

Soft skills complement hard engineering

Dean Petrella, director of program management at contract manufacturer **Tegra Medical**, discusses the role of soft skills for DFM, which is the cornerstone of the company's GENESIS Tech Center product development services.

As a contract manufacturer (CMO), Tegra Medical doesn't design medical devices, but it does design the process to manufacture them. Design for manufacturability (DFM) takes OEM customers' designs and makes them practical and possible. Starting early in the development of a medical device DFM:

- determines the smartest way to make the product
- ensures the design does what it is supposed to
- ensures the device will meet quality and regulatory targets
- makes the process efficient
- reduces costs as much as possible
- enables a repeatable manufacturing process.

Naturally, DFM requires in-depth engineering with a solid understanding of the raw materials, manufacturing technologies, and function of a device. But, while

technology and expertise play a huge role in the medical device industry, it's the soft skills that can help bring products to life. DFM requires that a manufacturer and OEM work together very closely, so willingness, trust and a solid partnership are essential.

Willingness

Ideally an OEM should be willing to make the first move by getting a CMO involved as early as possible, rather than blindly sending RFQs. They should then be willing to collaborate on DFM and have an open mind about what the CMO suggests. They need to understand that a gorgeous design drawing does not guarantee a product that can be manufactured.

The CMO needs to be willing to talk and explore options when handed a design that can't be manufactured as-is. They must look beyond drawings and specification to understand a product's function and strategise on the best way to manufacture the design.

Trust

Life-changing medical products require relationships of trust between doctor and patient, doctor and

OEM (to make an instrument or implant that works), and OEM and CMO (to manufacture a high-quality product according to agreed-upon specs). Specifically regarding DFM, the OEM trusts that the CMO is invested in making the process work, is an expert in tackling manufacturing challenges, and is willing to think outside the box. The engineering

relationship during DFM is where the magic happens to build trust.

Partnership

DFM is often the beginning of great OEM-CMO partnerships. And strong partnerships are the foundation of successful product launches. Mutual respect and support between the OEM and CMO are the key ingredients for these strong partnerships.

With a healthy OEM-CMO partnership the team can solve immediate problems together, launch great new products, and set the groundwork for future development. The benefits of investing in DFM right from the start are that the process is vastly more efficient, cost effective, and repeatable.

Where it all comes together

Tegra Medical has learned that the strongest DFM teams have the following important attributes:

- **Enthusiasm:** Excitement to take a design and turn it into something manufacturable.
- **Attitude:** The feeling is 'let's figure out how to do this' not 'that can't be done'.
- **Energy:** Both sides keep at it until they have examined all the angles.
- **Common sense with experience:** The CMO should know when to push back on a design that's not quite right, and when it's time to start production.
- **Open minds:** The solution might be to use lasers in an unexpected way, or to make a device in pieces rather than machining a solid block of metal.

DFM can be like magic, but it only happens when CMOs and OEMs form partnerships infused with willingness and trust. ●

www.tegramedical.com



Sometimes it takes a strong backbone.

We've got the backbone to tackle complex manufacturing challenges – like combining non-traditional and common technologies, creating precise anatomical bends, and making and maintaining the sharpest edges in the industry.

Our GENESIS Tech Center® experts have the combination of soft skills and engineering expertise to apply the most creative DFM solutions for your product's development.

And as a true end-to-end manufacturer we handle every process, so your device is infused with our renowned quality from development to final production and packaging.

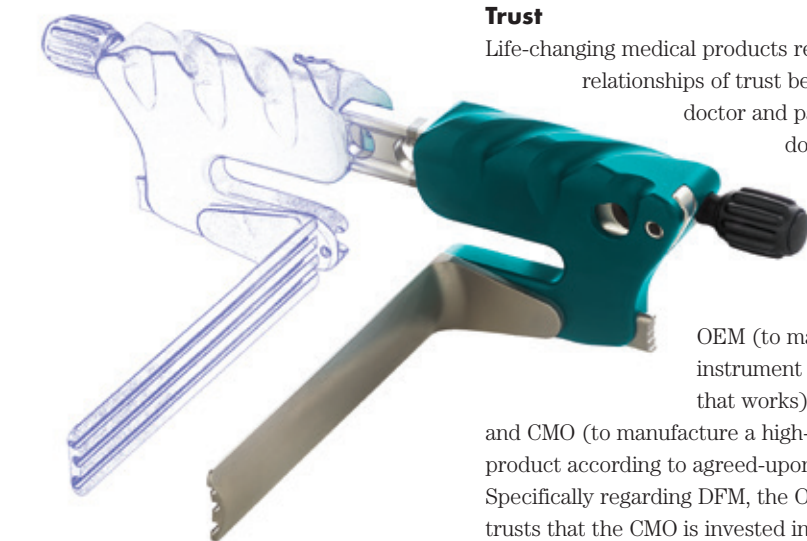


Where medical devices come to life.®



See our webinar on DFM for medical device manufacturing.

<https://bit.ly/3AluL22>



DFM turns customers' designs into reality.