



Automated robotic systems for therapeutic cell manufacturing: from “Donor-to-Patient”

What is AUTOSTEM?

Regenerative medicine offers new hope for many debilitating diseases and health conditions. Hundreds of clinical trials are testing new cell therapies, such as the treatment of patients with immune-mediated and other diseases with Mesenchymal Stromal Cells (MSCs). However, current manufacturing protocols for MSCs are inefficient, costly and labour intensive, requiring skilled teams of technicians operating in a clean-room environment.

AUTOSTEM is an EU H2020 project focused on developing a closed, automated cell production pipeline to produce safe, efficacious and affordable cell products.

What has AUTOSTEM achieved?

The AUTOSTEM project began on 1 January 2016 and finishes on 31 December 2018. As part of our work we have:

- Developed a new controlled suction device to harvest bone marrow, designed to improve patient discomfort and yield.
- Pioneered new methods for the isolation of a distinct, specially selected subpopulation of MSCs.
- Advanced protocols and formulations for the use of xeno-free medium to culture MSCs (to improve standards of quality and safety).
- Optimised bioreactors for large-scale, economically-viable production of cell products.
- Designed bespoke sensors that can provide real-time in-process monitoring of glucose,

lactate and ammonia levels throughout cell manufacture.

- Produced a flexible, automated cell production platform with related software and fully integrated functional modules.

In addition, we are biologically validating the cells that have been produced in the project *in vitro* and *in vivo*, in order to ensure the clinical-relevance of the AUTOSTEM product.

What about AUTOSTEM's legacy?

AUTOSTEM has demonstrated the feasibility of fully automated, end-to-end production of therapeutically relevant cells at scale. We have developed a prototype of the AUTOSTEM platform. More work will be needed to allow for direct clinical use in patients, but we believe AUTOSTEM provides the blueprint for this work.

As the project nears completion, we are exploring the commercial exploitation of our outputs. We have also generated new knowledge about MSC selection and expansion, bioreactor systems, sensor technology and MSC action, which will present new opportunities for further research and collaboration.

We believe that AUTOSTEM has paved the way towards the cost-effective manufacture of MSCs and other therapeutic cell products in the future. Ultimately, this will benefit patients, clinicians and health systems, yielding wider societal and economic benefits.





Members of the AUTOSTEM team meeting in Aachen

Read more about our research in the following AUTOSTEM publications:

- “Highly modular and generic control software for adaptive cell processing on automated production platforms” (Sven Jung et al) 51st CIRP Conference on Manufacturing Systems, Procedia CIRP 72(2018) 1245-1250. [DOI: 10.1016/j.procir.2018.03.189](https://doi.org/10.1016/j.procir.2018.03.189).
- “Developing an automated robotic factory for novel stem cell therapy production” (Qasim A Rafiq, et al) Regenerative Medicine 11/4 351-354. [DOI: 10.2217/rme-2016-0040](https://doi.org/10.2217/rme-2016-0040).
- “Automating decentralized manufacturing of cell and gene therapy products” (Richard P. Harrison et al), Cell Gene Therapy Insights 2016;2(4), 489-497. [DOI: 10.18609/cgti.2016.014](https://doi.org/10.18609/cgti.2016.014).
- “Automation in the context of stem cell production - where are we heading with Industry 4.0?” (Michael Kulik et al) Cell and Gene Therapy Insights 2/4 499-506. [DOI: 10.18609/cgti.2016.060](https://doi.org/10.18609/cgti.2016.060).
- “The evolving role of automation in process development & manufacture of cell & gene-based therapies” (Qasim A Rafiq et al) Cell and Gene Therapy Insights 2/4 473-479. [DOI: 10.18609/cgti.2016.058](https://doi.org/10.18609/cgti.2016.058).
- “Advances in automation for the production of clinical-grade mesenchymal stromal cells: the AUTOSTEM robotic platform” (Jelena Ochs et al) Cell and Gene Therapy Insights 2017; 3(8), 739-748. [DOI: 10.18609/cgti.2017.073](https://doi.org/10.18609/cgti.2017.073).

The AUTOSTEM Team



For further information visit the project website

<http://www.autostem2020.eu>

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Research Gate: <https://www.researchgate.net/project/Autostem-Automated-Stem-Cell-Manufacturing>

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