3D Printing: New Opportunities for the Medical Devices Industry
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Abstract

The medical devices industry has been facing a plethora of regulatory challenges leading to protracted lead times as well as high device development costs for new and enhanced medical devices. These costs assume worrying proportions in cases of low volume production for low volume product markets.

Not surprisingly, industry players are evaluating several alternatives to address these cost concerns. One promising option - 3D printing technology - involves leveraging additive manufacturing processes that use a layer by layer material build-up process to create 3-dimensional objects. 3D printing is already helping businesses to:

- Significantly reduce design iterations
- Integrate complex shapes or structures
- Personalize devices for the user
- Print 3D production grade samples for faster regulatory approvals
- Simplify manufacturing processes and supply chain

This paper discusses the wealth of possibilities that 3D printing offers to manufacturers of medical devices. We not only discuss the several new opportunities that manufacturers can leverage, but also present ideas on overcoming potential challenges. In addition, we analyze various 3D printing business models to improve ease of adoption.
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<tr>
<td>CAD</td>
<td>Computer Aided Design</td>
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<tr>
<td>CAM</td>
<td>Computer Aided Manufacturing</td>
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<tr>
<td>CFR</td>
<td>Code of Federal Regulations</td>
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<tr>
<td>CT/CAT</td>
<td>Computerized Tomography/Computer Assisted Tomography</td>
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<tr>
<td>FDA</td>
<td>Food and Drug Administration (USA)</td>
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<tr>
<td>MRI</td>
<td>Magnetic Resonance Imaging</td>
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<tr>
<td>OEM</td>
<td>Original Equipment Manufacturer</td>
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Introduction

Although 3D printing has been a highly discussed technology across several industries, opinions on what it comprises, its capabilities and challenges often differ vastly. 3D printing encompasses a set of Additive Manufacturing technologies that use a layer-by-layer material addition process to build parts. This process has been used for more than three decades for rapid prototyping purposes, primarily to reduce the number of design iterations.

Today, 3D printing is emerging as a cost effective, efficient, and customised manufacturing option for the medical devices industry—applicable to a range of devices such as dental implants, hearing aids, prostheses, custom-made knee and hip implants, and surgical instruments.

This technology promises to deliver on various counts such as personalization according to patients or users, flexibility in design and manufacturing, decreased material wastage, elimination of specialized tooling, and low lifecycle costs. Combined with the maturity of the 3D printing process (in terms of better materials, machines, and technological innovations), the technology can be used to develop many new medical devices that were earlier deemed difficult to create, expensive, or not patient friendly.

3D Printing can deliver more benefits than just the ability to develop new devices. The two greatest hurdles that most manufacturers face when bringing a device to market are tooling costs and stringent regulatory processes. 3D printing has the potential to reduce tooling costs and accelerate lead time and regulatory submissions substantially when compared to conventional methods.

3D printing is currently a USD 700 million industry, with only USD 11 million (1.6 percent) invested in medical applications.¹ However, recent projections suggest that in a decade’s time, 3D printing will rapidly develop into a multi-billion dollar industry, with spend on medical applications accounting for nearly a quarter of this.

Delivering disruptive innovation to the Medical Devices Industry

3D Printing is poised to bring about a number of landmark changes or enhancements, revolutionizing the medical devices industry. Some of these are:

Encouraging New Entrants:

3D Printing encourages small vendors to invest in the required equipment, leading to a more dynamic and cost-competitive market. Connecting this network of small vendors with the power of Cloud computing could create an entirely new eco-system that is extremely agile, flexible and cost-effective.

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Optimizing Device Design and Development:

3D Printing enables device manufacturers to create personalized devices with multiple integrated features, at reduced costs. It can also drive a marked decrease in processing costs as well as time, and will allow manufacturers to justify premium pricing to the consumer by building on the perceived value of personalization.

By eliminating or minimizing special tooling or manufacturing equipment requirements, 3D printing offers itself as a cost-effective alternative that can be employed to shorten the timelines for market entry.

This means that many medical devices can now be directly and economically 3D printed from digital device files using production grade materials. This in turn can help speed up regulatory approval submissions and penetrate new markets in a shorter time-span.

Reconfiguring Supply Chain:

3D printing has the capability to alter the way manufacturers look at supply chain investments.

For example, by using 3D printing, device companies can decrease their inventory levels by manufacturing on demand and hence save on the cost of inventory. They can also reduce the number of links in the supply chain by combining multiple processes and reducing the number of parts in a product.

3D printing technologies do not require extensive manufacturing infrastructure that conventional manufacturing demands, and are therefore not bound by economies of scale. This means that the cost of producing one unit will be the same as that of producing a thousand units. This has the potential to disrupt current manufacturing economics. It can result in a situation where the cost of producing a few custom medical devices may be the same or even lesser than producing thousands using conventional manufacturing methods.

Precision Planning for Surgeries:

Many surgeons may consider 3D printing for the surgical planning of complex procedures as well as for surgical guides, which were otherwise planned virtually, using imaging techniques only. This will not only reduce the duration of the surgical procedure but also help surgeons manage the threat of trauma for patients exposed to the dangers of trial and error. The doctors at Mayo Clinic are using 3D Printers to enable customized joint replacement surgeries.

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The Business Value of 3D Printing

Medical device manufacturers can leverage the multiple possibilities and business opportunities created by this technology. Some of the most evident benefits are:

Addressing the Market Need for Personalization of Medical Devices

There is a substantial need for truly individualized yet economical medical devices and solutions. A recent example of how such a market need can be translated into a business opportunity is the FDA approved Patient Specific Facial Device from Oxford Performance Materials (OPM) that was used to reconstruct up to 75 percent of a patient’s skull. The patient-specific maxillofacial implants are 3D printed in polymeric materials based on the individualized MRIs or CT digital image files shared by the surgeon. This reduces the overall cost of the complex procedure required to surgically reconstruct a face.

Increased Ability to Innovate

The integration of complex features such as solid and porous structures, hard and soft areas, multi-material and multi-color, which are otherwise difficult to manufacture using conventional manufacturing techniques, is made easier with 3D printing.

Reduced Time-to-Market

Design and development constitute a significant portion of the time required for medical devices to reach markets. Today, 3D printing is increasingly leveraged by medical device manufacturers for creating ‘clinical trial ready’ products directly from the CAD data. This will help them reduce the time and money invested in the production tooling process and overall time to market for the device.

Reduced Lifecycle Costs

3D printing results in less material wastage in the form of process scrap compared to conventional subtractive manufacturing processes. This is especially crucial for expensive implant materials such as titanium alloys. Most times, 3D printing eliminates the need for expensive tooling and reduces the number of manufacturing steps, thus leading to a leaner supply chain. The lifecycle costs for conventional manufacturing may include expenses for creating CAM programs, CNC programming of machines, transit time and costs for multiple operations, program management costs for multiple vendors, labor costs, and suchlike, which can be eliminated by using 3D printing.


Emerging Business Models and Use Cases

The adoption of 3D printing will introduce new business models for all the stakeholders in the medical devices industry, including:

For Patient-Specific or Personalized Devices:

- For OEM devices that need to be personalized, hospitals can use imaging to collect patient-specific data and transfer it to the OEM (over Cloud) along with the purchase order for the device. The OEM can integrate the patient-specific data with the generic devices already created (along with regulatory approvals) and ship the personalized device to the hospital or patient.

- Alternately, hospitals can have their own 3D printing facility where the device can be printed from personalized 3D data provided by the radiology department. To achieve this, hospitals need to invest in equipment, personnel, and clean room manufacturing facilities. One example of this is the Children’s Hospital of Illinois, Peoria, that has its own 3D printer, which is used to print practice models for pediatric surgeries[^6].

- Another popular model involves sending the patient’s data for creating 3D printed organs or bones for surgical planning to a 3D printing vendor, who prints out the models and ships them to hospitals. Replica 3dm, one such vendor based in the UK, serves around twelve UK National Health Service hospitals.[^7]

For Generic Devices:

- In the future, the OEM can have their own 3D printing facility or work with a 3D printing service provider to print generic devices and then ship them to the point of use.

- In addition, doctors can prescribe a generic medical device to the patient using a serial number or a Unique Device Identifier[^8]. The patient or consumer can then purchase the digital file of the approved medical device from the OEM and proceed to print it at a certified vendor of his or her choice.

Cloud Manufacturing:

- For both generic and patient-specific devices, the OEM or the hospital can leverage the ‘cloud manufacturing model’ whereby personalized or mass-customized data of the device is uploaded to a secure website. Pre-selected 3D Printing vendors can use this data to create parts or sub-assemblies for the device and ship them to the point of use.

- This model can be used to manufacture one to a few thousand devices by leveraging a flexible network of 3D printing vendors. The number of vendors in the network can be increased or decreased based on the requirement. With time, it is expected that this network will multiply drastically as 3D printing becomes popular, thus creating an entirely new and flexible supply chain for medical device 3D printing.


[^7]: Website accessed on November 19, 2014 http://www.replica3dm.com/medical.htm

Accounting for potential challenges

Despite being a highly advantageous technology, 3D printing does have its own set of challenges. Some of these are:

**Quality and Regulatory Challenges:**

The advent of 3D printing has equipped patients, consumers, as well as hospitals to print their own devices. This practice poses a challenge for regulatory bodies in terms of enforcing adherence to quality standards such as ISO 13485. Also, it is imperative to ensure traceability of a device throughout its lifecycle, right from the digital data stage to the patient or user-specific data (patient identification) stage. This may require extending the Unique Device Identification philosophy to 3D printed devices.

New and unapproved devices that need to be implanted into the patient's body on an emergency basis may have to go through emergency approval processes. One such case was that of the tracheal implant for a baby, which the FDA approved on an emergency basis. On the other hand, 3D printing offers doctors additional flexibility, helping them to take decisions in such cases and resolve the issue within a stipulated timeframe.

Users of this technology need to exercise immense caution to ensure there are no regulatory violations. However, a step in this direction has hopefully been initiated by the recently held public workshop hosted by the FDA, ‘Additive Manufacturing of Medical Devices: An Interactive Discussion on the Technical Considerations of 3D Printing’. The forum garnered inputs regarding technical assessments necessary for additively manufactured devices in order to provide a transparent evaluation process for future submissions. Industry players hope to receive guidance on these challenges from the FDA in years to come.

**Challenges related to choosing the Right Candidate for 3D printing**

Hypothetically speaking, most digital 3D files can be 3D printed. However, like any other manufacturing process, 3D printing also has certain limitations. Some of the key limitations include – lack of an exhaustive range of 3D printed materials that can mimic conventional materials (metals, plastics, ceramics, and so on), limited build size, difficulty in achieving tight manufacturing tolerances, fine surface finishes and the slow speed of production compared to traditional subtractive manufacturing processes.

Although device designers are becoming increasingly aware of the limitations of the 3D printing process, they have a long way to go in designing devices specifically for 3D printing.

TCS has created a simple framework that can help current and future users appreciate the many facets of 3D printing and make informed decisions on its applicability as an alternate manufacturing process.

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Mechanical Properties and Bio-compatibility Challenges

The FDA has identified mechanical properties, bio-compatibility, and interactive design of medical devices that are 3D printed as key considerations and is keeping an eye on these areas. Mechanical testing and bio-compatibility questions may arise with medical devices produced using additive manufacturing (3D printing)\(^2\).

Additional research on improving material characteristics and manufacturing methods related to 3D printing needs to be carried out to overcome these challenges.

Reimbursement Challenges

A number of insurance providers do not partially or fully cover the costs of 3D printed visualization aids (such as models of organs or bones) or implants\(^3\). This has slowed down the adoption of 3D printing of medical devices.

We predict that the industry will gradually evolve and develop well-defined medical codes for the reimbursement of 3D printed devices, encouraging the adoption of 3D printing.

Conclusion

As patients start appreciating benefits of 3D printing such as reduced surgery costs, time, trauma and healing periods, the demand for personalized medical devices will increase. With this increase in demand, insurance providers will eventually need to cover the costs of 3D printed devices.

Currently, regulatory bodies such as the US FDA and EU Commission have started work on a regulatory framework for the evaluation of 3D printed medical devices. As a step in this direction, the FDA has already approved a few 3D printed devices.

As with any new or emerging technology, the perceived obstacles or roadblocks will only open up room for further innovation and product revision, which could lead to the creation of more developed, innovative, and highly integrated 3D printed devices.

Through early adoption, 3D printing can help medical device manufacturers realize competitive advantage, while also reducing the time-to-market and manufacturing costs. Going beyond operations, medical device manufacturers can collaborate closely with partners to leverage this innovative technology and realize new efficiencies and deliver value to all stakeholders.


About TCS Life Sciences

With over two decades of experience in the life sciences domain, TCS offers a comprehensive portfolio in IT, Consulting, KPO, Infrastructure and Engineering services as well as new-age business solutions including mobility and big data catering to companies in the pharma, biotech, medical devices, and diagnostics industries. Our offerings help clients accelerate drug discovery, advance clinical trial efficiencies, maximize manufacturing productivity, and improve sales and marketing effectiveness.

We draw on our experience of having worked with 7 of the top 10 global pharmaceutical companies and 8 of the top 10 medical device manufacturers. Our commitment towards developing next generation innovative solutions and facilitating cutting-edge research - through our Life Sciences Innovation Lab, research collaborations, multiple centers of excellence and Co-Innovation Network (COIN™) - have made us a preferred partner for the world’s leading life sciences companies.

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