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3D Printing in Pharmaceutical Drug Delivery: Recent Advances and Future Perspectives.

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Abstract : *Three-dimensional (3D) printing, also known as additive manufacturing, has emerged as one of the most transformative technologies in the pharmaceutical sciences over the past decade. Unlike conventional subtractive or formative manufacturing methods, 3D printing builds a dosage form layer-by-layer directly from a digital model, enabling unprecedented control over the internal architecture, geometry, release kinetics, and dose of a medicine. This review presents a comprehensive overview of the principles, workflow, and major additive manufacturing technologies relevant to pharmaceutical drug delivery, including fused deposition modelling (FDM), stereolithography (SLA), selective laser sintering (SLS), inkjet and binder-jet printing, and semi-solid extrusion (SSE). The review further discusses the comparative advantages of 3D printing over traditional pharmaceutical manufacturing, its expanding application landscape spanning personalized dosage forms, polypills, orodispersible tablets, paediatric and geriatric formulations, hospital point-of-care compounding, veterinary medicine, space medicine, disaster relief, and bioprinting of tissues and organs.*

Particular attention is given to recent regulatory and industrial milestones, including the U.S. FDA approval of Spritam (levetiracetam) as the first 3D-printed drug, the clinical advancement of Triastek's Melt Extrusion Deposition (MED) platform, FabRx's Printlets and M3DIMAKER technology, and the United Kingdom's 2025 point-of-care manufacturing framework. The integration of artificial intelligence and machine learning into formulation design, printability prediction, and process optimization is examined as a key driver of the field's next phase of growth. Market analyses project the global 3D-printed drug sector to grow steadily over the coming decade, driven by rising demand for personalized medicine, an ageing global population, and increasing prevalence of chronic and orphan diseases. The review concludes by outlining the principal technical, regulatory, and economic challenges that must be addressed — including high capital cost, limited pharmaceutical-grade printable materials, lack of harmonized quality standards, and scale-up constraints — before offering perspectives on the future trajectory of 3D and 4D printing in mainstream pharmaceutical practice.

Keywords: 3D printing; additive manufacturing; pharmaceutical drug delivery; personalized medicine; fused deposition modelling; stereolithography; selective laser sintering; bioprinting; point-of-care manufacturing; artificial intelligence

I. INTRODUCTION

The pharmaceutical industry has, for over a century, relied on batch-based, one-size-fits-all manufacturing methods such as direct compression, wet granulation, and film coating to produce tablets and capsules in large, uniform quantities. While these processes are efficient at scale, they offer very limited flexibility to tailor a dose, release profile, or combination of drugs to the specific physiological needs of an individual patient. Genetic variability, age, organ function, disease state, and concurrent medication all influence how a patient responds to a fixed dose, yet conventional manufacturing can typically offer only a handful of discrete strengths of any given product.

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Three-dimensional (3D) printing, formally termed additive manufacturing, offers a fundamentally different paradigm. Rather than shaping a bulk material through cutting, moulding, or compression, additive manufacturing constructs an object layer-by-layer directly from a digital three-dimensional model. This layer-wise construction allows a level of geometric and compositional freedom that is simply unattainable with traditional tooling-based methods. In the context of medicine, this translates into the ability to print tablets with patient-specific doses, complex internal geometries that produce tailored release profiles, multi-drug "polypills" that combine several active ingredients in a single unit, and even living tissue constructs for regenerative medicine.

Interest in pharmaceutical 3D printing accelerated markedly after the United States Food and Drug Administration approved Spritam (levetiracetam), manufactured using Aprecia Pharmaceuticals' ZipDose technology, as the first 3D-printed drug product in 2015. Since then, a growing number of academic groups and companies — including FabRx, Triastek, Aprecia, Merck, and GlaxoSmithKline — have advanced the field from laboratory proof-of-concept toward regulated clinical and commercial products. This review article aims to consolidate the current state of knowledge regarding pharmaceutical 3D printing: its scientific fundamentals, the principal fabrication technologies in use, its comparative advantages and limitations relative to conventional manufacturing, its diverse clinical and industrial applications, the evolving global regulatory landscape, and the emerging convergence of 3D printing with artificial intelligence and 4D "smart material" printing.

II. HISTORICAL BACKGROUND AND EVOLUTION

The conceptual foundation of additive manufacturing dates to the early 1980s. Charles (Chuck) Hull is widely credited with developing stereolithography in 1984, patenting a photopolymer-based process capable of building solid three-dimensional objects from successive cured layers of a liquid resin — a method that he commercialised through the company 3D Systems. Around the same period, other additive techniques such as selective laser sintering and fused deposition modelling were developed, collectively giving rise to what was initially termed "rapid prototyping," since the earliest use of the technology was to produce design prototypes and models quickly, rather than final functional products.

Through the 1990s and 2000s, additive manufacturing steadily expanded beyond prototyping into end-use part production across the aerospace, automotive, dental, and orthopaedic industries. Its entry into pharmaceutical science followed a similar trajectory: early academic work in the 2000s explored 3D printing for controlled-release matrices and complex-shaped tablets, but the field only achieved mainstream visibility with Aprecia's 2015 FDA approval of Spritam. In the decade since, the number of peer-reviewed publications, patent filings, and industry entrants focused specifically on pharmaceutical 3D printing has grown exponentially, reflecting the technology's transition from a niche academic curiosity to an increasingly serious candidate for personalized and point-of-care medicine manufacturing.

III. FUNDAMENTALS OF 3D PRINTING

3.1 What is 3D Printing?

3D printing, or additive manufacturing, is the process of constructing a three-dimensional solid object from a digital file by depositing or solidifying material in successive layers until the entire object is formed. This stands in direct contrast to subtractive manufacturing (e.g., machining, milling) in which material is progressively removed from a larger block, and to formative manufacturing (e.g., moulding, compression) in which material is shaped under pressure using a fixed tool or die. Because each layer is built up independently under digital control, additive manufacturing can generate internal channels, graded compositions, and geometries of a complexity that would be impossible, or prohibitively expensive, to achieve using traditional tooling.

3.2 How It Works

The pharmaceutical 3D printing process generally begins with the creation of a virtual, three-dimensional design of the desired dosage form. This digital model is typically generated using computer-aided design (CAD) software or derived from a 3D scan of an existing object (for example, an anatomical structure obtained from patient imaging data).

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Specialised slicing software then converts this three-dimensional model into hundreds or thousands of thin, horizontal cross-sectional layers, generating the precise instructions — commonly in G-code — that direct the printer's motion, temperature, and material deposition. The 3D printer then executes these instructions, building the object one layer at a time until the complete three-dimensional dosage form, device, or tissue construct is produced.

IV. 3D PRINTING VERSUS TRADITIONAL PHARMACEUTICAL MANUFACTURING

Traditional pharmaceutical manufacturing — encompassing direct compression, wet and dry granulation, and film coating — is optimised for producing very large quantities of an identical product at low unit cost. This economy-of-scale model has served the industry well for mass medicines but is structurally mismatched to the growing demand for personalized dosing, rare-disease formulations, and rapid formulation iteration during drug development. Table 1 summarises the principal points of comparison between conventional manufacturing and pharmaceutical 3D printing.

Parameter	Traditional Manufacturing	3D Printing (Additive Manufacturing)
Manufacturing Principle	Batch compression, granulation, moulding	Layer-by-layer additive deposition
Customization	Limited to a few fixed strengths	Patient-specific dose and geometry
Design Complexity	Constrained by tooling/die shape	Virtually unlimited internal geometry
Production Scale	Efficient for large batch volumes	Best suited to small/on-demand batches
Lead Time for New Design	Weeks to months (new tooling required)	Hours (digital file modification only)
Material Waste	Higher (granulation losses, trimming)	Minimal (additive, near-net-shape)
Capital Investment	High for large-scale tooling/lines	Lower entry cost, but scale-up remains costly
Regulatory Pathway	Well established	Still evolving (case-by-case review)

As shown in Table 1, 3D printing does not aim to replace conventional manufacturing wholesale; rather, the two approaches are complementary. Large-volume, well-characterised generic medicines are likely to remain most economically produced via conventional routes, while 3D printing is expected to occupy the growing niche of personalized, complex-release, and low-volume/high-value products, including hospital and community pharmacy point-of-care compounding.

V. GENERAL WORKFLOW OF PHARMACEUTICAL 3D PRINTING

Irrespective of the specific additive technology employed, pharmaceutical 3D printing follows a broadly conserved three-stage workflow: pre-processing, processing, and post-processing (Figure 1). In the pre-processing stage, the dosage form is designed using CAD or specialised pharmaceutical modelling software (such as Mayo or Rhino-based tools), the design is converted into a 3D model, and this model is then processed by slicing software into printer-readable instructions. The processing stage involves the operation of the 3D printer itself, during which the drug-loaded material — whether a filament, powder bed, resin, or paste — is deposited or solidified layer by layer to build the final object.

The post-processing stage varies depending on the printing technology used but commonly includes removal of unbound powder or support material, curing or drying (for example, ultraviolet post-curing of photopolymerised resins, or thermal annealing of extruded filaments), and, where required, polymer or metal infiltration to achieve the desired mechanical strength, porosity, or surface finish. Quality control testing — including assay, content uniformity, dissolution, and mechanical strength testing — is then performed prior to release of the finished dosage form.

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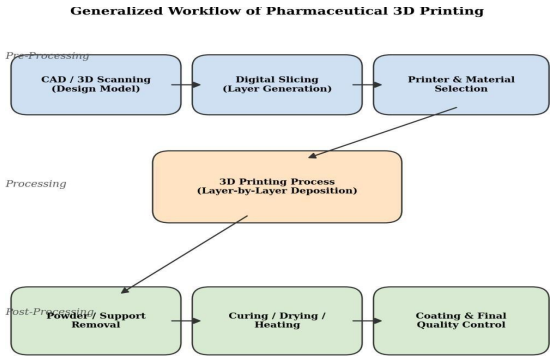


Figure 1: Generalized workflow of pharmaceutical 3D printing, from digital design through post-processing and quality control.

VI. METHODS AND TECHNOLOGIES

Several distinct additive manufacturing technologies have been adapted for pharmaceutical use, each differing in the physical mechanism used to build layers, the range of compatible materials, resolution, and throughput. The principal technologies of pharmaceutical relevance are described below.

6.1 Fused Deposition Modelling (FDM)

Fused deposition modelling is the most widely researched 3D printing technique in pharmaceutics, owing to its low cost, simplicity, and compatibility with hot-melt extrusion. In FDM, a drug-loaded thermoplastic filament (typically prepared by hot-melt extrusion of a polymer such as polyvinyl alcohol, hydroxypropyl cellulose, or Eudragit combined with the active pharmaceutical ingredient) is fed through a heated nozzle. The nozzle melts the filament and deposits it in a precise pattern, layer upon layer, onto a build platform, guided in both the horizontal and vertical directions by computer-aided manufacturing (CAM) software. The extruded material solidifies almost immediately upon deposition, allowing the next layer to be built on top. Drug loading is most commonly achieved by incubating or extruding the filament with the active ingredient dissolved or dispersed within the polymer matrix.

6.2 Stereolithography (SLA)

Stereolithography exploits photopolymerization to convert a liquid resin into a solid object. A vat of ultraviolet (UV)-curable photopolymer resin is selectively exposed to a focused UV laser, or to a digitally mirrored UV light pattern, which initiates a chemical cross-linking (gelation) reaction in the exposed regions only. This process is repeated layer by layer, with the build platform incrementally lowered (or raised, in inverted configurations) into the resin vat, until the complete three-dimensional object is formed. SLA offers very high resolution and smooth surface finish, making it attractive for complex, high-precision dosage forms, although the range of pharmaceutically acceptable photocurable resins remains comparatively limited.

6.3 Selective Laser Sintering (SLS)

Selective laser sintering uses a high-power laser to selectively fuse powdered material — which may include polymers, drug-excipient blends, or, in non-pharmaceutical contexts, metals and glass
— layer by layer. The laser scans across a thin layer of powder spread over the build platform, sintering (partially melting and fusing) the powder particles only in the regions defined by the digital cross-section. A fresh layer of powder is then spread on top, and the process repeats. Because SLS does not require a solvent or binder liquid and can produce porous, rapidly disintegrating structures, it has attracted particular interest for orodispersible tablet formulations.

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6.4 Inkjet Printing (Binder Jetting and Drop-on-Demand)

Inkjet-based pharmaceutical printing systems fall into two broad categories: continuous inkjet (CIJ) printing and drop-on-demand (DOD) printing. In continuous inkjet printing, liquid ink (which may be a drug solution or a binder fluid) is forced through a fine orifice, typically 50 to 80 micrometres in diameter, generating a continuous stream that is broken into uniformly sized droplets at controlled intervals using a piezoelectric crystal. These droplets are then electrostatically charged and deflected onto the substrate with high positional accuracy. In binder-jet systems — the technology underlying Aprecia's ZipDose platform used in Spritam — a liquid binder is selectively deposited from a print head onto a powder bed, layer by layer, binding powder particles together to build a highly porous, rapidly disintegrating tablet structure. Inkjet printing is especially well suited to precise, low-dose drug deposition and has been highlighted in recent market analyses as the fastest-growing 3D printing technology segment in the pharmaceutical sector.

6.5 Semi-Solid Extrusion (SSE) and Pressure-Assisted Micro-Syringe Systems

Semi-solid extrusion, also referred to as pressure-assisted micro-syringe (PAM) printing, dispenses a semi-solid paste or gel — typically composed of the drug dispersed in a polymer-based matrix — through a nozzle under applied pressure, without requiring the material to be melted. Because it avoids high processing temperatures, SSE is particularly advantageous for thermolabile drugs and biologics. Nozzle-based deposition systems, of which FDM and SSE are the two principal subtypes, share the common feature of extruding a continuous bead of material through a moving nozzle, differentiated primarily by whether the feed material is a melted thermoplastic filament or an unmelted semi-solid paste.

6.6 Overview of 3D Printer Types Used in Pharmaceutical Manufacturing

Printer Type	Working Principle	Representative Pharmaceutical Use
Inkjet Printing (CIJ / DOD, Binder Jetting)	Deposits liquid drug/binder droplets onto a substrate or powder bed	Precise low-dose deposition; ZipDose (Spritam)
Stereolithographic (SLA / DLP)	UV laser or projected light cures photopolymer resin layer by layer	High-resolution, complex-geometry tablets
Selective Laser Sintering (SLS)	Laser sinters powdered drug-polymer blend	Porous, fast-disintegrating orodispersible tablets
Powder-Based / Binder Jetting	Binder selectively bonds powder particles layer by layer	Highly porous fast-dissolving dosage forms
Nozzle-Based Deposition (FDM & SSE)	Extrudes melted filament or semi-solid paste through a nozzle	Multi-drug polypills, controlled-release tablets
Fused Deposition Modelling (FDM)	Thermoplastic drug-loaded filament melted and extruded	Widely used research and prototyping platform

Table 2: Overview of the principal 3D printer types used in pharmaceutical drug delivery.

VII. PRINTABLE MATERIALS IN PHARMACEUTICAL 3D PRINTING

The choice of printable material — often termed the "ink" or "feedstock" — is central to the performance of any pharmaceutical 3D printing process and must simultaneously satisfy processability requirements (melt viscosity, curing behaviour, powder flow) and pharmaceutical requirements (biocompatibility, stability, drug release performance). Commonly used polymer carriers include hydrophilic cellulose derivatives such as hydroxypropyl methylcellulose (HPMC) and hydroxypropyl cellulose (HPC), polyvinyl alcohol (PVA), polyethylene oxide (PEO), and pH-dependent methacrylate copolymers (Eudragit grades) used to engineer immediate, sustained, or delayed drug release. For semi-

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solid extrusion and bioprinting, hydrogels based on alginate, gelatin, and gelatin methacryloyl (GelMA) are widely used owing to their favourable rheological behaviour and biocompatibility.

In laser-based sintering and binder-jetting processes, mannitol, lactose, and other directly compressible sugar alcohols and saccharides frequently serve as the bulk powder matrix, valued for their rapid dissolution and pleasant mouthfeel in orodispersible formulations. For bioprinting applications, specialised "bioinks" incorporating living cells suspended within hydrogel matrices are used to fabricate tissue-mimetic constructs. The relatively narrow range of pharmaceutical-grade, regulator-accepted printable excipients remains one of the key bottlenecks constraining broader clinical translation of the technology, and considerable ongoing research is directed at expanding and formally validating new printable excipient grades.

VIII. ADVANTAGES OF 3D PRINTING IN PHARMACEUTICS

The adoption of 3D printing in pharmaceutical science is driven by a combination of manufacturing, clinical, and economic advantages, summarised below.

- High production flexibility and rapid design iteration, since changes require only a modification of the digital file rather than new tooling.
- Substantial time and cost savings during formulation development and small-batch or on-demand production.
- A clean, largely additive process that minimizes material wastage compared with subtractive or granulation-based methods.
- Enables true customization: with a suitable printer, raw material, and digital blueprint, virtually any dosage geometry, however complex, can be produced.
- Supports constant prototyping and increased productivity, enabling rapid generation of multiple prototype formulations or small-scale batches for testing.
- Improves communication between formulation designers and clinicians/patients through tangible, rapidly iterated physical prototypes.
- Enables complex, multi-drug, and multi-release-rate dosage forms (e.g., polypills) that are difficult or impossible to manufacture conventionally.
- Facilitates precise, patient-specific dosing, particularly valuable in paediatric, geriatric, and narrow-therapeutic-index medicines.

IX. DISADVANTAGES AND TECHNICAL CHALLENGES

Despite its considerable promise, pharmaceutical 3D printing faces a number of practical, technical, and regulatory constraints that currently limit its widespread clinical and industrial adoption.

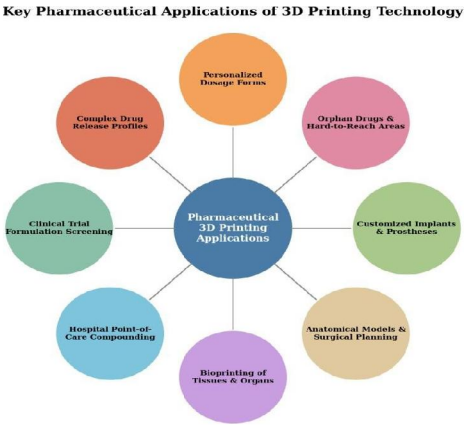
- High capital cost of pharmaceutical-grade 3D printers, with commercial-scale industrial systems commissioned at costs reported in the tens of thousands of US dollars and beyond.
- Unsuitability for very large-scale production runs, since layer-by-layer building is inherently slower than high-speed compression or coating lines.
- Difficulty of manual removal or installation of certain components (e.g., support structures, unbound powder) without specialised post-processing equipment.
- Mechanical and hardware reliability issues, including nozzle clogging, inconsistent extrusion, and calibration drift over repeated use.
- Printed components may not always possess the mechanical strength (hardness, friability) required for conventional handling, packaging, and transport.
- A comparatively limited range of validated, pharmaceutical-grade raw materials suitable for each printing technology.

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- Risk of misuse for the unauthorized or illicit production of controlled or dangerous substances outside regulated facilities.
- Printing speed remains a practical constraint: building even a small tablet or device can take a meaningfully longer time than conventional high-speed tableting.
- Absence of a single, universally accepted digital file standard; while the STL (stereolithography) format remains dominant, newer formats such as AMF have seen limited real-world adoption to date.

X. PHARMACEUTICAL AND BIOMEDICAL APPLICATIONS

The application landscape of 3D printing in pharmaceutical drug delivery has broadened considerably over the past decade, extending from simple dose customization to the fabrication of living tissue. Figure 2 summarises the principal



application domains discussed in this section.

Figure 2: Key pharmaceutical applications of 3D printing technology

10.1 Personalized Dosage Forms and Mass Personalization

Perhaps the most widely cited benefit of pharmaceutical 3D printing is its capacity for mass personalization — the ability to economically produce individualized doses, shapes, and release profiles for each patient, rather than a limited number of fixed standard strengths. This is particularly valuable for narrow-therapeutic-index drugs, where small deviations from the optimal dose can meaningfully affect efficacy or safety, and for patient populations such as children and the elderly, whose dosing requirements vary widely by body weight, renal and hepatic function, and concomitant disease.

10.2 Polypills and Complex Drug Release Profiles

Additive manufacturing enables the fabrication of "polypills" — single dosage units combining two or more active pharmaceutical ingredients, each potentially formulated with a distinct release profile within discrete compartments of the same tablet. This capability supports improved adherence in patients on complex multi-drug regimens, such as those managing cardiovascular disease or tuberculosis, by consolidating multiple medications into a single unit. Beyond combination products, 3D printing allows fine control of internal tablet architecture — for example, graded shell thickness or internal lattice porosity — to engineer immediate-release, sustained-release, delayed-release, or pulsatile release profiles that would be extremely difficult to achieve through conventional coating or matrix technology.

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10.3 Orodispersible and Paediatric/Geriatric Formulations

Binder-jet and laser-sintering technologies are especially well suited to producing highly porous, rapidly disintegrating orodispersible tablets, which dissolve almost instantly in the mouth without the need to swallow a solid dosage form whole. Such formulations are of particular value to paediatric and geriatric patients, and to individuals with dysphagia (swallowing difficulty), a population for whom Aprecia's Spritam — an orodispersible, high-dose formulation of the anti-epileptic drug levetiracetam — was specifically developed.

10.4 Hospital and Community Pharmacy Point-of-Care Manufacturing

An emerging application of considerable clinical significance is point-of-care 3D printing, in which hospital or community pharmacies use compact 3D printers to compound personalized medicines on-site and on-demand, rather than relying on centrally manufactured batch products. FabRx has piloted this model with its M3DIMAKER printer platform and its Printlets technology, including the world's first clinical trial of personalized 3D-printed chewable tablets for children with Maple Syrup Urine Disease (MSUD), a rare inherited metabolic disorder requiring precisely individualized dosing of specific amino acids. The United Kingdom's introduction of a formal point-of-care manufacturing regulatory framework in 2025 represents an important step toward legitimising this model at national scale.

10.5 Clinical Trials and Formulation Screening

3D printing offers pharmaceutical developers the ability to rapidly generate multiple formulation variants — differing in excipient composition, geometry, or internal structure — for early-phase testing, accelerating the traditionally slow, iterative process of formulation optimisation. Triastek, for example, has partnered with major pharmaceutical companies to apply its "3D Printing Formulation" approach, rapidly producing and screening prototype formulations to identify the most promising candidate for further development and eventual mass production.

10.6 Automatic Compounding and Extemporaneous Preparation

3D printing is being explored as a means of automating extemporaneous compounding — the traditional pharmacist practice of preparing customized medicines for individual patients — with the potential to improve dosing accuracy, reduce compounding errors, and provide a documented, reproducible digital record of each preparation, addressing long-standing quality and consistency concerns associated with manual compounding.

10.7 Veterinary Medicine

The same principles of dose customization apply readily to veterinary pharmaceuticals, where the very wide range of patient body weights across species (and even within a species) makes fixed-dose products particularly poorly suited to precise, weight-based dosing. 3D printing allows veterinary formulations to be tailored to the specific weight and species of an individual animal.

10.8 Space Medicine and Extreme/Hard-to-Reach Environments

For long-duration space missions, where resupply of a full pharmacy inventory is impractical, on-demand 3D printing of medicines directly aboard a spacecraft has been proposed as a means of ensuring astronauts have access to needed medications without carrying an extensive, potentially expiring, stockpile. The same rationale extends to other hard-to-reach environments, including remote or resource-limited regions, disaster-affected areas, and battlefield or emergency care settings, where centralized drug supply chains may be disrupted or unavailable.

10.9 Bioprinting of Tissues and Organs

Beyond conventional dosage forms, 3D bioprinting — the layer-by-layer deposition of living cells suspended in biocompatible hydrogel "bioinks" — is being developed to fabricate tissue constructs and, in the longer term,

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functional organs for transplantation, drug toxicity testing, and disease modelling. While full organ bioprinting for clinical transplantation remains an aspirational long-term goal, simpler tissue constructs (skin, cartilage) and organ-on-chip models are already contributing to preclinical drug screening.

10.10 Anatomical Models, Implants, and Prostheses

3D printing is well established in the fabrication of patient-specific anatomical models used for surgical planning and rehearsal, derived directly from a patient's own medical imaging data, as well as in the production of customized orthopaedic and dental implants and prosthetic devices whose geometry is matched precisely to an individual patient's anatomy.

XI. REGULATORY LANDSCAPE

The regulatory pathway for 3D-printed pharmaceuticals continues to evolve alongside the technology itself. The single most significant regulatory milestone to date remains the U.S. FDA's 2015 approval of Aprecia Pharmaceuticals' Spritam, which was authorised via the 505(b)(2) pathway, allowing the company to rely on existing safety data for the active ingredient levetiracetam while independently demonstrating the specific clinical benefit — rapid disintegration — conferred by its ZipDose binder-jet printing platform. That approval required the FDA and the sponsor to jointly define new quality specifications appropriate to the unique "layered" internal architecture of the tablet, since existing compendial tests for friability and hardness were not directly applicable. In 2025, the FDA extended Spritam's authorised route of administration to include delivery via nasogastric tube, further demonstrating the platform's clinical versatility.

Since Spritam, several additional 3D-printed drug candidates have progressed through regulatory review. Triastek has obtained multiple Investigational New Drug (IND) clearances in both the United States and China for its Melt Extrusion Deposition (MED)-based products, including candidates targeting cardiovascular disease, ulcerative colitis, gastric retention, and rheumatoid arthritis, and in September 2025 received China's first manufacturing licence specifically for 3D-printed pharmaceuticals. On the institutional front, the U.S. FDA has issued draft guidance addressing the additive manufacturing of pharmaceutical products, and has included at least one 3D printing-focused company within its Emerging Technology Program, intended to support early regulatory engagement for novel manufacturing platforms.

Perhaps the most consequential recent regulatory development for decentralized manufacturing is the United Kingdom's 2025 introduction of a formal point-of-care manufacturing framework, which for the first time provides a defined legal structure under which hospitals may produce personalized 3D-printed medicines on-site. This framework is widely regarded as a potential template for regulatory harmonisation in other jurisdictions, and its implementation will be closely watched as a bellwether for how quickly point-of-care 3D printing can move from pilot programmes into routine clinical practice. Despite this progress, no single, internationally harmonised regulatory standard yet exists specifically for pharmaceutical additive manufacturing; the current default remains a case-by-case review of each product and platform, which many stakeholders view as both a necessary safeguard during this formative period and a meaningful barrier to more rapid, standardized industry-wide adoption.

XII. INDUSTRY GROWTH AND MARKET ANALYSIS

Market research estimates for the global 3D-printed drugs sector vary considerably across analytical firms, reflecting differences in scope, segmentation, and forecasting methodology, but the underlying growth trend is consistently positive. Recent industry analyses place the 2024–2026 global market value in the range of roughly USD 100 million to several hundred million, with compound annual growth rates (CAGR) forecast by different analysts ranging from approximately 7% to over 15% through the early-to-mid 2030s, and at least one analysis projecting the broader personalized-3D-printed-medicine market to expand into the tens of billions of dollars by the mid-2030s under an

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optimistic technology-adoption scenario. Figure 3 illustrates a representative composite growth trajectory drawn from these industry forecasts.

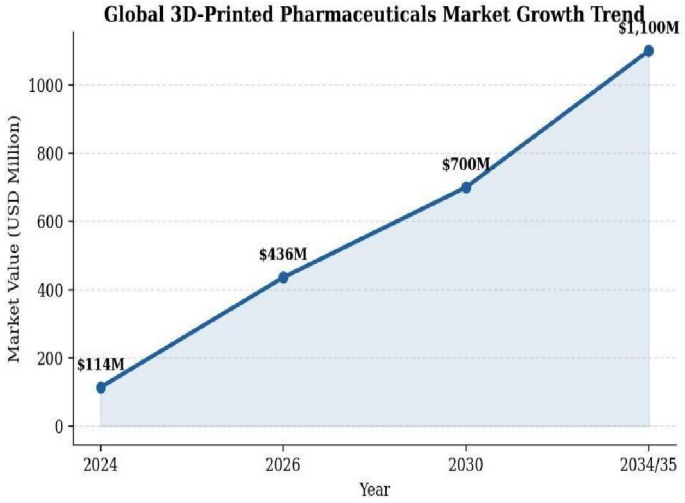


Figure 3: Representative composite growth trend of the global 3D-printed pharmaceuticals market (values illustrative, synthesized from multiple industry forecasts).

By technology, inkjet and binder-jet printing currently account for the largest share of commercial and clinical activity, benefiting from the established regulatory precedent of Aprecia's ZipDose platform, while several analyses identify inkjet printing as the fastest-growing technology segment going forward. By region, North America consistently leads global market share — commonly cited in the range of 30% to nearly 50% depending on the analysis — supported by early FDA approvals, strong pharmaceutical R&D investment, and companies such as Aprecia and Triastek's U.S. operations, while the Asia-Pacific region, driven substantially by China's rapidly scaling manufacturing capacity, is frequently identified as the fastest-growing regional market. Figure 4 presents the approximate relative share of the principal printing technologies discussed in Section 6, and Figure 5 illustrates end-use segmentation, in which hospitals and clinics represent the largest current adopter segment, followed by research laboratories and community/retail pharmacy settings.

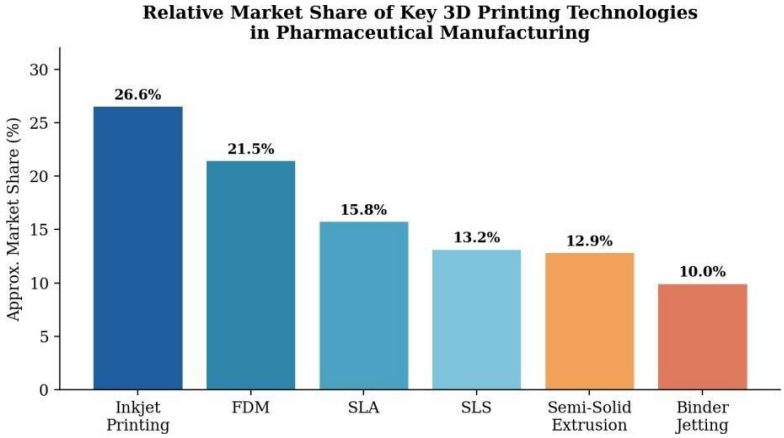


Figure 4: Approximate relative market share of key 3D printing technologies in pharmaceutical manufacturing (illustrative, based on synthesized industry data).

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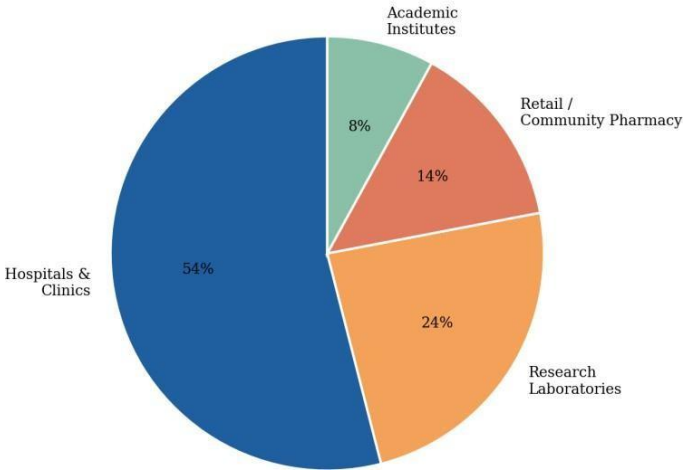


Figure 5: End-use segmentation of 3D-printed drug adoption (illustrative, based on synthesized industry data).

Key drivers underpinning this growth trajectory include the rising global prevalence of chronic diseases requiring long-term, individualized therapy; an ageing population with increasing rates of polypharmacy and dysphagia; growing regulatory acceptance following the Spritam precedent and emerging point-of-care frameworks; and continued capital investment by both established pharmaceutical companies (such as GlaxoSmithKline, Merck KGaA, and Johnson & Johnson) and specialised additive-manufacturing entrants (such as Aprecia, Triastek, and FabRx).

XIII. RECENT ADVANCES AND INDUSTRIAL CASE STUDIES

This section highlights several representative industrial and clinical case studies that illustrate the field's translation from research concept toward regulated clinical and commercial practice, summarised in Table 3.

Organization / Initiative	Core Technology	Key Milestone(s)
Aprecia Pharmaceuticals	Binder Jetting (ZipDose)	Spritam(levetiracetam) — first FDA-approved 3D-printed drug (2015); 2025 NG-tube administration approval
Triastek Inc.	Melt Extrusion Deposition (MED)	Multiple IND clearances (D23, T20G, T21, T24–T26); first Chinese 3D-printed drug manufacturing licence (2025); world's largest 3D-printed pharmaceutical facility under construction in Nanjing
Organization / Initiative	Core Technology	Key Milestone(s)
FabRx Ltd.	Semi-Solid Extrusion / SLS (Printlets, M3DIMAKER)	World's first clinical trial of personalized 3D-printed paediatric chewable tablets (Maple Syrup Urine Disease)
Triastek & BioNTech	MED (RNA formulation)	2024 collaboration to develop 3D-printed oral RNA therapeutics
UK Point-of-Care Framework	Regulatory (multi-platform)	2025 legal framework enabling hospital-based personalized 3D-printed medicine production

Table 3: Selected industrial and clinical case studies in pharmaceutical 3D printing.

Triastek's Melt Extrusion Deposition (MED) platform, which digitally designs the internal microstructure, material distribution, and drug-release architecture of a tablet, exemplifies the shift from empirical, trial-and-error formulation

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development toward a planned, computationally guided digital workflow. The company's D23 budesonide ileum-targeted tablet, for example, uses in vivo X-ray imaging-confirmed release only upon reaching the ileum, aligning drug exposure precisely with the site of disease origin in patients with IgA nephropathy — a level of spatial control over drug release that is difficult to achieve with conventional coating technologies.

FabRx's clinical work with paediatric Maple Syrup Urine Disease patients demonstrated, for the first time in a formal clinical trial setting, that personalized 3D-printed chewable tablets could be produced and dosed to match each child's individually varying amino-acid restriction requirements

— a use case that is essentially unaddressable through standard fixed-dose manufacturing. The company has further commercialised its M3DIMAKER printer as a hospital- and pharmacy-deployable platform, positioning its offering as "hardware as a service" rather than a single finished drug product, a business model that raises distinct regulatory questions concerning quality assurance at the point of dispensing.

The 2024 collaboration between Triastek and BioNTech to explore 3D-printed oral RNA therapeutics signals an important extension of additive manufacturing beyond small-molecule tablets into biologics and nucleic-acid medicines, a direction that, if successful, could substantially broaden the addressable scope of the technology.

XIV. ARTIFICIAL INTELLIGENCE AND 4D PRINTING: THE NEXT FRONTIER

14.1 Artificial Intelligence in Pharmaceutical 3D Printing

The integration of artificial intelligence (AI) and machine learning (ML) with pharmaceutical 3D printing is emerging as one of the most active research directions in the field. Machine-learning tools such as M3DISEEN and conditional generative adversarial networks have been used to predict a formulation's printability, optimal processing parameters, and expected drug-release behaviour prior to physical printing, and in some cases to generate entirely new, de novo FDM-printable formulations computationally. Reinforcement learning and deep neural network approaches are additionally being applied to predict optimal drug-excipient combinations, forecast formulation stability, and support integrated formulation-and-process design frameworks for pharmaceutical 3D printing platforms.

In principle, AI-guided design promises to substantially compress the traditionally slow, iterative, trial-and-error cycle of pharmaceutical formulation development, enabling more rapid identification of printable, stable, and clinically appropriate drug-excipient systems, while also supporting real-time process monitoring and adaptive control to maintain consistent product quality during printing. However, most published applications remain at a relatively early, largely academic stage, and considerably more work — including prospective clinical validation and regulatory engagement specific to AI-guided pharmaceutical manufacturing — will be required before such approaches see routine industrial deployment.

14.2 4D and 5D Printing: Stimuli-Responsive Drug Delivery

4D printing extends conventional 3D printing by incorporating "smart" materials that are engineered to change shape, structure, or function over time in response to an external stimulus — such as temperature, pH, humidity, or light — after the object has already been printed. In pharmaceutical applications, this principle has been explored to create temperature-responsive, self-folding drug delivery constructs capable of autonomously adjusting their configuration, and hence their drug-release behaviour, in response to the actual physiological environment encountered after administration, rather than following a fixed, pre-determined release profile. Machine-learning models have also been applied to help design and predict the behaviour of such stimuli-responsive 4D-printed constructs.

A further conceptual extension, 5D printing, adds rotational motion of the print head and build platform during fabrication (printing across five axes rather than the conventional three), enabling curved, multi-directional layer geometries that overcome a key limitation of standard 3D printing's

largely planar, layer-stacked construction. While 4D and 5D printing remain substantially earlier-stage than conventional 3D printing in terms of pharmaceutical translation, they represent a logical and actively researched extension of the technology toward genuinely adaptive, patient-responsive drug delivery systems.

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XV. FUTURE PERSPECTIVES

Looking ahead, pharmaceutical 3D printing is widely expected to change the nature of medicine manufacturing and distribution in ways that parallel the broader transformation additive manufacturing has brought to other industrial sectors — shifting a meaningful share of production from centralized, high-volume factories toward decentralized, on-demand fabrication closer to the point of patient care. Industry forecasts anticipate several converging trends over the coming decade.

- Wider clinical deployment of hospital and community pharmacy point-of-care manufacturing, following regulatory precedents such as the UK's 2025 framework, enabling truly individualized medicines to be produced and dispensed within a single clinical encounter.
- Expansion of validated, pharmaceutical-grade printable materials, including new excipient grades, biologics-compatible bioinks, and stimuli-responsive "smart" polymers for 4D printing applications.
- Deeper integration of artificial intelligence throughout the formulation lifecycle, from initial excipient selection and printability prediction through real-time in-process quality monitoring and adaptive process control.
- Continued growth in industrial-scale, GMP-compliant 3D printing facilities — exemplified by Triastek's large-scale Nanjing manufacturing plant — narrowing the throughput gap between additive manufacturing and conventional high-speed tableting.
- Gradual international harmonization of regulatory standards and quality specifications specific to additively manufactured pharmaceutical products, reducing the current reliance on case-by-case regulatory review.
- Expansion beyond oral solid dosage forms into 3D-printed biologics, RNA therapeutics, implantable and long-acting drug delivery devices, and increasingly sophisticated bioprinted tissue constructs for both therapeutic and preclinical testing applications.

Realising this future will require sustained, coordinated effort across multiple stakeholder groups: continued technical innovation from academic and industrial researchers; proactive, scientifically grounded regulatory engagement from national medicines agencies; investment in cost-effective, robust, and validated pharmaceutical-grade printing hardware and materials; and the development of appropriate training and professional competencies for pharmacists and manufacturing personnel who will operate this new generation of decentralized manufacturing technology. Provided these conditions are met, 3D printing is well positioned to become an established, mainstream component of the pharmaceutical manufacturing and personalized medicine landscape over the next decade.

XVI. CONCLUSION

Three-dimensional printing has evolved, over roughly four decades, from a niche rapid-prototyping technique into a genuinely disruptive pharmaceutical manufacturing platform capable of producing individualized doses, complex multi-drug combinations, and tailored release profiles that are difficult or impossible to achieve using conventional batch manufacturing methods. The regulatory approval of Spritam in 2015 established an important precedent that has since been built upon by companies such as Triastek and FabRx, whose clinical and industrial progress — spanning multiple regulatory clearances, the first dedicated 3D-printed drug manufacturing licence, and the first clinical trial of personalized paediatric 3D-printed tablets — demonstrates that the technology is steadily moving from academic promise toward regulated clinical reality.

Nonetheless, meaningful technical, material, economic, and regulatory challenges remain before pharmaceutical 3D printing can be considered a mature, mainstream manufacturing modality. High capital costs, a still-limited range of validated printable materials, comparatively slow production speeds relative to conventional high-throughput tableting, and the absence of harmonized international regulatory standards each represent real barriers to widespread adoption. The convergence of 3D printing with artificial intelligence for formulation design and process optimisation, together with the emerging capabilities of 4D "smart material" printing, points toward a future in which medicines are not only

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personalized in dose and geometry but potentially adaptive in their release behaviour to the individual patient's physiological state. For pharmacy education and practice, these developments signal the likely emergence of 3D printing as a core competency for the next generation of pharmacists, formulation scientists, and pharmaceutical manufacturing professionals.

XVII. ACKNOWLEDGEMENT

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