



A Review On- 3D PRINTING TECHNOLOGY IN MEDICAL FIELD

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Abstract:

This is a review paper on 3D printing and the various regulations. used in 3D printing and various techniques, applications in pharmaceutical technology and also advantages or disadvantages. The 3D printing techniques suitable for pharmaceutical manufacturing and also their applications to the development of drug dosage forms. 3D printing is platform technologies in which complex products are developed with a smaller number of additives the recent years have seen an increasing interest in applying 3D printing technology to the pharmaceutical manufacturing of the drug products. However, 3D printing technology exhibits many potential medical and economic benefits, there are also some technical and regulatory challenges restricting the wide applications of 3D printing technology to pharmaceutical products. The present review paper is mainly focused on the regulatory issues in pharmaceutical technology.

Keywords-

3d Printing Technology In Medical Field, Stereolithography (SLA), Fused Deposition Modelling (FDM), Selective Laser Sintering (SLS), Digital Light Process (DLP), Multi Jet Fusion (MJF), Polyjet, Direct Metal Laser Sintering (DMLS), Electron Beam Melting (EBM)

Introduction:

3D printing, also known as additive manufacturing, is a method of creating a three-dimensional object. It can be done in a variety of processes in which material is deposited, joined or solidified under computer control, with the material being added together, typically layer.

The earliest 3D printer' originated in 1981, When Dr. Hideo kodama invented one of the first rapid prototyping machines that created parts layer by layer, using a resin that could be polymerized by UV light.

In 1986, the first patent for Stereolithography (SLA) was filed by Chuck Hull, who is considered the inventor of 3D printing" for creating and commercializing both SLA and the format the most common file type used for 3D printing.

In 1988, Carl Deckard, a student at the University of Texas, licensed selective laser sintering (SLS) technology- another type of 3D printing that uses a laser to sinter powdered material. into solid structures shortly after, in 1989, Scott Crump patented fused. Filament deposition modeling (FDM) - also known as fused Filament fabrication (FFF) and founded Stratasys, one of the main players in the 3D printing industry to this day. That same year. Hull's Company, 3D systems corporation released the SLA-1 3D printer

The 1990s saw a great deal of growth for the early 3D printing industry, with new companies founded and new additive manufacturing technologies being explored. It wasn't until 2006, however, that the first SLS printer became commercially available.

How 3d Printing Was Invented:

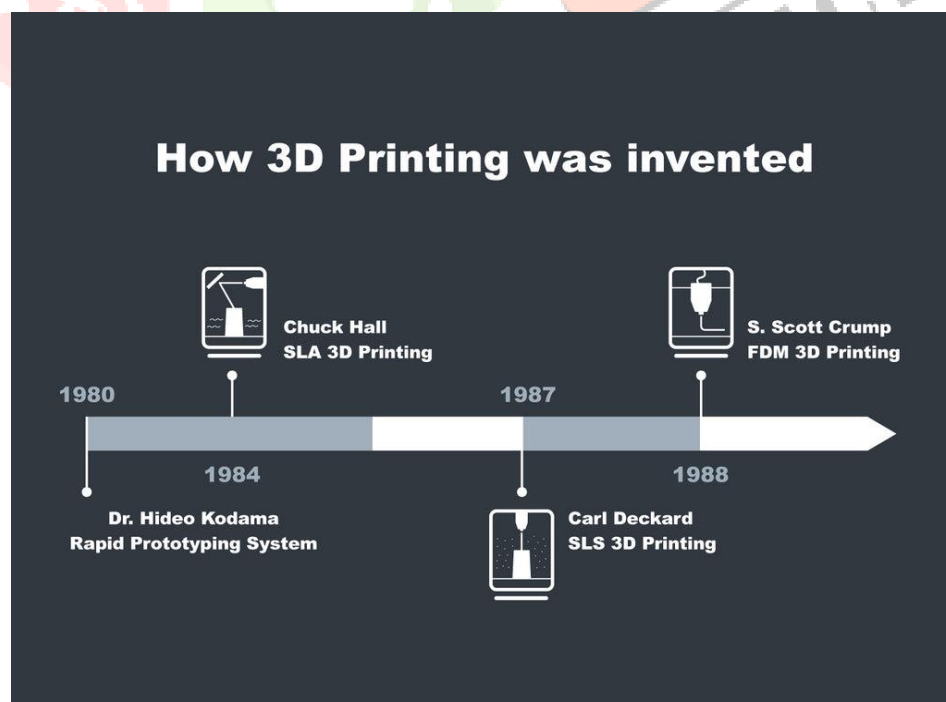


Fig no. 01 How 3d Printing Was Invented

Nowadays, 3D printers could be extended throughout the drug development process, ranging from preclinical development and clinical trials, to frontline medical care different types of drug delivery system such as oral controlled release systems, micro pills, fast dissolving tablets, drug implants and multiphase release dosage forms have been developed using three-dimensional (3D) printing technology.

It has been used for various applications in healthcare and medicine, such as creating prosthetics, organs, drugs, tissues and implants in healthcare and medicine is that it can provide customized and personalized solutions for patients for example 3D printing can create prosthetics and implants that match the shape and size of the patient's body, reducing the risk of infection, rejection or discomfort this is one of the main benefits of 3D printing.

Types Of 3D Printing Technology: -

3D printing includes a wide variety of manufacturing techniques, which are based on digitally controlled depositing of materials (layer-by-layer) to create free form geometries.

There are several types of 3D printing, which include:

- 1) Stereolithography (SLA)
- 2) Fused Deposition Modeling (FDM)
- 3) Selective Laser sintering (SLS)
- 4) Digital Light Process (DLP)
- 5) Multi Jet fusion (MJF)
- 6) Polyjet
- 7) Direct Metal Laser Sintering (DMLS)
- 8) Electron Beam Melting (EBM)

- **Stereolithography (SLA):**

Stereolithography (SLA) is the original industrial 3D printing process SLA printers excel at producing parts with high levels of detail, smooth surface finishes, and tight tolerances the quality surface finishes on SLA parts, not only look nice, but can aid in the part's function - testing the fit of an assembly, for example. It's widely used in the medical industry and common applications include anatomical models and microfluidics. we use vipers, Projects and iPros 3D printers manufactured by 3D systems for SLA parts.

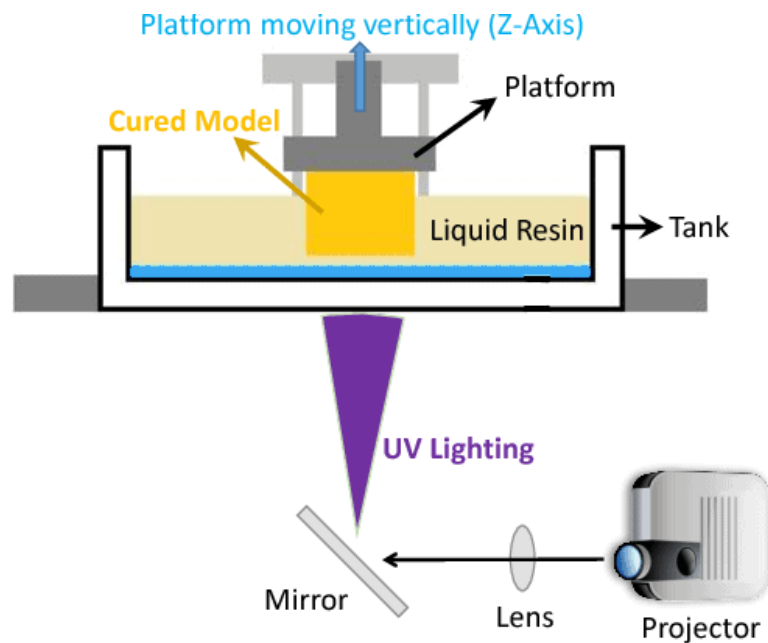


Fig no. 02 Stereolithography (SLA)

- **Selective Laser Sintering (SLS):**

selective Laser Sintering (SIS) melts together nylon-based powders. into solid plastic since SLS parts are made from real thermoplastic material, they are durable, suitable for functional testing, and can support living hinges and snap-fits. In comparison to SL. parts are stronger, but have rougher Surface finishes SLS doesn't require support structures so the whole build platform can be utilized to nest multiple parts into a single build-making it suitable for part quantities higher than other 3D printing processes. Many SLS parts are used to prototype design that will one day be injection – molded. for our SLS printers, we use sPro 140 machines developed by 3D Systems.

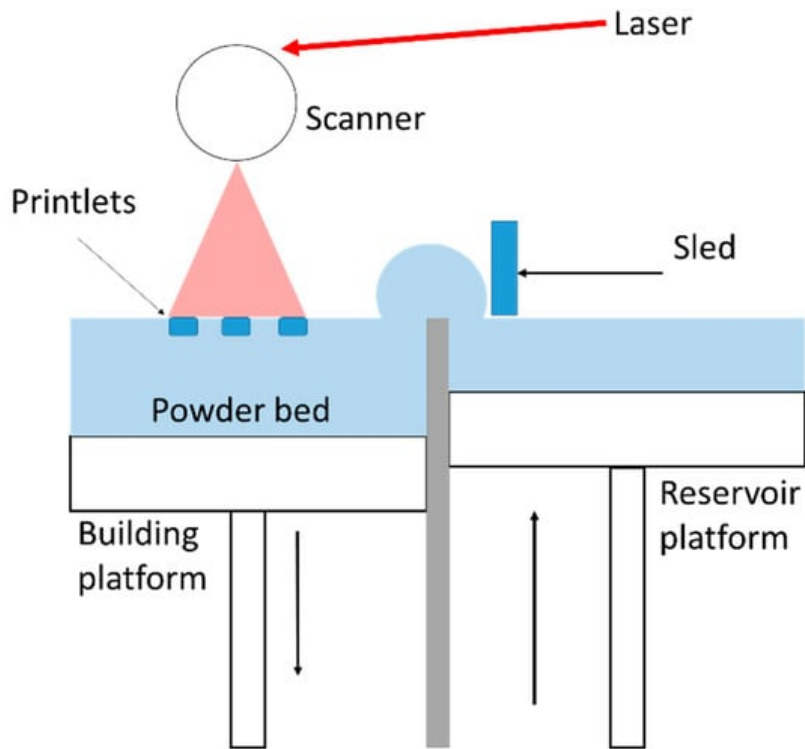


Fig no. 03 Selective Laser Sintering (SLS)

• Fused Deposition Modelling (FDM)

fused deposition modeling (FDM) is a common desktop 3D printing technology for plastic parts. An FDM printer functions by extruding a plastic filament layer-by-layer onto the build platform. It's a cost-effective and quick method for producing physical methods.

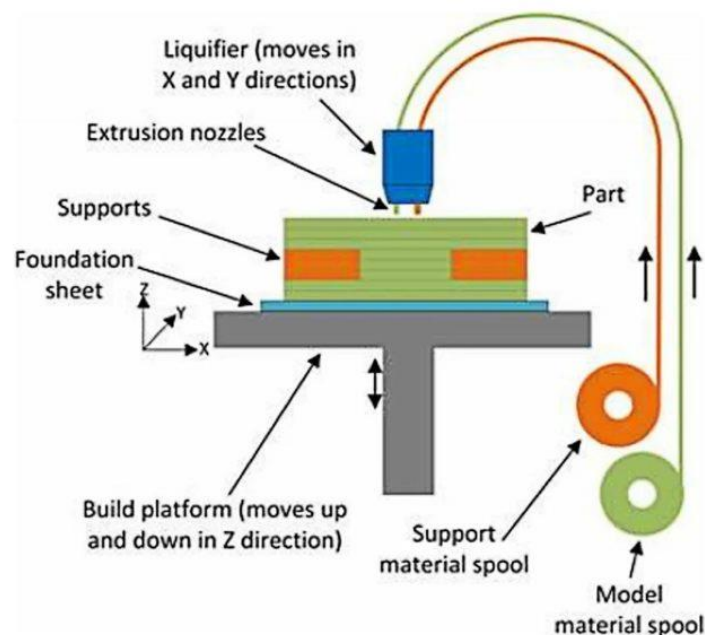


Fig no. 04 Fused Deposition Modelling (FDM)

Advantages

1. High Manufacturing Speed
2. Cost Efficiency
3. On-demand Preparation
4. Personalized Devices

Disadvantages

1. Less Resolution Quality in Comparison to Stereolithography
2. Supporting Only Few Thermoplastics
3. Manufacturing Difficulties for Filaments with Small Diameter
4. The Melting Point of The Incorporated Medicine Requires to Be Near or Higher Than Melting Point of Polymer

Applications Of 3d Printing:

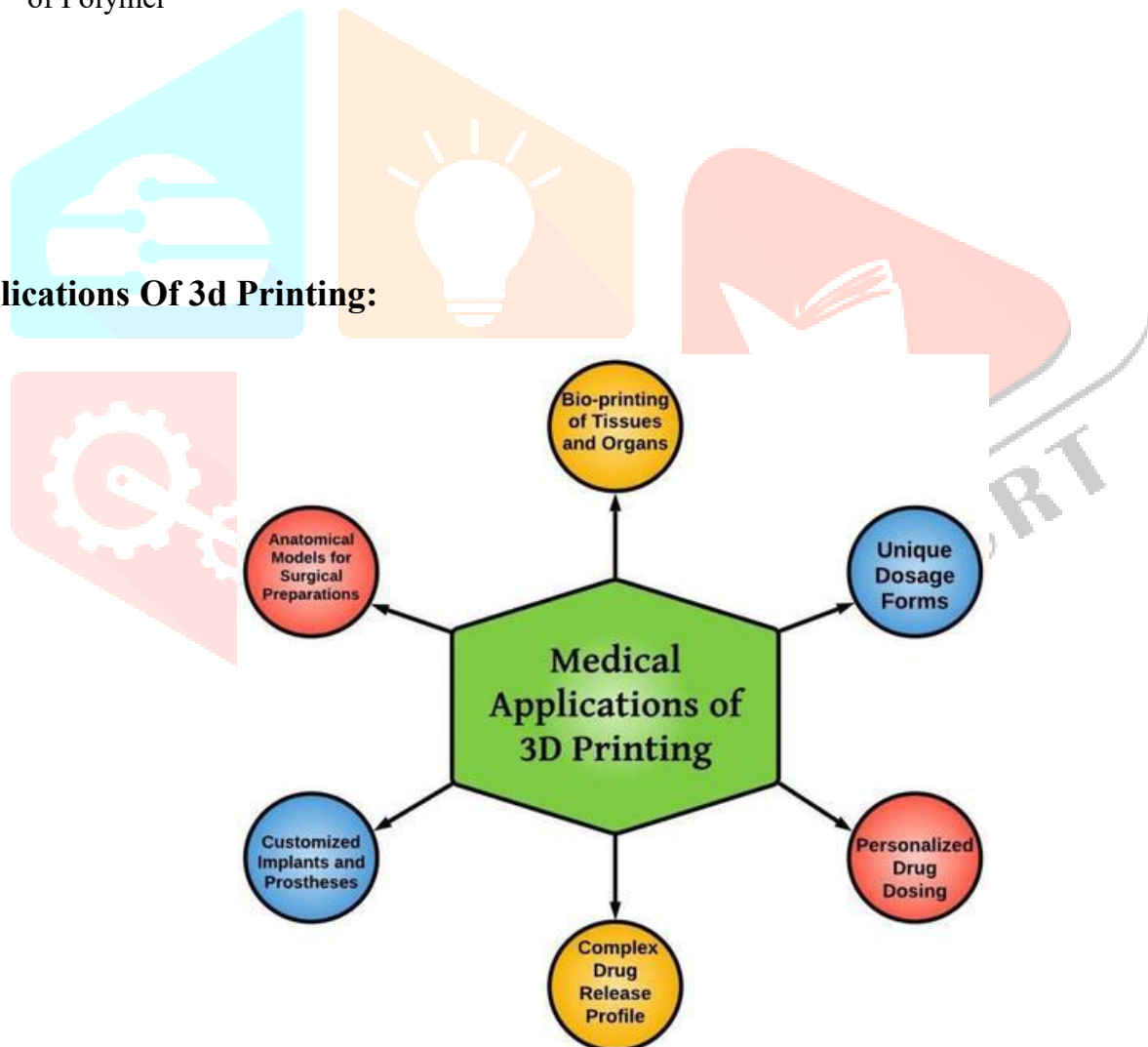


Fig no. 05 Applications Of 3d Printing

Regulations:

3D Printing (3DP), a critical emerging technology, has come into the limelight in the last decade. However, in spite of its huge potential and significance for the digital economy, there is no global policy on 3DP. While it has mostly escaped relevant regulation in countries such as India, in some countries, the regulation is centered only around singular sectors such as medical devices.

The countries leading in the implementation and regulation of 3DP are China, the US, and the EU. China has been working extensively to develop its 3DP market and the regulations to govern it. A year later, China's Center of Medical Device Evolution, issued guidelines for the regulation and registration of 3DP medical devices including custom-built additive produced medical devices. The EU has specific legislations for the use of 3DP for manufacturing of medical devices. During the COVID-19 pandemic, it issued special guidelines on using 3D printing for providing relief. In fact, the pandemic has accelerated the importance and implementation of 3DP. Recently, US FDA allowed 338 medical devices manufacturing of ventilator tubes and other accessories.

With 3DP set to dominate the future of manufacturing, standardisation is a key concern. In India, the two states, Maharashtra and Rajasthan recognise the importance of smart manufacturing in their industrial policies, yet do not provide policy guideline guidelines required for important component manufacturing. For 3DP, smart manufacturing currently India has only some sector or specific laws, such as in medicine, which can be interpreted to include 3DP. In the medical / pharmaceutical field, where 3DP is most used, BD printed objects include:

- a) Pharmacological, Immunological, or metabolic in nature (e.g. tablets, capsules, etc)
- b) Anatomical elements of the human body (organs, bones, etc)

Similarly, while the transplantation of Human organs and Tissues Act, 1994 deals with transplantation of organs from a person: donor, transplanting a 3D printed organ/ gland is beyond the scope of this legislation.

The COVID-19 pandemic will certainly boost the use of 3DP. Any relief material, cure or preventive vaccine or drug that is discovered can quickly go into mass production using 3DP. This is an opportune moment for India to consider a comprehensive policy on 3DP, or even the principles that should govern 3D printing. It can be the model for global guidelines. The comprehensive policy should address:

- (a) Purchase of BD printers and scanners
- (b) Manufacturing process using 3D printers
- (c) quality of input material and final product
- (d) Product sale and distribution

While policy and standards will create a conducive framework for the regulated growth of 3DP in India, the government needs to supplement this impetus with fiscal and tax incentives for those businesses adopting 3DP.

Recently, India announced production linked incentives for electronics manufacturing and for the domestic manufacture of medical devices and drugs.

With India's increased focus on self-reliance, 3DP can be a game changer especially in critical sectors where India is heavily reliant on raw material or final product from countries such as China. Sectors such as electronics, pharma, aviation or defence, can all be developed at home with a focus and clear policy on 3DP, with enormous benefit to the economy.

Challenges Facing 3D Printing:

1. Nearly anything can be printed by 3D printers and this is a troubling prospect if criminals use 3D printers to create illegal products.
2. One challenge is the lack of regulation. Because 3D printing is a relatively new technology, there are no clear guidelines on how to ensure that medical devices created using 3D printers are safe and effective.
3. Another challenge is the high cost of 3D printers and materials.
4. Then another challenge associated with 3D printing in healthcare is the lack of trained personnel.

Conclusions:

Depending on the knowledge raised from the information gained through several papers, few conclusions are acquired.

3D printing technology has the potential to open doors in product development, manufacturing and distribution for pharmaceutical companies.

It could help fulfill the promise of personalized medicine, a concept that is growing in popularity within the industry.

The medical advances that have been made using 3D printing are already significant and exciting, but some of the more revolutionary applications, such as organ printing, will need time to evolve.

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