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Pharma in Space

Microgravity-enabled medicinal product research, development and manufacturing

EU-IN Horizon Scanning Report

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Executive summary

"Pharma in space" is used in this report as a working term for microgravity-enabled medicinal product research, development and manufacturing. The topic covers the development of medicinal products intended for use on Earth where one or more steps in discovery, development, testing or manufacturing may use the space environment, especially microgravity.

The biggest opportunity lies in macromolecular crystallisation and structure-enabled research. Work on the International Space Station and other microgravity platforms suggests that reduced sedimentation and convection can improve crystal order for some proteins, with examples reported for therapeutically relevant targets and antibodies. Another opportunity is three-dimensional cell culture, tissue engineering and disease modelling, where real and simulated microgravity continue to be explored as environments for spheroids, organoids and tissue-chip systems. A third oppportunity comes from spaceflight pharmacy and medicine-stability studies, which are not direct evidence of future terrestrial products but do highlight issues around packaging, storage, degradation, shelf life and contingency planning in the space environment.

No dedicated EU framework specific to microgravity-enabled pharmaceutical development or manufacture was identified in the public materials reviewed for this report. However, the core medicines acquis, EU GMP, lifecycle-management tools and existing innovation-support channels appear broad enough to handle early exploratory cases under current law. The main questions are therefore operational rather than constitutional: how to define the regulated framework, how to demonstrate comparability and control, how to inspect or otherwise oversee remote or autonomous activity, how to assign legal responsibility across multiple actors, and how to address continuity-of-supply risks.

The most plausible near-term regulatory activity is early dialogue with subject matter experts rather than marketing-authorisation assessment. Over the next years, the most likely scenarios are early interactions with the Regulator. The appropriate regulatory response ceasing opportunities at this stage is preparedness: maintain targeted horizon scanning, develop first-case assessment tools, strengthen internal capability and only consider new guidance if repeated cases reveal recurring gaps.

1. Introduction

1.1. Rationale and objectives of the report

Horizon scanning is used by the European Medicines Agency (EMA) and the EU Innovation Network (EU-IN) to identify emerging developments that may create new regulatory questions or public-health opportunities over the next three to ten years (1, 2), aiming to improve regulatory preparedness. In that context, microgravity-enabled medicinal product development and manufacturing (referred to in this report as "pharma in space") has emerged as a relevant topic because it sits at the intersection of advanced manufacturing, life-science research, remote operations and industrial transformation.

The objective of this report is to describe the current state of the field, assess the likely implications for the European medicines regulatory network, and propose proportionate next steps. It is intended to support internal and external discussion on whether the network is sufficiently prepared to engage with developers whose medicinal-product programmes may involve microgravity-enabled research, development or manufacturing steps.

1.2. Scope of the report and working definition

In this report, "pharma in space" refers to medicinal products intended for the terrestrial market whose research, development, testing or manufacturing may use the space environment, especially microgravity, at one or more stages. This includes, for example, macromolecular crystallisation experiments, microgravity-enabled formulation work, three-dimensional disease models and tissue-chip platforms, and orbital or return-capable systems that may generate data or intermediates relevant to medicine development.

The scope excludes broad discussion of astronaut healthcare, countermeasures or routine operational pharmacy, except where those topics provide informative signals about quality, stability or logistics. The central question is whether a space-enabled step could become relevant to the evidence, control strategy or lifecycle management of a medicinal product intended for the European Union market.

Medical devices and device-specific regulatory questions are outside the primary scope of this report, except where a device, device-led platform or drug-delivery system becomes relevant to medicinal-product development, manufacture, evidence generation or administration.

Ground-based analogues such as clinostats, random positioning machines, magnetic levitation, drop towers and parabolic flights remain valuable for screening, method development and hypothesis generation. They can reproduce selected aspects of altered gravity or short-duration reduced gravity, but they do not reproduce weeks to months of sustained microgravity with the same suppression of buoyancy-driven convection and sedimentation. That distinction matters for regulation because it helps separate experiments that are mainly exploratory from those where orbital conditions may be claimed to add product-relevant value (6, 24).

Key emerging trends include microgravity-enabled formulation and particle engineering, advanced three-dimensional in vitro models, and other research activities that may, in time, support medicinal-product development. Regulatory relevance is more likely to arise downstream, when a space-enabled step is presented as material to medicinal-product development, manufacturing, quality or lifecycle management. More speculative but potentially important later use cases concern discrete, high-value manufacturing steps performed in orbit, or the generation of product-relevant intermediates for

subsequent terrestrial manufacture, with bulk production and most release activities remaining on Earth. This report therefore treats microgravity as a possible enabling step in a wider terrestrial development and supply chain, rather than as a rationale for moving whole medicine-production systems off-planet (3-6).

1.3. Why the topic matters to the European medicines regulatory network

Microgravity alters fluid behaviour, mass transport, sedimentation and certain aspects of cell organisation. Under the right conditions, those changes can influence crystal growth, suspension behaviour and three-dimensional tissue formation in ways that are difficult to reproduce for long durations on Earth. Not every microgravity experiment has regulatory significance, but the underlying physical differences are sufficient to justify monitoring where they intersect with product quality, manufacturability or the interpretation of development data (3-6).

Early preparedness enables the regulatory network to respond using existing tools while retaining credibility and avoiding over-regulation.

Ensuring that the network engages consistently and scientifically with emerging microgravity-enabled approaches supports Europe's attractiveness and competitiveness as a location for medicinal-product development, while remaining fully within the existing public-health and regulatory mandate.

2. Current status and key emerging trends

2.1. Macromolecular crystallisation and structure-enabled research

The most mature trend remains protein and antibody crystallisation in microgravity. National Aeronautics and Space Administration (NASA), Japan Aerospace Exploration Agency (JAXA) and International Space Station (ISS)-linked material describe longstanding interest in using the space environment to improve crystal order and to support structural biology relevant to drug design (3, 4). Published examples include higher-quality crystals of human haematopoietic prostaglandin D synthase and microgravity crystallisation work involving pembrolizumab, both of which illustrate that certain macromolecules may benefit from the altered mass-transport conditions of microgravity (5).

This demonstrates, that the scientific premise is not purely speculative. Public evidence suggests that microgravity can, in at least some cases, alter crystal morphology or crystal quality in ways that may be analytically relevant. What remains unresolved is how often those effects are reproducible, how often they generate a product-relevant advantage, and whether the cost and complexity of orbital execution can ever be justified for a medicine intended for routine terrestrial use.

2.2. Three-dimensional cell models, tissue engineering and disease modelling

A second cluster of activity concerns the use of real or simulated microgravity to generate spheroids, organoids and other three-dimensional models. Recent reviews describe recurring research on cellular response, tissue organisation and disease modelling under microgravity conditions, including work relevant to regenerative medicine and translational biology (6). Public programmes such as ISS National Laboratory calls on tissue engineering and biomanufacturing, together with the National Institutes of Health/ National Center for Advancing Translational Sciences (NIH/NCATS) Tissue Chips in

Space programme, indicate continued interest in using space-enabled platforms for model generation and biological insight (11, 12).

Spaceflight and ground-analogue research may also provide signals on disease mechanisms relevant to terrestrial medicine, for example in areas such as bone loss, vascularisation, ageing-related changes and metabolic dysfunction. For this report, such examples are relevant mainly where they may inform disease modelling, translational research or evidence generation for medicinal-product development, rather than as a separate assessment of astronaut healthcare.

The regulatory relevance of this cluster is mainly indirect at present. In the nearer term, these platforms are more likely to influence the evidence base used to understand disease mechanisms, candidate prioritisation, safety questions or translational relevance than to produce an immediately approvable product. Even so, if developers begin to rely on such data in support of regulatory decisions, questions of model validity, reproducibility, transport stress, assay control and comparability with terrestrial systems will become more prominent.

2.3. Stability, storage and spaceflight pharmacy

Spaceflight pharmacy is not equivalent to terrestrial product development, but it provides useful quality-related evidence. Analyses of ISS formularies and long-duration medicine highlight constraints for long-duration missions because many medicines would reach labelled expiry during planned exploration timelines, underscoring uncertainty when terrestrial shelf-life assumptions are applied to space conditions (7). Complementing this, on-orbit studies of remdesivir/cyclodextrin stability under repeated spaceflight exposure further illustrate that packaging, transport and environmental stress can be part of the quality question (8).

Operational formulary studies on board the ISS involve constrained inventories, mission-specific use conditions and small datasets. Nevertheless, from a regulatory-preparedness standpoint they are valuable because they expose practical issues that would also matter for any future space-enabled pharmaceutical step: long-duration storage, radiation or vibration exposure, container-closure performance, chain of custody and the quality consequences of launch and return.

Recent work on radiation exposure and medicine stability further supports the need for proportionate monitoring. Studies do not indicate that space radiation necessarily compromises all medicines. Rather, they highlight product-, formulation-, packaging- and container-specific considerations. For example, recent studies have examined simulated galactic cosmic radiation and neutron-radiation exposure, with findings including comparable degradation for selected solid oral medicines under the conditions tested, as well as container-related risks such as activation of glass vials. These findings reinforce the relevance of packaging, container-closure systems, storage duration, transport conditions and environmental monitoring when assessing any future space-enabled pharmaceutical step.

2.4. Infrastructure and ecosystem trajectory

The ISS remains the principal platform for repeated microgravity life-science activity, and NASA frames its continued role through the end of the decade (9). Public funding and programme activity also indicate continued interest in the topic. NASA’s In-Space Production Applications portfolio, ISS National Laboratory research announcements on tissue engineering and biomanufacturing, NIH/NCATS Tissue Chips in Space 2.0, and European Space Agency (ESA)-linked business or accelerator activity all point

to sustained institutional interest in the interface between space infrastructure and health-related research (10-12, 22, 23).

The research and development field remains early and heterogeneous, but the increase in public research and infrastructure supports proportionate monitoring from a Horizon scanning perspective. The combination of continued microgravity research, maturing automated platforms, return-capable hardware and visible public funding suggests that developers may increasingly explore whether orbital execution can create product-relevant value. The implications for the likely timing and nature of regulatory interactions are considered in section 2.5.

2.5. Anticipated timeframe for regulatory submissions

Based on the current level of development maturity, near-term activity is more likely to involve early informal regulatory interactions with Regulatory Agencies than evaluation of marketing-authorisation applications. In the coming years, developers may engage with regulators on whether a space-enabled development or manufacturing step could become material to a medicinal-product development programme.

A second stage, more likely over a three- to five-year horizon, would involve structured development submissions. These might include mock or partial chemistry, manufacturing and controls dossiers, comparability exercises, method-development proposals, validation strategies for remote or autonomous process data, or proposals for how an orbital step interfaces with terrestrial manufacture and quality release. Such submissions would still be preparatory rather than product-defining in most cases.

If marketing authorisation submissions eventually emerge in which a space-enabled step is presented as integral to manufacturing or to a claimed quality advantage, these would more likely arise at a later stage rather than in the near term. Any such timeframe remains indicative, depending on reproducibility, platform reliability, acceptable economics and, critically, whether the space-enabled step can be shown to deliver a pharmaceutically meaningful advantage over terrestrial alternatives.

3. Challenges and opportunities from a regulatory perspective

3.1. Quality, manufacturing and comparability

The first major challenge is to determine whether a space-enabled step is product-relevant. If a space-enabled step forms part of the proposed development or manufacturing strategy, developers would need to explain the role of that step, identify any quality attributes or data outputs affected by it, and demonstrate that the proposed control strategy is adequate for its intended regulatory use. This would not imply a general requirement to show superiority over a terrestrial route. Comparison with terrestrial data or benchmarks would only be relevant where needed to justify the proposed process, interpret observed differences, or support a specific quality or performance claim. Where relevant, launch, orbital execution, return and recovery may form part of the manufacturing or data-generation process and may need to be considered in the control strategy.

This creates comparability questions. A product made partly through an orbital step may need comparison not only against terrestrial batches but also against alternative terrestrial process routes.

Regulators would require critical quality attributes, acceptable variability, process capability and the point at which a change to the space-enabled step becomes a reportable lifecycle-management issue. These are familiar pharmaceutical questions in principle, but the operational context is unfamiliar. For an initial application, the relevant question would be whether the proposed manufacturing process and control strategy support the quality of the product. For a post-authorisation change from a terrestrial to a space-enabled step, comparability with the approved process would become relevant.

Similar questions may also arise for lifecycle changes or alternative process routes. Where a microgravity-enabled step is presented as material to quality or performance, applicants may need to justify comparability between orbital and Earth-based approaches, and, in some cases, provide evidence beyond routine analytical comparison where any differences could be clinically or pharmaceutically relevant (20).

A distinction should be maintained between exploratory or supportive microgravity research and activities intended to support regulated pharmaceutical development, manufacture or future submissions. For exploratory work, variability may be scientifically acceptable. Where data, materials or processes are intended to support regulated development or manufacture, expectations on documentation, reproducibility, traceability, data integrity and, where applicable, Good Manufacturing Practice and Good Laboratory Practice (GLP/GMP) compliance would need to be considered.

3.2. Inspectionability and regulatory oversight

EU GMP and associated inspection practice were built around terrestrial sites to which inspectors can travel, where equipment can be observed directly and where records can be reviewed in a conventional facility context. Remote, autonomous or orbital operations complicate that picture. Digitalisation may add a further layer of regulatory complexity where automated systems, AI-supported process models or digital twins are used to support remote monitoring, process understanding, comparability assessment or quality-related decision-making. In such cases, regulators would need sufficient visibility on model governance, validation status, data integrity, performance monitoring, human oversight and lifecycle management, including how model drift or updates would be controlled. If a regulated step were to occur off-Earth, regulators would need confidence in the remote evidence package: telemetry, sensor records, audit trails, calibration information, environmental data, deviation logs, intervention history and the integrity of any links between orbital execution and terrestrial quality systems.

Recent remote or hybrid inspection practice offers relevant precedent but not a complete solution. European Directorate for the Quality of Medicines & HealthCare (EDQM's) permanent use of remote inspections and the International Coalition of Medicines Regulatory Authorities (ICMRA) Collaborative Hybrid Inspection Pilot show that regulators are increasingly willing to combine on-site and remote evidence where appropriate (18, 19). However, those models were developed for terrestrial operations. They do not by themselves resolve how to oversee autonomous microgravity processes, hardware maintenance in orbit, or the relationship between the physical location of execution and the legal location of pharmaceutical responsibility.

Where biospecimens or biological data generated in orbit are intended to support regulated development decisions, sample handling, stabilisation, freezing, storage, transport, chain of custody and documentation would need careful assessment. Launch, return and constrained onboard

processing may introduce variability that affects data integrity and comparability with terrestrial reference conditions.

3.3. Accountability and legal architecture

Space-enabled pharmaceutical activity would likely involve multiple actors: a medicinal-product developer, one or more terrestrial manufacturing or analytical sites, a launch provider, a platform operator, a return or recovery provider, and possibly public infrastructure. The medicines framework already places regulatory responsibility on the relevant manufacturer and, where applicable, the marketing authorisation holder; the key question here is not whether that responsibility changes, but whether the underlying operational and contractual arrangements across the different actors are sufficiently clear to support compliance, data integrity, batch disposition and post-approval obligations. A technically successful orbital step would still be problematic if those arrangements were fragmented, insufficiently controlled or contractually opaque.

The interface with space law should therefore be treated as a boundary condition, not as a substitute for medicines regulation. Questions of registration, launch state or operator control may matter for jurisdictional understanding, but they do not replace the need for a clear accountability map. For the regulatory network, the practical issue is simpler and more immediate: can the developer identify the relevant sites, responsibilities, data flows and release arrangements in a way that fits existing medicinal-product oversight requirements?

A further question is which jurisdiction, and competent authority would apply to a space-based manufacturing or processing step, including where activity takes place on an international platform such as the ISS. This would affect how any GMP oversight, certification or inspection responsibility could be assigned. The ISS framework gives partners jurisdiction and control over registered elements and nationals, but this does not automatically answer EU GMP responsibility.

3.4. Supply continuity and operational resilience

Orbital execution introduces dependencies that are rare or absent in conventional pharmaceutical supply chains: launch windows, mission delays, payload constraints, return anomalies, platform availability and a relatively small set of service providers. Those risks may be manageable for exploratory research or niche development work, but they would become more significant if a space-enabled step were presented as essential to the quality or availability of a clinically important product.

From a regulatory standpoint, continuity-of-supply questions would therefore arise early. Developers may need to explain fallback manufacturing arrangements, acceptable interruption periods, stock strategy, return-failure contingencies and the circumstances in which a terrestrial substitute process is or is not acceptable.

3.5. Opportunities for regulators

The principal opportunity is preparedness under existing tools. By establishing a consistent, shared understanding, the network can address initial cases without suggesting that a completely new regulatory framework is necessary. The topic also offers a useful test case for broader regulatory capabilities that will matter beyond space: evaluation of advanced manufacturing, handling of data-rich remote evidence, oversight of automated operations, and proportionate engagement with cross-sector

developers. Preparedness should include identifying where jurisdictional or competent-authority questions would need legal and inspection input before any regulated space-based step could be assessed.

The field also illustrates the need to distinguish between scientific interest and regulatory relevance. Not every space-enabled experiment will be material to product quality, evidence generation or benefit-risk assessment. A proportionate regulatory approach should therefore focus on cases where a space-enabled step is claimed to be relevant to medicinal-product development, manufacturing or control.

4. Existing regulatory preparedness

4.1. Current regulatory approaches relevant to the innovation

The current EU medicines framework is broad enough to capture products or manufacturing steps that use the space environment when those products are intended for the Union market. Directive 2001/83/EC and Regulation (EC) No 726/2004 remain the core legal basis for product assessment and supervision (13, 14). From a quality perspective, the risk-based approach reinforced in Annex 1 to EU GMP is particularly relevant because it emphasises contamination-control strategy, environmental control, process understanding and documented risk management rather than a purely prescriptive view of facility design (15).

Lifecycle-management tools are also directly relevant. In the EU, post-authorisation chemistry, manufacturing and controls (CMC) changes are managed primarily through the EU variations framework, including the Variations Regulation and the applicable Variations Guidelines. ICH Q12 is relevant to pharmaceutical product lifecycle management, including established conditions, post-approval change management protocols and regulatory tools intended to support more predictable management of quality-related changes, but it operates in the EU within the applicable variations framework and its EU implementation.

Inspection practice has likewise evolved. Public precedent on remote or hybrid regulatory oversight is no longer exceptional, as shown by EDQM and ICMRA materials (18, 19). None of these tools constitutes space-specific guidance. However, taken together they suggest that the network is not starting from zero. The more accurate description is that the existing framework is usable, but that it has not yet been integrated around this specific topic.

Existing regulatory mechanisms offer opportunities for early interaction and regulatory orientation. Innovation Task Force briefings and scientific advice are the most relevant entry points where developers could explore whether a microgravity-enabled step may become material to medicinal-product development, manufacturing or control. This is also consistent with the broader EMA innovation-support architecture, where novel evidentiary or manufacturing questions are normally surfaced first through early dialogue rather than through creation of a dedicated new pathway. In October 2022, the European Medicines Agency (EMA) refused an orphan designation for melatonin to prevent spaceflight-related radiation and microgravity because the sponsor failed to prove that the condition affects fewer than 5 in 10,000 persons in the European Union. demonstrating that the space context does not itself justify a separate condition. Taken together, this public information supports a proportionate approach in which early cases are handled through existing mechanisms unless repeated

interactions, scientific-advice requests or applications reveal a clearer need for adaptation (16, 17, 21, 25).

This approach is also consistent with the March 2026 EU Innovation Network guidance on available scientific and regulatory support tools at national and European level, which positions National Innovation Office support, ITF briefings, scientific advice and related mechanisms as complementary routes that can be used at different stages of medicinal-product development (25).

Public information from other regulators similarly suggest approaching the topic through existing innovation, scientific-advice or early dialogue mechanisms rather than through dedicated microgravity-specific pathways.

4.2. Existing knowledge / expertise within the regulatory network

The European medicines regulatory network holds much of the component expertise needed for first-line preparedness: GMP inspection, CMC assessment, comparability, lifecycle management, advanced-therapy evaluation, innovation support and cross-network coordination. Those competences are directly relevant to any future case in which a microgravity-enabled step affects a medicinal product intended for the EU market.

The main gap is integrative rather than foundational. Most regulators are not trained in orbital hardware, autonomous payload operation, launch and return constraints, or how microgravity-specific parameters interact with pharmaceutical evidence packages. The current state can therefore be described as moderately prepared, but not yet operationally specialised. The network appears capable of handling exploratory contacts now but would be strengthened by targeted capability building and access to external technical expertise.

5. Recommendations

5.1. Suggested actions to address the challenges and opportunities

• Maintain targeted horizon scanning on microgravity-enabled medicinal product research, development and manufacturing to monitor developments in the field.

• Encourage early, non-binding engagement through existing national and European regulatory support tools for developers considering a space-enabled development or manufacturing step, in line with the March 2026 EU Innovation Network guidance on available scientific and regulatory support tools. Depending on the maturity and nature of the question, relevant routes may include National Innovation Office support, Innovation Task Force (ITF) briefings, scientific advice and other complementary support mechanisms (25).

• Develop an internal first-case assessment note or checklist covering scope, accountability, critical quality attributes, comparability, remote evidence, inspection ability, transport and continuity of supply.

• Consider scenario exercises and short training modules for assessors, inspectors and innovation-support staff. The purpose should be practical familiarity, not deep aerospace specialisation.

• Establish a framework for external technical input, drawing where appropriate on ESA, relevant national space agencies and academic experts in microgravity science, payload engineering and orbital

operations. Where justified, explore coordination with ESA to clarify technical requirements, data standards, operational constraints and access to flight and return infrastructure.

5.2. Possible changes to the regulatory framework (guidance, need for new regulatory approaches)

The evidence analysed does not support immediate creation of a dedicated framework for microgravity pharmaceutical development or manufacturing. The more sensible route is staged adaptation. The regulatory network should rely on existing legislation, GMP, innovation-support routes and lifecycle-management tools. If concrete cases emerge and common patterns become visible, the next step could be dedicated guidance materials covering, for example, scope, accountability, remote evidence, chain of custody and comparability.

5.3. Need for development of additional knowledge / expertise within the regulatory network or access to such knowledge / expertise via external experts

Capability building should be practical and limited to what is needed for first-case readiness. Priority topics include microgravity fundamentals relevant to crystal growth and three-dimensional models; the quality implications of launch, return and long-duration storage; the elements of a credible remote evidence package; and the basic operational characteristics of autonomous payload systems.

A potential model would combine concise e-learning, expert-led workshops, scenario exercises and a small number of focal points who can support early cases. These activities could be coordinated within the regulatory network, with contributions from relevant innovation, quality and inspection experts and, where appropriate, external technical specialists. External expertise will remain important, particularly on payload hardware, orbital operations, environmental control, containment, launch and return logistics, and the limits of what can be credibly monitored remotely.

A first package could include short modules on microgravity fundamentals and the limits of Earth analogues; focused workshops on payload automation, telemetry, data integrity and remote oversight; scenario exercises on comparability, release testing and return-failure contingencies; and a small number of focal points across innovation, quality and inspection functions who can support early cases.

5.4. Identification of regulatory / scientific groups who should be involved in further review / actions relating to this topic

Further review should remain tightly scoped and support effective information-sharing across the relevant innovation, quality, inspection and scientific functions within the regulatory network. The most useful near-term approach is cross-functional coordination between those areas, combined with targeted access to external expertise where questions arise that depend on microgravity science, payload operation, remote process control or return logistics. External engagement should therefore prioritise technical experts who can clarify the operational realities and evidentiary limits of microgravity-enabled activities, rather than broad stakeholder outreach.

ESA and relevant national space agencies are the most relevant public counterparts, complemented by academic experts in microgravity biology, crystallisation, tissue models, formulation, stability science

and remote instrumentation. The aim should be to support regulatory preparedness, not to endorse specific commercial platforms or operators.

Given the international nature of space infrastructure and pharmaceutical supply chains, early information exchange with international regulatory partners may also be useful, where appropriate, to support awareness of emerging approaches and reduce the risk of divergent expectations in first cases.

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7. Appendix

7.1. Methodology

The current state of the field and the key emerging trends described in this report were identified through targeted review of public scientific literature, public materials from space agencies and research infrastructures, public funding calls and programme documentation, public EMA and EU legal and guidance materials, and public information on innovation-support routes relevant to novel manufacturing approaches. The review focused on evidence likely to matter for the European medicines regulatory network within a three- to ten-year horizon.

The report scope was intentionally narrowed to medicinal products intended for terrestrial use whose discovery, development, testing or manufacture may use the space environment at one or more stages. Scientific examples were selected to illustrate plausible areas of relevance - particularly crystallisation, three-dimensional cell models, stability and storage, while regulatory analysis was framed around product quality, evidence, inspection ability, accountability and continuity of supply.

Regulatory challenges and opportunities were informed by the public sources reviewed for the report together with internal expert input used for scoping and draft review. The report was written as a horizon-scanning assessment rather than as a guidance document. Its recommendations therefore focus on regulatory preparedness, staged adaptation and capability building, rather than on immediate creation of new regulatory obligations.

7.2. Complementarity with existing EMA and EU initiatives

This topic aligns with existing work on innovation support, advanced therapies, complex biologics, continuous manufacturing, inspection modernisation and regulatory science. The relevant question is whether a space-enabled step becomes relevant to product quality, evidence generation or supply resilience under existing routes. In that sense, the most useful regulatory analogies may come from other complex manufacturing and evidence domains rather than from creating a separate framework from the outset.

7.3. Stakeholder and ecosystem

The external actors most relevant to follow-up are public space agencies and research infrastructures, academics working on crystallisation, tissue models, formulation and stability, and emerging commercial providers of orbital research or return-capable manufacturing services. For regulatory purposes, these actors matter as sources of technical understanding on payload operation, process control, environmental monitoring, return logistics and the evidentiary limits of current platforms.