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Advancements in Pharmaceutical Dosage Forms through 3D Printing: A Tailored Medicine Approach

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Abbreviation

P4: Predictive, Preventive, Personalized, and Participatory.

Introduction

Tailored medicine, often termed precision medicine as well as personalized medicine, is a medical model that categorizes individuals into distinct groups, with medical decisions, practices, interventions, and products customized based on each patient's anticipated response or disease risk. The terms tailored medicine, personalized medicine, precision medicine, stratified medicine, and P4 medicine are frequently used interchangeably to describe this approach, some authors and organizations distinguish between these terms based on specific nuances. P4 medicine stands for 'predictive, preventive, personalized, and participatory. Personalized medicine aims to guide patients in selecting the appropriate medication at the right dosage and timing. Researchers have been investigating innovative approaches to advance personalized medicine, such as molecular diagnostics, pharmacogenomics, genetic profiling, artificial intelligence, and three-dimensional printing technology. Numerous technologies are emerging that facilitate a shift from the conventional 'one size fits all' approach to personalized medicine, with three-dimensional printing being a key player. 3D printing involves the layer-by-layer fabrication of three-dimensional objects using various computer software. This technology enables the creation of diverse pharmaceutical dosage forms, each differing in shape, release profiles, and drug combinations. The primary 3D printing technologies explored in the pharmaceutical sector include inkjet printing, binder jetting, fused filament fabrication, selective laser sintering, stereolithography, and pressure-assisted micro syringe [1].

This editorial discusses key aspects of 3D printing technologies in pharma and health sciences. 3D printing has demonstrated significant value in various medical applications, such as tissue engineering, bioprinting of organs like hearts, and bone reconstruction. The additive manufacturing techniques have also been applied to drug production, with SPRITAM® becoming the first 3D-printed drug to reach the market in 2015, launched by Aprecia Pharmaceuticals. This pioneering approach is increasingly attracting the attention of pharmaceutical companies, who recognize the potential advantages of 3D printing for optimizing the entire lifecycle of medicines.

Unique Advantages of 3d Printing in Health Sciences

3D printing holds the potential to transform the pharmaceutical industry, and several companies are leading the way in this innovation. Notable among them are Aprecia Pharmaceuticals- USA, FabRx- UK, Merck-Germany, Triastek-China, and GlaxoSmithKline-UK [2].

Accelerate Drug Discovery and Development: By leveraging 3D printing technology, multiple batches of pills with varying formulations can be rapidly produced for in vitro, preclinical, or clinical trials. This approach facilitates the accelerated identification of critical parameters that

influence drug efficacy and safety. Unlike traditional manufacturing methods, 3D printing allows for the earlier collection of essential data during drug development, thereby expediting the initiation and completion of clinical trials and significantly reducing both development time and associated costs.

On-Demand Drug Manufacturing: 3D printing enhances healthcare accessibility by significantly reducing pharmaceutical development timelines and enabling on-demand drug manufacturing. Instead of relying solely on large-scale production facilities, medications can be produced locally at various sites, such as pharmacies or hospitals. This decentralized approach not only improves access to medicines by reducing patient wait times—particularly for rare diseases where production capabilities may be scarce—but also minimizes transportation costs [3].

Tailored Treatments: 3D printing technologies offer the capability to produce personalized medications tailored to patients who need specific dosages based on their weight, size, or medical condition. This is especially relevant for certain patient groups, such as geriatric and pediatric populations, where treatments often need to be adjusted to accommodate changes in physiological and metabolic functions [4].

Control/Change/Modification of API Release Rate: The precise compartmentalization of active ingredients within a single tablet can lead to the creation of tablets with tailored delivery profiles, allowing for release rates that are customized to meet the specific needs and indications of the patient. Numerous studies have established a connection between the geometry of a drug and the release kinetics of its active ingredient. 3D printing offers a method to explore various pill geometries, enabling the personalization of the active ingredient's release rate [5].

Polymedication Control: A patient managing multiple health conditions and taking several tablets daily could benefit from 3D printing technology, which allows for the creation of a single pill containing all the necessary active ingredients for their treatment. Polymedication is common, combining multiple active ingredients at personalized dosages into a single pill offers a tailored alternative, reducing the number of medications taken and ensuring doses are precisely adapted to the patient's needs.

Integration with Digital Health: 3D-printed drugs hold the potential for enhanced integration with digital health technologies, including wearable devices and mobile health apps. Through the use of 3D printing, patients can receive real-time updates on their medication status and easily access their medical records from any location, thereby enhancing the overall patient experience. Moreover, digital health technologies can provide patients with medication reminders and tools to monitor their symptoms, ultimately leading to improved health outcomes [6].

Challenges of 3d Printing in Health Sciences

Lack of Regulation: As 3D printing is still a young technology, there is no clear guidance to create strict regulatory controls for ensuring medical devices are produced from these methods: whether they follow safety and efficiency standards. Absence of uniform protocols and holistic regulatory frameworks renders it unclear for validation or quality control with 3D printed medical devices. The gap in the literature serves to highlight that widespread research and interdisciplinary partnerships are required for regulatory bodies, producers, doctors, etc. if guidelines can be developed with clarity on how exactly these issues should be practically tackled within this new technology [7].

Cost: One of the biggest hurdles to the widespread use of 3D printing within healthcare is all that cost—between the printers themselves and those materials. While 3D printer prices have been falling for some time, they are still expensive to the point where only hospitals with disposable income can afford them. Additionally, 3D printing materials are generally more costly than conventional manufacturing materials as well which is another issue making this bleeding-edge technology less economically implementable in routine medical practice. This is a financial wall placed in front of the very real need to make 3D printing more practical and economically viable for healthcare applications [7].

Quality: The requirement for in-depth quality assurance of 3D printed components is a significant bottleneck within the field, significantly among pharmaceutical and medical bioprinting applications. A hot topic in numerous fields that goes all the way to pharmaceutical dosage forms, medical devices, and even bioengineered organs. It is, therefore, critical that the 3D printed outputs are of the required quality and safety standards since even slight deviations could have drastic consequences on patient health and treatment results. While the 3D printing process and materials introduce additional layers of complexity to quality control, robust testing protocols and regulatory standards are needed for manufacturers looking to maintain reliability across their processes that meet or exceed industry benchmarks [8].

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