IAF MICROGRAVITY SCIENCES AND PROCESSES SYMPOSIUM (A2)
In-Space Manufacturing and Production Applications (8)

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MANUFACTURING BETTER DRUGS IN MICROGRAVITY

Abstract

To enable a thriving Low Earth Orbit (LEO) economy, there is a push to do more research leading to manufacturing in LEO with fewer flights. The Redwire Pharmaceutical In-space Laboratory (PIL) aims to do just that. The push to find new polymorphs and improve crystalline uniformity for the pharmaceutical industry have become a major focus for scientists and engineers not just in the pharmaceutical and biotechnology industries, but also the agricultural, food, and body care products worlds. The PIL family of hardware proposes to be the first hardware that can not only crystallize small and large molecule drugs but can track the process with real time video using dynamic microscopy. PIL can make a small quantity of seed crystals that can be used to create large quantities of crystals terrestrially – making PIL the first step toward a manufactured product in space for terrestrial use. Pharmaceuticals often are best formulated as crystals. The crystalline state is the most stable of matter. Small and large molecule drugs both suffer from polymorphism and size coefficients of variation that are too large. Some drugs can overcome these issues and make it to market many more cannot and fail. A potential solution to these problems was seen in the result found in the microgravity enabled crystal growing experiment of the monoclonal antibody, Pembrolizumab marketed by Merck as Keytruda. In on-orbit crystallization studies Keytruda produced crystals with significant uniformity (something not done on Earth where mixtures of crystals are produced) and size coefficients of variation below 8The PIL-BOX suite of hardware directly addresses the rising demand for crystalline pharmaceutical forms with improved stability, more convenient delivery, and new options for routes of administration. PIL allows us to go after products that are made on a large scale terrestrially without worrying that those billion-dollar products need to be made on a very large scale in space, this the value of the product is independent of the ultimate production volume.