



HERA HEALTH EMERGENCY
PREPAREDNESS AND
RESPONSE AUTHORITY

#HealthUnion

INNOVATIVE MANUFACTURING CALL, CP-g-24-12, EU4H-2024-PJ-01-3

HERA 3
29 May 2024



- HERA is the Health Emergency Preparedness and Response Authority
- Founded in the aftermath of the COVID-19 pandemic to ensure Europe is better prepared for future health emergencies
- HERA has 4 units with different areas of responsibility
- Unit 3 deals with Medical Countermeasures (medicines, vaccines etc)
 - Non-regulatory aspects of Medical Countermeasures (MCMs)
 - Including manufacturing
 - Will run this grant call

- A key responsibility of HERA 3 is pandemic preparedness. Ensuring that pandemic medicine manufacturing processes are suitable for rapid, efficient scale-up to meet pandemic demand surges is a critical part of this preparedness.
- In the past year, shortages of critical medicines have become more public and have had greater impact on patients across Europe. HERA is working with stakeholders to find long term solutions to the industrial policy aspects of these issues.
- HERA seeks to address these issues through innovation in Innovative Manufacturing grant call (CP-g-24-12)

- To implement the EU4Health Programme's general objective of improving the availability, accessibility and affordability of crisis-relevant products (Article 3, point (c) of Regulation (EU) 2021/522) through the specific objectives defined in Article 4, points (b) and (c), of Regulation (EU) 2021/522.
- Enable rapid scale-up of Union pharmaceutical production in the context of a health emergency or to prevent critical shortages of critical medicines.
- Support the Union's pharmaceutical industry to be better able to respond to public health needs in the context of health emergencies and critical medicine shortages.

- To support improved manufacturing technologies and processes that allow for a more effective, less expensive, easier to scale-up, more sustainable and cleaner production of medicines in the Union.
- Enable the development of tools that contribute to the improvement and optimisation of manufacturing of medicines.
- Reducing production costs (e.g., related to labour and energy consumption), and facilitating compliance with the Union's environmental occupational and social requirements, as well as the Union's current and future needs to scale-up pharmaceutical production.

SPECIFIC DELIVERABLES

- The grant supports the design and development of manufacturing technologies, processes and facilities that adhere to Good Manufacturing Practice principles.
- The specific focus of the grant is to develop new manufacturing technologies for the production of APIs, intermediates and/or excipients. Projects awarded under this grant shall address one or more of the following challenges:

SPECIFIC DELIVERABLES

- Optimizing existing manufacturing processes to improve efficiency, reduce costs, and/or improve product quality.
- Developing technologies to enable rapid scale-up of production of medicines.
- Developing new technologies for manufacturing medicines in real-time.
- Developing new technologies for manufacturing medicines in remote or resource-constrained settings.
- Designing manufacturing processes that are resilient to climate change and other environmental threats.

SPECIFIC DELIVERABLES

- Developing new manufacturing technologies for the production of high-potency APIs, which are difficult to produce using traditional/resource limited methods.
- Optimizing/developing new manufacturing processes for personalized medicines, which require individualized dosing and formulation.
- Developing new manufacturing technologies that can be used to produce medicines in extreme environments.
- Developing new technologies for recycling or upcycling waste generated during medicines' production.

- Projects should be led by economic operators, such as pharmaceutical companies, contract manufacturers, or technology start-ups.
- Applicants should have a clear understanding of the technical challenges they are addressing and a strong track record of innovation.
- If not an industrial economic operator, applicants should be able to demonstrate experience in transferring technologies to the pharmaceutical industry.

- The total funding available under this grant proposal is up to €17 million.
- HERA expects 3 projects to receive funding.
- The timelines for approved projects are expected to be 24-48 months.
- Deadline for applications is 17h CET, 5th September 2024.

INNOVATIVE MANUFACTURING CALL

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- Thank you for your attention.
- If you have questions, then please follow the instructions provided by the moderators.

Grant call CP-g-24-14
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