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Abstract

Laser powder bed fusion (LPBF) for the manufacturing of oral medication

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Patient-centric treatments improve over traditional treatment paradigms. Traits that influence the underlying disease, drug absorption, metabolism, or excretion are considered for small patient populations or individuals and inform therapies. This leads to a demand for small batch or even individual batch manufacturing of oral medication, which contrasts with traditional large-scale, high-throughput manufacturing. While different additive manufacturing (AM) technologies are investigated, they focus mainly on Point-of-Care preparation in decentralized settings.

We investigate laser-based powder bed fusion (LPBF) as a scalable technology for the industrial manufacturing of oral medications. Pharmaceutical LPBF differs significantly from processes in other industries. In all cases, material blends comprising at least a suitable thermoplastic, usually polymeric, binder and an active pharmaceutical ingredient (API) are used. Due to a tightly regulated material space, variations of raw materials are prohibited, and existing materials developed for other manufacturing processes must be used. This presentation will focus on the processing of different materials and quality control aspects during the LPBF process.

We show how fluidized bed processing can be utilized to significantly reduce the amount of binder, enabling printing of blends containing 90 % (w/w) API and only 10 % (w/w) binder, and opening the technology to high-dose drug substances. We demonstrate that the use of material blends can even have benefits for the fusion process. By avoiding polymers and using sugar alcohols as small molecular binders, we exploit the formation of eutectic mixtures in the fusion process. This enables a strong reduction of the energy density from 1.0 J/mm^3 to 0.5 J/mm^3, limiting the thermal stress on potentially thermo-sensitive APIs [1].

The last part of this presentation highlights a quality assurance approach to monitor the integrity of the powder layer and identify potential layering defects. We compare two machine learning algorithms (PointNet++ and a Convolutional Neural Network (CNN)) to process and classify point-cloud data from 3D surface layer scans of a variety of materials. While the algorithms perform comparably (label accuracies of 0.956 ± 0.003 and 0.951 ± 0.003, instance accuracies of 0.885 ± 0.005 and 0.881 ± 0.005), the inference times differ by a factor of 400 (218 ± 22 ms vs. 0.5 ± 0), highlighting the benefits of the CNN model for real-world deployment.

AUTHOR'S STATEMENT

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