



Advancing Safe and Sustainable by design Practices in Pharmaceutical Manufacturing

Addressing the urgent need for sustainability in the healthcare industry

Funded by the European Union and the private members of the IHI JU.
Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the aforementioned parties. Neither of the aforementioned parties can be held responsible for them.





Executive summary

Public private partnership advancing Safe and Sustainable by design Practices in Pharmaceutical Manufacturing

Project Goal:

Advancing sustainable practices in pharmaceutical manufacturing of small molecules, biologics and tides, as well as decontamination

-  Implementation of process optimizations and technological innovations at various stages of pharmaceutical manufacturing
-  Standardized sustainability assessment methods

Consortium:

-  31 international partners,
 - Including major pharmaceutical and medtech companies, research institutions, government bodies, and SMEs
 - 14 different countries
-  *Coordinator:* Ghent University (BE) / *Project leader:* Sanofi (DE)

Budget:

45M €, co-funded by the European Union and the private members of the IHI JU

Duration:

01/11/2024 – 31/10/2030

Expected outcome

Enhanced sustainable manufacturing with SSbD methods, reducing resource use and emissions, offering a public eco-design toolbox, and standardized sustainability assessment methodology in healthcare



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PHARMECO summary

WHAT:

- **Public-private partnership** led by Ghent University and Sanofi, uniting **31 partners** across 14 countries to advance Safe and Sustainable by Design (SSbD) practices in pharmaceutical manufacturing

Funding and duration:

- 45M €, co-funded by the European Union and the private members of the IHI JU
- 01/11/2024 – 31/10/2030

Mission:

- To enhance pharmaceuticals and biologics with sustainable methods, reducing use of water, energy, solvents, waste;
- Standardized sustainability assessment methodology in healthcare

Public-private partnership of 31 international collaborators

Uniting expertise to advance PharmECO's ambitious objectives

18 PUBLIC partners



13 PRIVATE partners



PHARMECO key objectives

- Integration of Safe and Sustainable by Design (SSbD) principles in pharmaceutical manufacturing practices
- Uptake of scalable, eco-friendly manufacturing optimizations and innovations in pharmaceutical manufacturing, focused on reducing greenhouse gases, solvent use, water, and energy consumption
- Development of digital support tools for prospective evaluation to guide sustainable production via process simulation
- Establish standardized environmental assessment systems for (bio)pharmaceuticals, ensuring consistency across the industry

PHARMECO anticipated long-term impact

Environmental impact:

- Targets a 50% reduction in GHG emissions, 30% decrease in solvent use, and substantial water and energy savings per kg of drug produced.

Industry advancement:

- Implementation SSbD principles to align with EU Green Deal goals and positioning the industry to meet rising regulatory expectations.
- PHARMECO creates sustainability benchmarks and a digital toolbox to guide companies in eco-friendly decision-making from design to disposal

Societal Benefits:

- Standardized sustainability assessments make it easier to compare providers' environmental and operational performance, leading to more informed decisions
- By prioritizing renewable materials and eco-friendly practices, PHARMECO reduces industry pollution and promotes a healthier, more environmentally responsible society

Contact information

- ✔ **PHARMECO website:** www.pharmeco.eu
- ✔ **IHI fact-sheet:** <https://www.ihieuropa.eu/projects-results/project-factsheets/pharmeco>
- ✔ **Follow us on LinkedIn:** <https://www.linkedin.com/company/pharmeco-ih/?viewAsMember=true>
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This project is supported by the Innovative Health Initiative Joint Undertaking (IHI JU) under grant agreement No 101165889. The JU receives support from the European Union's Horizon Europe research and innovation programme and COCIR, EFPIA, Europa Bio, MedTech Europe, and Vaccines Europe



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Critical unmet needs in pharmaceutical manufacturing

PHARMECO is designed to address critical unmet needs in the pharmaceutical manufacturing industry

🌱 Environmental impact of traditional manufacturing

- 🌱 *PHARMECO aims to trigger process optimizations and introduction of more sustainable technologies that minimize these impacts*

🌱 Increasing regulatory pressure to meet EU Green Deal and sustainability goals

- 🌱 *PHARMECO will provide a solution toolbox to help companies stay ahead of these requirements*

🌱 No consistent methodology for evaluating environmental impacts across the industry

- 🌱 *PHARMECO will deliver a guideline that is scientifically-robust, practical, and accepted by stakeholders.*

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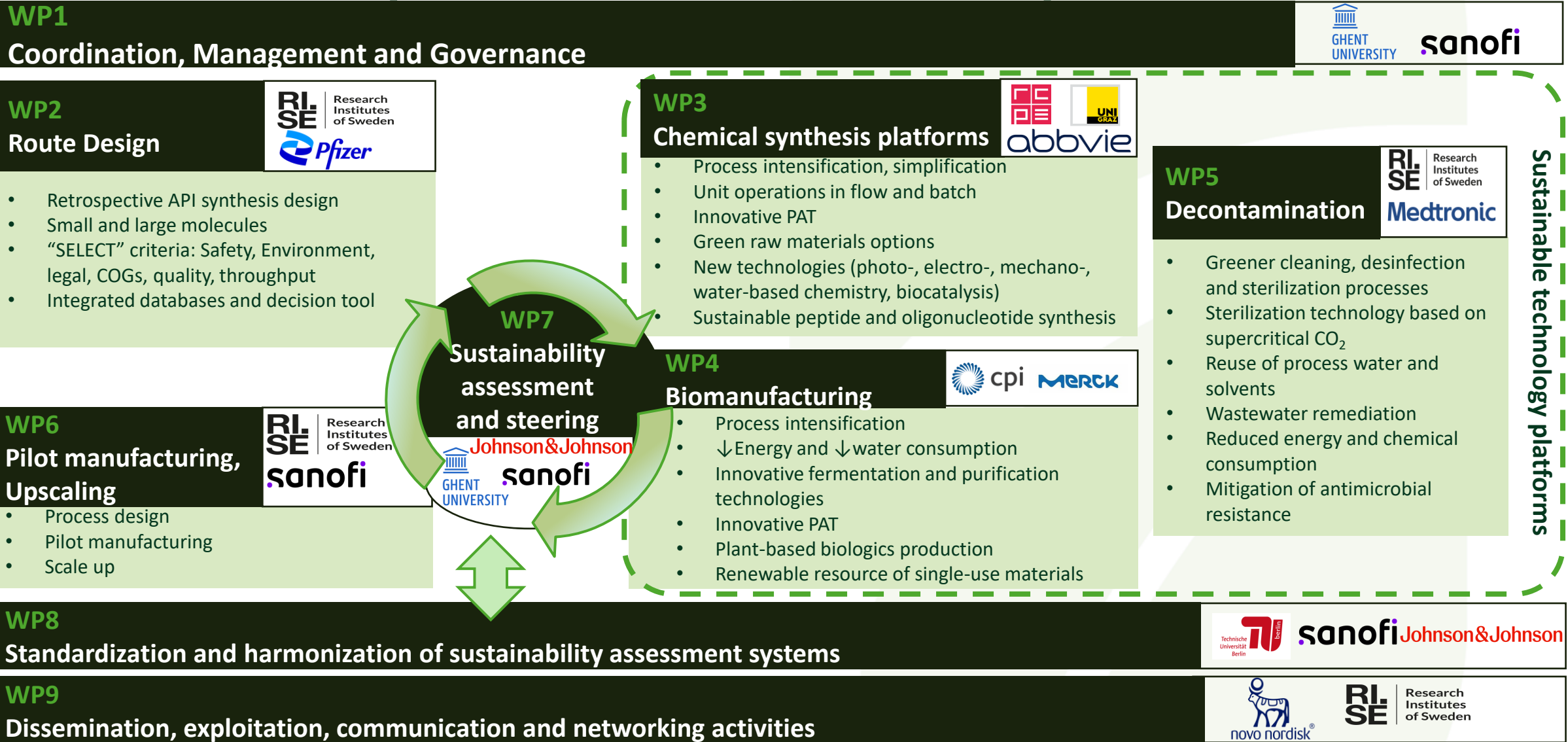


PHARMECO key objectives

Integration sustainable practices in pharmaceutical manufacturing

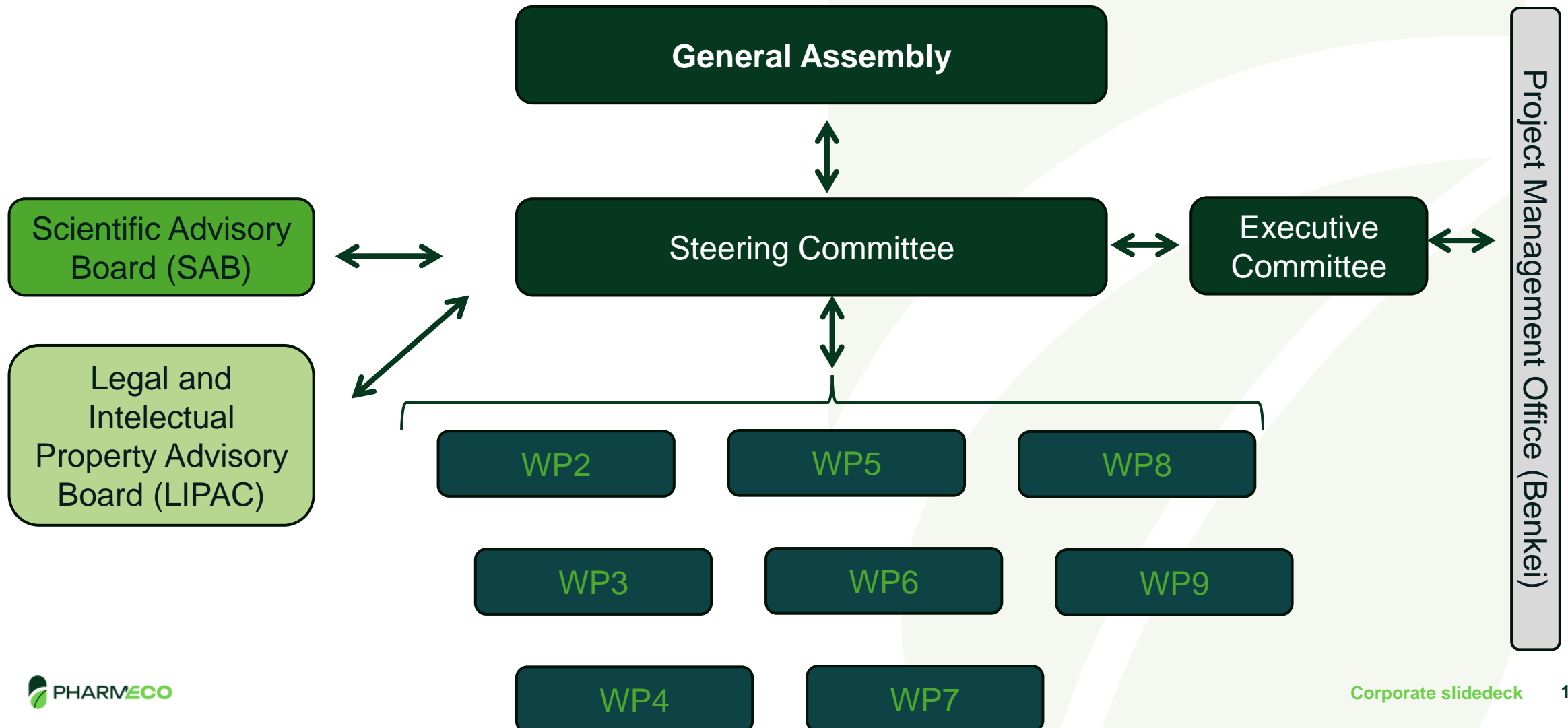
- Integration of Safe and Sustainable by Design (SSbD) principles in pharmaceutical manufacturing practices
- Uptake of scalable, eco-friendly manufacturing optimizations and innovations in pharmaceutical manufacturing, focused on reducing greenhouse gases, solvent use, water, and energy consumption
- Development digital support tools to guide sustainable production via process simulation and decision-making
- Establish standardized environmental assessment systems for (bio)pharmaceuticals, ensuring consistency across the industry

PHARMECO implementation: overall work plan structure



PHARMECO implementation

WP1: Coordination, Management and Governance



PHARMECO implementation

WP2: Route Design Optimization for Sustainable (Bio)Manufacturing

🌱 Objective:

- 🌱 Develop workflows and methodologies for designing optimal routes for synthesizing APIs during early-phase pharmaceutical development

🌱 Key focus areas:

- 🌱 Safety: Avoid explosive or hazardous intermediates
- 🌱 Environment: Reduce solvent and raw material usage, prioritizing green alternatives
- 🌱 Legal Compliance: Ensure adherence to regulatory standards, including IP
- 🌱 Economics: Calculate cost-effective strategies within route design
- 🌱 Control: Enhance quality and impurity control
- 🌱 Throughput: Optimize process efficiency for improved output

🌱 Outcome:

- 🌱 A refined, SELECT-based workflow for sustainable, energy-efficient, and scalable API synthesis from early development stages onward

PHARMECO implementation

WP3: Sustainable Synthesis & Process Development

🌱 Objective:

- 🌱 Develop sustainable, scalable methods for synthesizing APIs and intermediates, focusing on green chemistry to reduce waste, hazardous substances, and environmental impact

🌱 Key Focus Areas:

- 🌱 Bio-sourced synthesis with non-precious metal catalysis
- 🌱 Water-based continuous processing for key reactions
- 🌱 Solvent-free reactive extrusion protocols
- 🌱 Scalable biocatalytic and electro/photo-activation processes
- 🌱 Improved peptide and oligonucleotide synthesis with reduced environmental impact
- 🌱 Application of AI and PAT for optimization and quality control

🌱 Outcome:

- 🌱 Cleaner, cost-effective synthesis processes with reduced environmental impact, ready for industrial application

PHARMECO implementation

WP4: Sustainable Intensification of Biomanufacturing Processes

🌱 Objective:

- 🌱 Advance greener biomanufacturing practices by integrating innovative technologies, optimizing resource use, and enhancing process control

🌱 Key focus areas:

- 🌱 Process optimization/intensification to reduce water and energy use
- 🌱 Advanced expression, fermentation, and purification technologies with robust PAT
- 🌱 Model-based process control over CPP
- 🌱 Predictive modelling
- 🌱 Plant-based protein production
- 🌱 Single-use containers with recyclable/renewable materials

🌱 Outcome:

- 🌱 Scalable, eco-friendly process-intensified biomanufacturing methods/practices & unit operations supporting future industry applications with streamlined resource use

PHARMECO implementation

WP5: Sustainable Decontamination

🌱 Objective:

- 🌱 Save energy and reduce, replace or re-use water and chemicals in cleaning, disinfection and sterilisation processes while ensuring their efficiency and safety

🌱 Key focus areas:

- 🌱 Process optimization: energy-efficient, sustainable decontamination technologies, including supercritical CO₂ for cleaning and sterilization
- 🌱 Sustainable chemistry: replacement of harmful chemicals with eco-friendly alternatives and consumption reduction by re-use
- 🌱 Wastewater remediation: photocatalytic oxidation of harmful molecules
- 🌱 Antimicrobial resistance mitigation: assess new disinfection technologies and their potential to induce resistance.

🌱 Outcome:

- 🌱 More eco-friendly decontamination practices and adoption of more sustainable solvents and cleaning agents in pharma and medical device industries

PHARMECO implementation

WP6: Pilot Lines for Sustainable Pharmaceutical Manufacturing

🌱 Objective:

- 🌱 Validation of upscaled/pilot SSbD-driven pharmaceutical manufacturing processes regarding sustainability, operational compatibility, and regulatory compliance

🌱 Key focus areas:

- 🌱 Upgrade pilot manufacturing equipment
- 🌱 Implementation advanced data handling, analytical tools, and control systems
- 🌱 Alignment of pilot-scale operations with pharmaceutical regulatory and quality standards
- 🌱 Upscaling

🌱 Outcome:

- 🌱 Demonstration and validation of SSbD-driven pharmaceutical processes in pilot settings, preparing these technologies for efficient, compliant transition to commercial-scale GMP manufacturing

PHARMECO implementation

WP7: Sustainable Design and Evaluation Framework for Pharmaceuticals

🌱 Objective:

- 🌱 Evaluate sustainability of innovative (bio)manufacturing and decontamination technologies and pharmaceuticals, from a cradle-to-gate and eventually an end-to-end perspective via integrated assessment by tailoring the SSbD framework to pharma

🌱 Key focus areas:

- 🌱 Adapt the SSbD framework for early-stage sustainability guidance in pharmaceuticals
- 🌱 Environmental impact assessment for synthesis routes and innovative manufacturing technologies
- 🌱 Integration environmental, circularity, resource criticality, and health benefit metrics for holistic sustainability evaluations
- 🌱 Models and digital tools for prospective sustainability assessments, with industry input for scalability and accuracy

🌱 Outcome:

- 🌱 Modular digital support tool for prospective sustainability assessments for pharmaceutical manufacturing at early production and R&D stages

PHARMECO implementation

WP8: Harmonizing Life Cycle Assessment in the Pharmaceutical Industry

🌱 Objective:

- 🌱 Harmonization of Life Cycle Assessment (LCA) framework for pharmaceutical products, incorporating guidelines for effective data provision and exchange across the supply chain, with industry-wide applicability

🌱 Key focus areas:

- 🌱 Guideline for LCA harmonization, covering general and product-specific standards in the pharmaceutical sector.
- 🌱 Engage stakeholders through open consultation, iterative feedback, and "road-testing" to refine the guidelines

🌱 Outcome:

- 🌱 An industry-accepted LCA framework that enables consistent sustainability assessments and facilitates data exchange

PHARMECO strategy to maximize impact

WP9: Communication, dissemination and exploitation

🌱 Objective:

- 🌱 Promote uptake of PHARMECO's results through targeted dissemination, exploitation, communication, and networking activities, ensuring engagement with relevant stakeholders.

🌱 Key focus areas:

- 🌱 Targeted communication & dissemination
- 🌱 Build and sustain a stakeholder network, engage industry, NGOs, regulatory bodies, and global initiatives for collaboration. Organize workshops, webinars, and bilateral meetings to drive adoption.
- 🌱 Effective utilization, protection, and management of intellectual property and project results to maximize impact and enable commercialization or societal benefits.
- 🌱 Collaborate with EU/national regulators to address barriers, align with evolving frameworks, and ensure readiness for sustainable pharmaceutical innovation.

🌱 Outcome:

- 🌱 Robust dissemination and stakeholder engagement framework promoting PHARMECO's results, ensuring effective exploitation of key outputs, and facilitating regulatory preparedness for sustainable pharmaceutical innovation.

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