GERGONNE
The Adhesive Solution



FROM CONCEPT TO MEDICAL DEVICE:

Contact Elise Thomson and her team.

Designing a medical device is a demanding task that requires a range of rare and complementary skills: technical expertise, regulatory knowledge, a commitment to quality, and the ability to turn an idea into a product ready for industrial production. All too often, manufacturers end up having to coordinate a multitude of stakeholders themselves — a formulator here, a cutting specialist there, a regulatory service provider elsewhere — with all the risks that this entails: extended lead times, gaps in accountability, unforeseen additional costs and time-consuming change validation procedures at every stage of the process.

At GERGONNE, we have taken a different approach. Rather than leaving you to piece together a complex jigsaw puzzle, we have put together a multidisciplinary team dedicated exclusively to medical projects, capable of managing your entire development process. One team, one point of responsibility, one point of contact.

1. A dedicated contact from the very first conversation



It all starts with a conversation. **Élise Thomson, our sales manager**, is your first point of contact. Her role goes beyond simply identifying your needs: she acts as the central point of coordination for your project, the contact who mobilises the right resources at the right time and ensures that your expectations are understood and communicated to the whole team.

"After nearly 25 years in the field of adhesive medical devices, including more than 10 years at Gergonne, I am still driven by the new challenges our clients face. If I ask a lot of questions, that's because I want to understand your needs down to the smallest detail and work with our development team to create a solution that will meet your expectations, drawing on Gergonne's wealth of expertise." — Élise

Why entrust your project to GERGONNE?

Choosing GERGONNE as your development partner means enjoying a tangible benefit from day one: an integrated development process managed by a single team. Adhesive formulation, device design, prototyping, cleanroom cutting, packaging — every stage of manufacturing is managed in-house, and we also coordinate the sterilisation stage in line with your organisation's requirements. This results in shorter development times, accelerated trial-and-error cycles and seamless end-to-end traceability.

Finally, our model is designed for the long term: by managing our entire supply chain, we spare you the change validation procedures imposed by third-party suppliers, which are often costly and time-consuming. Your product remains consistent over time, and its total cost is controlled throughout its entire lifecycle.

2. A technical team to design and create prototypes



This is where the idea takes shape. Complementary areas of expertise work in synergy to transform your requirements into a solution ready for industrial production:

Johanna, project manager for die-cut parts, is the linchpin of your project. From the kick-off meeting right through to final approval, she coordinates all internal stakeholders, ensures deadlines are met and keeps you informed at every stage — so you never have to wonder where your project stands.

"I have the honour of supporting clients throughout their projects, from inception to delivery, balancing their expectations with our technical and quality requirements. Seeing an innovation take shape and become a product you can hold in your hands is a particularly rewarding source of satisfaction." — Johanna

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Vincent, head of the engineering department, translates your functional requirements into concrete technical solutions. From the system's architecture and design choices to the selection of materials and production processes, his expertise enables him to anticipate manufacturing constraints right from the design stage. Together with his team, he also oversees the prototyping and cost estimation for your project.



Ester, laboratory project manager, is responsible for formulation and testing. She ensures that our products' performance meets the requirements of your application.



Rémi, industrialization manager, acts as the link between the project teams and production. He ensures that every new device moves into mass production under the best possible conditions. His role is to ensure that what has been designed and prototyped is reproduced exactly as it is in every batch produced in series.

3. Integrated regulatory support

Regulatory matters are often a source of concern for medical device manufacturers. **Marion, head of medical regulatory affairs**, will guide you through the MDR 2017/745 framework. Depending on your organisation, GERGONNE can act as a subcontractor — providing you with the technical data required for your own CE marking — or handle the CE marking directly for Class I or Is devices.

"Turning regulatory requirements into concrete action plans, whilst balancing the needs of the technical, production and user teams, is a daily challenge in the development of medical devices. What drives me is helping to bring safe and effective innovations to market that bring about lasting improvements in patient care." — Marion



4. After the launch, a team that's always there for you



Christelle, sales administration manager, is your day-to-day point of contact for all matters relating to order management, monitoring delivery times and coordinating logistics. She anticipates your needs, facilitates communication and ensures that every delivery meets your agreed deadlines.



Frédérique, the quality manager, ensures that every batch produced complies with the requirements of your technical dossier and with ISO 13485 standards. She is your key point of contact for managing non-conformities, monitoring corrective actions and maintaining the documentation for your product throughout its production life cycle.

One team, one project, one responsibility

What sets this team apart is its consistency. Every member is familiar with the project, the constraints and the commitments made. There is no disconnect between the sales phase, the development phase and the production phase: everything takes place under one roof, within the same ISO 13485 quality system, with guaranteed end-to-end traceability.

Are you working on a new medical device project or do you need a bespoke skin adhesive? Get in touch with Élise and her team — they are ready to take on your challenge.

CONTACTEZ-NOUS - Pour plus d'informations, rendez-vous sur www.gergonne.com ou contactez-nous directement au +33 4 74 73 39 01 ou par e-mail à l'adresse suivante : contact.fr@gergonne.com.