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Abstract

Translating additively manufactured medicinal products into clinical applications

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An increasingly important application of additive manufacturing (AM) is the production of 3D printed pharmaceutical products and drug–device combination systems. These technologies expand the capabilities of conventional AM by enabling localized and controlled drug delivery directly at the site of therapeutic action. Despite their significant potential, the translation of such systems into clinical use presents substantial scientific, regulatory, and manufacturing challenges. Local therapy of the inner ear is an active field of research because systemic drug administration often fails to achieve sufficient therapeutic concentrations within the cochlea while potentially causing systemic side effects. To enable effective drug therapies of inner ear diseases we developed a patient-individualized, additively manufactured implant for placement in the round window niche of the middle ear, the round window niche implant (RNI). The implant is produced by direct ink writing and incorporates dexamethasone within a mechanically elastic matrix material. The geometry of the implant is designed to fit securely within the round window niche, thereby ensuring stable positioning and prolonged drug diffusion into the inner ear. Following extensive preclinical characterization, including drug release studies, biocompatibility and bioefficacy testing in vitro and in animal models, and evaluation of mechanical and handling properties, the project is now transitioning into the clinical phase. We are preparing for a first-in-human clinical study. The aim of the study is to evaluate the safety, feasibility, and preliminary therapeutic effects of sustained local dexamethasone delivery in the context of cochlear implantation, where inflammatory responses and fibrosis can negatively impact hearing preservation and implant performance. Since the sole function of the RNI is to deliver the active substance, it falls primarily under pharmaceutical legislation for the clinical trial and therefore must comply with the Clinical Trials Regulation (CTR) EU 536/2014 and ICH E6(R3) GCP guideline. However, the Medical Device Regulation (MDR) and ISO 14155 must not be disregarded, as the medical device component also plays a role in ensuring patient safety. Beyond the technical aspects of implant development, we will address the regulatory and manufacturing requirements associated with pharmaceutical AM. In particular, we will provide insights into the process of establishing a manufacturing authorization under Good Manufacturing Practice (GMP) guidelines for individualized additively manufactured medicinal products. By sharing our experiences, we aim to highlight both the opportunities and the challenges associated with translating 3D printed drug-delivery implants from laboratory research into clinical application. Furthermore, we hope to provide practical guidance for researchers and institutions seeking to navigate the complex regulatory landscape of medicinal additive manufacturing and to avoid common pitfalls during the implementation of GMP-compliant production processes.

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