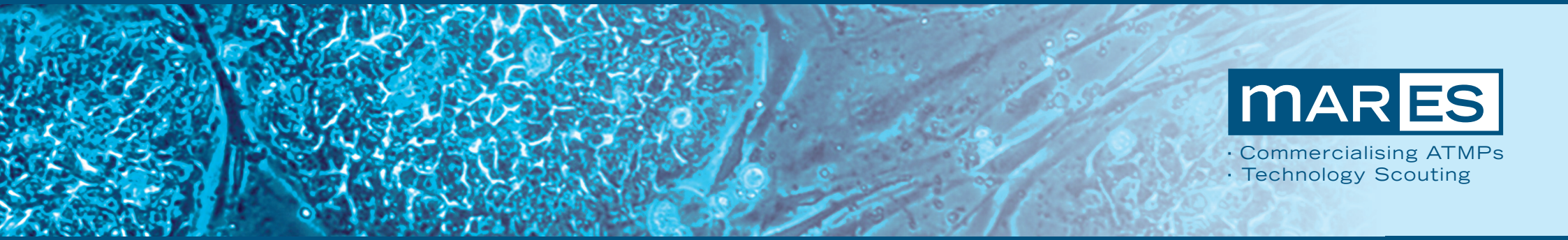
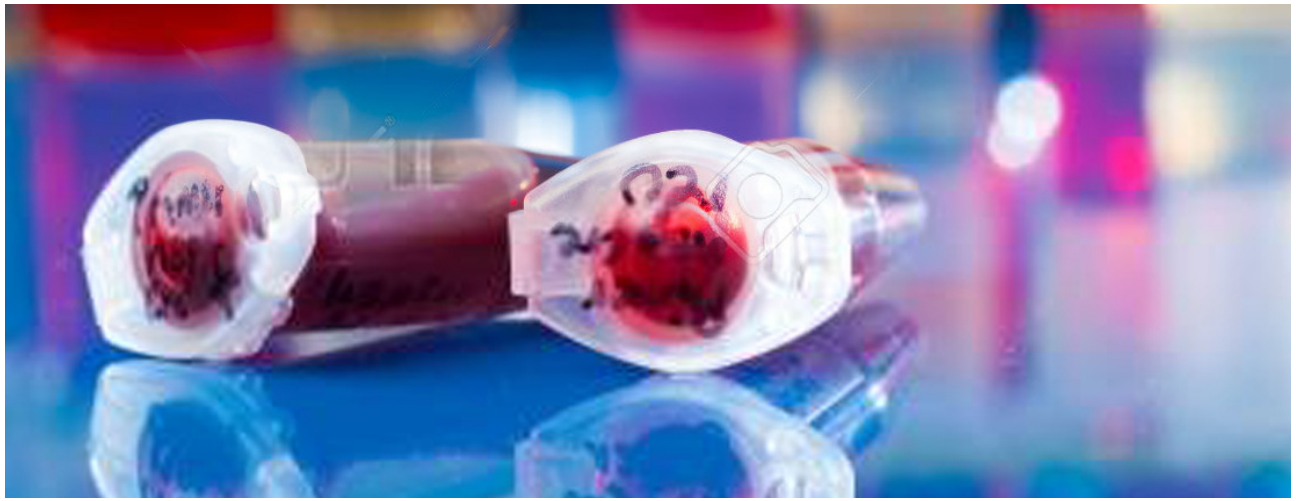


MARES

· Commercialising ATMPs
· Technology Scouting

Turning Innovation into Products



We support biotech/pharmaceutical companies in commercializing advanced-therapy medicinal products (ATMPs).

Gene and cell therapeutics as well as tissue-engineered products offer fundamentally new treatment opportunities for unmet medical needs. In Europe, such products are called "Advanced-Therapy Medicinal Products", or ATMPs, denoting them to be a third class of medicinal products in addition to drugs and medical devices. To market such products in the EU, a market of 500 million people, specific regulatory, quality and process parameters have to be observed.

Mares Ltd. provides the necessary knowledge and experience to bring ATMPs on the market in Europe.

We accelerate manufacturing, clinical and regulatory processes – so that innovators can market their products, and patients in the European Union and elsewhere can benefit from efficacious and safe new advanced therapies.

On behalf of pharmaceutical and chemical corporations we scout for new technologies in fields as diverse as agriculture, food, engineered materials, biologics and pharmaceuticals.

Technology Scouting – in Chemistry, Biotech and Beyond

Every industry needs to innovate in order to survive. Many roads lead towards innovation, some more successful than others. A particularly successful path is to define needs and to scout continuously for pertaining novel and potentially disruptive technologies.

While promising, such scouting requires tools, expertise, experience and the right mind set. Mares Ltd has been scouting for new technologies for several years and has grown to be a leading technology scouting enterprise in pharmaceuticals and chemistry. On behalf of our clients we scout in selected areas ensuring absolute confidentiality if so desired.

Whats more, our expertise includes taking such new technologies and turning them into real products working with industrial clients, academics and SMEs.

Guidance in the Early Stages of ATMP Development

Tailor-made solutions for your project:

GLP preclinical research and process development at scale

Early Research and Development

Our clients perform state-of-the-art research in cell therapy, gene-therapy, and tissue engineering. Mares Ltd. helps to ensure that this research is conducted in a way admissible for clinical trial applications. Key to this are the principles of GLP and an early contact to pertinent authorities.

Process & Technology Development

Processes for ATMP production are frequently developed out of research environments, and they use approaches and controls suitable for such environments. ATMP processes also tend to employ agents and components otherwise not used for the manufacture of medicinal products, thus presenting particular difficulties in regard to approvals.

When converting such processes into a product appropriate for human application, choosing materials according to quality aspects becomes an urgent need. Mares Ltd. helps choose the right materials and technologies.
We develop manufacturing processes and/or adjust your processes so that the resulting products meet relevant guidelines and hence are approvable and economically feasible.

Upscaling, Facility Planning & Realization

Manufacturing ATMPs for early research requires only a few product units, clinical trials may require hundreds, possibly thousands of units and commercial-scale manufacturing is essentially open ended. Technologies facilitating production of such different volumes differ vastly and require qualification and validation – time consuming activities. Thus, they need to be planned for and implemented early to be ready when needed.

Frequently, innovators choose to manufacture/produce their products in dedicated facilities. These facilities need to be GMP compliant – particularly for aseptic manufacture.

With decades of experience and a proven track record in developing, planning and realizing cell processing and tissue engineering plants, Mares Ltd. ensures that your production facility complies with pertinent standards.

We offer support/full service for

- Process development and validation
- Facility and production planning
- Equipment qualification (including clean rooms)
- Aseptic manufacturing processes
- Sourcing of materials

Marketing Authorization

Mares Ltd. provides all services to obtain marketing approvals.

Clinical Trials

Providing the required documents for a clinical trial application for ATMPs requires detailed understanding of this new class of medicinal products.

Mares Ltd. provides

- Ethics committee briefing document
- Investigator's brochure
- Clinical trial application

Multi-national clinical trials in Europe may involve several authorities. We guide sponsors through the European approval process and help them obtain harmonized assessments, avoiding the need for multiple applications.

Marketing Authorization

We offer full regulatory support in the process of marketing authorization, including the preparation of the necessary documents for marketing approvals (eCTD dossiers).

For our clients we

- Conduct scientific advice meetings
- Prepare all regulatory documents
- Provide support during the phase of authority review
- Attend to deficiency reports

Conducting Clinical Studies

Clinical Trials in ATMPs present fundamentally new challenges to all participating parties, regulatory authorities, sponsors and, most certainly, to CROs.
A profound understanding of ATMP-specific technology, regulatory requirements, organizational and logistical needs is crucial to design, plan and conduct such trials successfully.

Mares Ltd. provides an experienced network to get these demanding clinical trials designed, conducted and brought to successful conclusion – so that our clients can market their new products.

QP-Services · Audits · EU Import · Interim Management

Mares Ltd. has the experience and holds the necessary qualifications and permits to take on responsibility.

Qualified Person (QP) Services

We provide experienced QPs for assessing Advanced Therapy Medicinal Products on behalf of our clients – as stated in article 41 of the Directive 2001/83/EC.

GMP Audits

Inspecting the GMP compliance of biopharmaceuticals requires highly competent experts. EU GMP regulations allow to refer to third-party audits by external qualified auditors.

We provide

- Audit services for ATMP manufacturing and supplier sites
- Assessments of GMP compliance

EU Import and Legal Representative for Clinical Trials

Medicinal products intended for clinical trials in the EU but manufactured outside of the EU require an import permit as well as an importing organization based in the EU. At the same time EU regulations require a legal representative inside the EU in case of any legal repercussions.

Mares Ltd. obtains import permits on behalf of clients and provide QP services as well as legal representation services.

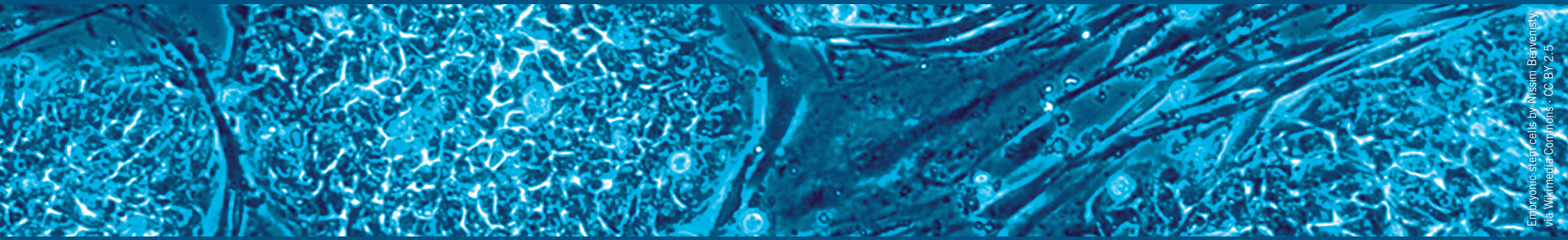
Beyond this, Mares Ltd. provides a comprehensive service package to clients e.g. interacting with authorities, hospitals, investigators, analytical facilities and so forth.

Interim Management

Our experience in technically challenging tasks as well as the pertaining strategic demands of business development and investor relations enables Mares Ltd. to take on comprehensive responsibility.

We offer

- General management
- Project planning and execution
- Budgeting
- Representations to investors and other audiences



Embryonic stem cells by Nissim Benvenisty
via Wikimedia Commons · CC BY 2.5

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