enviromed

Message from the Coordinator

It is always a great pleasure to collaborate with top-notch professionals from different disciplines, coordinating the joint efforts for a common cause. Coordinating the ENVIROMED project is such an example of an excellent uplifting and rewarding experience. 18 partners from 11 countries have joined forces to address the critical need to reduce the environmental footprint of pharmaceuticals and enhance sustainability in the pharmaceutical industry.



ENVIROMED follows a holistic, multi-disciplinary approach to support the transition towards greener pharmaceuticals, focusing on reducing the environmental impact of both the manufacturing processes and the pharmaceuticals throughout their lifecycle.

This is the first of a series of newsletters that will be published regularly to keep you updated on the project's news and achievements.

Welcome and stay tuned!

Stephanos Camarinopoulos | ENVIROMED Project Coordinator Director - Head of Software Development and R&I at RISA Sicherheitsanalysen GmbH

ENVIROMED – introduction of modern technologies and processes through cooperative effort

Pharmaceuticals have undoubtably made our world a better place, ensuring longer and healthier lives. However, pharmaceuticals and their active metabolites are rapidly emerging environmental toxicants. It is thus critical to understand, and mitigate where necessary, the environmental impact resulting from their production, use and disposal.

In this direction, ENVIROMED addresses two aspects of the environmental impact of pharmaceuticals:

a) impact of the processes in manufacturing the compound; and b) impact of the compound itself, during its lifecycle.

The project narrows the knowledge gap when it comes to the effect of pharmaceutical compounds, and their derivatives in the environment, as it enables the better understanding of the environmental impact of such compounds throughout their lifecycle. It aims to offer (via extensive monitoring campaigns and scientific studies) information regarding occurrence of pharmaceuticals in the environment, their persistence, environmental fate, and toxicity (via in-vitro and in-vivo models) as well as application of in-silico methods to provide information about the basic risk management and fate prediction in the environment.

Moreover, the project aims to develop a set of technologies that enable greener and overall, more efficient pharmaceuticals production, which include:

a) Green-by-design in-silico drug development;

b) Novel sensing to allow reduction of rinsing chemicals and cycles;

c) a robust Continuous Biomanufacturing line (CBM), which makes use of Alenabled process optimisation and prediction, using data assimilation based on chemical sensing and energy disaggregation/monitoring.

The main project outcomes are (a) Green Pharmaceuticals CBM process which includes studies, optimisation and reporting on strategies aiming to reduce consumption of chemicals by the pharmaceutical industry; (b) Three new sensors to be delivered for (i) inline liquid spectroscopy, (ii) surface inspection



during cleaning, and (iii) micropollutants detection in wastewater & marine environments; (c) Registry of pharmaceuticals micropollutants and LCA model for pharmaceuticals' compounds and (d) In-silico drug development services & models for pharmaceuticals, which will include new data (validation of the in-silico models in-vivo/in-vitro studies) in report/study, publications, S/W and the skills/know-how needed for the provision to pharmaceuticals in-silico drug development services.

ENVIROMED engages leading industrial partners in a participatory development of new methods, applies novel sensing methods and delivers a clear strategy roadmap for exploitable outcomes as well as engages citizens, health care providers and health systems for a Green Pharmaceuticals dialogue. 18 partners from 11 EU countries gathered for 42 months to cooperate in providing means and methodology, which shall contribute to the Green Pharmaceuticals concept in the EU and shall focus on scientific impacts aligned with the ENVIROMED vision for the deployment of optimised, green production methods and better understanding of pharmaceuticals' environmental impact.

ENVIROMED in a nutshell

- 18 partners
- 11 countries
- 42 months with a start date 01/06/2022
- 7.5 M€ total budget funded by EC

Bioprocess Engineering: Key technologies for sustainable drug manufacturing

Our partner TU Wien (TUW) is developing and deploying novel green pharmaceutical manufacturing approaches. The combination of intensified bioprocessing with digitalisation technology is the key for a more sustainable production of biopharmaceuticals. The benefits of the developed technology are demonstrated in laboratory scale experiments. Together with our partner PLEGMA Labs, an energy monitoring system was installed for selected upstream processing steps. This ensures a reliable monitoring strategy of the energetic footprint of our processes.

Continuous manufacturing and sustainability are key focus areas in the pharmaceutical industry, aiming to optimise production processes and minimise environmental impact. The development and optimisation of biopharmaceutical production processes can be supported by process



simulation for overall resource and energy integration. As an in-silico computational fluid process lens, dynamics (CFD) allows for the time and 3D-space resolved analysis of the multiphysics and multi- scale phenomena in core process equipment's like the bioreactor and other relevant upstream and downstream technology. TUW, within the scope of ENVIROMED, aims to benchmark areen pharmaceutical manufacturina processes and investigate strategies for making batch processes more continuous and circular. reduce energy and process media consumption and improve throughput.

In particular, a comprehensive benchmarking analysis of green pharmaceutical manufacturing processes is being developed. This analysis will assess the environmental impact and energy efficiency of a selected fed batch process allowing to extrapolate generic data. CFD simulations will be employed to model and optimise process parameters, such as reaction kinetics, mixing efficiency, and heat transfer, with the objective of achieving continuous and circular manufacturing. Furthermore, process simulation will be employed to identify potential bottlenecks and propose innovative solutions for process integration and material flow optimisation.

The findings of this research will contribute to the development of sustainable manufacturing practices in the biopharmaceutical industry. By transforming batch processes into more continuous and circular systems using modelling strategies such as CFD and process simulation, manufacturers can achieve significant reductions in waste generation, energy consumption, and resource utilisation. One of the outcomes of the project will provide valuable insights for pharmaceutical companies seeking to optimise their manufacturing processes while meeting sustainability objectives.

ENVIROMED joins forces with other Horizon Europe Green Pharma projects



ENVIROMED and four other Horizon Europe research projects, namely IMPACTIVE, ETERNAL, TRANSPHARM and SUSPHARMA, formed a Green Pharma Cluster, aiming to increase the sustainability of pharmaceutical products and exploit research synergies to boost the impact of its innovations.

Find out more here

First published results

The first two publications describing work performed in ENVIROMED are published! These publications have been authored by our partner TU Wien (TUW) and are as follows:

• Imran, F., Lueck, R., Jordan, C., Herwig, C., & Harasek, M. (2023). A Perspective on the Role of Digitalization Enablers in Sustainable Pharmaceutical Manufacturing. Chemical Engineering Transactions, 105, 361-366. <u>https://doi.org/10.3303/CET23105061</u>

• Ricchiuti, G.; Riedlsperger, L.; Dabrowska, A.; Rosenberg, E.; O'Faolain, L.; Lendl, B. Mid-Infrared Photothermal Spectroscopy for the Detection of Caffeine in Beverages. Sensors 2024, 24, 1974. https://doi.org/10.3390/s24061974

Plenary Meetings – meeting points for ENVIROMED partners



1st Plenary Online Meeting on 21st March 2023

It is always inspiring to see the passion and commitment that our partners bring to the table!



2nd Plenary Meeting on 15-16 June 2023 in Athens, Greece

The first F2F meeting of the consortium partners was hosted by RISA in Athens and provided the ideal opportunity to meet in person and foster collaboration, ensuring alignment in terms of organisational and technical aspects of the project.



3rd Plenary Meeting on 12-13 December 2023 in Nicosia, Cyprus

It was a fruitful 2-day meeting, hosted by the Cyprus Research & Innovation Centre (CyRIC), that enabled the consortium partners to hold technical workshops, present the progress and share valuable findings.



4th Plenary Meeting on 27-28 May 2024 in Naples, Italy

A successful 2-day meeting was hosted by Consiglio Nazionale delle Ricerche (CNR) in the beautiful city of Naples and featured fruitful discussions about project achievements, findings, and challenges, as well as technical workshops.



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