customer service. Ultimately, it becomes a commitment and willingness to share risks in the relationship, working to create a win-win scenario that is in the best long-term interest of both organizations.

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

Springett: OEMs face increasing scrutiny from the FDA for responsibility of their supply chain. As part of this, there is greater focus on validation processes and risk management. Thus, it is extremely important to find a contract manufacturer who truly understands FDA requirements and is in sync with the OEM as to how these requirements are interpreted, executed, and documented. Choosing a contract manufacturer that demonstrates a well thought-out and executed validation plan is insurance for the OEM against potentially expensive product specification changes or impact to the FDA submittal down the road.

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

Springett: There has been an emergence recently of suppliers expanding from other markets to the highly regulated medical market. For OEMs that may be entering into a relationship with a new contract manufacturer, a key aspect to keep in mind is managing risk. Visiting a supplier's facility and performing a thorough audit of their quality management system prior to entering the relationship can go a long way in ensuring the OEM's risk will be minimized.

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