

Supporting Opportunities



CENTRE OF EXCELLENCE

Exceptional products are supported by innovative technologies
Innovative technologies are supported by a superior knowledge base
A superior knowledge base is supported by outstanding people

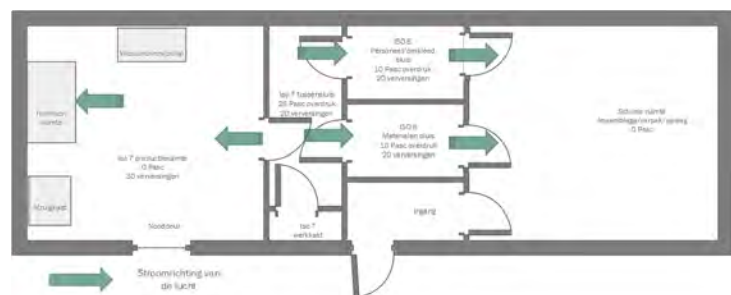
European Medical Contract Manufacturing (EMCM) is a centre of excellence in developing and manufacturing (sterile) medicinal products, catering to the Biomaterials, Pharmaceuticals and Tissue Engineering markets.

Be it ampoules, vials, pre-filled syringes, pouches, bottles or blisters, from small to large scale batches, EMCM is your partner in the development and manufacturing of Pharmaceuticals and Medical Devices.



Within our 2000 m² of GMP accredited facilities, we have a variety of cleanrooms ranging from grade D up to A (GMP class 100.000 up to class 100). In addition to the existing cleanroom facilities, EMCM has a new cleanroom complex that fully complies with EU GMP Annex 1 standards and just as for the existing cleanrooms equipped with a Lighthouse Facility Monitoring System.

Separate from the other cleanroom facilities, EMCM has a hormone processing facility, only accessible from the outside of the building and provided with an air handling system suited for working with “high potential drugs”.





Why EMCM?

As a customer driven organisation that believes in contributing to quality of life by delivering high quality products and services, EMCM incorporates a “no-compromise on quality” policy; your innovations are produced in the safest of environments.

At EMCM, our core focus is to harness our in-house expertise by developing processes for your products that target specific segments in the medical sector. We continuously look to enhance our service offering and expand through innovation and collaboration.

EMCM cooperates with global companies and various European universities in research and development projects that are aimed at increasing the depth of our portfolio.

Through our extensive facilities and expertise, we offer customers:

- quick turnaround time;
- cost efficiencies;
- traceability;
- understanding customer requirements;
- developing complete solutions.

Our Mission:
**We support our partners to
improve people's lives**



**EMCM, where exceptional products, technologies, knowledge and people unite
to deliver your innovations**



IN-HOUSE TECHNOLOGY

In order to best serve you, EMCM hosts a variety of in-house technologies. We have a complete range of formulation vessels and mixing devices for the manufacturing of liquids, suspensions, gels and powders.

Our core expertise lies in customised batch production with formulation techniques, (aseptic) processing and filling coupled with a variety of terminal sterilisation techniques as per the requirements or a complete aseptic closed manufacturing system.

Highly viscous and volatile products experience



Equipped with a range of (semi-) automatic mixing and filling units, EMCM has proven experience and expertise in the formulation, mixing, filling, packaging and sterilisation of highly viscous products, like temperature dependent suspensions and gels such as hydrogels, collagen and polymers.

Ampoule Filling



We house two fully automatic filling units for the aseptic filling of organic and volatile solvents and aqueous solutions into ampoules up to 30 ml. This aseptic process is validated by media simulation and executed by a qualified process team. This filling process can be further extended by fully automatic visual inspection, labelling and the positioning of an ampoule breaker.

Syringe Filling



EMCM has equipment installed that is suitable for the automatic filling of parenteral drugs, from aqueous solutions to highly viscous gels into vials and syringes. The equipment can fill syringes of various sizes for subsequent aseptically closure. The used technique (filling under vacuum) allows for filling high viscous gels without air bubbles in the barrel. Environmental monitoring in the ISO class 5 area is integrated in the Lighthouse Facility Monitoring System, providing detailed inline particle count during aseptic filling.



Vial Filling

For the (aseptic) filling of liquids, suspensions and gels into vials, a filling unit is available. The equipment can fill vials of various sizes for subsequent aseptically closure. The line is equipped with stopper/cap closure devices. If needed a freeze drying step can be added.



Pouch Filling

A dedicated filling line is available for the filling of liquids and gels into aluminium and plastic pouches. The filling line is also equipped with a variable data printing unit and a checkweigher to ensure product-to-product consistency. Upon special request, we can also design filling equipment for the filling of custom-made primary packaging.



Powder Mixing and Filling

For your powder mixing needs, our 300 liter powder mixer and range of sieving devices guarantee a homogenous bulk product. EMCM has the capacity to fill powder into vials, pouches and small containers. The equipment is controlled by product specific qualification and validation programs.



Tissue Engineering

EMCM has developed membranes for several applications, based on Porcine Pericardium. Such membranes are processed with eCOO[®] Technology, a proprietary platform to clean, sterilise and impregnate animal derived tissue, using supercritical carbon dioxide (scCO₂). After cleaning the product is freeze dried, sized and packaged in a double pouch and gamma or EtO sterilised. The product is used in dental and orthopaedic procedures.



SUPPORT SERVICES

In addition to aseptic production processes, EMCM provides a full range of finished product sterilisation services.

Steam sterilisation

A series of steam sterilisers, capable for steam-air sterilising are available at EMCM for the sterilisation of closed containers, filled syringes and the final heat treatment of products.

Sterilisation by gamma-, x-ray-, and beta-radiation, Ethylene-oxide

For all products where steam sterilisation is not an option, EMCM offers sterilisation services. We have many years of experience with reliable partners for the sterilisation of products through gamma-, x-ray- and beta-radiation or by means of Ethylene-oxide.

Additional Services



EMCM provides a complete custom-made service package from product development through purchasing, manufacturing, sterilisation, final packaging, warehousing and logistics. We continuously work with our clients to ensure how we can optimise their operations and cater to their needs and vision.

For storage of the raw materials and your final products EMCM makes use of a temperature controlled warehouse with highly qualified staff (IATA certified). We offer temperature controlled (dangerous) goods transportation for our customers around the globe.

Freeze-drying services are suitable for a wide variety of products. Our GMP-qualified lyophiliser has a fully automated CIP program, a condenser capacity of 40 kg and can be configured in 2,3 or 9 shelves.

As a full service CMO, EMCM also offers customised solutions:

- supplier audits;
- laboratory selection;
- analytical method validations;
- all forms of stability testing;
- quality control coordination and testing on incoming and finished products as per regulations.



QUALITY

EMCM is an EN ISO 13485:2016 certified company which understands the importance of implementing and maintaining the highest standards in business and manufacturing practices. EMCM has a Good Manufacturing Practice Licence for the manufacturing of Pharmaceuticals and a Tissue License for the storing, and distribution of human tissue. We are subject to several national, European and international inspections in order to maintain our certifications to manufacture products for global markets.

With our philosophy of Supporting Opportunities, we cater to the needs of our customers and take pride in providing high quality and reliable product development and manufacturing opportunities, with a high degree of flexibility.

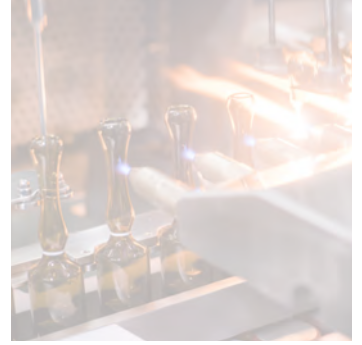
The EMCM advantage

EMCM is proud to support innovations and breakthroughs in the healthcare sector that will positively impact the lives of millions worldwide. If you have an opportunity, you can rest assured EMCM will support you.



We support opportunities while you deliver them, through:

- B2B model for development and manufacturing;
- compliant and reliable quality systems;
- end-to-end service solutions;
- upscaling, process validation, production, packaging, warehousing and distribution;
- fully licensed GMP operations.



European Medical Contract Manufacturing B.V.
Middenkampweg 17, 6545 CH Nijmegen, The Netherlands
+31(0)24 3715252, www.emcm.com, info@emcm.com

Supporting Opportunities