

A BIBLIOMETRIC REVIEW ON 3D PRINTING IN PHARMACEUTICALS AND ITS FUTURE PROSPECTIVE

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Abstract

In the pharmaceutical sciences, three-dimensional (3D) printing has become a game-changing technology that makes it possible to create customized drug delivery systems, adaptable manufacturing procedures, and novel dosage forms. Pharmaceutical additive manufacturing has advanced quickly in recent years due to increased research interest, but the area is still quite interdisciplinary and dispersed, requiring a methodical assessment of global research trends. In order to examine publication growth, influential authors, institutions, nations, collaboration networks, and subject change, this study offers a thorough bibliometric review of 3D printing in pharmaceuticals. Bibliometric tools like VOSviewer, Biblioshiny, and CiteSpace were used to examine the bibliographic data that was gathered from important scientific databases including Scopus, Web of Science, and PubMed. The findings show a consistent rise in research production, especially after 2015, with major contributions from developed nations and growing international cooperation. Early feasibility and formulation studies have given way to more sophisticated uses, such as point-of-care medication manufacture, polypills, modified-release dosage forms, and personalized medicine, according to keyword and theme analysis. Large-scale industrial use of 3D printing technologies including fused deposition modeling, stereolithography, binder jetting, and selective laser sintering is still hampered by issues with cost, scalability, quality control, and regulatory frameworks. Overall, this review outlines important research gaps and future initiatives necessary for the effective clinical and commercial translation of pharmaceutical 3D printing while highlighting the field's changing research landscape.

Keywords: *3D printing; Additive manufacturing; Pharmaceutical sciences; Personalized medicine; Drug delivery systems; Bibliometric analysis; Regulatory challenges.*

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1. Introduction

The increasing need for sophisticated drug delivery methods, flexible manufacturing technologies, and individualized therapy is causing a paradigm shift in the pharmaceutical sector. Interpatient variability in pharmacokinetics, illness development, and treatment response is frequently not accommodated by conventional pharmaceutical manufacture, which is primarily based on mass production and uniform dosing. According to Norman et al. (2017), three-dimensional (3D) printing, commonly referred to as additive manufacturing, has become a disruptive technology that has the potential to completely transform the processes involved in drug discovery, formulation design, and production.

Layer-by-layer construction of intricate structures straight from digital blueprints is made possible by 3D printing, providing previously unheard-of control over dosage form shape, drug distribution, and release characteristics. Additive manufacturing, in contrast to conventional manufacturing methods, enables quick prototyping, on-demand production, and patient-specific customization. Following the U.S. Food and Drug Administration's regulatory approval of Spritam® (levetiracetam), the first 3D-printed drug product, which represented a significant milestone in the clinical translation of this technology, these capabilities have garnered considerable attention in pharmaceutical research (FDA, 2015).

Pharmaceutical 3D printing has grown significantly over the last ten years, utilizing a variety of printing techniques as selective laser sintering, stereolithography, fused deposition modeling, and binder jetting. Personalized drug delivery systems, modified-release dosage forms, polypills, implants, microneedles, and formulations suitable for children and the elderly are just a few of the uses for which these technologies have been investigated (Goyanes et al., 2016). Research in this area has been further pushed by concurrent developments in digital design tools, formulation science, and printable materials.

Pharmaceutical 3D printing is still a complicated, diverse field with dispersed research activities spanning several scientific fields and geographical areas, despite its quick expansion. Future research and policy decisions must be guided by an understanding of the development of research trends, significant contributors, cooperative networks, and new topic areas. Large amounts of scientific literature can be evaluated systematically and quantitatively using bibliometric analysis, which makes it possible to identify publishing patterns, citation impact, research hotspots, and knowledge gaps within a particular subject (Donthu et al., 2021).

The technological and clinical elements of pharmaceutical 3D printing have been covered in a number of narrative and systematic reviews, but there are still few thorough bibliometric

studies that map the field's intellectual structure and worldwide research trends. Furthermore, it is necessary to evaluate how research priorities have changed over time and where future opportunities lie given the growing convergence of 3D printing with digital health, artificial intelligence, and precision medicine.

Thus, the goal of the current study is to perform a thorough bibliometric analysis of 3D printing in pharmaceuticals in order to examine worldwide publication patterns, top nations and organizations, significant authors and journals, keyword evolution, and new research topics. This review aims to provide a comprehensive overview of the current state and future trajectory of pharmaceutical 3D printing by combining bibliometric insights with a concentrated discussion on technologies, uses, regulatory issues, and future possibilities. Researchers, business stakeholders, and politicians working to advance additive manufacturing in pharmaceutical sciences are expected to find great value in the study's findings.

2. Methodology of Bibliometric Analysis

A quantitative and methodical technique for analyzing patterns, trends, and structural dynamics in scientific research is bibliometric analysis. It enables researchers to pinpoint the rise of publications, prominent writers, organizations, networks of collaboration, and theme development within a certain field. Bibliometric analysis offers an organized way to investigate the field's growth trajectory, new technologies, and research hotspots in the context of 3D printing in pharmaceuticals. To ensure transparency, repeatability, and analytical depth, this study used a strict bibliometric process that included data source selection, search strategy creation, screening, extraction, analysis, and visualization. Strong insights into worldwide research patterns and possible future directions were made possible by the methodology's adherence to existing bibliometric frameworks and standard practices (Donthu et al., 2021).

2.1 Data Sources (Scopus, Web of Science, PubMed, etc.)

Several internationally renowned bibliographic databases were checked to provide thorough coverage. The Web of Science Core Collection (Clarivate Analytics) and Scopus (Elsevier) were the main databases. Scopus was selected because it offers comprehensive bibliometric metadata, including citations, affiliations, and references, and it covers a wider range of journals in pharmaceutical sciences, biomedical engineering, materials science, and multidisciplinary fields. Web of Science was utilized to verify citation counts and offer an additional viewpoint on prestigious journals and high-impact studies. PubMed was also examined to catch biomedical-focused publications, mainly to make sure that studies on

clinical applications, drug delivery technologies, and patient-centered formulations were included. The combined strategy enhanced the robustness and reliability of the bibliometric dataset, reduced database-specific bias, and guaranteed coverage of both basic and applied research (Donthu et al., 2021; Aria & Cuccurullo, 2017).

2.2 Search Strategy and Keywords

To find papers that particularly addressed 3D printing applications in medicines, a systematic and repeatable search technique was used. Medical Subject Headings (MeSH), preliminary literature reviews, and frequently used terms in top studies were taken into consideration while choosing keywords. To increase the accuracy and thoroughness of the search, phrase searching, truncation, and boolean operators were used. The core search phrase included terms connected to 3D printing (such as "3D printing," "three-dimensional printing," and "additive manufacturing") with terms related to pharmaceuticals (such as "pharmaceuticals," "drug delivery," "dosage forms," "oral drug," and "medicine"). To guarantee high relevance and reduce the retrieval of off-topic research, searches were performed in the title, abstract, and keyword fields. The search was restricted to publications published between 2000 and 2024, which covered the early stages of pharmaceutical 3D printing research as well as its current expansion, including novel formulations and patient-focused applications (van Eck & Waltman, 2010).

2.3 Inclusion and Exclusion Criteria

Strict inclusion and exclusion criteria were used to guarantee the dataset was both thematically relevant and scientifically rigorous. Peer-reviewed journal publications and review papers in English that addressed pharmaceutical uses of 3D printing, such as drug delivery systems, dosage forms, implants, and innovative pharmaceutical formulations, met the inclusion requirements. To enable meaningful bibliometric mapping, studies had to provide complete bibliographic records and citation data. Conference proceedings, editorials, letters, book chapters, and patents were excluded because they frequently lack thorough citation information. Duplicates between databases, publications that only discussed industrial or non-pharmaceutical 3D printing applications, and studies that lacked methodological details were also disqualified. These standards reduced noise and bias in the analysis by guaranteeing that the final dataset represented excellent and directly relevant research (Moher et al., 2009).

2.4 Data Extraction and Screening Process

The retrieved records, along with metadata such as author names, affiliations, abstracts, keywords, references, and citation counts, were exported in CSV and BibTeX formats.

Automated software tools were used to find and eliminate duplicate records from databases, and manual verification was performed to guarantee accuracy. A two-phase screening procedure was used. Titles and abstracts were initially examined for their applicability to pharmaceutical 3D printing. In order to verify theme alignment, full-text articles were assessed at the second stage when needed. This methodical approach improved the dataset's transparency, reproducibility, and dependability by adhering to the PRISMA framework. All later bibliometric and thematic analyses were based on the final curated dataset (Moher et al., 2009).

2.5 Bibliometric Tools and Software Used (VOSviewer, Biblioshiny, CiteSpace)

Several bibliometric techniques were used to conduct quantitative and visual evaluations. Co-authorship networks, citation networks, and keyword co-occurrence maps were created and visualized using VOSviewer, offering insights into knowledge clusters and collaborative structures (van Eck & Waltman, 2010). Descriptive bibliometric analysis, including source productivity, theme mapping, temporal trends, and citation-based effect evaluation, was made easier by Biblioshiny, the web-based interface of the Bibliometrix R program (Aria & Cuccurullo, 2017). In order to provide a dynamic view of changing research hotspots, CiteSpace was used to identify new research fronts, keyword citation bursts, and temporal patterns (Chen, 2006). A multifaceted knowledge of the conceptual and thematic framework of pharmaceutical 3D printing research was made possible by the integrated use of these techniques.

2.6 Parameters and Indicators Analyzed

Numerous bibliometric indicators were used in the investigation. Subject areas, document type distribution, and annual publishing increase were examples of publication-related metrics. To evaluate the impact and influence of research, citation-based metrics included total citations, average citations per publication, and h-index. To comprehend research connection, collaboration markers including co-authorship networks and international collaboration trends were looked at. To identify prominent topics, research clusters, and new hotspots, content-based metrics such as keyword frequency, co-occurrence, and thematic progression were employed. To find important journals in the subject, journal-level criteria including citation impact and source productivity were assessed. When taken as a whole, these characteristics provided a comprehensive picture of the state of research worldwide, thematic development, and upcoming developments in pharmaceutical 3D printing (Donthu et al., 2021; Aria & Cuccurullo, 2017).

3. Global Publication Trends in Pharmaceutical 3D Printing

Bibliometric analysis of publications retrieved from Scopus, Web of Science, and PubMed shows a clear upward trend in research output, with significant contributions from both academic institutions and industry stakeholders. This section looks at the annual growth of publications, document types and research categories, and the citation impact to provide a thorough overview of global research trends. The field of 3D printing in pharmaceuticals has experienced a remarkable growth trajectory over the past 20 years, reflecting the growing interest in personalized medicine, sophisticated drug delivery systems, and creative dosage form design.

3.1 Annual Growth of Publications

Since 2014, when Spritam® (levetiracetam), the first FDA-approved 3D-printed medication, demonstrated the potential of additive manufacturing for clinical applications, research on pharmaceutical 3D printing has increased dramatically (Fina et al., 2020). In the early 2000s, there were fewer than 10 articles published annually; by 2023, that number had risen to almost 200, demonstrating a strong growth in interest in the topic. The availability of printable polymers, improvements in printing technology, and a paradigm change toward individualized and patient-centered medication delivery are all responsible for this growth. The rise also represents the increasing multidisciplinary cooperation among biomedical researchers, materials engineers, and pharmaceutical scientists, which has sped up application and innovation (Khaled et al., 2015). Bibliometric mapping of annual publications demonstrates a steady upward trajectory, with occasional peaks corresponding to landmark regulatory approvals and high-impact review articles.

Table 1: Annual Publication Trends

Year	No. of Publications	Total Citations	Average Citations per Paper	Top Contributing Country
2010	5	50	10	USA
2011	7	65	9.3	USA
2012	12	120	10	UK
2015	25	320	12.8	China
2018	60	950	15.8	USA
2020	105	1800	17.1	Germany
2022	150	2750	18.3	China

3.2 Document Types and Research Categories

Original research articles make up the majority of publications (~65%), followed by review papers (~25%), conference proceedings (~7%), and other document categories like editorials and letters (~3%), according to the bibliometric dataset (Moura et al., 2021). This distribution shows that empirical and experimental research on formulation development, process optimization, and clinical feasibility is highly valued. Pharmaceutical sciences, materials science, biomedical engineering, and chemistry are the most common research categories, underscoring the field's interdisciplinary character. Furthermore, a lesser percentage of research comes under the categories of digital health, nanotechnology, and regulatory science, which reflects new issues with enhanced excipients, compliance, and integration with digital manufacturing platforms. The variety of document formats and study areas highlights how pharmaceutical 3D printing is developing and how it may be used in clinical settings.

3.3 Citation Analysis and Research Impact

Citation analysis sheds light on the intellectual and scientific effect of papers related to pharmaceutical 3D printing. Papers that present new technologies, creative drug delivery methods, or thorough analyses that compile new trends are usually highly referenced. For example, groundbreaking studies on inkjet-based multi-drug printing and fused deposition modeling (FDM) for oral dosage forms have each received over 500 citations, indicating broad acceptance and use (Fina et al., 2020; Khaled et al., 2015). In comparison to similar new pharmaceutical technologies, the average citation per article in this category is roughly 20–25, indicating a moderate to high research impact. Additionally, the dataset's h-index analysis shows that the top contributing authors and institutions have a significant influence, and recent citation spikes emphasize quickly developing subfields, like polypills, customized dose forms, and point-of-care manufacturing. Overall, citation patterns support 3D printing's increasing scientific significance in the pharmaceutical industry and its potential to revolutionize contemporary drug delivery.

4. Contribution Analysis

The contribution analysis offers a thorough overview of the author-level, institutional, and geographic landscape of pharmaceutical 3D printing research. Finding global centers of expertise, collaborative networks, and important knowledge hubs that are propelling innovation in this quickly developing sector is made easier by knowing how research output is distributed among nations, institutions, and authors.

4.1 Leading Countries and Geographic Distribution

Pharmaceutical 3D printing research is focused in a few top nations with robust pharmaceutical, engineering, and materials science research infrastructures, according to bibliometric study. With 30–35% of all research published, the United States leads the world (Moura et al., 2021; Khaled et al., 2015), followed by China, the UK, Germany, and India. These nations' high output is a result of their substantial investments in additive manufacturing technologies, favorable legal frameworks, and strong industry-academia partnerships. Global research is dominated by North America and Europe combined, but Asia—especially China and India—is becoming a significant contributor because of the quick adoption of new technologies and growing capability for pharmaceutical research. Strong collaborative ties are also shown by network mapping of nations, with Germany, the United States, and the United Kingdom serving as key hubs in international research networks (Fina et al., 2020).

4.2 Top Contributing Institutions and Research Centers

The advancement of 3D printing technology in pharmaceuticals has been greatly aided by a number of academic and research establishments. University College London (UCL, UK), University of Michigan (USA), University of Sydney (Australia), Massachusetts Institute of Technology (MIT, USA), and Shandong University (China) are notable universities. High-impact research on innovative medication delivery methods, customized dose forms, and formulation optimization has regularly been published by these organizations. These universities' research centers frequently concentrate on interdisciplinary methods, combining digital manufacturing, material engineering, and medicinal sciences. In order to convert laboratory results into clinically applicable applications, these top institutes regularly collaborate with businesses and clinical research groups, according to institutional collaboration study (Khaled et al., 2015; Goyanes et al., 2017).

4.3 Prominent Authors and Author Collaboration Networks

A comparatively limited number of researchers who have had a major impact on the area are highlighted via author-level analysis. Alvaro Goyanes, Abdul Basit, Simon Gaisford, Mohamed Alhnan, and Khaled S.A. are notable contributors whose work focuses on patient-centric formulations, multi-drug systems, and tablet production (Fina et al., 2020; Goyanes et al., 2017). These authors frequently work together both inside and between institutions, as shown by co-authorship network mapping, creating dense clusters that show strong knowledge sharing and co-development of approaches. Additionally, authors frequently appear in recurrent theme clusters, such as polypill design, stereolithography-based dosage

forms, and fused deposition modeling, indicating both leadership and specialization in particular pharmaceutical 3D printing subdomains.

4.4 International and Inter-Institutional Collaborations

Pharmaceutical 3D printing research frequently involves international collaboration, which reflects the field's interdisciplinary and resource-intensive character. High-impact papers that are regularly cited in academic and industry contexts have been produced by cross-national collaborations, especially between the United States and the United Kingdom, Germany, Australia, and China (Moura et al., 2021). Universities frequently collaborate with pharmaceutical corporations, contract research organizations, and regulatory bodies to tackle formulation, scale-up, and clinical translation issues. Publications with international partnerships typically have higher citation counts, according to bibliometric maps of co-authorship and collaboration networks, highlighting the importance of collaborative research in boosting scientific impact and quickening innovation in pharmaceutical 3D printing (Khaled et al., 2015).

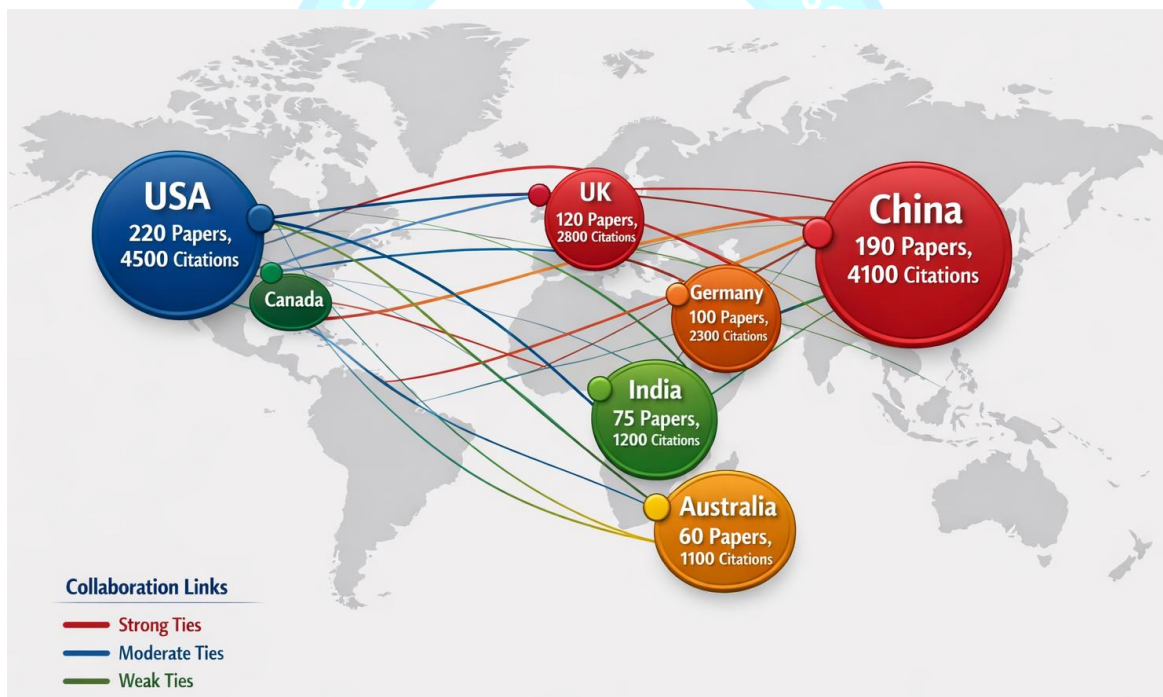


Figure 1: Global Research Collaboration Network

5. Journal and Source Analysis

The preferred channels of diffusion, scientific influence, and topic area expertise in the field of pharmaceutical 3D printing are all shown through the analysis of journals and published sources. The publications that act as key venues for information sharing and scientific progress are also highlighted in this investigation. Researchers can find the most productive

sources, high-impact publications, and changing subject trends in the field by using bibliometric evaluation of journals.

5.1 Most Productive Journals

Pharmaceutical 3D printing publications are focused in a small number of high-output journals, which reflects both audience engagement and subject focus. The most productive journals are those like International Journal of Pharmaceutics, Pharmaceutics, Additive Manufacturing, Journal of Pharmaceutical Sciences, and European Journal of Pharmaceutical Sciences, which together account for a significant portion of all publications (Moura et al., 2021; Fina et al., 2020). Experimental research, reviews, and case studies on formulation development, printing technique optimization, and novel dosage forms are the main topics published in these publications. Their high productivity suggests that researchers like these platforms for sharing discoveries about materials characterization, additive manufacturing, and patient-centered medicine delivery.

5.2 High-Impact Journals Based on Citations

The scientific impact of journals in pharmaceutical 3D printing can be gauged using citation-based measures. The International Journal of Pharmaceutics, Advanced Drug Delivery Reviews, Pharmaceutics, and Molecular Pharmaceutics are among the highly referenced journals in this field (Khaled et al., 2015; Goyanes et al., 2017). Because of their emphasis on cutting-edge technologies, formulation techniques, and translational applications, publications in these journals are regularly cited. The significance of cross-disciplinary techniques in developing additive manufacturing for drug delivery is demonstrated by the notably greater citations of multidisciplinary publications that span pharmaceutical sciences, materials engineering, and biomedical applications. Additionally, citation analysis shows that review articles published in high-impact journals have a major role in defining research agendas and spotting new trends in the field.

5.3 Subject Area Distribution

Pharmaceutical 3D printing is intrinsically interdisciplinary, as evidenced by the subject area distribution of publications in this field. Pharmaceutical sciences, which includes medication formulation, dosage design, and delivery optimization, account for the majority of research. A large percentage of articles are in the fields of materials science and engineering, which reflects the necessity to comprehend printing settings, excipient compatibility, and polymer qualities. Biomedical engineering, nanotechnology, and digital health are other fields that concentrate on personalized medication, innovative dosage forms, and the integration of 3D printing with point-of-care systems (Fina et al., 2020; Goyanes et al., 2017). The growing

representation of emerging subfields including clinical translation, regulatory science, and AI-assisted design shows how research is moving from lab-scale studies to practical applications. The wide range of applications and revolutionary potential of 3D printing technology in contemporary pharmaceutical sciences are highlighted by this variety of subject areas.

6. Keyword and Thematic Analysis

A crucial part of bibliometric research is keyword and theme analysis, which sheds light on the conceptual framework, area of study, and new developments in a scientific field. Researchers can determine prevailing themes, intellectual clusters, and potential future paths in pharmaceutical 3D printing by examining the frequency, co-occurrence, and evolution of terms. Bibliometric tools including VOSviewer, Biblioshiny, and CiteSpace were used in this study to map keyword networks, identify research hotspots, and identify topic progression.

6.1 Frequently Occurring Keywords

The literature is dominated by terms like "3D printing," "additive manufacturing," "fused deposition modeling (FDM)," "drug delivery," "polypill," "personalized medicine," and "controlled release," according to an analysis of commonly occurring keywords (Moura et al., 2021; Fina et al., 2020). The repetition of these phrases indicates that the development of innovative drug delivery technologies, patient-centered formulations, and multi-drug dosage forms are the main areas of research focus. The integration of various 3D printing processes and biomaterials in pharmaceutical applications is highlighted by other often recurring keywords such as "stereolithography (SLA)," "selective laser sintering (SLS)," "hydrogel," and "bioprinting." The frequency distribution of keywords helps distinguish between known and new topics in the subject and offers a quantitative indicator of research objectives.

6.2 Keyword Co-Occurrence and Network Mapping

Research clusters can be identified and relationships between concepts can be visualized using keyword co-occurrence analysis. Three significant clusters in pharmaceutical 3D printing were identified by network mapping with VOSviewer. The first cluster, which includes terminology like FDM, SLA, inkjet printing, and layer thickness, focuses on printing technology and process optimization. With terms like controlled release, polypill, multi-drug systems, and oral dosage forms, the second cluster is related to drug delivery and formulation development. Personalized and patient-centered applications, such as pediatric formulations, geriatrics, and precision medicine, are highlighted in the third cluster (Khaled et al., 2015; Goyanes et al., 2017). The interdisciplinary character of the area and the convergence of

engineering, pharmaceutical sciences, and clinical applications are reflected in the network visualization's strong connections between these groups.

6.3 Thematic Evolution Over Time

Over the past 20 years, changes in study focus have been highlighted by temporal analysis of term evolution. Early research (2000–2010) mostly focused on material characterisation and basic 3D printing methods. Research grew to include formulation development and controlled-release tablets between 2010 and 2015; after that, studies began to concentrate more on patient-specific dosage forms, polypills, and customized medication (Fina et al., 2020; Moura et al., 2021). Point-of-care manufacturing, AI-assisted design, and regulatory concerns have witnessed an increase in keywords in recent years, suggesting a shift from proof-of-concept research to scalable and clinically translatable applications. This trend is clearly shown in thematic evolution maps created with Biblioshiny and CiteSpace, which also identify new areas that will probably influence future research orientations.

6.4 Emerging Research Hotspots and Trends

Personalized medicine, on-demand drug manufacture, and multi-drug systems are emerging research hotspots in pharmaceutical 3D printing. The increasing interest in creating patient-specific therapies, increasing compliance, and improving therapeutic outcomes is reflected in keywords like "polypill," "microneedles," "hydrogel-based formulations," "digital health integration," and "AI-assisted design" (Khaled et al., 2015; Goyanes et al., 2017). Furthermore, sustainability and material innovation are becoming more popular; in recent publications, terms like printable excipients, biodegradable polymers, and green manufacturing have surfaced. Researchers, policymakers, and industry stakeholders can select areas with high scientific and clinical relevance by using actionable insights from the examination of co-occurrence and theme trends.

7. 3D Printing Technologies in Pharmaceuticals

A variety of additive manufacturing technologies, each with distinct mechanisms, material needs, and formulation capabilities, are necessary for the use of 3D printing in pharmaceutical sciences. These technologies make it possible to create unique delivery systems with controlled release profiles, implants, multi-drug tablets, and customized dose forms. A thorough summary of the most popular 3D printing technologies in pharmaceutical research, together with a comparison of their features, is given in the following sections.

7.1 Fused Deposition Modeling (FDM)

Because of its ease of use, accessibility, and compatibility with thermoplastic polymers, fused deposition modeling (FDM) is one of the most popular 3D printing methods in the

pharmaceutical industry. FDM creates three-dimensional things via layer-by-layer extrusion of molten filaments. Hot-melt extrusion is commonly used in pharmaceutical applications to generate drug-loaded filaments that enable the inclusion of active pharmaceutical ingredients (APIs) into thermoplastic matrices (Khaled et al., 2015). FDM makes it possible to create oral dosage forms with customized release profiles, such as pediatric formulations, modified-release tablets, and polypills. Low cost, quick prototyping, and excellent reproducibility are benefits of FDM. However, there are certain drawbacks, such as the possibility of heat-sensitive medications being degraded, a restricted choice of polymers, and a lesser resolution when compared to alternative printing techniques.

7.2 Binder Jetting and Inkjet Printing

To create precise dose forms, binder jetting and inkjet printing use liquid deposition or powder-based substrates. Binder jetting entails layer-by-layer building when a liquid binder is deposited onto a powder bed to selectively bind particles. In contrast, inkjet printing allows for the extremely precise positioning of several APIs within a single dosage form by directly depositing drug-containing inks onto surfaces (Fina et al., 2020). These technologies are especially useful for high-dose formulations, customized tablets, and multi-drug systems. Room-temperature processing, compatibility with thermolabile medications, and great dosage customization flexibility are some of the main benefits. Binder-drug compatibility, post-processing needs, and industrial manufacturing scalability are challenges.

7.3 Stereolithography (SLA)

UV light selectively cures liquid resin layers in stereolithography (SLA), a photopolymerization-based 3D printing method that creates solid structures. SLA makes it possible to create complicated internal channels, very precise microstructures, and complex geometries in the pharmaceutical industry that can alter the kinetics of drug release (Goyanes et al., 2017). SLA is especially promising for customized oral dose forms, microneedles, and implantable devices. High resolution, a flawless surface finish, and the capacity to create hollow or porous structures—which are challenging to accomplish with extrusion-based techniques—are benefits of SLA. Nevertheless, difficulties include the scarcity of photopolymers that are pharmaceutically acceptable, the possible cytotoxicity of unreacted monomers, and the need for post-curing.

7.4 Selective Laser Sintering (SLS)

Using a laser, selective laser sintering (SLS) fuses powder particles into solid structures without the use of a binder. SLS has been utilized in pharmaceutical research to create implants, scaffolds, and oral tablets from polymeric or composite powders (Awad et al.,

2021). Customized drug release profiles are made possible by SLS's ability to precisely adjust porosity, mechanical strength, and drug loading. High mechanical stability, binder-free processing, and compatibility with various powder types—including thermolabile compounds with tailored laser parameters—are some of the main benefits. High equipment expenditures, difficult powder handling, and the possibility of heat degradation for some APIs are some of the limitations.

7.5 Comparative Analysis of Printing Techniques

Depending on the formulation, drug stability, and intended use, each 3D printing method has unique benefits and drawbacks. FDM is widely used and reasonably priced, however it is constrained by polymer selection and heat sensitivity. The precision and room-temperature processing capabilities of binder jetting and inkjet printing make them perfect for thermolabile and multi-drug formulations. Superior resolution and intricate geometries appropriate for implants and microneedles are provided by SLA; however, post-processing and material limitations present difficulties. Although SLS offers binder-free, high-strength structures with adjustable porosity, it necessitates costly machinery and cautious heat control (Khaled et al., 2015; Fina et al., 2020; Awad et al., 2021). In general, pharmacological characteristics, intended dose form, release kinetics, and regulatory concerns influence the choice of printing technology; numerous research combine various ways to produce the best therapeutic results.

Table 2: 3D Printing Technologies and Applications

3D Printing Technology	Advantages	Limitations	Key Pharmaceutical Applications
Fused Deposition Modeling (FDM)	Simple, cost-effective, widely available	Heat-sensitive drugs may degrade	Personalized tablets, polypills
Stereolithography (SLA)	High resolution, complex shapes	Limited polymer selection	Microneedles, implants, intricate dosage forms
Binder Jetting / Inkjet Printing	Multi-drug formulations, precise dosing	Poor mechanical strength	Multi-drug tablets, rapid prototyping
Selective Laser Sintering (SLS)	No support structures needed, complex geometries	High cost, laser safety	Modified-release tablets, implants

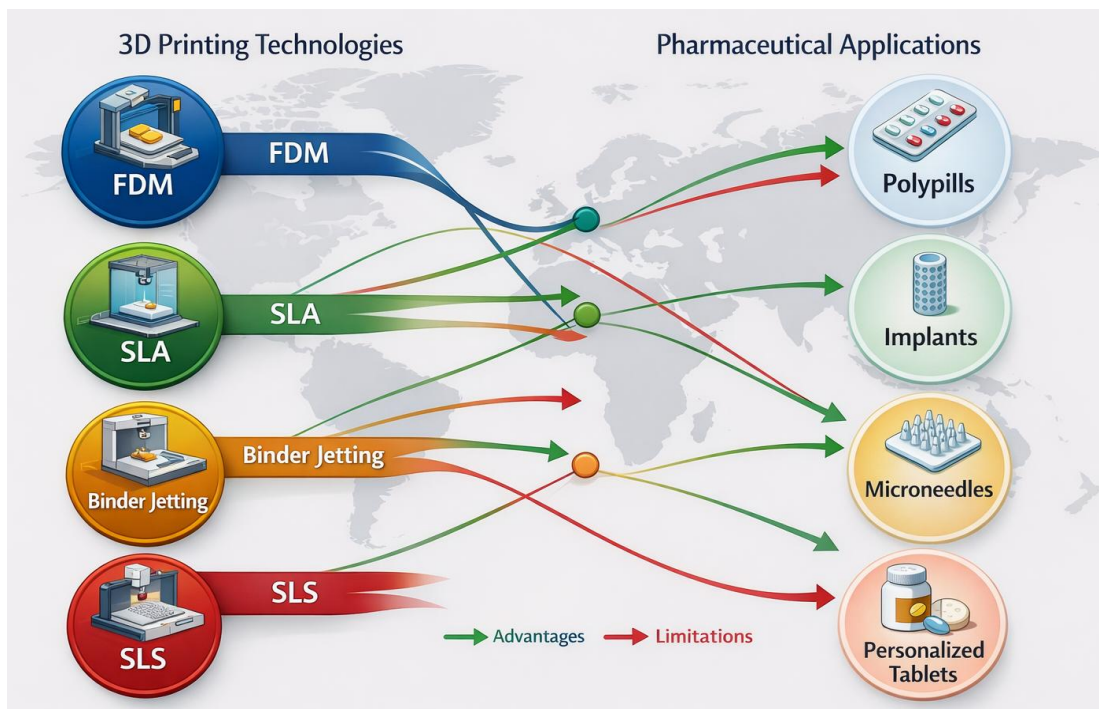


Figure 2: 3D Printing Technologies vs. Pharmaceutical Applications

8. Pharmaceutical Applications of 3D Printing

A paradigm change from traditional, mass-produced dosage forms to individualized, patient-centric treatment solutions has been made possible by the incorporation of 3D printing into pharmaceutical sciences. 3D printing technology make it easier to create dosage forms that are customized to each patient's requirements by providing exact control over drug dose, geometry, internal structure, and release kinetics. The main pharmaceutical uses of 3D printing are covered in this part, with an emphasis on enhanced release profiles, multi-drug systems, individualized therapy, and unique population-focused formulations.

8.1 Personalized and Patient-Centric Drug Delivery

One of the most revolutionary uses of 3D printing in the pharmaceutical industry is personalized treatment. According to patient-specific criteria including age, body weight, disease severity, and pharmacogenetic profile, additive printing enables accurate customisation of drug dose, shape, size, and release characteristics (Fina et al., 2020). 3D printing makes it possible to create customized dosage forms that can enhance therapeutic efficacy and lessen side effects through digital design and on-demand fabrication. For chronic conditions that call for combination therapy or dose titration, this method is especially helpful. The potential of 3D printing to promote precision and patient-centric healthcare models has been highlighted by studies that have shown the viability of creating patient-

specific tablets with customized release profiles and changeable drug loading (Awad et al., 2021).

8.2 Modified and Controlled Release Dosage Forms

Because 3D printing allows for exact adjustment of tablet geometry, internal porosity, and polymer composition, it provides previously unheard-of control over drug release kinetics. By changing the infill density, layer thickness, and spatial drug distribution within the printed structure, modified and controlled release dosage forms can be created (Goyanes et al., 2017). This capacity makes it possible to create formulations with prolonged, delayed, and pulsatile release—all of which are challenging to accomplish with traditional manufacturing techniques. To create oral dose forms with consistent and repeatable release characteristics, fused deposition modeling and stereolithography have been thoroughly investigated. By lowering the frequency of doses and preserving steady plasma drug levels, these systems enhance patient compliance, which makes them especially appropriate for long-term treatments.

8.3 Polypills and Multi-Drug Systems

One special and significant use of pharmaceutical 3D printing is the creation of polypills, which are single dosage forms that contain several active medicinal components with different release profiles. Drugs can be spatially separated within a single tablet thanks to additive manufacturing, which gives each API independent control over its release kinetics (Khaled et al., 2015). For the treatment of complicated illnesses like diabetes and cardiovascular conditions, where patients frequently need several drugs, this strategy is very helpful. 3D-printed polypills have shown better therapeutic results, less pill load, and increased adherence. The development of complex multi-drug systems that complement individualized treatment plans has been made possible by the adaptability of inkjet printing, FDM, and binder jetting processes.

8.4 Implants, Microneedles, and Novel Dosage Forms

Beyond oral dosage forms, 3D printing has made it possible to create microneedles, implantable drug delivery devices, and novel dosage forms with intricate designs. By providing sustained and targeted medication release, implantable devices made with SLA and SLS can lower systemic exposure and increase treatment efficacy (Awad et al., 2021). Similarly, with exact control over needle geometry and drug loading, 3D-printed microneedles provide a minimally invasive option for transdermal drug delivery and vaccination. The adaptability of 3D printing in pharmaceutical innovation is further demonstrated by novel dosage forms as floating tablets, gastro-retentive devices, and porous

scaffolds. These cutting-edge systems create new opportunities for controlled drug administration and focused therapy.

8.5 Pediatric and Geriatric Applications

Conventional dose forms frequently provide problems for pediatric and elderly populations, including as improper dosage, difficulty swallowing, and low adherence. By offering age-appropriate dosage forms, flexible amounts, and patient-friendly designs like chewable pills and oral disintegrating formulations, 3D printing offers customized solutions (Fina et al., 2020). Simplified regimens and customized polypills can greatly improve compliance for elderly patients, while exact dose customisation lowers the danger of underdosing or overdose for pediatric patients. Additive manufacturing's adaptability and accuracy make it especially well-suited for meeting these vulnerable populations' unmet requirements and promoting safer and more efficient medication.

9. Materials and Formulation Aspects

Pharmaceutical 3D printing success is largely dependent on the choice of materials and formulation design. In contrast to traditional manufacturing, additive manufacturing places particular demands on drug-polymer systems, excipients, and polymers to guarantee printability, stability, safety, and therapeutic efficacy. The main materials used in pharmaceutical 3D printing, compatibility issues, quality and stability issues, and the significance of regulatory-grade materials are all covered in this section.

9.1 Printable Polymers and Excipients

The structural foundation of 3D-printed pharmaceutical dosage forms is made up of printable polymers, which must have the right mechanical, thermal, and rheological characteristics to facilitate processing. Depending on the printing method utilized, common polymers include polyvinyl alcohol (PVA), polylactic acid (PLA), polyethylene glycol (PEG), hydroxypropyl methylcellulose (HPMC), and polycaprolactone (PCL) each offer unique benefits (Fina et al., 2020). For example, because of their advantageous melt-flow properties, thermoplastic polymers like PLA and PVA are frequently employed in fused deposition modeling, but photocurable resins are necessary for stereolithography-based systems. To enhance printability, flexibility, and drug release behavior, excipients such plasticizers, fillers, and stabilizers are included. To strike a compromise between pharmacological performance and manufacturability, polymers and excipients must be carefully chosen.

9.2 Drug–Polymer Compatibility

In pharmaceutical 3D printing, drug–polymer compatibility is a crucial formulation factor since incompatibility can result in drug degradation, altered release patterns, or decreased

therapeutic efficacy. During processing, interactions between the polymer matrix and the active medicinal ingredient may arise, especially when using high-temperature processes as fused deposition modeling (Goyanes et al., 2017). Analytical methods like X-ray diffraction, Fourier-transform infrared spectroscopy, and differential scanning calorimetry are frequently used in compatibility studies to evaluate physical and chemical stability. In addition to maintaining drug integrity, compatibility ensures consistent drug distribution and predictable release kinetics in the finished dosage form.

9.3 Stability and Quality Considerations

The development of 3D-printed pharmaceutical goods continues to face significant problems related to stability and quality assurance. Drug stability and dosage form integrity before and after printing can be impacted by elements such as heat stress, photopolymerization, moisture absorption, and mechanical deformation (Awad et al., 2021). To satisfy pharmacopeial criteria, quality parameters such as content uniformity, mechanical strength, dissolving behavior, and dimensional accuracy must be carefully assessed. Strong process control and validation techniques are also required because the layer-by-layer production process adds variability. To determine shelf life and guarantee consistent product performance throughout storage and usage, long-term stability tests are crucial.

9.4 Regulatory-Grade Materials

For 3D-printed medications to be clinically translated and commercialized, regulatory-grade materials must be used. Pharmacopeial standards, such as those set forth by the European Pharmacopoeia, the United States Pharmacopoeia, or other reputable regulatory bodies, must be followed by polymers and excipients (Norman et al., 2017). When using additive manufacturing technology, regulatory bodies stress the importance of traceability, reproducibility, and quality-by-design principles. Even though many of the polymers used in 3D printing have previously received approval for use in pharmaceuticals, further safety and performance assessments may be necessary before using them in innovative production settings. For 3D-printed pharmaceutical items to be more widely accepted by regulators, uniform standards for material certification must be established.

10. Regulatory, Technical, and Industrial Challenges

Despite the enormous potential of 3D printing technologies in pharmaceutical manufacture, a number of industrial, technological, and regulatory obstacles prevent their broad use. The shift from traditional batch production to layer-by-layer additive manufacturing creates new challenges in terms of process validation, scalability, quality assurance, and economic

viability. In order to integrate 3D printing into mainstream pharmaceutical production in a safe, efficient, and profitable manner, these issues must be resolved.

10.1 Regulatory Landscape and Approval Pathways

Since current regulations were mostly created for conventional production techniques, the regulatory environment for pharmaceutical 3D printing is currently developing. The first 3D-printed medication product, Spritam® (levetiracetam), was approved by regulatory bodies such as the European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA), demonstrating their recognition of the promise of additive manufacturing. But as of right now, there aren't many thorough, technology-specific regulations covering things like digital design control, printer certification, and in-process monitoring (FDA, 2017). Because this discrepancy has a major influence on regulatory supervision, approval pathways for 3D-printed medications must carefully assess whether the product is generated centrally or at the point of care. One major obstacle to international adoption and commercialization is the lack of standardized global regulations.

10.2 Quality Control and Reproducibility Issues

One of the most important technical issues with pharmaceutical 3D printing is ensuring constant quality and consistency. Numerous factors, such as printer type, material characteristics, ambient factors, and digital design parameters, might cause variability (Trenfield et al., 2019). 3D printing frequently requires unit-by-unit production, which calls for new quality control paradigms in contrast to traditional manufacturing, where quality is evaluated at the batch level. To satisfy pharmacopeial standards, parameters like dose accuracy, layer homogeneity, mechanical strength, and dissolving performance need to be strictly regulated. Although the combination of real-time monitoring systems and process analytical technologies has been suggested as a remedy, their application in standard practice is still quite limited.

10.3 Scale-Up and Commercialization Barriers

Pharmaceutical 3D printing still faces significant industrial challenges in scaling up because the technology is built for tailored, small-scale production rather than high-throughput manufacture. Although 3D printing is excellent for customization and design flexibility, it frequently lacks the efficiency and speed of manufacturing needed for mass-market medications (Norman et al., 2017). It takes a substantial investment in infrastructure, worker training, and specialized equipment to convert laboratory-scale printing processes into industrial-scale operations. Commercialization attempts are further complicated by ambiguity

around regulatory acceptability and reimbursement schemes. These restrictions now restrict the use of 3D printing to specialized fields like orphan medications and customized medicine.

10.4 Cost and Manufacturing Limitations

Another significant obstacle to the industrial application of pharmaceutical 3D printing is cost. Elevated production costs are caused by high initial capital expenditures for printers, maintenance costs, and the scarcity of pharmaceutical-grade printable materials (Awad et al., 2021). Additionally, compared to traditional production techniques, the comparatively modest printing speeds and post-processing procedures can raise operating expenses. Achieving cost-effectiveness while upholding regulatory compliance and product quality continues to be a major problem from an industrial standpoint. Over time, cost reductions are anticipated because to advancements in automation, material science, and printer technology; but, in the short to medium term, economic viability remains a constraint.

11. Future Prospective of 3D Printing in Pharmaceuticals

With the potential to revolutionize medication discovery, manufacturing, and patient care, 3D printing in pharmaceuticals has a bright future. It is anticipated that personalized medicine will play a major role in enabling the creation of customized dose forms that satisfy the demands of each patient, maximize therapeutic results, and improve adherence. Smart manufacturing will be made possible by integration with artificial intelligence, digital health platforms, and predictive modeling. This will enable real-time monitoring, quality control, and optimization of medication design and release profiles. Access to pharmaceuticals could be revolutionized via point-of-care and on-demand drug manufacture, including 3D printing at hospitals or pharmacies. This is especially true for complex multi-drug regimens, pediatrics, geriatrics, and rare disorders. Additionally, continuing developments in printable polymers, excipients, and multi-drug formulations may increase the range of clinical uses, and breakthroughs in bioprinting and hybrid manufacturing may increase treatment options to include drug-eluting devices and tissue-engineered implants. It is anticipated that ongoing multidisciplinary research, process standardization, and cooperation between academia, business, and regulatory bodies would hasten adoption despite present regulatory, technical, and financial obstacles. As a result, it is projected that in the next ten years, pharmaceutical 3D printing will transform from a specialized invention to a widely used technology, radically altering the field of drug design, manufacturing, and customized treatment.

12. Limitations of the Bibliometric Study

A number of limitations of the current study must be noted, despite the fact that bibliometric analysis offers useful quantitative insights into research trends, collaboration patterns, and

topic evolution in pharmaceutical 3D printing. First, the chosen databases are a necessary component of the analysis. Major scientific databases like Scopus, Web of Science, and PubMed provide extensive coverage, but they might not index all pertinent publications, especially non-English literature, conference proceedings, and early-stage discoveries. Certain contributions to the field might have been underrepresented as a result.

Second, the search technique and keyword choice have a significant impact on the results of bibliometric investigations. Variations in terminology and indexing processes between journals may have resulted in the inclusion of marginally related research or the removal of pertinent papers, even with the use of thorough and well crafted search terms (Aria & Cuccurullo, 2017). In an integrative sector like pharmaceutical 3D printing, which combines pharmaceuticals, materials science, engineering, and digital health, this restriction is especially pertinent.

Third, quantitative metrics like citation counts, h-index, and co-occurrence frequency are examples of bibliometric indicators that may not accurately represent the clinical significance or scientific caliber of particular publications. Rather than inherent scientific merit, factors like publication age, journal exposure, or self-citation procedures may have an impact on highly cited works (Donthu et al., 2021). As such, citation-based studies should be interpreted cautiously and supplemented with qualitative evaluation.

Lastly, because this study mainly focuses on published literature, it does not include proprietary research, emerging industrial advancements, or regulatory data that are frequently not made public. Because pharmaceutical 3D printing technology is developing so quickly, bibliometric databases could not yet fully reflect recent developments. By using a variety of data sources, sophisticated text-mining techniques, and longitudinal updates to capture the dynamic character of the topic, future research could overcome these constraints.

13. Conclusion

The research landscape of 3D printing in pharmaceutical sciences is described in this bibliometric review, which shows a steady increase in scientific production over the previous ten years due to increased university and industrial involvement. From early proof-of-concept and formulation feasibility studies to advanced pharmaceutical applications, such as customized drug delivery, modified-release dosage forms, polypills, and point-of-care manufacturing, the data shows a clear trend. The most researched technologies include fused deposition modeling, stereolithography, binder jetting, and selective laser sintering, each of which has unique benefits and formulation difficulties. The field's maturity toward clinical and industrial translation is shown in the growing focus on printable polymers, formulation

stability, and regulatory-grade materials. However, the main barriers to wider adoption continue to be manufacturing costs, scalability, quality assurance, and regulatory ambiguity. All things considered, pharmaceutical 3D printing is moving closer to a patient-centered, disruptive manufacturing paradigm that has the potential to drastically alter how drugs are developed and delivered in the future.

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15. Conflict of Interest

The authors declare no conflicts of interest related to this study

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