

# MEDICAL DESIGN BRIEFS

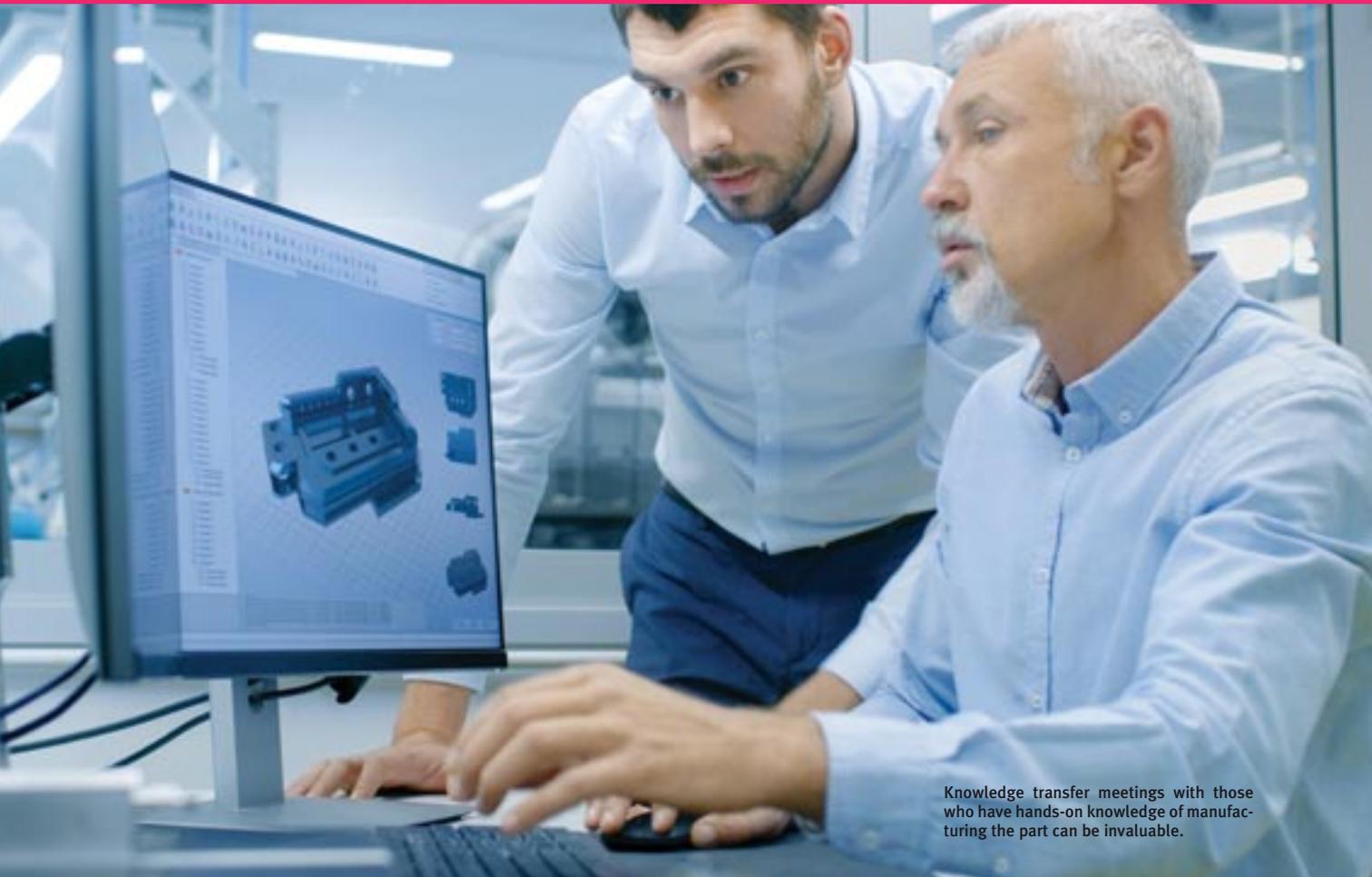
Thin-Film Coatings for  
Dental Implants

Miniature Connections  
Drive Emerging  
Neuro Technologies

EMC for Medical  
Devices: Changes in  
IEC 60601-1-2

*Medical  
Manufacturing  
& Machining/Robotics*

**SPECIAL SECTION:**  
Technology Leaders in  
Contract Manufacturing/  
Outsourcing



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## Seven Steps to Successful Contract Manufacturing for the Medical Industry

Contract manufacturing, or outsourcing, has typically been associated with a company using an offshore manufacturer and lower labor rates to produce their products at a lower cost than would be possible domestically. However, contract manufacturing also provides opportunities for companies looking to utilize the knowledge and experience of existing manufacturers, both domestic and foreign. This option allows companies to avoid large capital expenditures on machinery to build product, as well as the operating cost associated with running this machinery. While this can be an attractive option for companies operating in a wide array of industries, the medical equipment and device segment is one where substantial benefits can be realized.

The need for machinery capable of producing precision-dependent products paired with a well-trained, highly skilled workforce could be seen as a barrier by some companies looking to enter the medical device and equipment manufacturing arena as an OEM. These factors can also be the reason why some existing OEMs decide to exit the market altogether.

This does not always have to be the case. There are contract manufacturers who have the necessary equipment as well as a skilled staff capable of supplying precise medical products that adhere to the highest quality standards. This allows the OEM to spend less capital, hire fewer laborers, spend less time on quality control, worry less about purchasing, and

know that someone else is ensuring the technical skills of the people involved.

For companies considering transitions or moving production to a contract manufacturer, the process is very much the same as when entering any long-term business relationship. It's all about gathering as much information as possible and then making an educated, informed choice. This article presents some guidelines that can be used as a road map for a successful partnership between a medical industry OEM and a contract manufacturer.

### Step 1: Finalizing Design Considerations

While contract manufacturing does allow the shifting of many responsibilities to the company that will be producing the product, the task of clearly defining

the requirements and specifications required for the product remain with the OEM. This all begins by creating a part in the design phase that will be both capable of successfully being manufactured without being cost prohibitive, and that will function as designed when assembled or completed. This process of defining the manufacturability and functionality of the part needs to consider many aspects, including not only the form of the part, but also material composition, product life cycle, and any standards that must be adhered to during the manufacture and use of the product. All of these design and specification questions must be answered before moving into a manufacturing stage.

### Step 2: Contractor Selection

Turning over responsibility for one or more of your products to a contract manufacturer can understandably conjure up feelings of handing the keys of your '67 Corvette to a friend. That transaction involves a fair amount of trust. Likewise, choosing an appropriate contract manufacturer requires trust, but this trust must be bolstered with diligence on the part of the OEM.

As with any good business relationship, there needs to be a thorough understanding between the OEM and the contract manufacturer of its capabilities, strengths, weaknesses and relevant experience with manufacturing similar products. Contacting other customers of the contract manufacturer to elicit their feedback on how well the contract manufacturer has performed historically is always a prudent move. The selection process is akin to interviewing a potential employee, with as much knowledge as possible about the contract manufacturer being gathered, so that an informed decision can be made.

### Step 3: Knowledge Transfer and Development of Process

After an agreement has been reached with the contract manufacturer to begin making product, and all relevant intellectual property safeguards have been put in place, the work of developing the manufacturing process for the product needs to begin. If this is an existing product being transferred from the OEM, all existing work instructions and current raw material sources should be



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shared with the new contract manufacturer. These knowledge transfer meetings need to include not only mid- to upper-level OEM staff such as engineers and operations managers, but also those production and assembly workers who have hands-on knowledge of manufacturing the part. Being able to collect as much wisdom as possible from those sources can be invaluable.

If this is a new launch, the contract manufacturer will be tasked with developing the assembly flow and work instructions for the build. Nonetheless, the OEM may still be able to assist the contract manufacturer with this process. There is no need to reinvent the wheel. At the very least, the OEM can only benefit from offering assistance at this stage, if for no other reason than establishing a rapport between the two parties, which will hopefully lead to open and frequent communication.

### Step 4: Supply-Line Development

Concurrent to the development of manufacturing and assembly processes, the raw material and/or ancillary part supply chain should be established. The entire development, qualification, and supply line management for components takes an experienced team who are familiar with the processes and standards particular to manufacturing medical products, such as medical injection molding, ISO Class 8 cleanliness standards, lot number traceability, medical

drying procedures, and superior tight tolerance precision molding.

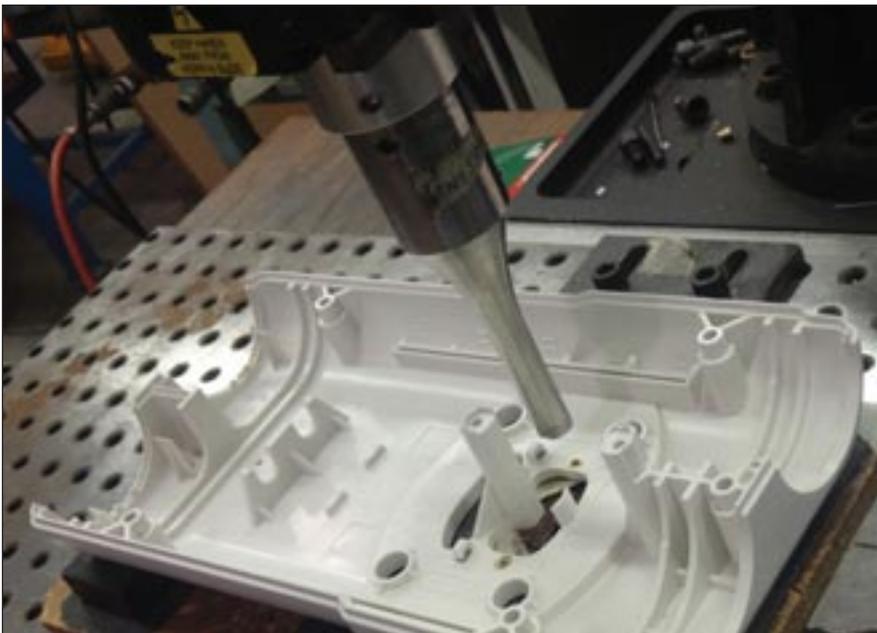
Finding and building strategic relationships with suppliers who can meet and exceed any processing or quality standards is only one aspect of supply line development. The process also needs to include risk management, so that interruptions in raw material deliveries are essentially eliminated. This can be accomplished by verifying the capacity and fiscal soundness of several potential suppliers for each raw material or outsourced component. Doing this legwork will help to verify that the supplier can effectively manage resources to ensure on-time deliveries.

### Step 5: Training and Process Qualification

Once the flow, work instructions, and components are all in place, operator training and qualification can start. Whatever the product is, there is an optimum process for making it efficiently with adherence to rigorous quality standards. This process needs to remain consistent, regardless of the machine being used or the operator who is running the machine. The contract manufacturer's design and engineering team will need to create custom manufacturing instructions that are critical to turning out finished products that meet high quality standards. Thorough, documented training needs to take place so that these instructions are understood by all operators.



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Having a well-trained group of associates who can operate equipment consistently and perform work routines within established process parameters streamlines the process qualification process, and leads to a well-made part.

#### Step 6: Pilot Builds

The last major effort in a successful transition or start-up of production for the contract manufacturer is the pilot build. Hopefully, this is where all the

preparation by both the OEM and contract manufacturer shines through, with the production of the first part coming off flawlessly. More than likely though, that will not be the case, with opportunities for improvement being identified. This is the goal of the pilot build, so that work flows can be tweaked, machine settings can be adjusted, and work instructions can be improved.

There is a natural tendency to accelerate the process leading up to and during

the pilot build, but the urgency and excitement to get the first part made can cause hasty, careless decisions to be made. Patience and forethought need to prevail when the process is close to the finish line.

#### Step 7: Entering the Production Phase

When the pilot builds have been satisfactorily completed, the production phase is entered. For this to unfold as seamlessly as possible, there must be a solid production plan in place. Typically, this means employing an accurate demand forecast that is the basis from which stock levels, reorder points, and raw material procurement schedules are derived.

Most importantly, there should not be any barriers that inhibit communication between the OEM and contract manufacturer when it comes to the forecast, or any information that could potentially impact the demand for the product, with this information being shared as often as possible. This will promote a robust production plan that is built to withstand the peaks and valleys of typical business cycles.

Finally, shipment of finished product needs to be coordinated in advance. Having a contract manufacturer who is willing to maintain stock at their facility can be advantageous. Similarly, a manufacturer who has the flexibility to make JIT shipments or drop ship to individual customers can greatly increase service levels and customer satisfaction.

#### Conclusion

Contract manufacturing provides a tremendous opportunity for medical industry OEMs who want to focus on their core competencies and not the process of manufacturing their product. Capital expenditures and operating costs are greatly reduced, as are the typical responsibilities of running a production facility. By taking a methodical approach to selecting a qualified contract manufacturer, the OEM can ensure that the transition will avoid setbacks from the knowledge transfer phase, all the way through the pilot build and production phases. When done correctly, the process will result in great customer satisfaction and great performing product.

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