Nemera
we put patients first

Contract Development and Manufacturing Services

YOUR COMBINATION
PRODUCT PARTNER

Nemera is your partner for the combination product journey from device selection through product lifecycle management.

We are your single partner for the whole of the combination product journey.

We have developed end-to-end services and expertise in device development, device consulting, and contract manufacturing to complement our diverse portfolio of products to help you through every step of the journey. We apply this know-how and our singular focus on healthcare to realize our vision of becoming the most patient centric drug-device company in partnership with our customers.

We provide integrated services to deliver highly patient-centric solutions that encourage adherence and provide better healthcare outcomes. This focus makes a real difference in supporting users along every stage of patient journey.

From Patient to Combination Product Journey

Whether you're looking to develop a novel device or select a platform solution, it should always begin with a thorough understanding of the patient journey.

It is critical to have a solid understanding of the patient population, the specific use cases, their capabilities and limitations, and how they change over time, to help avoid potential safety or efficacy risks.

The deep understanding of the user experience can help us to design products which are not only safe and effective but can also make a real difference in the quality of our patient's lives by supporting every stage along the patient's journey.

When we incorporate user needs into combination product development, we create solutions that encourage adherence and better support users throughout the patient journey resulting in improved healthcare outcomes.

Our services

Our services have been developed to support
for the development and lifetime of your device.

1. DEVICE STRATEGY AND SELECTION

   Establishing your device and combination product strategy from the patient journey, technology selection, and combination product planning.

2. DEVICE DEVELOPMENT AND CONSULTING

   World class development blending design house creativity with electronics and manufacturing know-how.

3. CLINICAL TRIAL SUPPORT

   Clinical trial device supply to execute your early manufacturing strategy with an eye to commercial manufacturing.

4. INDUSTRIALIZATION

   Employing a proven and rigorous approach to define and implement the ideal process and industrial approach for your product.

5. COMMERCIAL MANUFACTURING

   Global manufacturing expertise to ensure timely, quality, safe, and effective supply.

6. LIFECYCLE MANAGEMENT

   Extending the value of your assets holistically.




Why you can trust us: Our capabilities

The comprehensive set of our capabilities enable us to find unique solutions at the centre of user and customers needs.

CONTRACT DEVELOPMENT — INSIGHT INNOVATION

Developing safe, effective, and differentiated combination products.

With locations in the United States and Europe, our team of 200 experts. A passionate and team-work driven community focused on gaining insight into patients, the healthcare landscape, and technology innovation we drive better healthcare outcomes.

DESIGN RESEARCH

Understanding users and contexts of use

HUMAN FACTORS

Optimizing usability, meeting regulatory requirements, and reducing risk

VERIFICATION

Extensive laboratory and analytic services

ENGINEERING AND PROTOTYPING

Designing, building, testing and optimizing systems to meet user and performance requirements

USER EXPERIENCE DESIGN

Designing innovative solutions and experiences that support the patient journey

PROCESS ENGINEERING & INDUSTRIALIZATION

The right process and assets for your device.

We ensure that our approach for your process development and requirements for pilot production leading to high scale manufacturing is aligned to your goals. This includes definition and selection of the proper assembly and automation approach as well as a global approach to mold development and sourcing with a proven supply base.

Quality by Design: Systemically reducing risk throughout scale-up.

We apply quality by design principles throughout of the whole of the industrialization process. This is driven by a diverse team who integrate design for manufacturing with all aspects of quality management. This includes verification and validation testing leading to all of the controls necessary to ensure reliable production.

PRODUCTION FACILITIES

Global footprint to meet your requirements, from small series to high scale.

We will deploy your customer process and fit for purpose assets in one of our global five manufacturing facilities with over 42,000 square meters of clean room facilities.

We will work with you to select the appropriate site for your needs based on your specific requirements. Nemera has a long track record of providing high scale, precision injection molded parts, and assemblies to leading pharmaceutical companies. This also includes drug handling and final assembly as well as the integration of electronics into the manufacturing strategy for your device.

From cleanroom manufacturing environments to the latest in process monitoring technology, we are continually enhancing our processes and capabilities to meet the needs of the most demanding customer standards and quality requirements.

Certifications available in our plants

ISO 14644 ISO 13485 ISO 15378 ISO 14001 ISO 50001	US FDA 21CFR Part 820 MDR 2017/745 MDSAP; Brazil RDC	Complete Turnkey Solution with Drug Handling

More than 42,000 sqm of cleanrooms and plants in France, Germany, Poland, US, Brazil.

The Value of Integrated Services

1. Device Selection
2. Device Development and Consulting
3. Clinical Trial Support
4. Industrialization
5. Commercial Manufacturing
6. Lifecycle Management

PATIENT CENTRICITY

Integrated services positions Nemera to deliver highly patient-centric solutions that encourage adherence and provide better healthcare outcomes. This focus during development makes a real difference in supporting users along every stage of patient journey.

DE-RISKING THE PROCESS AND ACCELERATING MARKET ACCESS

Experience matters, and we bring our end-to-end know how to bear at every steps of the process to ensure consistent execution. This alleviates the potential for essential information to get 'lost in translation across each step of the process'. We meet your device requirements with agile development process or through leveraging our extensive device platforms while increasing your time to filings and market.

NAVIGATING THE COMBINATION PRODUCT ECOSYSTEM

We recognize the developers must navigate a complex ecosystem to achieve market success. Considerations beyond the patient include providers such as healthcare professionals and networks, payers, and regulators who must be satisfied to ensure your success. Our services are aligned to help you meet these goals.

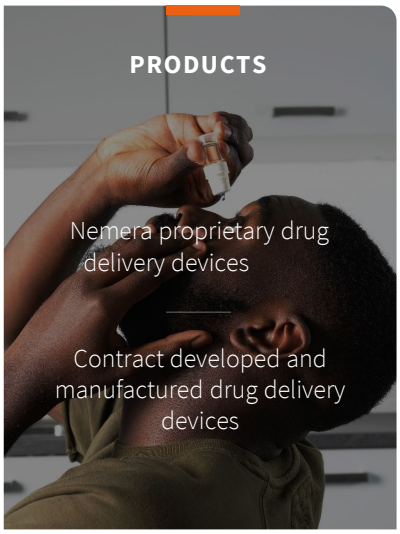
100% quality and compliance

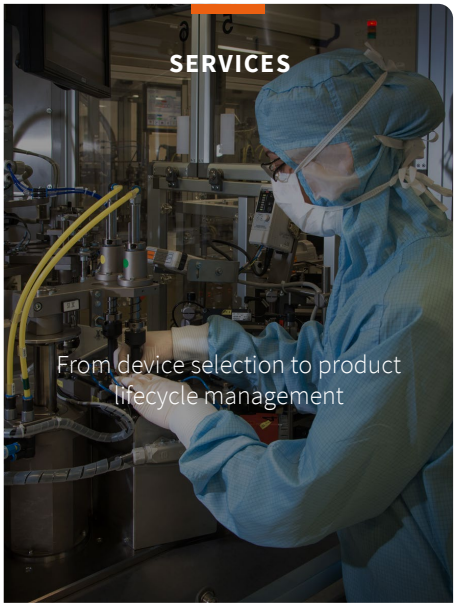
- One harmonized and integrated product development process
- Regulatory support & compliance from early project stage
- Process & System validation compliant to cGMP and technical standards
- In-house laboratory, analytical and metrology capabilities
- GMP manufacturing processes and cleanrooms
- Digital Quality System and integrity of data and records

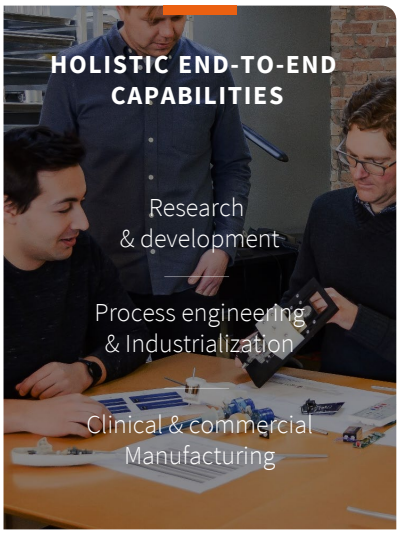
- Quality by design
- Usability engineering (EN 62366)
- Risk management (ISO 14971)
- Design verification
- Design history File
- Design transfer

Our broad offering

Offering a broad range of solutions in major delivery routes, we are the holistic development and manufacturing partner for your custom drug delivery device solution.







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