One of the most crucial decisions in taking a medical device from concept to market is the selection of an electronics manufacturing service. Making the right choice can be the difference between the smooth, on-time and on-budget delivery of a device, and a nightmare production process fraught with unforeseen complications and hidden costs. **Mo Ohady** and **David Estes** from Digicom Electronics lay out the key things to consider when selecting an EMS company.

What Medical Device Companies Need to Consider in Selecting an EMS Company

What makes for a successful contract electronics manufacturing relationship, and what does a medical device company need to keep in mind and consider during the selection process?

Once the decision has been made to use an electronics manufacturing services company (EMSC), choosing one involves several steps. Although most EMSCs perform the same basic services, every one is different. You can tell when you walk into a place, examine the equipment and processes, and speak to the people.

The initial basis for narrowing down your selection is to prepare a list of the basic requirements you expect an EMS provider to meet and detail specifically what you

want the EMSC to do – design, prototyping, material selection and purchasing, manufacturing, test, process validation, shipping and logistics… Do you need manual or automated processes, small quantities or volume manufacturing? Is the EMSC able to offer the range of services that meet your needs? Does the EMSC have the appropriate quality certifications to manufacture the product?

There is no room for error with medical devices. A basic requirement for the medical market is ISO 13485:2003 medical device manufacturing certification. This certification states the requirements for a comprehensive management system for the design and manufacture of medical devices, ensures that medical devices meet customer and regulatory requirements, and establishes a commitment to quality.

The FDA's Quality System Regulation 21 CFR (Code of Federal Regulations) 820 requires medical device manufacturers to perform a process validation when the process is not fully verified by a subsequent inspection or test.

Process validation ensures that a process consistently produces a product that meets its specifications. It is an important component in the design, prototyping and manufacturing process, and one that, if done correctly, can save a considerable amount of time, money and resources. By using an EMSC that already has ISO 13485:2003 certification, regulatory bodies know that certain procedures and requirements will be met, so certification is less labour-intensive and approvals proceed more easily.

Consider this

Check out where the EMSC is located, where design and manufacturing are done, and make sure the size of the company is a good fit for your needs and products. Do you want the product manufactured close to where your company is located, close to where the product will need to be distributed or are you manufacturing large volumes where cost is a major factor so a low-cost geography might be more beneficial?

Considerations when choosing a location are the complexity of the device, process transfer, intellectual property protection, shipping costs and time, and the degree of involvement you will need throughout the process.

One differentiator that is sometimes difficult to discern initially is the degree and type of service and support you will receive; no matter what company you select, make sure that they consider each job they do to be special. Find out who your point of contact will be, who will be managing and supervising the manufacture and work, who will ultimately be responsible if changes need to be made or problems arise and how they deal with these problems.

Is the person you deal with a high-level engineer? How much actual engineering support and troubleshooting will be done to make sure your design can be manufactured accurately? The EMSC

Mo Ohady
Mo Ohady is general manager of Digicom Electronics having started the company in 1982. He has a degree in electrical engineering, and MBA and masters degrees from the University of California. Previously, he was the operations manager at a telecommunications equipment OEM.

should have the expertise to analyse your design for manufacturability and potential problems, evaluate the bill of materials and optimise the manufacturing process to find more cost-effective ways to make the product. A lot of this has to do with forecasting.

Who controls and is responsible for the inventory, and how much inventory will the EMSC hold? A good EMSC can analyse your bill of materials (BOM) and offer insight into potential issues before manufacturing begins. Obsolescence, counterfeiting and sourcing hard-to-find components are all issues that an experienced EMSC can advise a device manufacturer about. Open lines of communication and robust quality procedures will ensure that problems are prevented, and a more reliable product will result.

Review the procedure for setting up the project. Look for a company that has tracking mechanisms in place. If something is defective or fails in the field, a tracking system will often help you determine where the failure occurred and what caused it, which batches might be defective and what parts were used, so additional problems can be avoided.

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How transparent is the operation? Each step of the assembly process should be noted electronically and sequenced in the order that it needs to take place. Inspection points should be set at every stage, as first-article checks ensure that the process flows free from errors. In some plants, every operator has a unique identifier, providing complete traceability from when a job enters the EMSC to the finished product.

Quality is often the first thing mentioned in the rankings of what is wanted from an EMSC, but the degrees of quality provided can run the gamut. Examine the test procedures used. What types of inspection and tests are done and how are they performed? Inspection equipment has changed dramatically over the past few years – it is now better able to capture defects, and help explain where they come from and how to prevent them.

However, neither machines nor people are infallible, so, for medical devices in particular, having some additional manual inspection procedures in place can provide an extra level of protection.

When in the manufacturing process are inspections and tests performed? Make sure you select a company that takes inspection very seriously. Some EMSCs will do inspections at every station along the manufacturing process and test every board. Non-conforming parts are identified, and errors are marked for correction and captured for statistical process analysis for quality-control purposes.

Studies show that a major cause of failures in the field is printed circuit boards that are not completely clean. There is a gap in the market caused by new technologies that make it more difficult to ensure circuit board integrity.

Today's chemistries in fluxes and solder, plus the extremely low board-height of components, make cleaning more difficult. It is not enough to put the boards through a wash cycle. It takes a special combination of chemicals, temperature, wash cycles and timing to get the boards thoroughly clean.

Digicom has developed sophisticated custom cleaning and analysis techniques to ensure even ultra-low levels of contaminants that are by-products of the soldering process are removed to enhance the production of the delicate circuits.

IPC, the global trade association serving the printed board and electronics assembly industries, established a base standard for cleanliness and set an acceptable range of 2–65µg/in^2 of sodium chloride. The MIL-P-55110/50884 standards allow 2.00–10.06µg. Independent labs have shown the method of cleaning devised by Digicom gets boards 75% cleaner than the IPC standard and with zero ion contamination.

The whole package

Is the company environmentally friendly? What attention is given to electrostatic discharge (ESD) protection and cleanliness? The floors should have ESD protection, and the operators should all observe practices to ensure that ESD is not an issue. How are chemicals and waste disposed of? The EMSC should comply with all local and government regulations.

Is it an ergonomic environment for the workers? How long have most of the workers been there? What is the company's history for accurate and on-time delivery? If the workers are happy and there is little worker turnover, there is more chance that your job will be completed accurately and on time.

An EMSC is your partner and is on your side. They want you to be successful. Visit the company, talk to the people, meet the person/team you'll be working with. Are the key personnel accessible? Does the culture of your company mesh with that of the EMSC? Look at work that's been done. Make sure the company has a plan in place that clearly delineates the responsibilities of each party.

Resist looking at costs alone. There is more to consider than simply the initial outlay; it may not be a bargain when issues come up and changes result in large increases, when items aren't delivered on time, or when you have to deal with after-sale issues from failures or poor quality. The wrong choice could damage or destroy your company's relationship with customers, its reputation in the market and even its standing in the financial community.

It's important to carry out due diligence when choosing an EMSC, but the rewards can be great: a properly functioning one brings decades of experience and knowledge to embrace and enhance the product you want to build in a time-efficient and cost-effective manner. ■

David Estes
David Estes is an engineer with Digicom Electronics. He has worked in the electronics industry for 49 years, obtained patents for a medical device electrical stimulator, and assisted in the research and development of Digicom's state-of-the-art board-cleaning system.