REVIEW ARTICLE

3D Printing of Personalized Oral Solid Dosage Forms: Formulation Strategies, Clinical Drivers, and Translational Challenges

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Abstract

Background: Over the past decade, additive manufacturing has enabled on-demand fabrication of patient-specific oral solid dosage forms in which dose, geometry and internal architecture are programmed from a digital design—capabilities conventional batch tableting cannot readily deliver.

Scope & Approach: This review critically examines formulation strategies underlying the development of 3D-printed personalized OSDs, with emphasis on material selection, printability, drug–polymer interactions and the impact of processing parameters on critical quality attributes, including content uniformity, mechanical integrity, and drug release performance.

Clinical Drivers: Clinical needs for personalization—such as pediatric and geriatric dosing, narrow therapeutic index drugs and scenarios requiring patient-specific release profiles—are summarized to highlight unmet therapeutic needs.

Key Findings: Advances in fused deposition modeling, semi-solid extrusion, binder jetting and inkjet printing are evaluated in the context of formulation flexibility and translational feasibility.

Conclusions: Despite substantial progress, clinical implementation remains constrained by regulatory uncertainty, scalability–personalization trade-offs, quality assurance requirements and stability considerations. Future opportunities integrating QbD, PAT and digital design tools are discussed as enablers for robust, regulatory-compliant translation of personalized 3D-printed OSDs into clinical practice.

Keywords: 3D printing, Personalized medicine, Oral solid dosage forms, Additive manufacturing, Formulation strategies, Patient-centric drug delivery, Regulatory science.

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Introduction

Evolution of oral solid dosage forms

Oral solid dosage (OSD) forms remain the cornerstone of drug therapy because of their convenience, stability, cost-effectiveness, and high patient acceptance.[1] Despite these advantages, conventional OSD manufacturing is fundamentally rooted in a "one-size-fits-all" paradigm, which often fails to accommodate inter-patient variability in pharmacokinetics, pharmacodynamics, age, comorbidities, and genetic makeup. Increasing recognition of this variability has intensified the demand for personalized pharmaceutical products, particularly in therapeutic areas requiring flexible dosing and tailored release profiles. [2, 3]

Limitations of Conventional OSD Manufacturing

Traditional tablet and capsule manufacturing relies on large-scale batch processes optimized for uniformity and cost efficiency rather than individual patient needs.[1] Such processes inherently limit dose flexibility, restrict the incorporation of multiple actives with independent release profiles, and necessitate post-manufacturing modifications such as tablet splitting, which can lead to dosing inaccuracies and compromised product performance. These limitations are especially problematic for patient populations such as pediatrics, geriatrics, and individuals with dysphagia, where standard strengths and dosage forms are frequently unsuitable.[2-5]

Why Personalization Matters: Patient-Centric Therapy, Polypharmacy and Compliance

Personalization plays a critical role in addressing polypharmacy, a growing challenge in aging populations and patients with chronic and complex diseases. Polypharmacy is associated with increased pill burden, dosing errors, drug–drug interactions, and poor treatment adherence. Personalized oral dosage forms, enabled by advanced manufacturing technologies such as three-dimensional (3D) printing, offer the possibility of integrating multiple active pharmaceutical ingredients into a single, patient-specific dosage form with customized release profiles. Such design flexibility may simplify dosing regimens, reduce medication burden, and improve therapeutic outcomes by enabling synchronized or sequential drug release tailored to individual treatment plans.[6-9]

Patient compliance remains one of the most significant determinants of clinical effectiveness for oral therapies. Factors such as pill size, swallowing difficulty, taste, dosing frequency, and regimen complexity substantially influence adherence. The formulation strategies discussed in this review demonstrate how 3D printing can overcome these limitations by enabling precise control over tablet size, shape, internal structure, and drug distribution. For example, chewable, dispersible, or rapidly disintegrating personalized OSDs can be designed for pediatric and geriatric patients, while modified-release systems can reduce dosing frequency and improve convenience. By aligning dosage form design with patient preferences and physiological needs, personalized OSDs directly support improved medication adherence and patient experience.[2,10-12]

From a broader therapeutic perspective, personalized drug delivery supports dose individualization based on patient-specific factors such as pharmacokinetics, disease progression, and therapeutic response. The ability of additive manufacturing to fabricate dosage forms on demand with high content uniformity and reproducibility, as emphasized in this abstract, positions 3D printing as a key enabler of precision pharmacotherapy. When integrated with digital design tools, quality-by-design principles, and process analytical technologies, personalized OSDs have the potential to bridge the gap between clinical needs and pharmaceutical product design, ultimately advancing patient-centric healthcare.[11,13-15]

Emergence of 3D Printing as an Enabling Technology

Three-dimensional printing (3DP), or additive manufacturing, has emerged as a disruptive pharmaceutical manufacturing technology capable of fabricating patient-specific dosage forms directly from digital designs through layer-by-layer deposition of drug-loaded materials. Unlike conventional manufacturing, 3DP enables precise spatial control of active pharmaceutical ingredients (APIs) and excipients, allowing the creation of complex geometries, internal porosity gradients, and multi-compartment structures that are otherwise impractical or impossible to achieve.[2,15,16]

Overview of 3d Printing in Pharmaceuticals

Multiple 3DP platforms including fused deposition modelling (FDM), binder jetting, inkjet printing, semi-solid extrusion (SSE), and stereolithography (SLA) have been successfully adapted for pharmaceutical use, each offering unique advantages in terms of material compatibility, resolution, and process scalability. These technologies have opened avenues for on-demand production of personalized OSD forms with tailored dose strengths, customizable release kinetics, and improved patient-centric attributes such as swallowability and palatability.[17,18]

Types of 3D Printing Technologies for Pharmaceutical Applications

Fused Deposition Modeling (FDM)

Fused deposition modeling (FDM) is the most extensively investigated 3D printing technology for pharmaceutical oral solid dosage forms. In this method, drug-loaded polymer filaments are melted and extruded layer-by-layer to fabricate dosage forms with defined geometry and internal structure. FDM enables precise control overdose, infill density, and tablet architecture, which directly influences mechanical strength and drug release behavior. Its compatibility with a wide range of pharmaceutical polymers and its suitability for producing immediate- and modified-release systems make FDM particularly attractive for personalized therapy. However, exposure to elevated processing temperatures may limit its applicability for thermolabile drugs.

Advantages for oral dosage forms: high dose flexibility, robust mechanical integrity, tunable release profiles, and suitability for on-demand personalization.[11,13]

Binder Jetting

Binder jetting involves selective deposition of a liquid binder onto a powder bed containing drug and excipients, resulting in layer-wise construction of dosage forms without thermal stress. The technology enables fabrication of highly porous tablets with rapid disintegration, Clinical precedent exists in 2015 the FDA cleared Spritam® (levetiracetam) as the first 3D-printed medicine, a porous tablet that disintegrates rapidly with a sip of liquid. Binder jetting is particularly advantageous for high-dose drugs and applications requiring fast disintegration; however, challenges remain related to mechanical strength and post-processing requirements.

Advantages for oral dosage forms: low thermal stress, suitability for high drug loads, extremely rapid disintegration, and patient-friendly dosage forms.[19,12]

Inkjet Printing

Inkjet printing deposits drug-containing solutions or suspensions onto substrates in a precise and non-contact manner. This approach offers exceptional accuracy for low-dose drugs and enables spatial control of drug deposition, supporting complex release patterns. Inkjet printing is particularly suited for pediatric dosing and personalized low-strength formulations but is limited by ink formulation constraints and relatively low achievable doses.

Advantages for oral dosage forms: high dosing precision, suitability for low-dose personalization, minimal material waste, and flexible design capability.[20,21]

Selective Laser Sintering (SLS)

Selective laser sintering (SLS) uses a scanning laser to fuse regions of a pharmaceutical powder bed, enabling solvent-free tablets whose porosity, mechanical strength and dissolution are tuned by polymer choice and laser energy input. This design freedom can program immediate to controlled release, although the thermal budget must be managed to preserve API solid-state stability.

Advantages for oral dosage forms: solvent-free processing, high design freedom, adjustable porosity, and controlled release potential.[22,8]

Advantages of 3D Printing for Oral Dosage Forms

Complex Geometries

Additive manufacturing permits oral dosage forms with engineered internal architectures and geometries that are impractical with compression or casting, allowing surface-area and tortuosity to be deliberately tuned.

Multi-Drug Layering

A key advantage of 3D printing is its ability to spatially separate and precisely position multiple active pharmaceutical ingredients within a single dosage form. Layer-by-layer manufacturing facilitates the creation of polypills with discrete compartments or layered structures, enabling independent control of drug dose and release for each component. This capability is particularly valuable for managing polypharmacy, as it can reduce pill burden while minimizing drug–drug interactions and dosing complexity.[7,8]

Controlled Release Profiles

3D printing offers unparalleled control over drug release kinetics through manipulation of geometry, material selection, and internal structure. Immediate, sustained, delayed, or pulsatile release profiles can be engineered within a single platform by adjusting formulation and design parameters. Such precision supports patient-centric dosing strategies and enhances therapeutic effectiveness by aligning drug release with individual pharmacokinetic and clinical requirements.[13,14] The advantages outlined in Table 1 highlight how 3D printing enables a shift from formulationcentric to designdriven oral dosage form development, while introducing new regulatory considerations related to quality and process control.

The formulation advantages enabled by three-dimensional (3D) printing complex geometries, multi-drug layering, and programmable release profiles translate directly into clinically meaningful personalization, particularly for patients with variable pharmacokinetics, polypharmacy, or adherence challenges. Within a quality-by-design (QbD) framework, attributes such as tablet geometry, internal architecture, and spatial drug distribution are no longer incidental, but become deliberate design inputs linked to predefined clinical objectives. These attributes therefore constitute critical quality attributes (CQAs), as they directly govern mechanical integrity, dissolution behavior, and in vivo performance.[1]

From a regulatory perspective, the same flexibility that enables patient-centric therapy necessitates rigorous control strategies. Printer settings, material properties, and layer-by-layer deposition conditions must be justified as critical process parameters (CPPs) with demonstrated impact on CQAs and reproducibility. Both EMA and FDA perspectives emphasize establishing transparent CPP–CQA relationships supported by mechanistic understanding and robust in vitro testing. Consequently, 3D printing challenges conventional manufacturing paradigms, bridging formulation and regulatory science translation.[14,7,22]

Table 1: Summary of Advantages of 3D Printing for Oral Dosage Forms with Regulatory Considerations (Insert formatted table here)

Advantage	*Description*	*Key Examples*	*Regulatory Considerations*
Complex geometries	Precise control over tablet shape, internal architecture and porosity enables modulation of mechanical strength and drug release without changing formulation composition.	Geometrydriven immediate release of hydrochlorothiazide (BCS IV) using FDM Paracetamol tablets exhibiting immediate-to-sustained release from a single formulation	Geometry considered a critical quality attribute (CQA) linked to performance within (QbD) framework Robust digital design control and inprocess monitoring required
Multidrug layering	Layerbylayer fabrication allows spatial separation of APIs within a single dosage form, enabling independent dosing and tailored release profile.	Fivedrug cardiovascular polypill with immediate and sustained release layers Threedrug polypill for diabetes and hypertension	Content uniformity must be ensured for each API Drug–drug and drug-excipient interaction risk must be evaluated Typically assessed as fixed-dose combination products
Controlled release profiles	Drug release kinetics can be tailored via geometry, polymer selection and access parameters to achieve immediate, sustained, delayed, or pulsatile release.	SLS- printed paracetamol tablets with polymerdependent release behavior Spritam® enabling rapid disintegration of highdose tablets	Release mechanism must be welldefined and reproducible Critical process parameters influencing release require strict control Alignment with pharmacopeial expectations aids approval

Continuous Manufacturing With 3d Printing in Osds

Definition and Principles

Continuous manufacturing (CM) integrated with three-dimensional (3D) printing represents an advanced pharmaceutical manufacturing paradigm in which materials are continuously fed, transformed, and removed, while 3D printing enables digitally controlled, layer-by-layer fabrication of patient-specific oral solid dosage forms (OSDs). Under ICH Q13,[23] CM is defined by maintaining a state of control over time, rather than producing discrete batches, with product quantity determined by run duration instead of scale. When combined with 3D printing, CM principles are extended to include digital design control, allowing real-time adjustment of dose, geometry, and release characteristics within the same manufacturing framework, supporting on-demand and personalized production.[6,24-26]

Key Components in a CM–3D Printing Workflow

Feeders

Loss-in-weight feeders provide continuous and precise delivery of APIs and excipients to upstream blending or filament/granule preparation steps. Feed rate accuracy is a critical process parameter (CPP), directly linked to content uniformity and dose accuracy, particularly important when producing drug-loaded filaments or printable inks for downstream 3D printing.[27,6]

Blenders

Continuous blenders ensure homogeneous mixing of formulation components prior to granulation, hot-melt extrusion, or printing feedstock preparation. Blend uniformity is an intermediate critical quality attribute (CQA) that must be maintained across residence time distributions to ensure reproducible printability and dosage accuracy.[27,14]

Granulators / Feedstock Preparation

Twin-screw wet or dry granulators, or hot-melt extrusion units, are used to continuously produce granules or filaments suitable for 3D printing (e.g., FDM). Parameters such as screw speed, temperature, and liquid addition rate function as CPPs affecting granule size, filament mechanical strength, and printability attributes that directly influence printed dosage-form performance.[28,7]

Tablet Presses/3D Printers

In CM–3D printing systems, conventional tablet presses may be replaced or complemented by 3D printers that fabricate tablets continuously from digitally defined designs. Printing speed, layer height, extrusion temperature, and infill density are CPPs linked to CQAs such as tablet strength, drug release, and content uniformity. These parameters require the same level of control and justification as compression force or dwell time in traditional CM tableting.[29,7]

Benefits of CM Integrated with 3D Printing

Real-Time Quality Monitoring (PAT Tools)

CM provides an optimal platform for Process Analytical Technology (PAT) implementation, including in-line Raman or NIR spectroscopy for monitoring blend uniformity, assay, moisture, and even printed tablet attributes. This supports real-time release testing (RTRT), aligning with regulatory expectations that quality should be built into the process rather than tested post-production.[23,30-32,11]

Reduced Variability

Operating under steady-state conditions reduces batch-to-batch variability and segregation risks. When coupled with digital control of 3D printing parameters, CM enables tighter control of CPP–CQA relationships, resulting in more consistent dose delivery and drug release performance for personalized OSDs.[14,27]

Faster Scale-Up

Scale-up in CM is primarily time-based, while scalability in 3D printing is achieved through parallelization or extended run times rather than equipment resizing. This combination accelerates development, simplifies post-approval changes, and supports flexible, decentralized manufacturing models.[6,27]

Regulatory Perspective: FDA and EMA

Regulatory agencies increasingly recognize CM and 3D printing as enabling technologies for modern pharmaceutical manufacturing. The FDA's adoption of ICH Q13 (2023) provides harmonized guidance on CM for drug products, emphasizing control strategies, RTD understanding, PAT, and clear CPP–CQA linkages. These principles are directly applicable to CM-enabled 3D printing workflows, as demonstrated by the FDA approval of Spritam® as the first 3D-printed oral medicine.[6,33]

From the EMA perspective, while no standalone CM–3D printing guideline exists, the approach is fully compatible with existing EMA guidance on finished dosage form manufacture and QbD expectations. EMA requires comprehensive process description, justified control strategies, and evidence that real-time monitoring provides assurance of consistent product quality comparable to or better than batch processes.[34,31] As illustrated in Figure 1, 3D printing can be integrated into continuous manufacturing workflows for oral solid dosage forms.

Applications In Personalized Medicine

At point-of-care, miniaturized NIR/Raman spectrometers have enabled accurate, non-destructive dose verification of hospital-printed tamoxifen capsules using a hub-and-spoke chemometric workflow, illustrating practical QC for decentralized personalized manufacture.

Three-dimensional (3D) printing enables patient-specific control of dose, geometry, internal architecture, and release

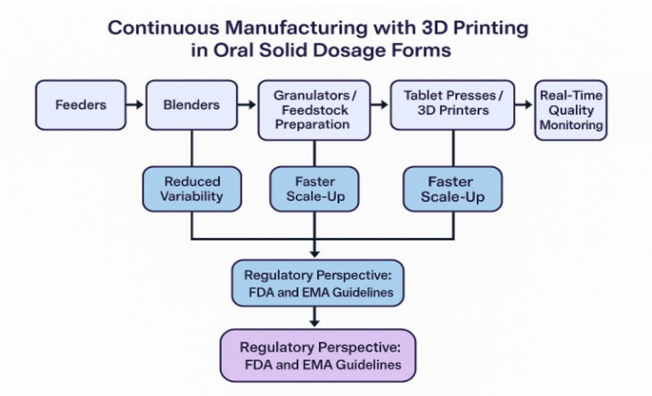

Figure 1: Continuous manufacturing workflow integrated with 3D printing for oral solid dosage forms (image to be supplied)

kinetics in oral solid dosage (OSD) forms, directly addressing clinical needs that are difficult to meet with conventional batch manufacturing. Priority application areas include pediatric and geriatric therapy, polypharmacy, dose titration for chronic diseases, and translation through case studies and prototypes.[35,2,15]

Pediatric and Geriatric Formulations

Pediatric and geriatric patients require age-/weight-adjusted dosing, improved swallowability, and better palatability; manipulation of fixed-strength products (splitting/crushing) compromises accuracy and acceptability.[33,36,37] 3D printing allows on-demand dose individualization by digitally varying tablet dimensions and infill while keeping composition constant, and it enables child-friendly Oro-dispersible print lets/films and low-density, fast-disintegrating geriatric tablets with maintained content uniformity.[2,33,36,37] Hospital and near-patient implementations are emerging, pairing decentralized manufacture with rapid, non-destructive dose verification (handheld NIR/Raman) to support clinical use.[38]

Polypharmacy Tablets (Multi-Drug Combinations)

High pill burden undermines adherence in chronic, multimorbid populations. 3D printing uniquely fabricates multi-API tablets with spatially separated compartments or core–shell architectures, enabling co-formulation of otherwise incompatible drugs and independent control of release profiles. Proof-of-concepts show layered, compartmentalized, and core–shell constructs that deliver immediate + sustained or sequential release from a single unit—an approach that can reduce dosing errors and simplify regimens in elderly patients.[39,40,41]

Dose Titration for Chronic Diseases

For therapies requiring fine dose adjustment (e.g., cardiovascular, neurological, psychiatric; narrow therapeutic index), commercial strengths rarely provide the needed granularity. 3D printing supports precise titration ladders by digitally stepping size/geometry/infill while holding excipients and process constant.[2,42] Recent studies demonstrate selective laser sintering of prednisone across stepped strengths (5–25 mg) that meet pharmacopeial quality criteria, illustrating practical, QA-compliant titration series.[43] QbD/PAT frameworks (e.g., inline drop counting, at-line verification) further ensure dose accuracy and content uniformity during personalized production.[42]

Case Studies and Prototypes

Regulatory precedent was established with Spritam® (levetiracetam), the first FDA-approved 3D-printed tablet (2015), validating pharmaceutical additive manufacturing for OSDs.[34,44,45] Since then, hospital pharmacy and point-of-care pathways have progressed, including clinical-trial-ready compounding with on-site QC and proposed frameworks for conducting clinical trials of 3D-printed medicines at the point of care.[38,46] Contemporary reviews chart the translational trajectory —from feasibility printlets to pilot clinical deployments—while underscoring the need for harmonized regulatory guidance and scalable QA systems.[35,2,15,46] The expanding role of 3D printing in enabling patientcentric oral solid dosage forms is summarized in Figure 2. The schematic emphasizes how dose customization, release modulation, and multidrug integration converge to support personalized therapy.

Challenges And Limitations

Despite the significant promise of three-dimensional (3D) printing for the manufacture of personalized oral solid dosage (OSD) forms, several scientific, regulatory, and practical challenges continue to limit its widespread clinical adoption. These constraints must be addressed to enable robust, scalable, and regulatory-compliant translation of personalized 3D-printed medicines into routine pharmaceutical practice.[11,8,2,15]

Regulatory Hurdles

Regulatory uncertainty remains one of the most significant barriers to the clinical implementation of 3D-printed personalized OSDs. Current regulatory frameworks are largely

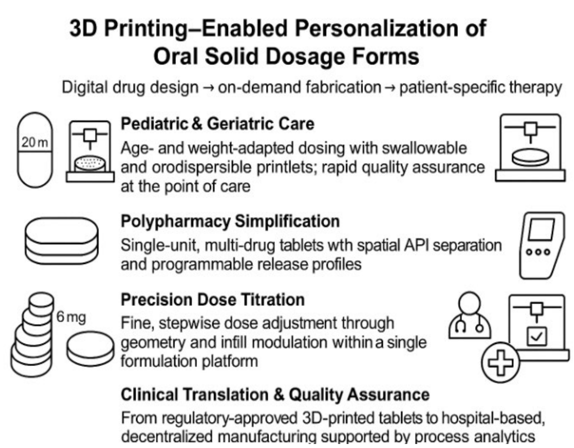

Figure 2: Schematic overview of 3D-printed personalized OSD applications (image to be supplied).

designed around centralized, batch-based manufacturing paradigms and are not readily adaptable to digitally driven, small-batch or patient-specific production models. Key unresolved questions include the definition of batch size, validation requirements for frequently changing digital designs, and the regulatory classification of decentralized or near-patient manufacturing environments.[11,8,2]

In addition, ensuring consistent quality across individualized products challenges traditional approaches to process validation and quality assurance. While the regulatory approval of the first 3D-printed tablet demonstrated feasibility, broader guidance on data requirements, lifecycle management, and post-approval change control for personalized products remains limited.[12,25,34] Harmonization of regulatory expectations across regions will be critical for enabling scalable adoption of 3D printing in personalized medicine.[11,8,24]

Stability and Shelf-Life Concerns

Stability and shelf-life assessment of 3D-printed dosage forms present unique challenges due to the diversity of materials, printing technologies, and internal structures employed. Many printable formulations rely on thermoplastic polymers, plasticizers, or hygroscopic excipients, which may exhibit altered physical or chemical stability compared with conventionally manufactured tablets as a result of thermal processing, amorphization, or increased surface area.[11,8,2] Porous or highly structured geometries, while advantageous for rapid disintegration or modified-release performance, may increase susceptibility to moisture uptake, mechanical degradation, or unintended changes in drug release behavior over time, thereby complicating stability assurance.[8,23,47,13]

Furthermore, patient-specific or on-demand manufacturing models challenge conventional long-term stability testing strategies, which are traditionally based on large, fixed-strength batches subjected to ICH climatic conditions. In decentralized or near-patient production scenarios, generating full long-term stability datasets for each personalized design may be impractical or infeasible.[11,2] In such contexts, real-time or predictive stability approaches, supported by material science understanding, quality-by-design (QbD) principles, and process analytical technologies (PAT), may be required to ensure product quality throughout the intended period of use.[48,49,24] The development of science- and risk-based stability frameworks will therefore be critical to support regulatory acceptance and routine clinical deployment of personalized 3D-printed medicines.[11,2,48]

High Initial Investment

The adoption of pharmaceutical 3D printing requires substantial upfront investment in specialized equipment, software infrastructure, and facility adaptation. Beyond the cost of printers themselves, additional expenditures include validated digital design platforms, material qualification, environmental controls, and quality control instrumentation, all of which are necessary to ensure reproducible product quality and regulatory compliance. These costs may be difficult to justify for low-volume or early-stage implementations, particularly in hospital or compounding pharmacy settings where resources and technical expertise may be limited.[11,8,2] From an industrial perspective, economic viability is further influenced by the inherent trade-off between personalization and throughput. While 3D printing excels in formulation flexibility, design freedom, and patient-specific customization, its production speed and unit output generally remain lower than those of conventional high-volume tableting processes optimized for mass manufacture.[8,15] As a result, careful identification of clinical scenarios in which personalization delivers clear therapeutic or economic benefit such as pediatric dosing, polypharmacy management, or narrow therapeutic index drugs will be essential to support sustainable business and manufacturing models for personalized 3D-printed oral solid dosage forms.[11,8,12]

Need for a Skilled Workforce

Successful implementation of 3D-printed personalized oral solid dosage (OSD) forms requires a multidisciplinary workforce with expertise spanning pharmaceutical formulation, additive manufacturing, digital design, and quality assurance. The operation, optimization, and troubleshooting of 3D-printing platforms demand skills that are not yet widely embedded within traditional pharmaceutical manufacturing or pharmacy practice, particularly with respect to printer hardware, material printability, and digital workflow control.[11,2] In addition, interpreting process data, managing digital design files, and implementing quality-by-design (QbD) and process analytical technology (PAT) frameworks necessitate advanced technical training and cross-disciplinary knowledge that extends beyond conventional formulation science.[8,49]

Bridging this skills gap will require targeted education initiatives, structured training programs, and close collaboration between academia, industry, and healthcare institutions. The development of standardized competencies covering digital design control, process validation, and regulatory compliance for personalized manufacturing will be essential to ensure consistent product quality and patient safety.[11,8,48] Without adequate investment in human capital, the full potential of 3D printing as a patient-centric manufacturing technology is unlikely to be realized, regardless of advances in equipment capability or regulatory frameworks.[11,2]

Future Directions

The next phase of three-dimensional printing (3DP) for personalized oral solid dosage (OSD) forms is expected to be driven by AI-enabled design, digitally augmented dosage forms, decentralized/point-of-care manufacture, and sustainable practices, building on the evolving clinical and regulatory trajectory of pharmaceutical additive manufacturing.[11,8,2]

AI-Driven Formulation Design

Data-centric and AI-assisted methods have the potential to significantly shorten development cycles by predicting printability, mechanical integrity, and drug-release performance from drug–excipient properties and process parameters prior to fabrication, followed by iterative refinement under quality-by-design (QbD) control.[8,2,42] Recent QbD-based studies integrating semi-solid extrusion with drop-on-demand API dosing and inline/at-line verification strategies (e.g., drop counting, ink concentration checks) have demonstrated accurate personalized dosing while maintaining pharmacopeial content-uniformity requirements.[42] Foundational reviews anticipate that such digital twin and AI-enabled workflows will increasingly integrate design, printing, and verification steps within regulatory-ready manufacturing frameworks for precision pharmacotherapy.[11,8,2]

Smart Dosage Forms (Digital Pills)

3DP enables multi-material and compartmentalized architectures that can incorporate functional elements for ingestion tracking, release monitoring, or stimulus-responsive delivery, extending beyond conventional passive printlets.[8,2,40] Core–shell, layered, and multi-drug constructs already demonstrate independent and programmable release profiles, forming a technological basis for future smart polypills integrating pharmacotherapy with digital health platforms.[40,41,39] Demonstrations of triple-drug and sequential-release fiber systems further highlight the potential for precise spatiotemporal control, which could ultimately be coupled with ingestible sensors or external monitoring devices.[41,39] Translational reviews across pharmaceutics and neurological therapeutics forecast connected, on-demand OSDs as promising tools to improve adherence and therapeutic oversight.[50,15]

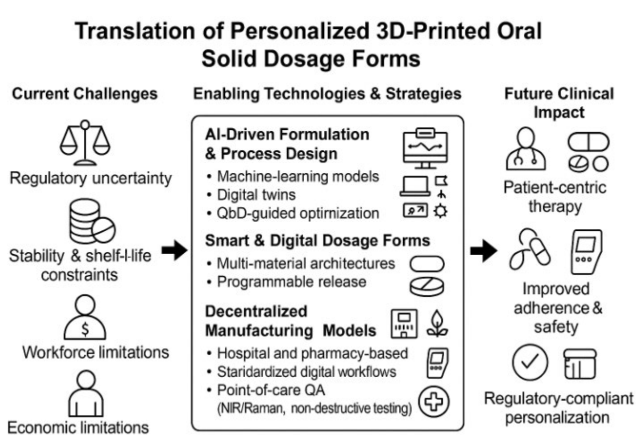

Figure 3: Translational roadmap for personalized 3D-printed OSDs (image to be supplied)

Decentralized Manufacturing (Hospital or Pharmacy-Based)

Point-of-care and decentralized 3DP is progressing from conceptual exploration toward hospital-pharmacy pilots and clinical-trial frameworks. Miniaturized Raman and near-infrared (NIR) spectroscopy systems have enabled rapid, non-destructive dose verification for small-batch, patient-specific products using hub-and-spoke quality-control models. [38] A recent regulatory framework proposes structured approaches for conducting clinical trials of 3D-printed medicines at the point of care, addressing documentation, quality systems, and oversight requirements. [46] Strategic analyses indicate that hospital and compounding-pharmacy settings represent among the most feasible near-term deployment scenarios when supported by standardized workflows and PAT. [51, 52] The regulatory precedent established by Spritam®, the first FDA-approved 3D-printed tablet, provides a critical bridge toward broader acceptance of decentralized manufacturing as guidance continues to mature. [25, 34, 44]

Sustainability and Green Manufacturing

Three-dimensional printing can contribute to reduced material waste, shortened supply chains, and lower inventory and transport-related emissions through on-demand production proximal to the patient. Key sustainability priorities include: (i) solvent-free or low-solvent processes such as fused deposition modeling (FDM) and selective laser sintering (SLS); (ii) bio-based or biodegradable polymers qualified for pharmaceutical use; and (iii) life-cycle assessment approaches tailored to small-batch, personalized workflows. [8, 2] As decentralized printing scales, combining green materials with energy-efficient printers and digital inventory management could substantially improve the environmental footprint of selected therapies compared with centralized, high-volume manufacturing. [8, 2, 35] The roadmap presented in Figure 3 highlights the stepwise translation of personalized 3Dprinted OSD technologies from digital design to clinical implementation, underscoring the need for early integration of regulatory and quality considerations.

Conclusion

Three-dimensional printing has progressed from a prototyping aid to a clinically meaningful platform for patient-centric oral solid dosage (OSD) forms, enabling programmable control of dose, geometry, internal architecture, and release—capabilities that conventional batch methods cannot readily deliver. By aligning formulation design with individual needs (e.g., pediatrics, geriatrics, narrow-therapeutic-index drugs, and polypharmacy), 3D printing offers a credible route to precision pharmacotherapy and improved adherence. This review has shown that these advantages are technically feasible across multiple printing modalities and are increasingly supported by QbD/PAT-oriented control strategies and digital design workflows. Yet, translation at scale depends on resolving system-level barriers: regulatory ambiguity around decentralized, small-batch production and evolving digital designs; stability and shelf-life characterization for porous/structured architectures; and the economics and skills required for hospital- or pharmacy-based manufacture. Encouragingly, regulatory precedent (e.g., Spritam®) and emerging point-of-care quality assurance (hand-held NIR/Raman) demonstrate that compliant pathways are achievable when robust control strategies are in place.

Looking forward, the transformative potential of 3D-printed personalized OSDs will be realized by coupling AI-driven formulation/process design with smart dosage forms, decentralized manufacturing networks, and sustainability-focused practices. These directions can shorten development cycles, embed real-time verification, and localize supply—ultimately delivering regulatory-compliant personalization where and when patients need it.

Achieving this vision requires deliberate collaboration among industry, academia, regulators, and hospital pharmacies. We advocate (i) co-creation of reference processes and material–printer "playbooks"; (ii) harmonized guidance and clinical-trial frameworks for point-of-care production; and (iii) shared training programs that blend formulation science, additive manufacturing, and digital/PAT analytics. Coordinated efforts across these communities will convert today's pilots into routine, scalable clinical practice, bringing the full promise of 3D-printed personalized medicines to patients.

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Declaration of Competing Interest

The authors declare no competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data Availability

No datasets were generated or analyzed for this review.

Declaration of Generative Ai

During the preparation of this work the authors used AI-assisted tools for language refinement and structural organization. After using these tools, the authors reviewed and edited the content and take full responsibility for the content of the article.

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