# Roundtable Q&A: Contract Manufacturing

Mike Gaul, Al Hoffmann, Ruben Macias Jr., Tim Nakari, Chris Paolo, and Mike Treadway

**Question 1: What is your best recommendation to ensure clear communication between the CM and the OEM?**

**Mike Gaul**
**General Manager, Sparton Medical**

It is imperative to spend adequate time to establish expectations and agree on project scope, project timing, and deliverables. At Sparton, we utilize the Sparton Production System (SPS), and part of this company's operating philosophy includes a process to clearly identify communication links and dedicated checklists. Clear, concise communication at the front end of the project helps to ensure the project gets off to a good start.

**Al Hoffmann**
**Director Medical Business Development, North America, Interplex Industries**

A single point or main point of contact at both customer and CM that are very close to the program. We address that by assigning a project engineer/program manager who is essentially responsible for managing all aspects of the program. This ensures consistent, complete exchange of information and develops a trusting and effective partnership. At the same time, this approach gives our point people an opportunity to develop a broad understanding of the needs of our customers and, ultimately, the customers they serve. Gaining a thorough understanding of our customer's business is a key to the communications process.

**Ruben Macias Jr.**
**VP Operations, DC Electronics**

At DC Electronics, we have two essential ways of operating that we feel ensure clear communication. First, we've built a process that is as transparent as possible. Every step in the process is traceable and the documentation is instantly accessible. We even give customers access to our BOMs so they can see exactly where our costs lie. Second, we make it easy to access engineers. This way, questions get answered fast. And finally, if mistakes happen, we don't hide it. We find them, fix them, and show the customer what we've learned.

**Tim Nakari**
**Director of Marketing, Spectrum Plastics Group**
Have well defined project managed processes and procedures that force regular communication with the OEM. We have two mantras at Spectrum Plastics Group relative to communication: the first is, “know everything from anywhere;” and the second is, “the customer should only have to tell us once.” We have transitioned our most critical communication paths to a cloud-based CRM that allows our entire team to collaborate, share info, and work effectively together, at the same time saving our customers time and “wowing” them with exceptional service.

**Chris Paolo**
**Vice President, Manufacturing Operations, Ximedica**
The OEM and CM should work to create a collaborative relationship where objective and direct communication is fostered. Ximedica employs a documented process that establishes responsibilities, goals, ownership, and sign offs in the very early stage of an engagement. Formal phase gate reviews are established within our process but the varying scale and duration of different medical programs we see demand multiple levels of documented reporting to convey program metrics such as schedule, budget, and risk. Therefore we create a master plan that outlines and aligns both OEM and CM activities within a single document.

**Mike Treadaway**
**Vice President of Operations, The Tech Group**

All too often, communication is informal, verbal, and sporadic at best. This can lead to misunderstandings and misinformation. Have a formal structure in place tailored to the specific customer or project that clearly defines communication methods and frequency of the communication. Establishing a structure for communication at all levels within the relationship, as well as documenting and distributing meeting minutes, enhances communication and ensures that all interested parties are well informed. It's also important to define the roles and responsibilities of the stakeholders on both sides of the relationship so responsibility for the communication is clearly understood.

**Question 2: How do you alleviate concerns of the potential for you to work with a customer's competitor?**

**MG:** As a contract manufacturer, we face this situation regularly. The best protection for the CM and the customers is to operate under a Non-Disclosure Agreement (NDA). Sparton also has multiple facilities, allowing leverage for competitive products to be manufactured in different locations. Alternatively, competitive products are physically located in different locations of the facility. Confidentiality is crucial in dealing with the right contract manufacturer.

**AH:** We take customer confidentiality very seriously and do the utmost to protect it. When we assign a program manager, we ensure that there is no conflict with existing customers. Internally, information pertaining to current or future projects is shared only on a "need to know" basis. We configure our facility and operations to protect confidential information and from day one, we train our people to closely guard all information shared. We think of ourselves as caretakers of the important information our customers share.

**RM:** To protect customers' IP, DC Electronics has established multiple layers of defense. First, we follow a strict NDA policy, but probably the more important protection comes in creating physical separation. We make sure industry-similar projects do not share program managers or estimators. Finally, we never intermingle production lines.

**TN:** We hold our Customer's IP in very high regard, and take the NDAs and CDAs we sign with them very seriously. Furthermore, for more sensitive programs, we have

the space to set up work cells inside enclosed areas, we can prevent tours from seeing sensitive components, and we always receive permission to show anything used in our marketing. The fact that many of our customers trust us and continue to work with us, program after program, means a lot and speaks highly about their concerns about a competitor seeing their product.

**CP:** It's a double-edged sword, in general. Customers generally want a CM that has experience with their particular product or category. To gain that experience, a CM most likely has worked with, or is currently working with, a competitor. The key is to ensure that while engaged, you will not work on the same type of product. In cases where this cannot be avoided, it can be approached by utilizing separate teams in a separate team space. Independent reviews can be staffed by upper management at the CM, limiting the employees with direct knowledge of both programs.

**MT:** Most companies require employees to sign confidentiality agreements that ensure customer information, intellectual property, and know-how are protected. This is a basic requirement. Beyond that, steps can be taken to segregate the manufacturing areas if the manufacturing takes place in the same facility. Access to the area can be monitored and limited to specific employees and visitors. In some cases, manufacturing can be done in a different facility altogether. Steps can also be taken to make sure work teams are specific to one account or project and not assigned to competitive programs.

**Question 3: How do OEMs benefit from CMs who develop products for other industries outside of medical?**
**MG:** OEMs can benefit from a CM such as Sparton that has diverse industry experience. Our reach across several industries provides us with more exposure to new technology and innovation that is broader in scope than just one industry segment. Additionally, a CM with broader reach has greater ability to internally collaborate and share best practices for the benefit of all customers.

**AH:** Although the end product may be very different, factors that drive innovation in the medical industry are often the same as those that stimulate advances in other industries. Faster, more reliable, and less expensive are requirements you are just as likely to hear from an automotive customer as a customer developing a minimally invasive surgical product. Using a CM that can leverage technological development from outside the medical space gives OEMs a leg up on the competition and ultimately provides them with an opportunity to offer a better product. The medical industry can benefit from discoveries, inventions, and findings developed in other industries and apply them to medical devices.

**RM:** It depends on what kinds of products you are talking about. If it's car parts or iPod cables, maybe not much benefit, but if a CM is working in the aerospace/defense sector, for example, it would require ISO 9100, which demonstrates a higher level of sophistication. Having an ISO 9100 in addition to the 13485 medical is solid proof that the CM really knows what it's doing. A diverse product mix also ensures a healthy company. A CM with a limited customer base or single focus has trouble weathering downturns.

**TN:** The biggest advantage is that we have a wealth of experience from other industries that allows us to bring fresh thinking to new problems. For example we may need to learn how to do custom shielding and plating for a defense customer, then later apply a similar technology to an adhesive application on a medical product. Or, an electronics program may challenge us more on the assembly and automation side of things, which in turn, only helps our engineers better handle medical programs.

**CP:** Ximedica made the decision several years ago to only work in the medical space. However, we have a long history in many areas of the product development field and we continuously see the real value these different industry perspectives bring to our medical clients. For instance, our roots in the toy market taught us one hugely important lesson, “Christmas comes once a year,” meaning we understand that hitting timelines is critical to our client’s business. Additionally, we find that a team with varying backgrounds from within the medical field as well as outside is beneficial particularly in the early stages of a program where too much of a medical bias can bog programs down.

**MT:** The biggest benefit is the ability to apply manufacturing technologies that have been developed and proved in other industries. Examples would be multi-component molding, micro molding and some advanced automation concepts.

**Question 4: Since this is our “Miniaturization Issue,” do you have any thoughts or comments on that topic you would like to share with medical device manufacturers to aid them?**
**AH:** Miniaturization is vitally important in the medical device industry. It allows easier access to anatomical areas and structures that may not have been accessible before. It allows for the use of more minimally invasive surgical techniques and products, which results in less patient trauma, lower overall procedural cost, and reduced patient recovery. Advances in new materials and micro fabrication technologies will be key to developing safer and effective medical devices in the future.

**RM:** Using ultrasonic welding machines instead of traditional solder helps reduce size and costs. Ultrasonic welding allows the presentation of a single leg to solder rather than aligning multiple conductors.

**TN:** Think of the entire product lifecycle and supply chain, then design your product to meet those requirements. It’s one thing to innovate a product and make it smaller or cheaper to mold, but if that change results in additional assembly time, inefficient packaging processes or challenging sterilization management, then the potential benefits may be lost. Product design is more than just what the product looks and feels like—it includes how it’s molded, assembled, packaged, serviced, and disposed of.

**CP:** The shift to technology, wearable devices, and minimally invasive procedures is certainly fueling a movement toward miniaturization, and this trend not only challenges the capability of component manufacturing techniques, but also the ability to accurately and cost effectively measure the components. The medical

device industry utilizes statistics to provide confidence in designs and processes, and the practical significance of variation found in miniature parts make meeting a statistical confidence and limiting measurement system variance difficult. As OEMs begin development of miniature devices, careful consideration should be given not only to the product design, but to measurement system analysis to ensure the parts can be measured accurately and repeatedly.

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