Joint Statement from the UK Space Agency, the Medicines and Healthcare products Regulatory Agency, the Regulatory Innovation Office and the Civil Aviation Authority

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UK Space Agency, MHRA, RIO and CAA set out support for in-orbit manufacturing of pharmaceuticals

The UK Space Agency, the Medicines and Healthcare products Regulatory Agency (MHRA), the Regulatory Innovation Office (RIO) within the Department for Science, Innovation and Technology (DSIT) and the Civil Aviation Authority (CAA) are working collaboratively to provide a supportive regulatory environment to space, biopharma and pharmaceutical companies through collaborative work on guidance, regulatory sandboxes, case studies and supply chain engagement.

The UK is committed to advancing its leadership in space-enabled manufacturing. In-Orbit Manufacturing (IOM) is one subset of the wider In-Orbit Servicing, Assembly, and Manufacturing (ISAM) market. It represents a transformative opportunity to produce materials and products in space that offer superior quality and performance compared to those manufactured on Earth.

The UK Space Agency is providing funding for three in-orbit manufacturing feasibility studies including a £250,000 feasibility study for BioOrbit, a pioneering start-up that is designing a scalable in-orbit manufacturing system to crystallise biologic drugs for cancer treatments. This study, funded through the UK Space Agency’s Unlocking Space Portfolio, will involve collaborative work between MHRA, the UK Space Agency and BioOrbit to provide clarity on the regulatory pathway for in-orbit manufacturing of pharmaceuticals.

The microgravity advantage

The unique properties of the microgravity environment enable more precise drug formulation, particularly for biologics and protein-based drugs such as monoclonal antibodies, vaccines, or insulin. Microgravity conditions can improve drug solubility, purity, crystallisation and stability supporting more effective delivery and potentially lowering manufacturing risk and cost.

In-orbit manufacturing of pharmaceuticals offers transformative potential across multiple domains, from precision medicines for oncology and rare diseases to drug stability for remote and crisis-affected populations. This reinforces the UK’s commitment to enabling innovation in pharmaceutical manufacturing. This includes supporting the development of novel modalities that could enhance drug quality, improve supply chain resilience and unlock new therapeutic possibilities for patients. As this sector evolves, the UK remains focused on ensuring the highest standards of safety, quality and regulatory compliance, creating a clear and supportive pathway for innovators while safeguarding public health.

Current Regulatory Framework

Existing medicines regulations are applied to established and novel medicines available to patients and also to potential treatments currently in development. Building on the MHRA's experience in developing innovative and proportionate regulatory pathways, including the MHRA's world-first framework for decentralised and modular manufacturing launched in 2025, the Agency works closely with developers and partners to ensure that existing and future regulations remain fit for purpose for medicines manufactured using advanced and novel manufacturing approaches. This includes manufacturing that may take place in microgravity or other unique environments, where modular manufacturing and atypical distribution practices may occur. This approach enables innovation, providing regulatory clarity and confidence to innovators exploring cutting-edge biomanufacturing methods.

BioOrbit's in-orbit demonstrator feasibility study, funded by the UK Space Agency and running until March 2026, includes specific work to clarify the relevant regulatory requirements for pharmaceutical manufacturing in-orbit. This collaborative work between the UK Space Agency, MHRA and BioOrbit will deliver clarity to space biotech companies on whether existing regulations for terrestrial manufacturing will also apply to manufacturing of pharmaceuticals in-orbit for patient use.

Alongside this, the UK has a flexible and outcome-focussed approach to regulating spaceflight activities, which can accommodate the licensing of novel activities such as operating in-space manufacturing platforms.

For example, see recent demonstration missions such as Space Forge's ForgeStar 1, the UK's first in-orbit manufacturing platform, which was licensed by the Civil Aviation Authority (CAA) and launched in June 2025. This mission, which has since successfully fired up its miniature furnace and generated plasma in orbit, is a British breakthrough in in-orbit manufacturing technology, and has helped set a precedent and framework for licensing in-orbit manufacturing activities. Additionally, the UK has established itself as a frontrunner in licensing other novel emerging technologies, including Astroscale UK's ELSA-D, a world first commercial space debris removal demonstration mission launched in 2021. The UK has established a track record of blazing a trail in licensing novel and emerging ISAM missions in line with its ambitions to continue leadership in these technologies.

While the UK's existing spaceflight legislation under the Space Industry Act 2018 and Outer Space Act 1986 has already provided a flexible framework for licensing such missions, the UK government is working to provide additional clarity to support the predicted growth of manufacturing activities in the emerging in-orbit economy. In line with the recommendations of the Space Regulatory Review 2024 we are therefore developing new guidance products and regulatory sandboxes to support innovators and investors by providing clarity and transparency on the steps to licensing UK operated in-orbit manufacturing platforms.

This will be in line with the UK's non-prescriptive, outcome-focussed approach where spaceflight licence applicants demonstrate what steps they propose to take to ensure that the risks associated with their planned activities are as low as reasonably practicable, including for the re-entry and safe landing of platforms with the manufactured products on board. To support this activity, the Government is launching a Re-entry Regulatory Sandbox. This sandbox will aim to support re-entry activities, such as IOM, and builds on the learnings from the recent Rendezvous & Proximity regulatory sandbox.

The CAA and government are also exploring opportunities to streamline spaceflight licensing processes, in particular to support progression to larger-scale, higher cadence operations.

The UK's modern legislative frameworks for human medicines and spaceflight activities represent a unique opportunity to demonstrate a clear end-to-end regulatory pathway for UK in-space manufactured pharma products. To promote investment into the UK and support innovators seeking to seize this opportunity, the UK Space Agency and MHRA are collaborating to produce principles-based case studies which illustrate the regulatory pathway to be followed by space, biotech and pharmaceutical companies.

Potential applicants for UK operated In-Orbit Manufacturing platforms are encouraged to engage with the CAA as early as possible to discuss proposed missions by contacting the CAA at commercialspaceflight@caa.co.uk. Further information on the licensing process can be found here - Space licensing in the UK.

Government initiatives

Alongside providing regulatory clarity through the production of joint case studies with the MHRA, the UK Space Agency is leading a wide range of initiatives to drive growth and development of the in-orbit pharmaceuticals sector. This work contributes directly to the ambitions of the Life Sciences Sector Plan and the Modern Industrial Strategy 2025 to support economic growth and strengthen health outcomes for the United Kingdom. These actions are intended to provide coordinated support and clarity to the supply chain on the adoption pathway. UK Space Agency interventions include:

Unlocking demand signals and driving engagement and sector understanding:

- Engaging with the NHS and biopharma supply chain through events and workshops, to build user demand and explore the barriers faced by different public and private sector organisations along the adoption pathway.

- Undertaking a literature review of experiments on the International Space Station on pharmaceuticals and biologics, to identify the UK's competitive advantage and capabilities for future focused development.

- Inaugural UK-Swiss Dialogue in June 2026, bringing experts and senior decisionmakers from space and pharma together for the first time, to identify challenges and solutions to advance microgravity for biopharma R&D.

Technology, infrastructure and R&D capability development:

- UK Space Agency Space Clusters Infrastructure Funding including £8 million provided in 2023 to Cardiff-based Space Forge, for a National Microgravity Research Centre, embedded within the Centre for Integrative Semiconductor Materials in Swansea, Wales.

- Funding in-orbit manufacturing feasibility studies including a £250,000 BioOrbit feasibility study for a scalable in-orbit manufacturing system designed to crystallise biologic drugs. BioOrbit was also supported through the UK Space Agency Accelerator, a national programme which provides tailored support to UK-based entrepreneurs in the space sector to help accelerate their growth.

- The National Space Innovation Programme (NSIP) has invested around £2.2m in grants to support innovative in-orbit manufacturing technologies. These include funding to support: Frontier Space Technologies, to improve their microgravity research SpaceLab to support development of pharmaceuticals, drug discovery, materials and industrial biotechnology; Biologic Technologies, to develop their “Space Biocomputer” to enable bio-manufacturing capabilities for products such as RNA medicines; Imperial College London to develop cold spray metal additive manufacturing for applications in space; Space Forge to develop a retractable solar array to power their in-space manufacturing satellite platform; University of Glasgow to develop a Earth-based rig to test additive manufacturing materials under space conditions; and University of Leicester to develop on-orbit welding capability to enable repair and manufacture of structures in space.

- Funding UK-led international projects supporting biotechnology research in microgravity and astronaut healthcare, through the UK Space Agency’s International Bilateral Fund.

Access to finance:

- £13 million UKI2S Space Portfolio, an evergreen pre-seed and seed stage fund which is actively open to considering all space opportunities including life science space companies.

MHRA Collaboration

To complement these UK Space Agency commitments, the MHRA is contributing to the development of a supportive regulatory environment for novel, space-enabled manufacturing processes. This includes:

- Joint case study development: Producing collaborative case studies with the UK Space Agency to clarify regulatory expectations and illustrate real-world pathways for developers.

- Facilitating Scientific and Regulatory Advice meetings: Supporting developers through early engagement with MHRA experts to clarify requirements, expectations, and best regulatory practices within existing frameworks.

- Innovation Accelerator involvement: Continuing to develop industry and academic engagement through the MHRA Innovation Accelerator, ensuring proactive thinking and guidance for emerging space-enabled biomanufacturing technologies.

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