From Biotech to Pharma: Sustainable and innovative manufacturing strategies for Europe

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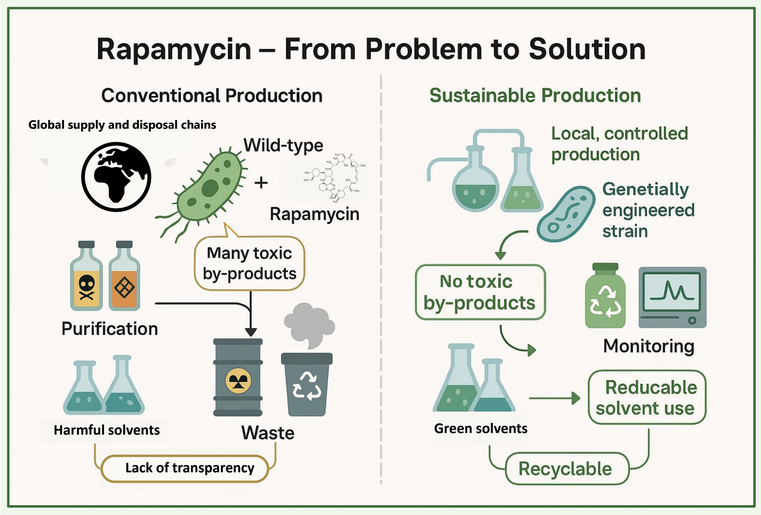
Boosting the reduction of the environmental impact

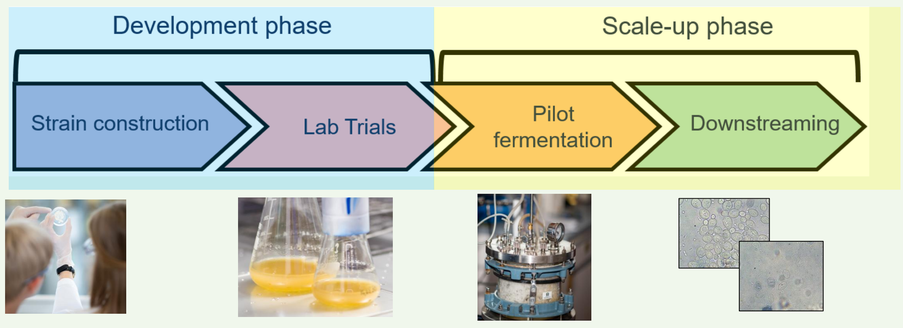
From Biotechnology



The complex global supply chains involved in drug production can be challenging to monitor and regulate, leading to potential environmental violations in less stringent regions.

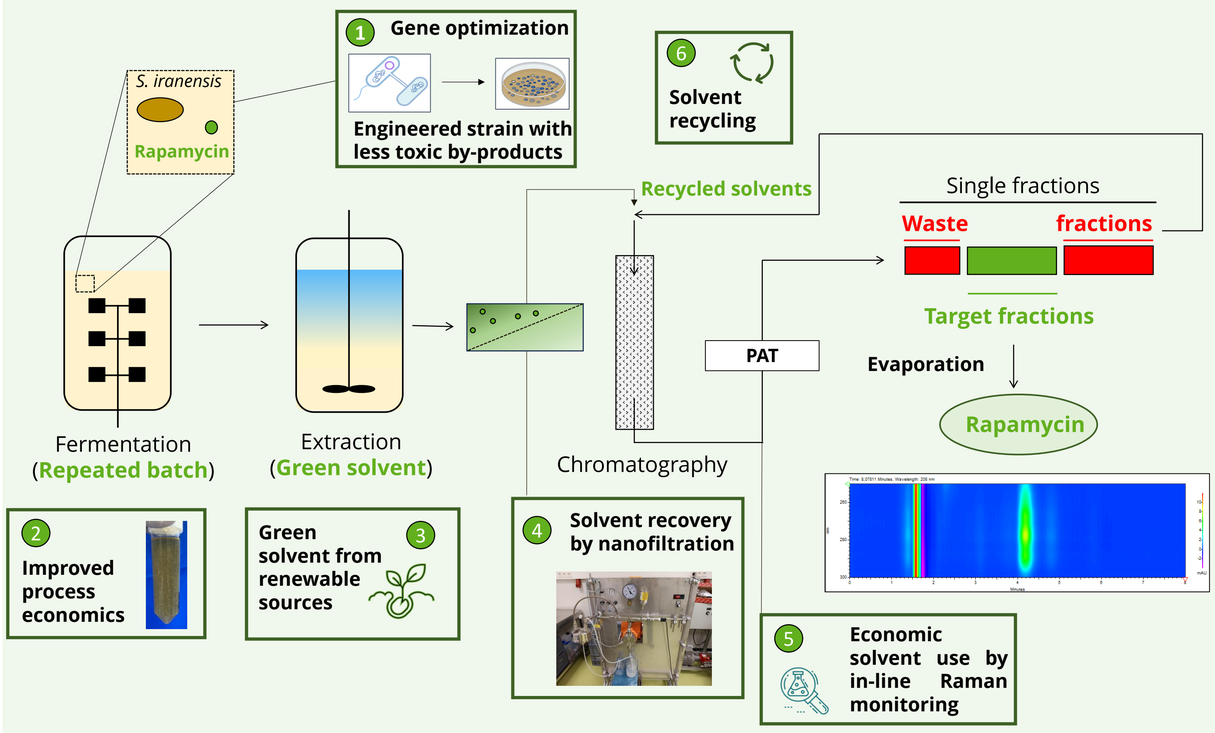
- Ecotoxicity and persistency of chemicals from pharmaceutical manufacturing processes poses **risks to human health and the environment**
- Negative Impact on **Water quality and ecosystems** by significant volume of waste, including wastewater containing pharmaceutical residues

Many of these issues can be relieved by more localised manufacturing based upon well established green chemistry principles and more efficient process design, harnessing the operational efficiencies of **continuous manufacture** with the control advantages of advanced **in-line monitoring methods** and digitalization.



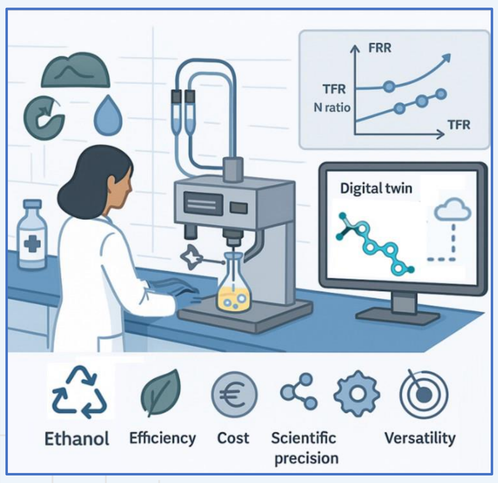
Our approach in the **ETERNAL project** starts with **reduction of toxic and bioactive side products** from metabolically engineered bacterium A bioprocess has been developed, employing green downstreaming strategies for **both cost-effective solvent recycling and isolation of rapamycin as a high quality, high purity product**

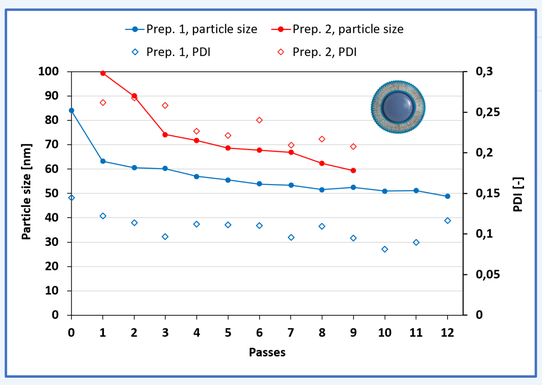
Process schematics: Improved, greener bioprocess



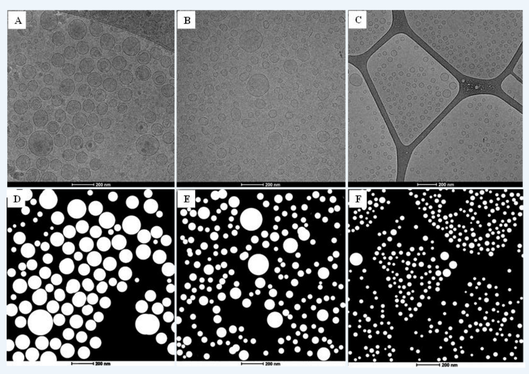
To Pharma

Lipid-based drug delivery systems can encapsulate a broad spectrum of therapeutically important compounds advantageously, but the batch-wise methods by which they are conventionally made are insufficiently scalable, sustainable, and reproducible.
In **ETERNAL**, MyBiotech collaborates with project partner Reig Jofre in a case study to minimize solvent use and environmental footprint through ethanol recycling and process simulation via digital tools.





Influence of No. of passes on particle size and PDI



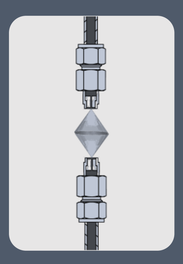
Cryo-TEM images of loaded diclofenac liposomes formulated by the sonication (A), microfluidics (B) & microreactor (C). D-F Image J analysis from A-C.

MyBiotech's innovative manufacturing technologies were employed to reach:

Low Particle size - 50 nm
Low PDI - < 0.3
High EE - 95%

Innovative microreactors maintain high-quality particle production while throughput is one order-of-magnitude higher compared to traditional microfluidics.

The technology combines:



- **Excellent scale-up capabilities**
- **High reproducibility**
- **Homogenous distribution**
- **Tight control on particle properties**

Conclusions & Next Steps

- Development of an **innovative end to end process** for the manufacturing of high purity rapamycin
- Demonstration of **carbon footprint and environmental impact reduction**
- Successful **Deletion of 5 DNA regions** responsible for biosynthesis of unwanted compounds

➡ **Future steps aim to surpass purity and sustainability further**

- Demonstration of high throughput, continuous production using high-turbulence microreactors
- **Best quality/throughput compromise** on industrial scales for innovative nanoformulation manufacturing.

➡ **Expansion of experimental parameters to increase particle quality**

References

[1] I. Naveira-Souto, R. F. Alsina, E. Rosell-Vives, E.Pena-Rodríguez, F. Fernandez-Campos, J. Malavia, X. J. Camprodon, M. Schelden, N. Günday-Türeli, A. Cruz-Conesa, M. Lajarin-Reinares, Pharmaceutics 2026, 18, 105

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Establishing safe and sustainable pharmaceutical life cycles by design

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