

Contract Manufacturing

Excellence that precisely fits your needs

As medical breakthroughs occur faster than ever, you need absolute confidence in every product you bring to market. And you need a contract manufacturing partner you can trust to care as much as you do.

We provide vertically integrated capabilities, absolute quality standards and a pure medical focus. We also provide the vital care required to empower and support excellence, while delivering exceptional results.

The best, most recognized names in the industry have relied on us for more than 50 years to deliver critical medical devices to market. And we're eager to earn your trust, too.

Let's get the conversation started.

What are your contract manufacturing capabilities?

We provide exactly the level of support you need, from a single manufacturing process to a complete solution, for high- and low-volume needs. Manufacturing operates on a continuous basis to meet supply chain and forecast needs.

Our vertically integrated services span medical device design, development and prototyping through validation, manufacturing, assembly, barcoding, packaging, labeling, sterilization management and delivery.

Our team of engineers, designers, machinists and toolmakers will

work closely with your team to scientifically determine the most reliable, accurate and cost-effective parameters for your product.

Our state-of-the-art facility features controlled environments and ISO 7 (class 10,000) certified cleanrooms, as well as cleanroom production cells with integrated vision systems that can operate at ISO 5 (class 100) level.

Tell me about your absolute quality standards.

Maintaining the highest level of quality and innovation in manufacturing products is exactly what you can expect from us. In fact, we've set the standard of excellence for quality systems – our

facility is FDA registered and inspected with no Form 483 observations.

From design through shipment, our quality assurance processes utilize ISO-9001 and ISO-13485 certified systems.

Which industries do you serve?

We focus exclusively on medical device design, development and manufacturing, especially for intricate applications – like high-risk, long-term implants and disposables – where precision, tolerances, validation and timelines are critical.

Why should I choose Donatelle?

At Donatelle, we pride ourselves in upholding an unparalleled standard of excellence. In fact, we've earned – and maintain – an impeccable track record for regulatory compliance, meeting deadlines and on-time delivery.

We take our work seriously, because we understand how much it matters – to you and the patients who count on you.

We hope this helped answer your preliminary questions.

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Please contact
+1.651.633.4200 or
info@donatelle.net
for more information.



Deliver your medical device promise

At Donatelle, we make products that sustain – and save – lives.

We manufacture medical devices and components. That's all we do. And we do it with the utmost precision, consistency and rigor, because for you – and your customers – quality is essential. Reliability is a must. And delivering on what's promised is vital.

Learn more about how we can help bring your medical devices to market – with confidence.

- Contact **+1.651.633.4200**
- Visit **donatellemedical.com**

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