

# The end-to-end difference

**Mike Treleaven**, senior vice president, engineering, Tegra Medical, examines the importance of evaluating a contract manufacturer’s end-to-end service.

**W**hen Original Equipment Manufacturers (OEMs) decide it’s time to outsource their medical device manufacturing – as more are realising they need to do – evaluating the contract manufacturing organisation’s (CMO’s) ability to provide end-to-end services is a must.

### WHAT ARE END-TO-END SERVICES?

As the term implies, end-to-end services cover the entire process of making a medical device. While OEMs typically have their device designs already in hand, the CMO handles all the remaining steps beginning with a plan for programme management and Design for Manufacture and Assembly (DFMA). This service fine-tunes the entire manufacturing process to reduce cost and risk, increase quality, and shorten the development cycle of a medical device. It typically includes a review of the design, materials, and processes.

After handling the remaining phases of prototyping, validation, and full-scale production, an end-to-end CMO handles final assembly, packaging, and sterilisation management as needed to finalise the product.

### WHY IT MATTERS

Why is it so important to work with an end-to-end CMO? It’s a matter of priorities. OEMs need to simplify their manufacturing processes so they can focus on other areas of their businesses that are harder to outsource such as research and development of new products, marketing existing products to new channels, and mergers and acquisitions.

Their strategy is to focus on their core business and let a contract manufacturer take on a larger role in getting their products manufactured. This often means asking the supplier to create their whole device from top to bottom and handling the entire process from prototyping to production.



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### THE ESSENTIAL MIX OF CAPABILITIES AND EXPERTISE

OEMs must do their homework and ensure a potential CMO partner isn’t just talking about end-to-end services; they are really offering them. While many companies claim to offer this suite of services, true end-to-end providers are vertically integrated with all the development, quality management, validation, manufacturing, and packaging services necessary to get medical devices and components to market.

Many medical device manufacturers that specialise in either metal or plastic claim to offer end-to-end services, but they actually just manage the supply chain. An ideal manufacturing partner has the expertise for intricate work with both metal and plastic that many other suppliers cannot handle. This means that a single manufacturer can support customers all the way through the process of making their devices.

From the sharp metal tip to the ergonomic plastic handle, a device can require several different machines to be completed. It’s best to work with one partner that offers all the various manufacturing methods that are

required – milling, machining, grinding, moulding, laser processing, EDM etc. Another benefit: with a wide variety of capabilities, the contract manufacturer is not only equipped to make the OEM’s current product, but it gives them the flexibility to make more of the different kinds of devices an OEM needs in the future.

It’s not just about what machines the CMO has; it’s about their expertise. Anyone can buy machines. If the “business end” of a device is sharp metal, it’s essential that the manufacturer’s core competency is in making the most important part.

And speaking of sharpness, with medical devices this is not something that can be compromised. Just making a device sharp is not enough. The true end-to-end CMO knows how to keep it sharp all the way through moulding, assembly, and packaging.

A contract manufacturer is doing more than just making an OEM’s products. They are guardians of their brand and their reputation for quality. A true end-to-end partner will offer the mix of capabilities, expertise, quality, and customer dedication OEMs need.

