

Consortium

The **AMECRYS** network is an interdisciplinary expert group of research scientists from two National Research Organizations, four Academic Institutions and three Industrial partners, from four European Countries:

- Consiglio Nazionale delle Ricerche, Italy
- Imperial College London, UK
- Università della Calabria, Italy
- Centre National de la Recherche Scientifique, France
- Université Libre de Bruxelles, Belgium
- University of Strathclyde, UK
- Centre for Process Innovation, UK
- GVS S.p.A., Italy
- Fujifilm Diosynth Biotechnologies, UK



Information

AMECRYS is a research project funded by the European Commission under the Horizon 2020 programme, in the framework of Future and Emerging Technologies topic (FETOPEN-RIA), supporting early-stages of the science and technology research and innovation around new ideas toward radically new future technologies.

To find more information about our research activities, please visit:

www.amecrys-project.eu



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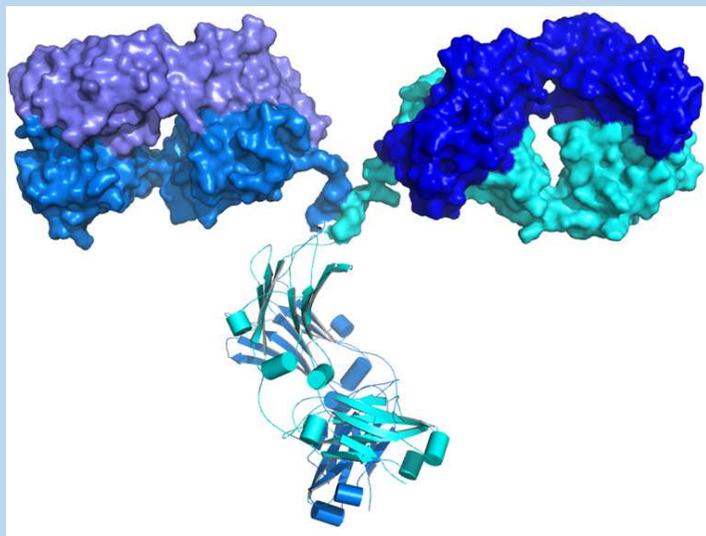
AMECRYS

Revolutionising Downstream Processing of Monoclonal Antibodies by Continuous Template-Assisted Membrane Crystallization



The challenges

Recombinant monoclonal antibodies (mAbs) represent one of the greatest therapeutic/diagnostic modalities in modern medicine, with applications in the treatment of cancer, inflammatory and autoimmune disorders, cardiovascular and many others major diseases.

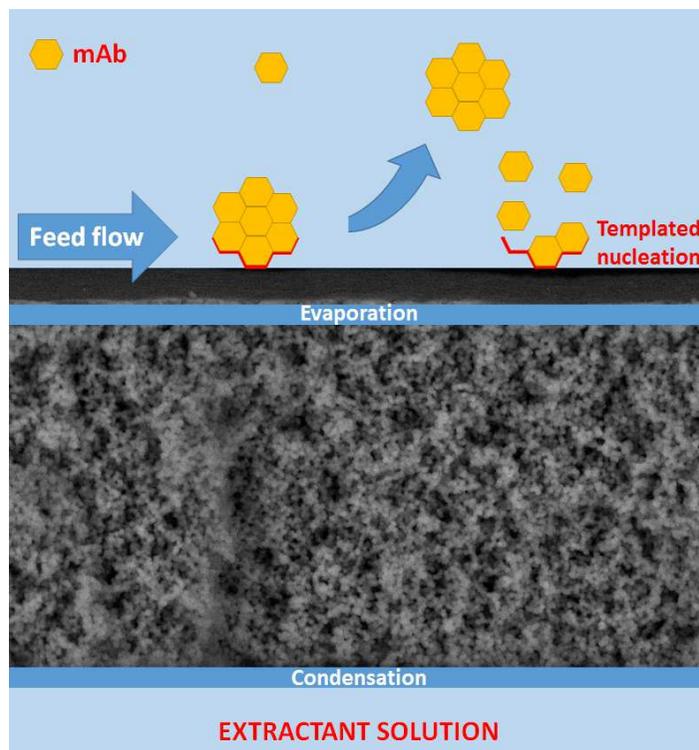


Downstream processing (DSP) of mAbs still relies on expensive and cumbersome multi-step chromatography platforms, often operated in batch mode. **The challenge now moves to enable access to mAbs by enhanced purification on an industrial scale with reduced manufacturing costs.**

Although crystallization is a cost effective and easily scalable purification technique for small size molecules, its utilization for mAbs recovery directly from fermentation broths is currently hindered. This is due to the structural complexity and flexibility of such biomacromolecules, and to the inherent multicomponent nature of cell culture media, that discourage the early stages of crystallization.

The idea

The ambitious idea of the **AMECRYS** project is to enable efficient crystallization of mAbs directly from complex solutions **by developing an innovative Continuous Template-Assisted Membrane Crystallization process as a single key-unit operation.**

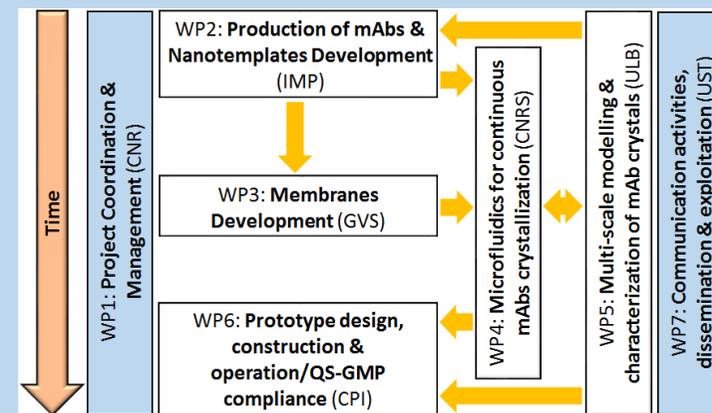


The replacement of conventional chromatography-based platform with a single continuous membrane-crystallization unit in mAbs DSP, is expected to lead to a decrease >60% for both capital expenditure and O&M costs, 30-fold footprint reduction, and high-purity solid dosage formulation with preserved biological activity.

The objectives

As ultimate scientific and technological results of the research strategy, **AMECRYS'** achievements are expected to boost medical advancement and increase efficiency in biopharmaceutical productions by matching a twofold objective:

- 1) Expanding basic knowledge in the crystallization of structurally complex molecules, allowing an easier structural determination, useful to define their biological function;
- 2) Giving a significant contribution to the assessment of crystallization as cost effective and efficient purification step in the DSP of therapeutic proteins, with benefits in terms of product quality and generalized reduction of production costs.



Major research topics will include: i) the synthesis of 3D-nanotemplates with specific molecular recognition ability towards mAbs in complex solutions; ii) the development of tailored membranes for advanced control of crystallization; iii) the design of microfluidic devices for high-throughput crystallization screening under continuous flow (pharma-on-a-chip concept); iv) technology scale-up to a demonstration prototype.