



From pellet to product: A strategic guide to medical device manufacturing with OGM

A strategic guide to medical device manufacturing | Guide



Innovation is at the heart of healthcare. Whether it's new medications or innovative devices, ongoing progress is essential in advancing diagnoses, treatments and patient outcomes – particularly as the burden on healthcare systems continues to increase.

Today, there are over two million medical technologies that are categorised into more than 7,000 device groups, with new surgical instruments, diagnostic solutions and other key vital products emerging every day.

However, taking a medical device from concept to prototype to market is a challenging process. It involves iterative designs and in-depth clinical trials, with quality control and regulation at the very forefront of health and pharma industry.

Every decision, be it material selection or final validation methods, can have a huge bearing on the overall success of a product. The pressures on product development teams are massive. Timelines are tight and standards are high.

To ease the burden, many manufacturers opt to lean on qualified partners by outsourcing various aspects of their medical device development, moulding and assembly processes. It's a strategy that can provide several merits. Yet relying on too many suppliers can come with its own potential issues.

Fragmented supply chains can result in miscommunications during the manufacturing process, exacerbating the risk of delays, and introducing compliance challenges in a sector where accuracy and accountability are critical. In this white paper, we explore a better way.

OGM's "Pellet to Product" approach is a fully integrated manufacturing solution designed specifically for medical device companies. From design for manufacture (DFM) and tooling to cleanroom moulding, assembly, testing, and regulatory support, OGM is a single, accountable partner capable of covering every key step of the medical device manufacturing process.

Whether you're an R&D engineer refining a prototype, a regulatory manager preparing for audit, or a supply chain lead looking to simplify operations, this white paper will outline the benefits of working with a single, proven supplier – helping to enable faster launches while reducing risk.

Industry challenges

Today, the medical device manufacturing sector is moving more quickly than ever before. The average global research and development investment rate (R&D spend as a percentage of sales) is estimated to be around 8% in the medical technology sector. As a result, products frequently have approximately 18-24 months before a new alternative becomes available.

More than 15,000 medical technology patents are filed with the European Patent Office (EPO) annually.

That pace of change is essential. Healthcare demands it. But it also creates an environment in which manufacturers must turn complex designs into high-performance devices at speed while grappling with several challenges:

1 – Regulatory complexity

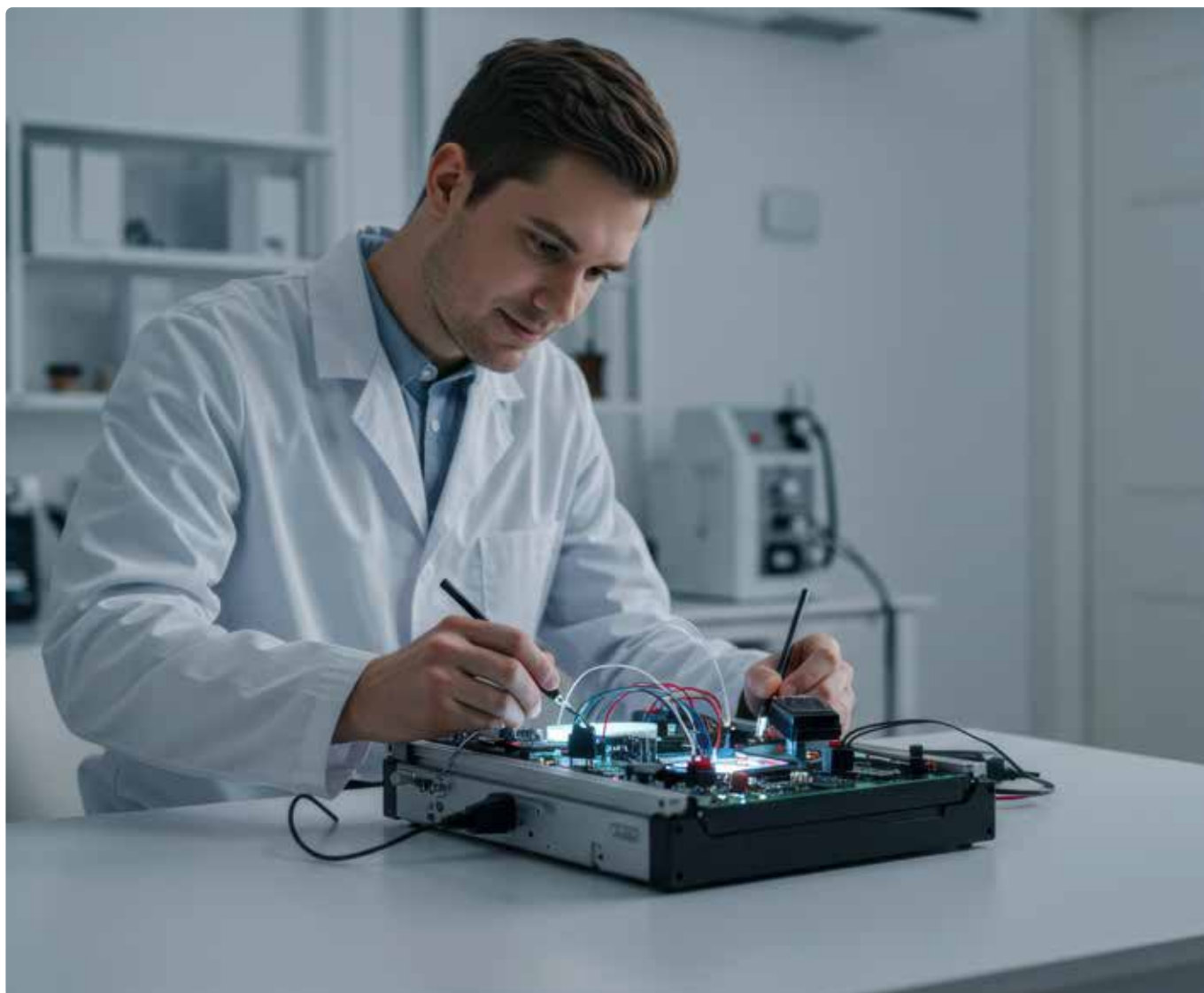
Regulations are vitally important to the success of healthcare systems globally. However, developers must commit significant resources, time and expertise to ensure that they adhere to ever-evolving legislation – from MDR to UKCA, CE marking and international standards such as ISO 13485.

Manufacturers must ensure they interpret changing guidance appropriately and ensure their operations align. Failing to do so can lead to compliance gaps which may have severe consequences – from costly product re-designs and delayed launches to the worst outcome cancelled projects.

2 – Time-to-market pressures

While medical device firms need to meet regulatory guidelines, they must simultaneously ensure their devices reach approval, completion and in turn the market as quickly as possible. That is no easy feat. Prototyping, verification and validation all create potential bottlenecks that can become exacerbated when working with multiple suppliers and their own intricacies.





3 – Cost constraints

The process of developing medical devices from concept to approval is notoriously expensive. The high costs involved in R&D and long development timelines is a combination which is ripe for significant outlays that can quickly escalate.

Advanced technologies and automated systems can make major differences in terms of quality and repeatability but require significant upfront investment. Appropriate development environments such as cleanrooms are also crucial in healthcare but again, can be costly to setup and manage.

4 – Quality assurance demands

In medical manufacturing, quality isn't negotiable. Every single device among hundreds of thousands must be made to the same exacting standards. Nonetheless, this imposes significant quality control demands on the manufacturer.

One missed issue may result in product recalls and liability implications, leading to a deterioration of trust and reputation. Establishing good quality management systems (QMS) that work on the principles of traceability, repeatability and compliance are a necessity, but the investments required can be significant, and potentially unfeasible.

The case for outsourcing

Critically, it is very rare that a single medical device manufacturer will have all the resources and expertise within their company to overcome every hurdle during medical device development and launch.

Medical device development is far from straightforward. From tooling to assembly and testing, there are a variety of complex processes involved in manufacturing highly precise components that often require specialist equipment and expertise.

This is where key suppliers and partners can add value. Outsourcing certain sections of the manufacturing process to specialists can provide structure, speed and confidence in the process as well as alleviating various burdens:

- **Cost:** Outsourcing specific aspects of the manufacturing process that require niche tools or specialist expertise can help keep costs down, reducing the need to invest in expensive and extensive equipment, facilities or personnel to establish complex operations internally.
- **Speed:** Third parties will typically have specific skillsets and knowhow. This will offer reliable experience in relation to product quality, while also helping to accelerate development cycles such as prototyping.
- **Scalability:** The ability for manufacturers to scale production up or down in line with market demand can be incredibly useful – particularly when producing products that experience demand fluctuations, such as seasonally relevant medical devices.
- **Fluctuations:** A safe manufacturing partner will have other customers, giving them the flexibility required to manage vast fluctuations in demand. Even companies with extensive product portfolios can find themselves with labour excesses and shortages due to demand peaks and troughs. A partner, meanwhile, can manage and move their labour to other customers and parts, quickly addressing any issues.
- **Risk:** Leveraging the skills of existing setups can also help to reduce risk. Established partners will already align with relevant regulations and have implemented the required quality management systems, helping to avoid the potential for non-compliance challenges.
- **Enablement:** Outsourcing will help free up the time of internal employees so that they may focus on higher-value tasks. This might mean more time available to spend on research and development that can enhance future innovation cycles, progressing current projects and improving historical products.





The problem with supplier fragmentation

Outsourcing can offer numerous advantages to medical device manufacturing companies, however thoughtful consideration is needed concerning the approach, strategies and overall model. It may appear efficient to divide production and have different suppliers handling the design, tooling, moulding, assembly and logistics. However, this can lead to issues that may worsen production risks:

- **Coordination:** Every supplier will have different capabilities, operational preferences, priorities, processes and timelines. Managing that across a fragmented supplier base can become a complicated task, with delays and issues with one cascading across broader networks.
- **Administration:** The more suppliers you work with, the greater the administrative burden, with more oversight, project management, and documentation required, and frequently longer development cycles. That can create new workloads and operational burdens, and the associated costs will quickly follow.
- **Quality control:** Different suppliers will have different approaches and different standards that they meet. As a result, it can be challenging to ensure that each of those different partners is on the same page in regard to regulation, standards and QC, which can cause potential problems and complications.

Without the appropriate measures in place, there can be many risks that come with working with third parties, from component shortages to delays and missed deadlines. Consequently, it is imperative to select the correct partners and develop outsourcing and supply chain practices that are built on integrity, integration and resilience.

The pellet-to-product advantage

OGM offers a smart approach to outsourcing that provides the certainty and reliability that medical device manufacturers need. As a specialist in medical-grade plastic injection moulding, we deliver a fully integrated, end-to-end manufacturing solution – from raw material (“pellet”) to finished, validated product.

Our services include:

- Design for Manufacture (DfM)
- Tooling and injection moulding
- Component assembly and cleanroom operations
- Testing, validation, and compliance support
- Logistics.

This unified, multi-faceted offering eliminates the complexity that manufacturers face in managing complex, fragmented supplier networks, with close alignment between each stage of development and production.

Our goal is to help medical device manufactures design and develop key components, products and solutions in an efficient, cost-effective and compliant manner – all without compromising on performance, reliability, or biocompatibility.



Material selection and designing for manufacture (DfM)

Material selection is a critical factor for medical device product developers. From surgical instruments and drug delivery systems to implantable devices and prosthetics, the selection of materials will impact product safety, effectiveness and durability.

Medical devices typically must be:

- Strong and impact-resistant
- Sterilisable and chemically resistant
- Biocompatible and compliant with ISO 10993
- Cost-effective and scalable for production.

The unique demands of medical devices have meant that metals have typically been relied upon to manufacture medical components. However, new developments in polymer science have begun to change this trend toward plastic injection moulding of medical devices.

At OGM, we focus on ensuring that your components are designed to perform in the optimal manner. We work with a broad variety of approved polymers that include:

- Commodity polymers: PP, PE, ABS
- Engineering polymers: PC, Nylon, PBT
- High-performance polymers: PEEK, PPSU
- Elastomers and urethanes: TPE, TPU, PCU.

With so many different polymers available for medical device applications, we work with you to evaluate the right material based on cost, availability, regulatory requirements, manufacturing volumes and application environments and functional requirements (i.e., mechanical, thermal, electrical, and sterilisation needs).





Tooling and injection moulding

Once the most suitable material has been selected for your manufacturing needs, we can begin to think about both precision tooling and injection moulding. These are at the core of OGM's end-to-end medical device manufacturing offering. We have over 60 years working as a plastic injection moulding company, supporting customers across the industry.

Our extensive injection mould toolmaking department is equipped with conventional EDM and CNC milling, turning and grinding systems. The use of advanced 3D printing capabilities ensure we're ideally positioned to advise on the best methods of producing injection mould tools, in house or through third parties.

As your partner, we're focused on providing unbiased advice and guidance to help you develop the highest quality injection moulded parts, cost-effectively and to your exact specification, no matter how complex or challenging that may be.

We can support you in developing injection moulded components that are:

- Tough and flexible, resistant to wear, vibration and sudden impact
- Sterilisable, able to undergo high temperature and chemical cleaning processes
- Light weight, ideal for handheld instruments and ergonomic surgical tools
- Electromagnetically shielded, using specialised coatings that will allow for concerns for clinical environments.

Additionally, we can manufacture components made from biodegradable and single use plastics, supporting sustainability without compromising on performance.

Assembly and cleanroom operations

In medical device manufacturing, precision and cleanliness are non-negotiable. Even the most advanced components can fall short in the face of patient safety standards or regulatory requirements if they are manufactured in environments that are not controlled.

Cleanroom environments mitigate contamination risks by:

- Using HEPA filters to capture and remove airborne particles
- Monitoring and testing levels of particles and microbes
- Using specialised equipment designed for clean manufacturing
- Maintaining strict hygiene practices
- Completing all moulding, assembly and packing processes in cleanroom environments as necessary.

At OGM, our ISO Class 7 cleanroom environment ensures that any products produced in our facility are done so in tightly controlled parameters with continuous monitoring of humidity, temperature and particulate matter. Each component is produced in compliance with the highest possible standards.





Testing and validation

Testing and validation are crucial aspects of medical device manufacturing that help to assess and enhance product performance. At OGM, this is a core part of our service offering. We're focused on ensuring that every component functions in the optimal manner, meeting quality standards, compliance requirements, customer and patient expectations prior to full-scale production.

Our validation process is tailored to each product, with a dedicated project manager overseeing every stage, from initial planning to final approval. We also prepare a bespoke master validation plan and validation protocol for you including a full production part approval process (PPAP) that includes:

- IQ (Installation Qualification) documentation
- A process flowchart, OQ (Operational Qualification) trial
- A metrology report
- A PQ (Performance Qualification).

Our goal is to help you accelerate development timelines while simultaneously de-risking development thanks to our ISO 13485 (medical) and ISO 9001 (manufacturing) accreditations.

Compliance and quality assurance

Quality, in medical device manufacturing, is more than a standard. It's a regulatory obligation. Every part must conform to high performance, safety, and traceability standards. Failure to do so may generate expensive recalls plus damage to your reputation and regulatory punishment or scrutiny.

OGM implements quality assurance throughout our operations. We work to the highest standards recognised internationally, including:

- ISO 13485:2016 – Medical device quality management
- ISO 9001:2015 – General manufacturing quality
- ISO 14001:2015 – Environmental management.

Our cleanroom facility in ISO Class 7 and lean manufacturing practices allow us to ensure every product's production in a controlled, compliant, and efficient way. We continuously invest in automation and robotics to improve the reliability, precision, and repeatability of our processes.

Our commitment to quality does not stop with certifications. It is a core priority within our culture. We offer a combination of effective QA principles and manufacturing process expertise to deliver:

- Consistent product quality across all volumes and batches
- Minimise the risk of failure or non-compliance
- Faster time-to-market with validation.

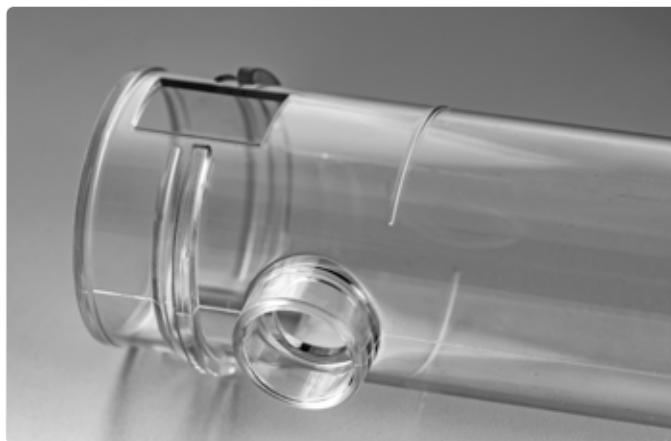


The result

Conventional outsourcing to multiple suppliers comes with risks – you may experience delays, miscommunications, or compliance gaps. OGM's integrated model provides a better alternative.

When you partner with a single provider who is accountable for each phase of the process, there is less risk involved: material selections, design, moulding, assembly, testing, validation and logistics can all be managed, under one roof. For medical device manufacturers, the benefits include:

- Faster time-to-market
- Reduced operational and regulatory risk
- Simplified compliance and documentation
- Scalable, high-quality manufacturing solutions.





Solving your pain points

The development of medical devices entails many varied stakeholders – each with their own priorities, pressures, and problems. Whether it is within design and engineering, procurement, or regulatory affairs, the complexity across roles leads to unproductivity, sometimes at considerable risk.

The following table identifies key pain points, matching them with job titles, and demonstrates how OGM's integrated solution addresses these issues and makes your life easier – increasing development effectiveness, improving compliance, and getting you to market faster.

Job Title	Pain Points	How OGM Solves It
Product Development Manager	Juggling multiple suppliers, project delays, compliance risk	One partner for moulding, assembly, and testing → faster launches, fewer handoffs
R&D / Design Engineer	CAD designs failing in production, slow prototypes, DfM challenges	Early DfM input, rapid prototyping, seamless scale-up to validated production
NPD Director	Budget overruns, Capex pressure, board-level delivery risk	Variable cost model, predictable scale-up, proven partner for pipeline projects
Manufacturing / Process Engineer	Scaling from prototype to volume, validation headaches, fragmented suppliers	End-to-end validation protocols, ISO 13485 cleanrooms, in-house QA + SPC
Quality / Regulatory Manager	Audit pressure, traceability gaps, risk of non-compliance	Single QMS, full traceability, ISO certifications, validated testing
Procurement / Supply Chain Manager	Supplier sprawl, overseas risk, logistics complexity	One UK-based supplier, reduced supplier base, simplified logistics & invoicing

Case Study 1



The challenge

NeuPulse is a UK startup that developed a wearable device for mitigating the severity and frequency of tics in people with Tourette syndrome. Following a successful clinical trial, the company needed to refine its prototype for scalable, compliant manufacturing – an important step in the regulatory process and bringing a viable product to market.

The solution

OGM partnered with NeuPulse to optimise the device for injection moulding and high-volume production. Our team provided:

- DfM support to rework the design for manufacturability and cost-efficiency
- Material and supplier recommendations based on performance and compliance needs
- Tooling expertise to simplify the mould design and reduce cycle times
- Design improvements including a two-part moulding process that eliminated the need for post-mould sealing
- Tool qualification to ensure repeatable, high-quality output.

The result

OGM helped NeuPulse transition from prototype to production-ready design, reducing complexity and improving efficiency. CEO Paul Cable praised OGM's role in guiding the start-up through the NPI process, noting the value of our ISO 13485-certified expertise and collaborative approach.



Case Study 2

RAPIDPRODUCTION
mould tools

ConformL
COOL INSERTS

The challenge

During the COVID-19 pandemic, supply chain pressures and high reject rates exposed inefficiencies in traditional injection moulding processes. Uneven cooling in complex mould tools led to distortion, poor crystallisation, and increased waste – especially in parts with intricate geometries.

The solution

OGM developed ConformL Cool, a hybrid manufacturing process that combines additive manufacturing (AM) and CNC machining. Using a custom-built machine – the first of its kind in the UK – we produced mould tools with conformal cooling channels that can precisely follow the cavity's contours.

- Layer-by-layer laser sintering combined with automated machining
- Improved cooling efficiency for complex mould shapes
- High surface finish and dimensional accuracy with minimal secondary processing
- Reduced production time and cost compared to typical methods.

The result

ConformL Cool provided opportunities to create advanced mould tools with more efficient cooling, resulting in a considerable reduction in reject rates with improved part quality. This innovation helped customers maintain production standards during a period of global disruption.



Simplify your path to market

Medical device development is complex – but your manufacturing process should be simple. By partnering with OGM, you gain a single, accountable supplier that brings together design, moulding, assembly, testing, and validation under one roof. An integrated approach to developing your medical device decreases risk, improves time-to-market, and ensures compliance along the way.

Whether you're refining a prototype, scaling up for production, or navigating regulatory approval, OGM is here to help. Let's turn your next medical innovation into a manufacturing success.



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About OGM

OGM was established in 1962 in Oxford. B E Wightman grew the business over the next 40 years with a dedication to high-quality products and a strong commitment to offering excellent customer service. Today, these values remain at the heart of everything OGM does.

OGM offers total manufacturing solutions for precision injection moulding, from design consultancy and prototype tooling through to high-volume world-class production. OGM customers include international blue-chip organisations, from across a range of sectors, including electronics, general industry, medical and utilities.

