TRIASTEK

3D Printed Pharmaceuticals

From Inception to the Present

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JULY 13-18, 2025

NEXT-GENERATION DELIVERY INNOVATIONS

Principles of 3D Printing Technologies

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Creating objects using Computer Aided Design (CAD)

Building objects with structures layer by layer based on CAD controlled by computer

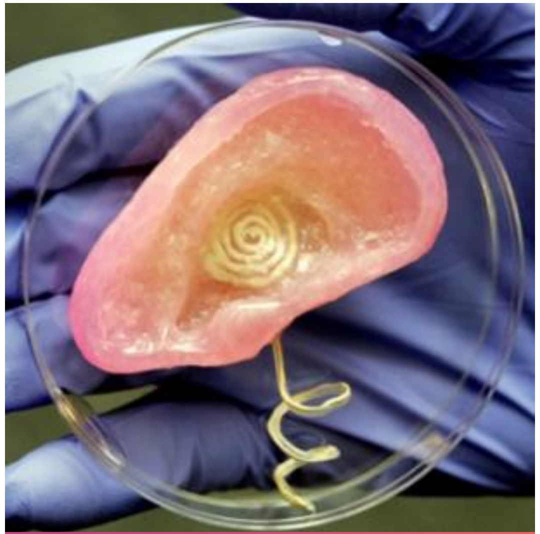
In situ polymerization
- Chemical reaction
- Free radical formation

Melt and solidification
- Extrusion
- High energy beam

Binding of powder
- Binding agents
- High energy beam

Applications of 3D Printing in Biosciences

Creation of organ models for surgical operation planning and treatment analysis



Tissue engineering

- Tissue scaffolds
- Constructing tissues and organs

Personalized repair/ restructure of tissue, organ and body parts

- Bone, tooth
- Transplantation
- Artificial limb/finger

Pharmaceutical products

- Drug delivery
- Personalized medicine

3D Printing Technologies for Pharmaceutical Applications

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1980 — First patent application for Rapid Prototyping (RP) Technology was filed by Kodama

1996 — MIT Professor Michael Cima published the first 3D printed drug delivery device (Massachusetts Institute of Technology)

1997 — The first 3D Printing pharmaceutical company Therics was founded in USA (THERICS)

2003 — Aprecia was founded in USA to focus on binder jetting for commercial production of dosage forms (APRECIA)

2014 — FabRx was founded in UK to focus on personalized dosing (FABRX)

2015 — Triastek was founded in China to focus on MED® 3D printing technology for drug delivery and manufacturing (TRIASTEK)

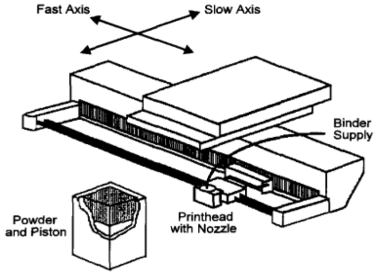
2015 — July 31st, FDA approved the first 3D printed drug Spritam® by Aprecia (Spritam (levetiracetam) Tablets for Oral Suspension)

2017 — Laxxon was founded in Germany to focus on 3D screen printing technology manufacturing (LAXXON 3D PRINTED PHARMACEUTICALS)

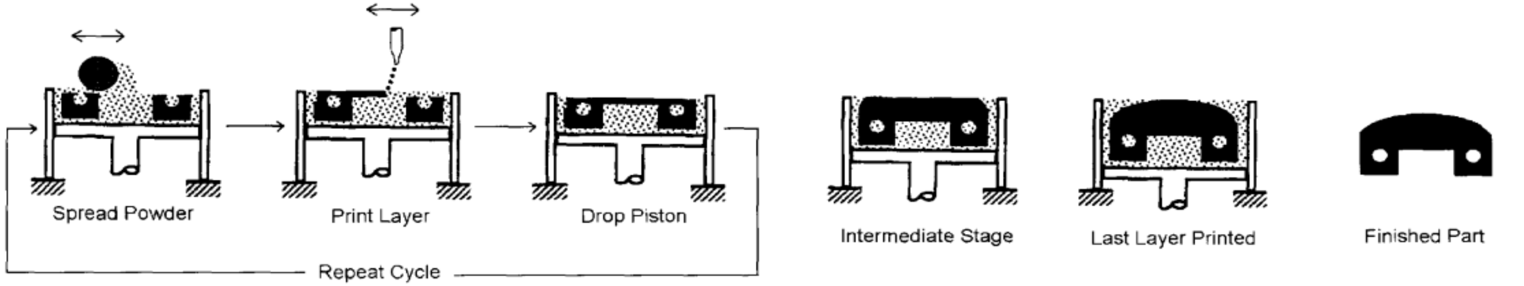
- Material Extrusion ✓
- Binder Jetting ✓
- Powder Bed Fusion ✓
- VAT Photopolymerization ✓
- Sheet Lamination ✓
- Material Jetting ✓
- Directed Energy Deposition

First 3D Printing Application in Pharmaceuticals

Michael J. Cima, PhD
Professor of Materials
Science and Engineering

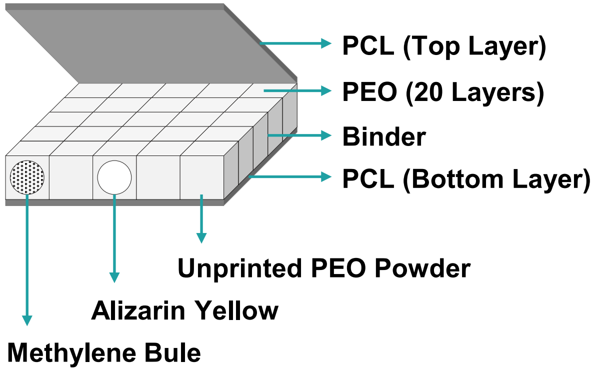


The Desktop 3DP machine (PB)



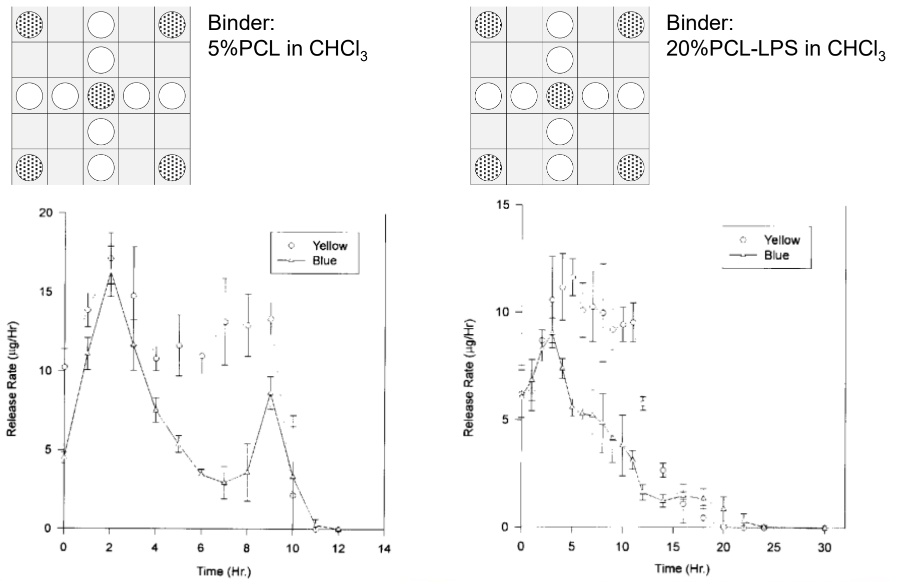
The 3DP sequence of operation

Model drug delivery device

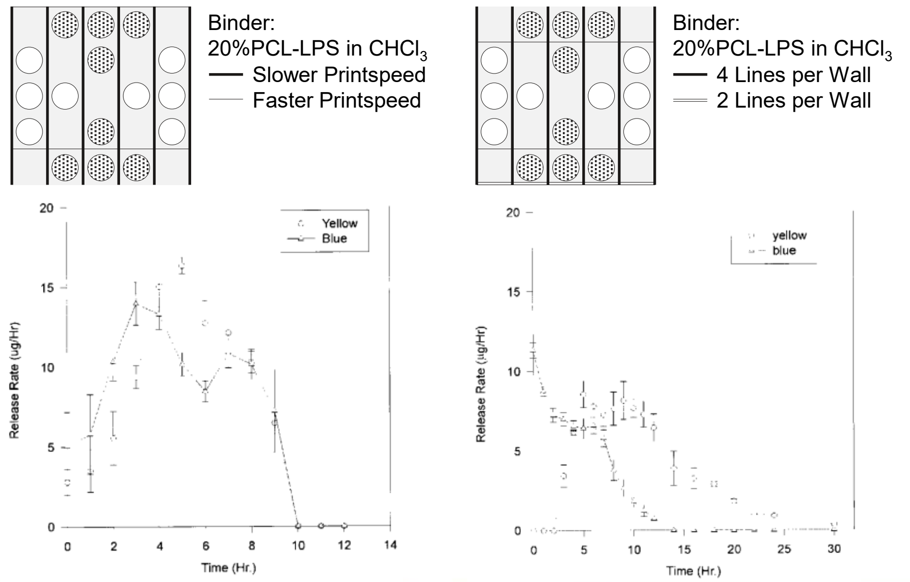


Hydrolytic degradation: PCL << PEO

Positional Control
Asymmetric spatial distribution Identical walls



Microstructural Control
Symmetric spatial distribution Varying wall microstructure

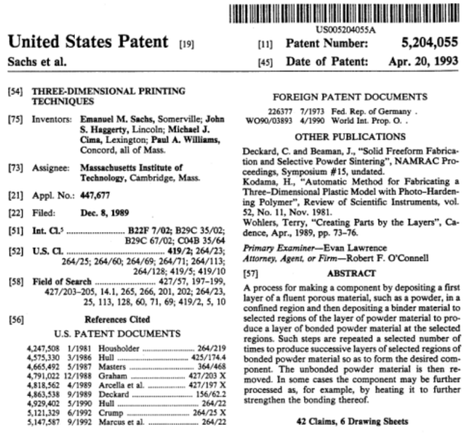


Early Commercialization Attempts

Massachusetts Institute of Technology

IJ-Powder 3DP patent

Filed in 1989


US005204055A

United States Patent [19] Sachs et al.

[11] Patent Number: 5,204,055

[45] Date of Patent: Apr. 20, 1993

[54] THREE-DIMENSIONAL PRINTING TECHNIQUES

[75] Inventors: Emanuel M. Sachs, Somerville; John S. Haggerty, Lincoln; Michael J. Cima, Lexington; Paul A. Williams, Concord, all of Mass.

[73] Assignee: Massachusetts Institute of Technology, Cambridge, Mass.

[21] Appl. No.: 447,677

[22] Filed: Dec. 8, 1989

[51] Int. Cl.5 .... B22F 7/02; B29C 35/02; B29C 67/02; C04B 35/64

[52] U.S. Cl. 419/2; 264/23; 264/25; 264/60; 264/69; 264/71; 264/113; 264/128; 419/5; 419/10

[58] Field of Search 427/57, 197–199, 427/203–205, 14.1, 265, 266, 201, 202; 264/23, 25, 113, 128, 60, 71, 69; 419/2, 5, 10

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4,575,330 3/1986 Hull 425/174.4
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5,121,329 6/1992 Crump .... 264/25 X
5,147,587 9/1992 Marcus et al. 264/22

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WO90/03893 4/1990 World Int. Prop. O. .

OTHER PUBLICATIONS

Deckard, C. and Beaman, J., "Solid Freeform Fabrication and Selective Powder Sintering", NAMRAC Proceedings, Symposium #15, undated.
Kodama, H., "Automatic Method for Fabricating a Three-Dimensional Plastic Model with Photo-Hardening Polymer", Review of Scientific Instruments, vol. 52, No. 11, Nov. 1981.
Wohlers, Terry, "Creating Parts by the Layers", Cadence, Apr., 1989, pp. 73–76.

Primary Examiner—Evan Lawrence
Attorney, Agent, or Firm—Robert F. O'Connell

[57] ABSTRACT

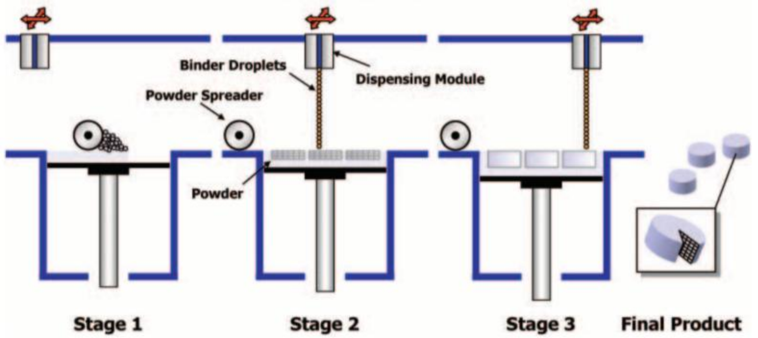
A process for making a component by depositing a first layer of a fluent porous material, such as a powder, in a confined region and then depositing a binder material to selected regions of the layer of powder material to produce a layer of bonded powder material at the selected regions. Such steps are repeated a selected number of times to produce successive layers of selected regions of bonded powder material so as to form the desired component. The unbonded powder material is then removed. In some cases the component may be further processed as, for example, by heating it to further strengthen the bonding thereof.

42 Claims, 6 Drawing Sheets

Its applications in healthcare were licensed exclusively to Therics, Inc.

THERICS® (Founded in 1993)

Theri-form™ Technology



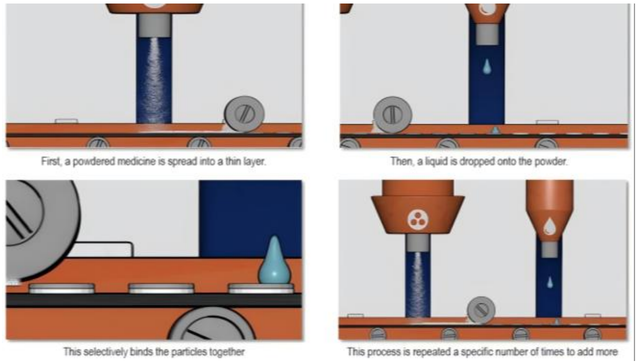
Print Drug Approach

Print Glue Approach

Therics asset sale in 2005

APRECIA (Founded in 2003)

ZipDose® Technology



FDA approved Spritam® in 2015

First 3D printed Pill Approved by FDA

1. Hsiao, W. K., et al. (2017). Expert Opinion on Drug Delivery, 15(1), 1–4.
2. Massachusetts Institute of Technology, 1993, Three-dimensionalprinting techniques.US5204055.

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3D Printing Technology in Pharmaceutical Applications

Drug Delivery

- Unique dosage form designs
- Controlled delivery
- Predetermined release characteristics (onset and duration time, location, kinetics, mode)

Product Development

- Digital Product Development
- Formulation by Design
- Fast prototyping
- Predictive and accelerated development time

Manufacturing

- Different scale of production / Linear scaling
- Continuous manufacturing
- Automatic and intelligent manufacturing line
- Reproducibility
- Real-time PAT
- 100% Quality control
- Reduce labor costs

Pharmacy Practice

- Personalized dosing
- Extemporaneous compounding
- Traceable and anti-counterfeit distribution

Main Players in the 3D Printing Pharmaceuticals Field

Personalized dosing

- FABRX
- MultiplyLabs
- MSD
- Craft Health
- DiHeSys Digital Health Systems
- AstraZeneca
- GDPU 1958
- ......

Academia Research

- Massachusetts Institute of Technology
- UCL
- The University of Nottingham
- King's College London
- The University of Mississippi 1848
- Texas A&M University
- University of Central Lancashire UCLan 1828
- Texas The University of Texas at Austin

Manufacturing and Production

- Aprecia
- Triastek
- Laxxon 3D Printed Pharmaceuticals
- Merck
- MSD
- Grünenthal
- gsk GlaxoSmithKline
- TNO innovation for life

Research Publications on 3D Printing Pharmaceuticals

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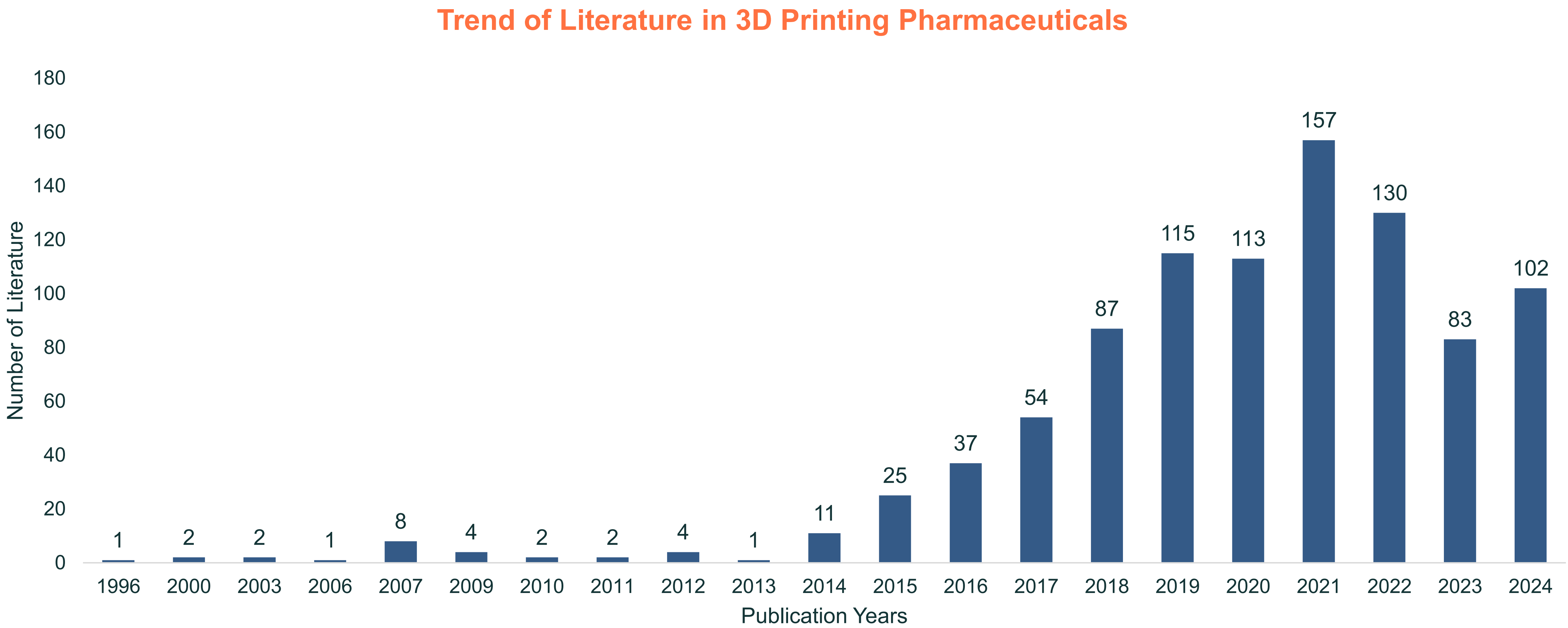
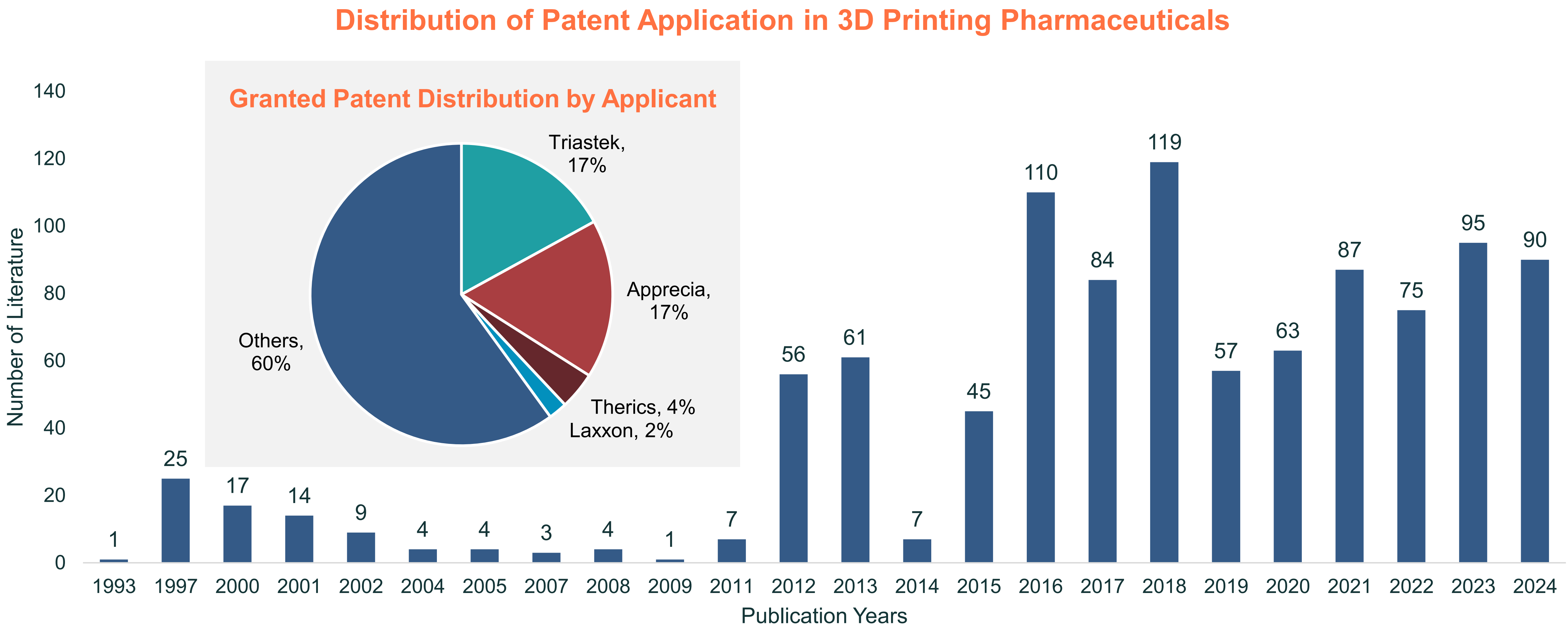


1. The data was obtained from Triastek's statistics.

3D Printing Pharmaceuticals: Patent Applications



1. The data was obtained from Triastek's statistics.

3D-Printed Pharmaceuticals for Personalized Dosing: Current Status & Challenges

Current Status

Regulatory Milestones
- Growing interest from EMA and national agencies for patient-tailored dosing

Clinical & R&D Advances
- Proof-of-concept trials for polypill combinations and on-demand dosing
- Emerging platforms using inkjet, fused deposition modeling (FDM), and stereolithography

Manufacturing Trends
- Point-of-care compounding
- Integration of AI-driven design for dose optimization

FABRX

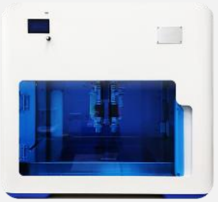
DiHeSys Digital Health Systems

Craft Health

M3DIMAKER

Mark II M3DIMAKER

FLEXDOSE®



CRAFTMAKE™

Key Challenges

Quality & Reproducibility
- Ensuring uniformity, dissolution, and mechanical strength
- Quality control: analytical technologies (PAT), cleaning validation

Regulatory & IP Framework
- Lack of harmonized guidelines for on-site manufacturing
- Intellectual property issues related to customized formulations

Technical & Scalability Hurdles
- Multi-drug printing capability and cross-contamination control
- Printing speed vs. throughput for commercial viability

Patient Acceptance & Economics
- Cost of printers, materials, and skilled operators
- Education of healthcare professionals and patients

Pharmaceutical Product Development and Manufacturing

Product Development	Manufacturing
Personnel: Multidisciplinary team	Production rate
Digital product design	GMP
Instrumentation	Continuous manufacturing, automation and PAT
Materials	Instrumentation and materials: FDA approved

MED® 3D Printing and Digital Manufacturing

Continuous Manufacturing

- Precise and continuous MED® 3D printing process design
- Production line and equipment support continuous processing
- Integrated units ensure continuous production

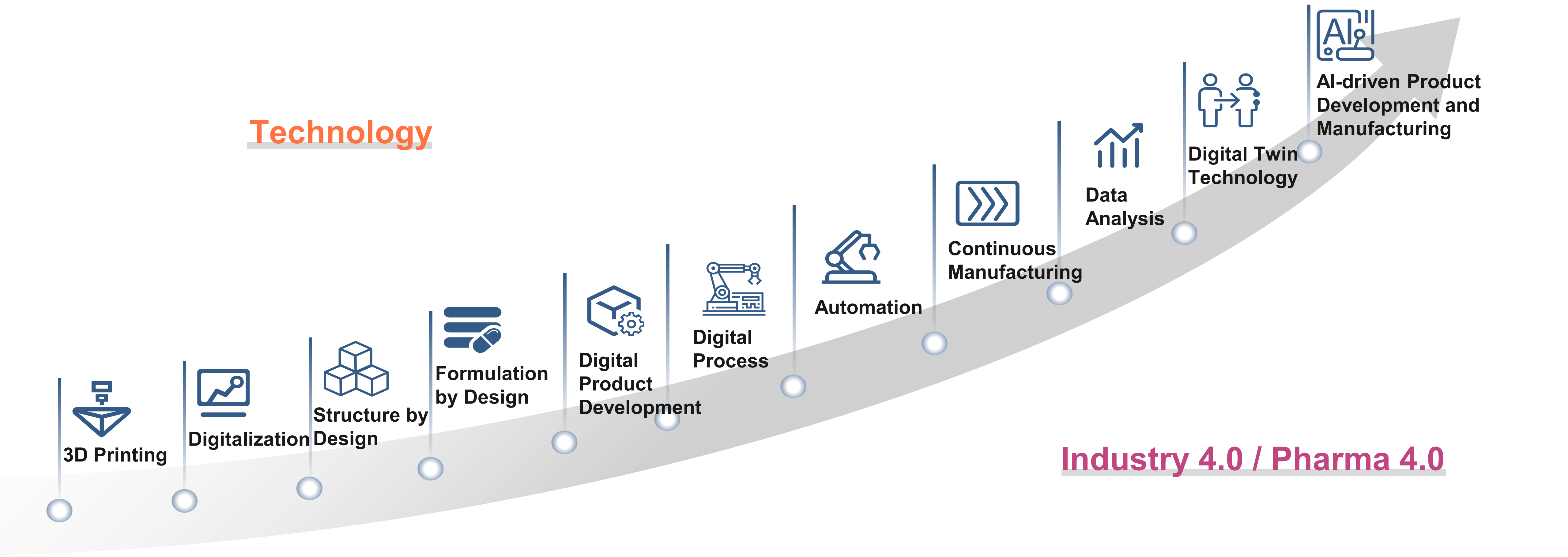
Digital Process Monitoring

- In-line process sensors
- Real-time collection and interaction of large process data sets
- Precise and flexible digital printing control
- Centralized control and monitoring in the control room

Digital Quality Control

- PAT systems tailored to the characteristics of MED® 3D printing at each stage of the production line
- Development and validation of pat models
- Digital identification and traceability technology for products
- 100% finished product QC

3D Printing and Digital Product Development and Manufacturing



Summary

Applications of 3D printing technology create a new dimension by incorporating structures into the dosage form design and fabrication.

3D printing technologies have matured and ready for the pharmaceutical product development and manufacturing of challenging compounds and meeting clinical needs.

3D printing technology has paved a road for digital product development and continuous digital manufacturing.