COLLAGEN MATRIX
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Outsourcing the development and manufacturing of biomaterials for competitive advantage

Leading medical technology companies have long recognized the value of outsourcing the development and manufacturing of biomaterials. Today, in an environment of constrained labor markets and disrupted global supply chains, choosing a partner for contract development and manufacturing makes even more sense.

No matter what's happening in the world, patients could be better off, and the urgency is still there. Medical technology companies are looking to partners like Collagen Matrix, which offers a full line of collagen and mineral-based medical devices in markets across the globe.

"Patients are waiting for better solutions that can help improve their lives, and we're best positioned to give those solutions to them," says Collagen Matrix CEO Shawn McCarthy. "Our team gets it. We feel for the patients, and that drives us to hustle—to move swiftly to advance the science of tissue repair and regeneration."

As the rate of innovation in biologics increases, finding a collaborator who can keep pace becomes vitally important to commercial success. The rapidly evolving regulatory landscape calls for the kind of deep knowledge most easily found in a specialized supplier. These two key considerations—biologic expertise and regulatory knowledge—are essential to peak performance of the finished product.

"The selection of the right partner is critical for speed to market and consistent high-quality supply of product in the long term," says General Manager, Contract Development and Manufacturing and SVP, Regulatory and Clinical Affairs, Peggy Hansen.

Shawn McCarthy
Chief Executive Officer

Peggy Hansen
General Manager, Contract Development and Manufacturing and Senior Vice President, Regulatory and Clinical Affairs

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Why outsource? Quality, safety, cost effectiveness and time saved

Being first to market holds competitive advantages for both established medical technology enterprises and startups. Partnering with a supplier who already has best-in-class infrastructure, deep knowledge of the regulatory environment, trusted processes, experienced staff and integral leadership can put you months or even years ahead in the development of a new product.

With an outsourced model, there is no capital outlay, uncertain ROI or unpredictable time to value. When development and production are largely de-risked, costly missteps can be avoided and patients can benefit from life-changing and life-saving advances even sooner.

KEY CONSIDERATION 1 Biomaterials expertise

Because biomaterials are often components of medical devices, a collaborative development model can bring equal levels of expertise to each part. A partner like Collagen Matrix has the cross-disciplinary teams to meet clients wherever they are in the development and manufacturing pipeline. "For example, we helped a partner develop a product for tendon repair. The client came to us with a product concept. The designers of the device had expertise in mechanical engineering, and their strength was in the mechanical delivery system, but they needed help designing the biologic implantable component of the product," explains Hansen.

"We were charged with designing a product that would support tissue repair and regeneration. Collagen Matrix provided product design and guidance on how to test the implant itself. Our regulatory strategy included a phased approach for the United States and beyond. And now the products are sold globally. We're the contract manufacturer, and since product launch, we've scaled up the process to support the customer's growth. Looking ahead, Collagen Matrix has developed improvements for the next generation of the product. It's been a fantastic collaboration that ultimately benefits the patients."

Fit-for-purpose design

Working with an expert in biomaterials means a higher degree of customization is achieved. The matrix behind the name Collagen Matrix offers this kind of flexibility. "We look at the clinical application, and then we design a matrix—a three-dimensional scaffold—to meet those clinical requirements. Other approaches take a tissue with existing characteristics and try to fit it to a clinical application. We do the opposite. We look at the problem that needs to be solved in the body, and we design for that. This allows us to customize a matrix with design characteristics most suitable for the biological environment and the type of defect or injury," says Hansen.

Hansen continues, "One example of matrix customization would be in the area of bone repair. If the bone defect is irregular in shape, we design a moldable bone graft that can be shaped to fit the irregular contours of the defect. On the other hand, if the bone repair requires mechanical strength, we create a bone graft that has more density and compressive resistance. We're able to change design characteristics to meet specific clinical needs."

McCarthy remarks, "We can iterate and toggle each of those characteristics. For example, if our clients want greater porosity or faster resorption time here's the technology, here's what you might be trading off and here's how we can deliver it for you. That's how the products get better." Choosing a contract development and manufacturing partner who is experienced, connected and adaptable can help your product exceed expectations for utility and efficacy.

Chain of custody, chain of quality

Given the inherent variables of biologic sources and the critical applications of medical devices and components, quality and purity are paramount. Working with a single supplier who is an expert in animal tissue sourcing and processing can provide an extra layer of confidence and ensure the highest degree of safety.

Collagen Matrix is a recognized leader in the field, with end-to-end control of their manufacturing logistics and a proprietary production process called TruSource. Their raw materials are sourced from Australia, New Zealand and the United States and processed according to ISO 22442, an international standard for handling and processing animal tissues for use in medical devices. A documented chain of custody provides transparency and reduces the risks of working with multiple subcontractors. "If you're working with multiple subcontractors, oftentimes you may not be aware of minor changes they could be making in the process or component. By owning the manufacturing process from beginning to end, we reduce the risk of unknown, uncontrolled changes that can impact quality and purity," says Hansen.

"You have a better chance of controlling the best possible performance of your product if you can bring it all together," adds McCarthy.

KEY CONSIDERATION 2 Regulatory knowledge

"The biggest issue facing our clients is global regulatory approval of products that contain materials of animal origin."

— Peggy Hansen

Even if you have a pure, high-quality product, it's not marketable without the proper approvals. Reaching your addressable market requires meeting diverse regulatory requirements. Not only do regulations vary from country to country, but the regulatory approval landscape is also rapidly evolving.

"The biggest issue facing our clients is global regulatory approval of products that contain materials of animal origin," states Hansen. A supplier needs to have both a historical view of the regulatory compliance requirements and a forward-looking approach to anticipate and prepare for coming changes.

"With 25 years of experience developing collagen-based products and regulatory approvals in more than 80 countries, we feel that we are the best resource to provide regulatory strategy and technical support for product approvals," explains Hansen.

"We've met the thresholds for some of the biggest regulatory agencies on the planet. We're opening up in China and India, and we've met the bar in Japan with the Pharmaceuticals and Medical Devices Agency (PMDA). We have Medical Device Single Audit Program (MDSAP) certification, which involves multiple major countries. And we have a strong relationship with our notified body in Europe, which gives us access to regions that require the CE mark," says McCarthy. "We're opening up more and more markets every day because we know that the global marketplace will be even more important to our customers in the near future."

It is easy to underestimate the complexity of regulations and the rigor of filing; a trusted partner can guide every step of pre-clinical and clinical testing and regulatory filing.

In addition to technical documentation, certifications and availability for audits, there are other necessary business capabilities that a full-service partner can provide. "We have approved suppliers for language translations to support international submissions, instructions for use, labeling and promotional materials. In addition, we have expertise in the import and export of animal tissues and medical devices containing such materials. These are also important aspects of serving global markets," says Hansen.

More must-haves for a successful partnership

Beyond biologic expertise and regulatory knowledge, customers are in search of innovation, speed and a quality partner they can rely on. McCarthy says, "Once our customers begin working with us, they always add more facets to their projects—and that's because we have earned their trust."

When evaluating a potential outsourcing partner, look for:

- ✓ Biologic expertise
- ✓ Regulatory knowledge
- ✓ Customization
- ✓ Innovation
- ✓ Depth of experience
- ✓ Comprehensive services
- ✓ End-to-end supply chain
- ✓ Quality
- ✓ Speed

Dental | Spine | Orthopaedic | Dural Repair | Nerve Repair | Sports Medicine | Wound Repair

Consider Collagen Matrix for your contract development and manufacturing needs.

Collagen Matrix offers a full line of collagen and mineral-based medical devices to support the body's natural ability to regenerate. Our TruSource process guarantees the highest level of biomaterial quality to enable peak performance from your finished product.

To learn more about Collagen Matrix and the TruSource process, visit collagenmatrix.com >>

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