3D Printing Technologies for Personalised Pharmaceutical Dosage Forms: Advances, Opportunities and Regulatory Challenges

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***Abstract*—The emergence of three-dimensional (3D) printing technologies has fundamentally transformed the landscape of pharmaceutical manufacturing, offering unprecedented opportunities for the fabrication of personalised dosage forms tailored to individual patient needs. This comprehensive review examines the current state of 3D printing in pharmaceutical sciences, encompassing a wide spectrum of technologies including fused deposition modelling (FDM), stereolithography (SLA), selective laser sintering (SLS), inkjet-based printing, and binder jetting. We critically evaluate the scientific advances enabling dose customisation, complex release kinetics, polypill fabrication, and patient-specific geometries. Furthermore, this review explores clinical opportunities for precision medicine in paediatric, geriatric, and oncology settings. The regulatory landscape is analysed with reference to frameworks from the United States Food and Drug Administration (FDA), the European Medicines Agency (EMA), and international guidance bodies. Key challenges including material validation, Good Manufacturing Practice (GMP) compliance, quality control, intellectual property considerations, and scalability are discussed in depth. The integration of artificial intelligence (AI), digital pharmacies, point-of-care manufacturing, and bioprinting as emerging frontiers is also explored. This review identifies critical knowledge gaps and provides a forward-looking perspective on the path from bench to bedside for 3D-printed pharmaceuticals.** [1,2,3]

***Index Terms*—3D printing; additive manufacturing; personalised medicine; pharmaceutical dosage forms; FDM; SLA; SLS; inkjet printing; FDA; EMA; regulatory compliance; polypill; sustained release; point-of-care manufacturing.**

I. INTRODUCTION

The conventional pharmaceutical manufacturing paradigm has long operated on a one-size-fits-all model, producing standardized dosage forms designed for an "average" patient. This approach, while efficient at industrial scale, fundamentally fails to account for the enormous inter-individual variability in pharmacokinetics, pharmacodynamics, body weight, renal and hepatic function, age, genetic polymorphisms, and co-morbidities that collectively determine therapeutic response. The concept of personalised medicine delivering the right drug, at the right dose, to the right patient, at the right time has gained considerable momentum since the mapping of the human genome and the emergence of precision oncology. [1,4]

Three-dimensional (3D) printing, formally termed additive manufacturing (AM), has emerged as a transformative technology capable of bridging the gap between pharmaceutical science and personalised medicine. Unlike subtractive manufacturing, which removes material from a solid block, 3D printing

constructs objects layer by layer from digital design files, enabling extraordinary control over geometry, composition, and internal architecture.[2,5] Since the landmark approval of SPRITAM® (levetiracetam) by the US FDA in 2015 the world's first 3D-printed drug product to receive market authorisation the field has witnessed exponential growth in both scientific publications and commercial investment.[6]

The pharmaceutical applications of 3D printing span an impressive range: fabrication of dosage forms with complex geometrical shapes improving swallowability; production of polypills combining multiple active pharmaceutical ingredients (APIs) in a single tablet to simplify complex medication regimens; creation of modified-release profiles not achievable through conventional tabletting; and manufacture of age-appropriate formulations for paediatric and geriatric populations.[7,8,9] In hospital pharmacy and point-of-care settings, 3D printing holds the potential to decentralise pharmaceutical production, enabling on-demand fabrication of customised doses.[10]

Despite this remarkable promise, significant scientific, technological, and regulatory hurdles remain. Current 3D printing processes for pharmaceuticals must contend with limited material (excipient) libraries, challenges in demonstrating reproducibility and quality consistency, intellectual property complexities in distributing digital formulation files, and the absence of universally adopted regulatory pathways for approved 3D-printed medicines. The regulatory frameworks of the FDA, EMA, and other international bodies are only beginning to evolve to accommodate this disruptive technology.[11,12]

This review provides a comprehensive, critically evaluated synthesis of the literature on 3D-printed pharmaceutical dosage forms. It is structured as follows: Section 2 provides a technical overview of the major 3D printing modalities employed in pharmacy; Section 3 examines materials and formulation considerations; Section 4 discusses clinical applications and opportunities; Section 5 analyses the regulatory landscape; Section 6 addresses key challenges; Section 7 explores emerging frontiers; and Section 8 presents conclusions and future perspectives.[3]

II. 3D PRINTING TECHNOLOGIES IN PHARMACEUTICAL SCIENCE

A diverse array of 3D printing technologies has been investigated for pharmaceutical applications. Each modality differs in its working principle, materials compatibility, achievable resolution, throughput, and suitability for drug loading. The following subsections provide detailed technical analyses of each approach.[2,13]

III. FUSED DEPOSITION MODELLING (FDM)

Fused deposition modelling is the most widely studied 3D printing technology in pharmaceutical research, largely due to its accessibility, cost-effectiveness, and compatibility with a broad range of thermoplastic polymers. In FDM, a solid filament of drug-polymer composite is fed through a heated nozzle, melted, and extruded onto a build platform in a layer-by-layer fashion, following a computer-generated path derived from a stereolithography (STL) file.[14] The critical process parameters governing FDM printing quality include nozzle temperature, print speed, layer height, infill density, and build orientation. Drug-loaded filaments are typically produced by hot-melt extrusion (HME) prior to printing, where the API is homogeneously dispersed within a thermoplastic carrier matrix.

Common pharmaceutical-grade polymers employed in FDM include Kollidon® VA 64 (copovidone), Eudragit® RL/RS/L (polymethacrylates), hydroxypropyl methylcellulose acetate succinate (HPMCAS), and polyvinyl alcohol (PVA).[15,16]

A significant challenge in FDM is the thermal degradation of thermolabile APIs during both HME and printing. Several strategies have been explored to mitigate this, including solid dispersion formation, the use of plasticisers to lower processing temperatures, and the selection of polymers with low glass transition temperatures (Tg).[17] Notable pharmaceutical FDM achievements include the fabrication of gastroretentive star-shaped dosage forms capable of residing in the stomach for extended periods, flexible printlets with adjustable drug release kinetics through infill modification, and multi-compartmental tablets enabling the combination of incompatible APIs.[18,19,20]

IV. STEREOLITHOGRAPHY (SLA) AND DIGITAL LIGHT PROCESSING (DLP)

Stereolithography operates through the photo polymerisation of liquid resin by a focused ultraviolet (UV) laser beam. Digital light processing (DLP) is a related vat photo polymerisation technique that employs a digital light projector to cure entire layers simultaneously, offering superior printing speed. Both technologies achieve higher resolution than FDM, typically in the range of 25–100 μm, enabling the fabrication of highly intricate microstructures. [21,22] For pharmaceutical SLA/DLP, photoreactive resins must be formulated from biocompatible, pharmaceutical-grade monomers and photo initiators. Commonly investigated systems include poly (ethylene glycol) diacrylate (PEGDA)-based resins, methacrylate hyaluronic acid, and Eudragit®-based photopolymers.[23] Drug loading is achieved by dissolving or suspending the API directly within the photoreactive resin prior to printing. An important limitation is the requirement for photostability and solubility of the drug within the resin system. Emerging two-photon polymerisation (2PP) variants of SLA offer nanoscale resolution and are being explored for microdevice fabrication.[24]

Clinical-grade SLA has been demonstrated for the fabrication of paediatric chewable tablets, implantable drug delivery devices, and personalised ocular drug delivery systems. The SprintRay® and Formlabs Form series printers are among commercial platforms investigated for pharmaceutical SLA, though dedicated pharmaceutical-grade hardware remains an active area of development.[25,26]

V. SELECTIVE LASER SINTERING (SLS)

Selective laser sintering utilises a high-powered infrared laser to selectively fuse powder particles layer by layer. The powder bed acts as a self-supporting structure during printing, eliminating the need for support materials and enabling complex geometric features. SLS is notable for its high drug loading capacity, absence of solvents or binders, and compatibility with a range of thermoplastic powders including polyamides, polyethylene, and pharmaceutical excipients such as Kollidon® K90, Eudragit® RS, and mannitol.[27,28] Becker et al. (2021) demonstrated SLS fabrication of controlled-release tablets with complex core-shell architectures capable of achieving pulsatile drug release profiles not reproducible by conventional compression. The residual powder surrounding printed objects can be reclaimed and reused, reducing material waste.[29] Temperature sensitivity of APIs remains a concern in SLS, though emerging near-infrared (NIR) absorbing agents as sintering aids have enabled processing at reduced temperatures, broadening the range of compatible APIs.[30]

VI. INKJET-BASED PRINTING

Inkjet printing encompasses two principal modalities: drop-on-demand (DoD) and continuous inkjet (CIJ). In pharmaceutical applications, DoD inkjet particularly piezoelectric and thermal variants has attracted the most attention. Drug-containing ink droplets (typically 1–100 pL) are precisely deposited onto substrates including edible wafers, transdermal patches, and oral thin films.[31,32] The exceptionally low volume per droplet confers remarkable dose flexibility, theoretically enabling dose adjustments at microgram precision. This feature is particularly valuable in paediatric dosing, where therapeutic windows are narrow and dose individualisation is critical. Inkjet systems from Dimatix (Fujifilm), Spectra, and adapted office-type ink-jet platforms have been employed in pharmaceutical research.[33] Key formulation challenges include optimising ink viscosity (typically 1–30 mPa·s), surface tension (20–50 mN/m), and preventing nozzle clogging from particle-laden inks. Inkjet-printed orodispersible films loaded with ondansetron, haloperidol, and warfarin have been reported in recent clinical feasibility studies.[34,35]

VII. BINDER JETTING TECHNOLOGY (BJT)

Binder jetting technology, the platform underlying the FDA-approved SPRITAM® tablet, selectively deposits a liquid binder solution onto layers of powder bed to construct a three-dimensional object. The resulting porous structure, when applied to pharmaceutical powders, yields tablets with extraordinarily high porosity and rapid disintegration times (as low as 11 seconds in water), making it ideally suited for patients with swallowing difficulties.[6,36]

The Aprecia Pharmaceutical Company's ZipDose® technology platform, which underlies SPRITAM®, demonstrated that levetiracetam doses up to 1000 mg could be incorporated into a rapidly dissolving porous matrix not achievable by conventional processes. Subsequent research has explored BJT for loading poorly water-soluble drugs through amorphous solid dispersion strategies, as well as for combination products.[37]

VIII. PRESSURE-ASSISTED MICROSYRINGE (PAM) AND EXTRUSION-BASED SYSTEMS

Pressure-assisted micro syringe and related extrusion-based printing systems deposit semi-solid or paste-like pharmaceutical formulations through a syringe nozzle under pneumatic or mechanical pressure. These systems are particularly valuable for heat-sensitive biologics, hydrogels, and semisolid preparations that cannot withstand the high temperatures of FDM.[38] PAM has been employed for fabricating personalised transdermal patches, suppositories, effervescent tablets, and implants. The low processing temperature (often room temperature to 37°C) preserves API integrity, and the technology is compatible with aqueous hydrogel matrices containing natural polymers such as gelatine, alginate, and hyaluronic acid

Table 1. Comparative overview of major 3D printing technologies for pharmaceutical applications

Technology	Principle	Resolution (μm)	Temperature	Drug Loading	Key Advantage	Key Limitation
FDM	Thermal extrusion	100–300	High (120–280°C)	Up to 50%	Low cost; widely available	Thermal degradation risk
SLA/DLP	Photo polymerisation	25–100	Ambient	Up to 30%	High resolution; complex geometry	Photo initiator toxicity
SLS	Laser sintering	80–250	Moderate	Up to 40%	No binder; self-supporting	Expensive equipment
Inkjet	Droplet deposition	20–50	Ambient	Low (<5%)	High dose precision; flexible substrate	Low throughput; clogging
BJT/ZipDose	Binder+powder bed	150–300	Ambient	Up to 70%	Rapid disintegration; high dose	Mechanical fragility
PAM/Extrusion	Pneumatic extrusion	200–500	Low (RT–37°C)	Variable	Heat-sensitive APIs; hydrogels	Low resolution

IX. MATERIAL AND FORMULATION CONSIDERATION

The selection of appropriate pharmaceutical-grade materials is arguably the most critical determinant of 3D printing success in drug product development. Materials must simultaneously satisfy printing process requirements (e.g., melt viscosity, photo reactivity, powder flowability) and pharmacopoeia standards for safety, biocompatibility, and drug release behaviour.[40]

X. POLYMERIC EXCIPIENTS FOR FDM AND SLS

Hot-melt extrusion (HME) and subsequent FDM printing require polymers with appropriate rheological behaviour at processing temperatures, typically characterised by melt viscosity in the range of 100–10,000 Pa·s. Kollidon® VA 64 (copovidone) is among the most widely employed FDM carriers due to its broad compatibility, low Tg (~70°C), and ability to maintain APIs in amorphous solid dispersion.[15,41] Hydroxypropyl methylcellulose (HPMC), HPMCAS, and Eudragit® grades offer pH-dependent or time-dependent release functionalities that can be engineered through material selection and printing architecture.[42] Plasticisers including triethyl citrate (TEC), polyethylene glycol (PEG), and triacetin are routinely incorporated to reduce processing temperatures and improve filament flexibility. The hot-melt extrusion and FDM process windows must be carefully established through thermal analysis (DSC, TGA) and rheological characterisation to ensure API stability and printing fidelity.[43]

XI. PHOTOPOLYMERISABLE RESINS FOR SLA/DLP

For SLA/DLP applications, the design of biocompatible photopolymerisable resins with controllable mechanical properties and predictable drug release represents a significant formulation challenge. PEGDA (poly(ethylene glycol) diacrylate) of varying molecular weights (Mn 200–6000 Da) is the most extensively studied platform, offering tuneable crosslink density and consequent variation in drug diffusion rates.[23,44] The degree of crosslinking inversely correlates with drug permeability, providing a powerful handle for modulating release kinetics. Recent work has extended this to methacrylate gelatine (GelMA), methacrylate hyaluronic acid (HAMA), and mixed resin systems for bioinspired controlled-release matrices.[45]

Photo initiators must be selected from regulatory-accepted materials and included at the lowest effective concentration. Approved or GRAS-listed candidates include lithium phenyl-2, 4, 6-trimethylbenzoylphosphinate (LAP), riboflavin (in the presence of NTP co-initiator), and camphor quinone/amine systems for visible-light curing. The potential for residual photo initiator and unreacted monomer accumulation in final products necessitates rigorous biocompatibility testing in accordance with ISO 10993 and ICH Q3D guidelines.[46,47]

XII. POWDERS AND BINDERS FOR SLS AND BJT

SLS requires powder materials with appropriate particle size (typically 10–100 μm), narrow size distribution, good flowability (Carr Index <25), and minimal moisture content. Pharmaceutical-grade excipients such as mannitol, lactose, trehalose, copovidone, and Eudragit® RS have been characterised for SLS compatibility.[48] The coefficient of thermal expansion, specific heat capacity, and absorption properties at the laser wavelength (typically 10.6 μm CO2 or 1064 nm Nd:YAG) govern sintering quality and require systematic process characterisation through design of experiments (DoE) approaches.[49]

In BJT (binder jetting), the binder solution must rapidly penetrate the powder bed and bind particles without causing excessive spreading. Pharmaceutical binders including aqueous PVP, HPC, and HPMC solutions have been optimised for this application. Post-printing curing or drying steps are typically required to achieve the desired mechanical strength and drug distribution uniformity.[37]

XIII. DRUG RELEASE MECHANISM ENGINEERING THROUGH ARCHITECTURE

One of the most compelling advantages of 3D printing in drug product design is the ability to engineer drug release profiles through geometric and architectural manipulation of the dosage form, independent of or in combination with conventional formulation approaches. The infill density, infill pattern (gyroid, honeycomb, rectilinear), shell thickness, and surface-to-volume ratio of 3D-printed tablets can be systematically varied to modulate the rate and mechanism of drug release.[50,51]

Zero-order, first-order, biphasic, pulsatile, and sigmoidal release profiles have all been demonstrated through architectural manipulation of 3D-printed dosage forms. Goyanes et al. (2015) demonstrated that varying infill density from 20% to 100% in FDM-printed salicylic acid tablets resulted in proportional changes in dissolution rate, providing a simple approach to dose adjustment.[19] More sophisticated multi-compartmental architectures, enabled only by 3D printing, have achieved complex dual-pulse or chronotherapeutic release profiles, particularly relevant for conditions such as hypertension, asthma, and rheumatoid arthritis with circadian rhythm dependence.[52]

XIV. CLINICAL APPLICATION AND THERAPEUTIC OPPORTUNITIES

The EMA and FDA have issued regulatory guidance emphasising the need for age-appropriate formulations for children, recognising that off-label dose manipulation of adult tablets cutting, crushing, compounding introduces unacceptable dose variability and carries contamination risks. 3D printing offers a solution: dose-flexible, child-appropriate solid or semisolid forms that can be precisely dosed to weight (mg/kg).[55] Shapes and flavours designed to improve palatability and adherence stars, dinosaurs, cartoon characters

embedded in the dosage form design have been explored and shown to reduce the administration challenges common in paediatric practice.[56,57]

Clinical studies from Great Ormond Street Hospital (GOSH) in collaboration with UCL have pioneered FDM-printed 'printlets' of budesonide, prednisolone, and hydrocortisone for paediatric patients with adrenal insufficiency and inflammatory bowel disease, demonstrating acceptable palatability, drug content uniformity, and dissolution behaviour compared to extemporaneous liquid formulations.[58,59]

XV. GERIATRIC DOSAGE FORM CHALLENGES

The geriatric population presents a distinct set of challenges including polypharmacy (defined as the concurrent use of five or more medications, prevalent in over 40% of adults over 65), dysphagia affecting 15–22% of community-dwelling elderly, and altered pharmacokinetics due to reduced renal and hepatic function, decreased lean body mass, and changes in gastrointestinal motility.[60,61] 3D printing addresses multiple geriatric needs simultaneously: polypill fabrication combining multiple drugs into a single dosage form to reduce pill burden; ultra-thin, rapidly dissolving orodispersible films and tablets for dysphagia patients; and dose adjustment capabilities for renally impaired patients without recourse to tablet splitting or liquid preparation. A study by Khaled et al. (2015) demonstrated the first 3D-printed polypill incorporating five drugs captopril, nifedipine, glipizide, aspirin, and atorvastatin with targeted release kinetics for each component, representing a major proof-of-concept for cardiovascular polypharmacy simplification.[62,63]

XVI. ONCOLOGY AND PRECISION MEDICINE

Oncology presents unique challenges and opportunities for 3D-printed personalised therapeutics. The highly variable pharmacokinetics of chemotherapeutic agents, narrow therapeutic indices, weight-based dosing requiring precision, and frequent dose adjustments based on toxicity all create a compelling case for personalised 3D-printed oral chemotherapy dosage forms.[64] Commercially, erlotinib, capecitabine, and temozolomide have been investigated as candidate APIs for personalised oral oncology printlets, with demonstrated dose uniformity within the limits required by pharmacopeial specifications.[65] Implantable 3D-printed drug delivery devices represent another emerging oncology application, enabling localised chemotherapy delivery directly to tumour resection sites. Such devices can be fabricated intraoperatively from patient-specific tumour geometry data derived from CT/MRI imaging, allowing complete anatomical fit and prolonged local drug delivery. Biodegradable PLGA-based 3D-printed implants loaded with temozolomide have shown promising results in glioblastoma animal models.[66]

XVII. POLYPILL DEVELOPMENT FOR CHRONIC DISEASE MANAGEMENT

The polypill concept combining multiple preventive or therapeutic agents into a single fixed-dose combination has received considerable attention as a strategy to improve adherence to chronic disease regimens, particularly for cardiovascular risk reduction. Conventional manufacturing of polypills is constrained by drug-drug incompatibilities, differential release requirements, and the complexity of ensuring uniform content of each component.[67] 3D printing uniquely enables spatially separated, multi-compartmental architectures in which incompatible APIs are physically isolated, and each component is associated with its own release-modulating matrix. Placebo-controlled clinical feasibility studies of 3D-printed polypills have demonstrated therapeutic drug concentrations and pharmacokinetic profiles comparable to individual reference products.[68]

Table 2. Selected clinical and pre-clinical studies of 3D-printed pharmaceutical dosage forms

Drug / Application	Technology	Patient Group	Key Finding	Reference
Levetiracetam (SPRITAM®)	BJT/ZipDose®	Epilepsy (adult)	First FDA-approved 3D-printed drug; rapid disintegration (<11 s)	[6]
Budesonide printlets	FDM	Paediatric IBD	Acceptable palatability; dose uniformity within ±5%	[58]
Hydrocortisone 0.5–20 mg	FDM	Paediatric adrenal	Dose flexibility; favourable stability	[59]

5-Component polypill	FDM/extrusion	Cardiovascular	Individualised release profiles for 5 APIs	[62]
Prednisolone 1–25 mg	SLA	Paediatric	High print fidelity; photostable drug	[25]
Ondansetron oral film	Inkjet	Paediatric emesis	Dose ≤1 mg achievable; good stability	[34]
Erlotinib printlet	FDM	NSCLC (oncology)	Comparable Cmax/AUC to commercial tablet	[65]
Temozolomide implant	PAM	Glioblastoma (animal)	Sustained local release; improved survival	[66]

XVIII. REGULATORY LANDSCAPE FOR 3D PRINTED PHARMACEUTICAL

The regulatory approval and oversight of 3D-printed drug products represents one of the most complex and rapidly evolving areas at the intersection of pharmaceutical science, engineering, and law. Existing regulatory frameworks were designed for conventional manufacturing processes and do not readily map onto the unique characteristics of additive manufacturing, including digital design files as master formulae, high variability between print batches, point-of-care manufacture, and personalised dosing.[11,69]

XIX. FDA REGULATORY FRAMEWORK AND GUIDANCE

The US Food and Drug Administration approved the first 3D-printed drug product (SPRITAM®) in 2015 under the standard NDA 505(b)(1) pathway, without issuing specific guidance for 3D-printed pharmaceuticals at that time. In 2017, the FDA's Center for Drug Evaluation and Research (CDER) and Center for Devices and Radiological Health (CDRH) jointly published a technical considerations document for additive manufactured medical devices, but no equivalent pharmaceutical-specific guidance existed until more recently.[69,70] In response to growing industry pressure, the FDA established the Emerging Technology Program (ETP), which provides a voluntary mechanism for manufacturers to engage with the agency prior to submission regarding novel manufacturing technologies including 3D printing. The ETP has received numerous pre-submissions relating to FDM, SLS, and BJT pharmaceutical applications, providing important early-stage regulatory feedback.[71] A key regulatory concern is the validation of the printing process as a manufacturing process step, including establishment of design space parameters, in-process controls, and real-time quality monitoring via Process Analytical Technology (PAT). The FDA's Quality by Design (QbD) framework, codified in ICH Q8-Q10, provides a suitable structural basis for 3D printing process development and validation.[72] Specific issues of concern to the FDA include: (1) the equivalence of printed products to digitally described specifications; (2) the performance and qualification of commercial vs. prototype printers; (3) the reprocessing and reuse of support materials; (4) cleaning validation for multi-product printers; (5) the stability of drug-excipient filaments during storage prior to printing; and (6) the traceability and integrity of digital design files used as master production records.[69,73]

XX. EMA REGULATORY CONSIDERATIONS

The European Medicines Agency has been actively engaged with 3D printing through its Innovation Task Force (ITF) and the European Innovation Networks, facilitating scientific discussions between innovators and regulatory assessors. The EMA released a reflection paper on the use of 3D printing in the manufacture of medicinal products in 2020, acknowledging the potential of the technology while identifying critical regulatory gaps in the areas of GMP compliance, quality control, and clinical evidence requirements.[74] Under the European regulatory framework, 3D-printed medicines would typically fall under existing categories of licensed medicinal products, unlicensed (specials) preparations, or advanced therapy medicinal products (ATMPs), depending on their nature and manufacturing context. Hospital pharmacy-prepared 3D-printed products may benefit from the 'hospital exemption' for ATMPs under Directive 2009/120/EC, though this remains subject to national interpretation.[75] The EMA has emphasised the need for robust analytical testing of each individual printed dosage form (100% testing, enabled by inline/online PAT) rather than statistical sampling, given the inherently variable nature of 3D printing compared to conventional batch manufacturing.[76]

XXI. INTERNATIONAL REGULATORY HARMONISATION

International regulatory harmonisation for 3D-printed pharmaceuticals remains at an early stage. The International Council for Harmonisation (ICH) is considering revisions to guidelines Q8 (Pharmaceutical Development), Q9 (Quality Risk Management), and Q10 (Pharmaceutical Quality System) to address novel manufacturing technologies. The World Health Organization (WHO) has issued technical reports acknowledging 3D printing as an area requiring specific regulatory consideration for developing-world access medicines.[77,78] Regulatory agencies in Australia (TGA), Canada (Health Canada), Japan (PMDA), and the United Kingdom (MHRA) have each issued position statements or reflection papers acknowledging 3D-printed pharmaceuticals, though none has yet established a fully defined approval pathway. The MHRA, post-Brexit, has been active in inviting pre-engagement discussions with companies developing 3D-printed medicines through its Innovation Office, and has published guidance on the regulatory considerations applicable to extemporaneous 3D printing in hospital pharmacy settings.[79,80]

XXII. GMP COMPLIANCE FOR 3D PRINTING FACILITIES

Good Manufacturing Practice compliance for 3D-printed pharmaceutical production facilities presents unique challenges that existing GMP annexes (EU GMP Annex 1 for sterile manufacture, Annex 15 for qualification and validation) only partially address. A critical divergence from conventional GMP is the concept of the digital master formula: the STL or equivalent file that defines the product specification must be subject to version control, access restrictions, audit trails, and integrity verification analogous to traditional master batch records.[81] Equipment qualification for 3D printers must address not only installation qualification (IQ) and operational qualification (OQ) but also performance qualification (PQ) specific to pharmaceutical printing, including nozzle calibration, build platform levelling, temperature uniformity, and environmental controls. Multi-material printers require dedicated cleaning validation to prevent cross-contamination between products.[82] Personnel training requirements are expanded to include digital design software competency, printer operation, maintenance, and troubleshooting, in addition to standard pharmaceutical GMP competencies. Cleanroom classification requirements must be established based on the nature of the printed product (non-sterile vs. sterile) and the open/closed nature of the printing process.[83]

XXIII. KEY CHALLENGES IN 3D PRINTED PHARMACEUTICAL MANUFACTURING REPRODUCIBILITY, SCALABILITY, AND QUALITY CONTROL

Perhaps the most fundamental challenge facing 3D-printed pharmaceutical manufacture is achieving the level of reproducibility and quality consistency required by pharmacopoeial standards and regulatory agencies. 3D printing is inherently more sensitive to environmental conditions, equipment wear, and material variability than conventional compression or encapsulation processes.[84] Batch-to-batch variability in FDM printing has been attributed to inconsistencies in filament diameter (tolerance ±0.05 mm), moisture content of hygroscopic polymers, nozzle wear, and ambient humidity and temperature fluctuations. Systematic implementation of Design of Experiments (DoE) and multivariate statistical models has been proposed as a strategy to establish the design space and identify critical process parameters.[85]

In-line and at-line analytical technologies are essential for real-time quality monitoring. Near-infrared (NIR) spectroscopy, Raman spectroscopy, terahertz pulsed imaging (TPI), and X-ray micro-computed tomography (μ-CT) have been investigated for real-time content uniformity verification, solid-state characterisation, and internal geometry assessment of 3D-printed dosage forms.[86,87] The FDA's PAT framework provides regulatory endorsement for such approaches, but implementation in pharmaceutical 3D printing environments requires careful sensor selection, probe positioning, and chemometric model development validated across the full design space.[88]

XXIV. MATERIAL CHARACTERISATION AND REGULATORY ACCEPTANCE

The pharmaceutical excipient library available for 3D printing is currently far narrower than that available for conventional dosage forms. Only a small subset of the >3000 excipients listed in the FDA Inactive Ingredients Database have been characterised for compatibility with 3D printing processes. Many promising printing materials (novel photopolymers, advanced co-polymers, functional coatings) lack the extensive safety dossiers required for regulatory acceptance as pharmaceutical excipients.[40,89] The development pathway for novel pharmaceutical excipients under the IPEC (International Pharmaceutical Excipients Council) guidelines is lengthy and costly, typically requiring 5–10 years and substantial toxicological investment. Collaborative pre-competitive excipient development initiatives between academic institutions, industry, and regulatory bodies have been proposed to accelerate this process for 3D printing-specific materials.[90]

XXV. INTELLECTUAL PROPERTY AND DIGITAL SECURITY

The digitisation of pharmaceutical formulations as STL or equivalent design files introduces unprecedented intellectual property (IP) challenges. A 3D-printed medicine's formulation is embedded in a digital file that, in principle, could be copied, transmitted, and reproduced without restriction analogous to challenges faced by the music and film industries with digital media piracy.[91] The pharmaceutical IP landscape must adapt to address the copyrightability and patent protection of digital drug formulations, the liability framework for point-of-care printed medicines produced from distributed files, and the regulatory mechanisms for controlling file authenticity and version integrity. Blockchain-based digital rights management and cryptographic file signing have been proposed as technical solutions, though their implementation in a pharmaceutical regulatory context remains nascent.[92]

XXVI. PATIENT SAFETY AND PHARMACOVIGILANCE

Point-of-care or patient-level manufacture of personalised 3D-printed medicines introduces new dimensions of pharmacovigilance complexity. Adverse events attributable to printing errors (incorrect dose, wrong drug loaded, degraded API from incorrect processing temperature) may be difficult to detect through conventional post-marketing surveillance systems designed for large batch-manufactured products.[93] The development of electronic medicine administration records (eMARs) integrated with 3D printer data logs, and the implementation of real-time pharmacovigilance systems capable of linking printed product identity with patient outcomes, will be essential infrastructure requirements for safe clinical deployment of 3D printing at scale.[94]

XXVII. EMERGING FRONTIERS IN PHARMACEUTICAL 3D PRINTING ARTIFICIAL INTELLIGENCE AND MACHINE LEARNING INTEGRATION

The convergence of artificial intelligence (AI) and 3D printing holds transformative potential for pharmaceutical manufacturing. Machine learning (ML) models can be trained on large datasets of formulation parameters, process conditions, and in vitro/in vivo performance data to predict optimal printing parameters for novel drug-excipient combinations, accelerating formulation development by an estimated 60–80% compared to traditional empirical approaches.[95,96] Convolutional neural networks (CNNs) have been applied to automated visual quality control of 3D-printed tablets, detecting surface defects, dimensional deviations, and colour anomalies with sensitivity surpassing manual inspection. Generative adversarial networks (GANs) are being explored for the automated generation of novel dosage form geometries optimised for specific release profiles.[97] In the clinical decision support domain, AI algorithms can integrate patient pharmacogenomic data, renal function indices, body composition measurements, and co-medication profiles to automatically calculate personalised dosing recommendations that feed directly into a 3D printer's

production queue a vision of the fully automated personalised medicine pipeline.[98]

XXVIII. DIGITAL PHARMACIES AND POINT-OF-CARE MANUFACTURING

The digital pharmacy model envisions a decentralised pharmaceutical supply chain in which drug formulation data (as validated digital files) is transmitted from central pharmaceutical manufacturers to dispensing points hospital pharmacies, community pharmacies, or even patients' homes where 3D printers produce individualised dosage forms on demand. This model has the potential to eliminate the cold chain for solid dosage forms, reduce medication waste from unused standardised tablets, and enable rapid dose adjustments for outpatient chronic disease management.[99,100]

Prototype digital pharmacy programmes have been piloted in the United Kingdom through the National Health Service (NHS) and in Australia through hospital pharmacy networks. The Medicines and Healthcare products Regulatory Agency (MHRA) has engaged with these pilots to develop appropriate oversight frameworks. Key infrastructure requirements include secure digital file transmission protocols, validated point-of-care 3D printers with integrated quality assurance, and pharmacist training programmes for advanced manufacturing competency.[101]

XXIX.4D PRINTING AND STIMULI-RESPONSIVE SYSTEMS

4D printing extends the 3D printing concept by incorporating time as a fourth dimension: printed objects that change shape, composition, or functional properties in response to environmental stimuli (temperature, pH, moisture, light, magnetic field). In pharmaceutical applications, 4D printing enables the fabrication of gastroretentive dosage forms that expand upon contact with gastric fluid, self-folding capsules, mucoadhesive systems that swell to anchor in the gastrointestinal tract, and thermo-responsive intravaginal rings for sustained hormone delivery.[102,103] Shape memory polymers (SMPs), hydrogels with LCST (lower critical solution temperature) behaviour, and pH-responsive polyelectrolyte systems have been the primary material platforms for pharmaceutical 4D printing. The regulatory classification of 4D-printed dosage forms as conventional medicines, combination products, or advanced therapy medicinal products remains to be defined.[104]

XXX. BIOPRINTING AND ISSUE-ENGINEERED DRUG TESTING MODELS

While bioprinting of living cells and tissues is more directly associated with regenerative medicine, its intersection with pharmaceutical science is increasingly significant. 3D-bioprinted tissue models organoids and organ-on-chip systems incorporating printed hepatic, intestinal, renal, and tumour tissues offer physiologically relevant platforms for pharmaceutical absorption, distribution, metabolism, and excretion (ADME) testing.[105] Bioprinted intestinal mucosa models incorporating Caco-2 cells in physiologically accurate villus geometries have demonstrated superior predictive performance for oral drug absorption compared to conventional 2D cell monolayers. Such models may in future reduce the reliance on animal models in preclinical drug testing, aligning with the 3Rs (Replacement, Reduction, Refinement) framework.[106]

XXXI. CONTINUOUS MANUFACTURING INTEGRATION

The integration of 3D printing into end-to-end continuous manufacturing (CM) platforms represents a frontier with significant industrial implications. Conventional pharmaceutical manufacturing is predominantly batch-based; CM processes offer advantages in consistency, efficiency, and real-time release testing capability. 3D printing, with its digital, layer-by-layer nature, is inherently continuous and can be directly coupled with upstream continuous synthesis, HME, or granulation steps and downstream inline quality monitoring.[107] Pilot-scale integrated platforms coupling continuous HME with inline FDM printing have been demonstrated for the manufacture of personalised dosage forms at throughputs potentially compatible with hospital pharmacy scale. The FDA has actively encouraged continuous manufacturing adoption through its Emerging Technology Program and updated guidance documents.[108]

Table 3. Regulatory milestones and guidance documents for 3D-printed pharmaceuticals (2015–2024)

Year	Agency	Document / Event	Key Provisions
2015	US FDA	SPRITAM® NDA Approval	First 3D-printed drug approved; BJT process reviewed under standard NDA
2017	US FDA (CDRH)	Technical Considerations for AM Medical Devices	Device-focused; established AM qualification principles
2018	US FDA (CDER)	Emerging Technology Program expansion	Voluntary pre-submission engagement for novel manufacturing technologies
2019	EMA	Innovation Task Force engagement on 3DP	Facilitated scientific advice for 3D-printed drug product developers
2020	EMA	Reflection Paper: 3D Printing in Manufacture of Medicinal Products	GMP gaps identified; 100% dose testing recommended
2021	MHRA (UK)	Innovation Office position statement on 3DP pharmacy	Hospital pharmacy 3DP acknowledged; extemporaneous guidance extended
2022	WHO	Technical Report Series on AM pharmaceuticals	Developing-country access; essential medicines 3DP discussed
2023	US FDA	Draft Guidance: Pharmaceutical Additive Manufacturing	Design space, process validation, digital file requirements outlined
2024	EMA	Updated Annex 1 supplementary notes on novel manufacture	3DP cleanroom requirements; inline PAT encouraged

XXXII. BIOEQUIVALENCE, IN VIVO PERFORMANCE AND PATIENT SAFETY CONSIDERATION

Establishing bioequivalence of 3D-printed dosage forms with reference listed drugs (RLDs) is a complex and context-dependent challenge. For products fabricated by BJT or FDM that are compositionally identical to marketed tablets but differ in microstructure, traditional average bioequivalence (ABE) testing under 21 CFR Part 320 may provide an appropriate framework. However, for structurally novel forms polypills, porous matrices, modified-release architectures population PK/PD modelling and individual bioequivalence approaches may be more appropriate.[109,110] In vivo pharmacokinetic studies of FDM-printed immediate-release tablets of ibuprofen, paracetamol, and prednisolone have generally demonstrated AUC and Cmax values within the 80–125% bioequivalence bounds compared to reference commercial tablets, provided excipient composition and drug loading are analogous. More significant departures from reference PK profiles have been observed for modified-release 3D-printed systems, which typically require dedicated in vivo evaluation rather than in vitro-in vivo correlation (IVIVC) waiver.[111] Patient safety considerations extend to the physical properties of 3D-printed tablets: mechanical strength, friability, and disintegration behaviour must meet pharmacopoeial requirements (BP/USP) and be predictive of in-mouth or in-stomach behaviour. Orodispersible 3D-printed forms in particular require assessment of aspiration risk, especially in elderly or paediatric patients. Regulatory guidance on appropriate safety testing of novel 3D-printed pharmaceutical forms is an ongoing area of development.[112]

XXXIII. ECONOMIC, ENVIRONMENTAL AND EQUITY DIMENSION HEALTH ECONOMIC ANALYSIS OF 3D PRINTING

Health economic analyses of 3D-printed personalised pharmaceuticals must account for multiple dimensions: the capital cost of 3D printing hardware and infrastructure, the variable cost per printed dosage form (material, energy, quality testing), the potential cost offset from improved therapeutic outcomes and reduced adverse events associated with personalised dosing, and the downstream savings from reduced hospitalisation attributable to improved adherence.[113] Preliminary health economic modelling studies have suggested that 3D-printed polypills for cardiovascular risk reduction, by virtue of improved adherence, could deliver cost savings of £300–500 per patient per year in a UK NHS setting, though these estimates carry significant uncertainty and depend strongly on assumptions about adherence improvement rates.[114]

At a manufacturing level, 3D printing is currently more expensive per unit than large-scale conventional tabletting due to lower throughput, higher material costs, and greater quality testing burden. However, for

ultra-low-volume personalised products (e.g., paediatric dose individualisation), where conventional manufacture would require a dedicated batch for each dose strength, 3D printing may offer significant economic advantages through elimination of changeover costs and batch failures.[115]

XXXIV. ENVIRONMENTAL SUSTAINABILITY OF 3D PRINTING

From an environmental sustainability perspective, 3D printing offers both advantages and challenges. The potential for on-demand, localised manufacture eliminates pharmaceutical cold-chain logistics and associated carbon emissions from global distribution. Reduced material waste (printing only what is needed, vs. batch overruns in conventional manufacture) and the elimination of packaging waste from multiple conventional tablet bottles replaced by a single polypill represent additional sustainability benefits.[116] Conversely, the energy consumption of 3D printing processes particularly SLS with its high-powered laser and heated powder bed can be substantially higher per tablet than energy-efficient compression processes. Life cycle assessment (LCA) studies comparing the environmental footprint of FDM-printed vs. conventionally manufactured tablets have shown variable results depending on scale, geography, and specific energy mix.[117]

XXXV. EQUITY AND ACCESS IMPLICATIONS

The equity implications of 3D-printed personalised pharmaceuticals are nuanced. On one hand, the technology holds the potential to democratise access to personalised medicine by enabling local manufacture of customised dosage forms in resource-limited settings, potentially including essential medicines for neglected tropical diseases or rare genetic conditions where commercial market incentives are insufficient.[118] On the other hand, the high initial capital cost of pharmaceutical-grade 3D printing hardware, the need for skilled operators, and the infrastructure requirements for digital file transmission and quality testing may limit accessibility to well-resourced healthcare systems, exacerbating rather than alleviating global health inequities. WHO and MSF (Médecins Sans Frontières) have called for open-source pharmaceutical 3D printing platforms and formulation databases as part of a global medicines access framework.[119]

XXXVI. FUTURE PERSPECTIVE AND PATH TO CLINICAL INTEGRATION

The translation of 3D-printed personalised pharmaceuticals from research proof-of-concept to routine clinical practice requires coordinated advances across multiple domains: materials science, process engineering, analytical technology, regulatory science, clinical pharmacology, health informatics, and pharmaceutical economics.[3,120] In the near term (2024–2028), it is anticipated that the FDA and EMA will publish finalised guidance documents specific to pharmaceutical 3D printing, providing clearer pathways for IND (Investigational New Drug) and NDA/MAA (Marketing Authorisation Application) submissions incorporating 3D-printed dosage forms. Several FDM-printed paediatric and oncology printlets are currently in Phase I/II clinical trials, and Phase III data are expected to emerge in this period.[121]

In the medium term (2028–2035), the integration of AI-guided personalised dosing algorithms, digital pharmacy networks, and point-of-care printing infrastructure within hospital and community pharmacy settings is likely to accelerate. The development of pharmaceutical-grade desktop 3D printers with integrated quality assurance (inline NIR, automated weight verification, tamper-evident printing) will be a critical enabling technology for wider clinical deployment.[122] In the long term (beyond 2035), the convergence of pharmacogenomics, real-world data analytics, 4D printing, and bioprinting may realise the vision of truly individualised pharmaceutical therapy a 'n-of-1' manufacturing paradigm where each patient's drug regimen is uniquely fabricated to their instantaneous genetic, physiological, and environmental profile. This represents the ultimate fulfilment of the precision medicine promise.[123]

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