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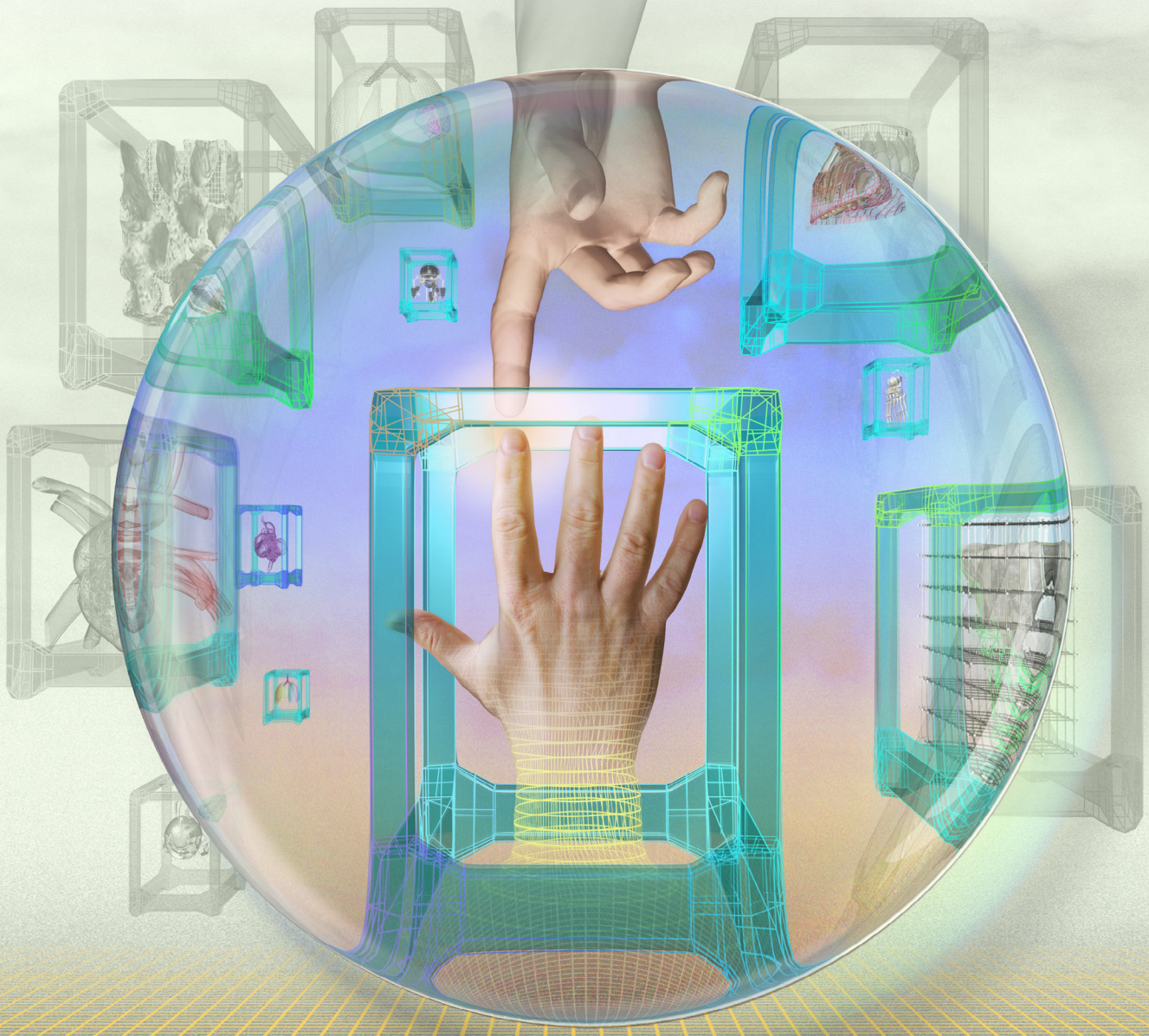
3D opportunity for health care

Demystifying FDA regulations for medical devices



A Deloitte series on additive manufacturing

Deloitte Consulting LLP's Supply Chain and Manufacturing Operations practice helps companies understand and address opportunities to apply advanced manufacturing technologies to impact their business's performance, innovation, and growth. Our insights into additive manufacturing allow us to help organizations reassess their people, process, technology, and innovation strategies in light of this emerging set of technologies.

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Introduction

ADDITIVE manufacturing (AM) has the potential to deliver radical change to the health care landscape. AM technologies allow for the systematic addition of materials to form a final product, as opposed to subtractive manufacturing, where material is removed to form the product. This is more than just a mere change of how a product comes to be; instead, it introduces new possibilities for the entire health sector. AM can introduce entirely new abilities for:

- **Manufacturing at the point of use.** AM disrupts the traditional supply chain, allowing for goods to be produced closer to the point of use at the time of need, which limits material waste, economies of scale, and lead times.[1] This feature is particularly relevant in health care, where demand can be unpredictable, and patients' health can even be impacted by longer shipping and wait times.
- **Greater customization.** AM allows for mass customization at the point of use. Devices can be tailored to a patient's exact anatomy,[2] which can improve the patient experience and patient outcomes.
- **Innovation in design.** AM provides designers freedom to create manufactured works with fewer constraints, removing limitations on design imposed by the limitations of traditional manufacturing methods in assembly and manufacture.[3] Limitless design achieved through AM can support new medical innovations and improve patient care.
- **Cost-effective, quality solutions.** AM can be profitable at much lower scales of production than traditional manufacturing techniques. This can enable life sciences and health care professionals to utilize devices or tools whose economies of scale may previously have made them impractical. With the rising costs of health care, AM solutions can provide patients with affordable solutions, while achieving quality standards at or above those realized using traditional manufacturing methods.
- **Ethical research and development (R&D).** Drugs and disease models can be tested on 3D-printed tissues instead of on animals or humans.

Despite these potential benefits, many companies and organizations are hesitant to incorporate AM due to a lack of understanding of potential applications and US Food and Drug Administration (FDA) regulations. While these companies are likely familiar with FDA regulation, navigating the new elements added by AM can seem daunting. For example, how can you preapprove a customizable medical device made by AM since it changes each time it is made for a different patient?

While AM does introduce some unique considerations, they are by no means insurmountable. In order to be competitive and deliver greater innovations, companies should be fully aware of how they can use AM while navigating FDA regulations. This article provides an introduction to the regulatory issues around AM in health care and shows how companies can use their strategy for AM to inform their path to regulatory approval.

Early wins: Unregulated uses of AM

PERHAPS the simplest strategy of dealing with AM regulation is to merely stick to those uses of AM that are unregulated. There are many unregulated uses of AM that can be applied within any health care organization to forge innovations that can improve patient outcomes. Even without directly touching the patient, these applications of AM have the potential to dramatically improve patient care.

Makerspace

One of the applications health care organizations can leverage is the *makerspace*. A makerspace attracts like-minded individuals, who work together on projects to create, innovate, and design; they share resources, tools, and expertise.[4] Makerspaces can comprise manufacturing equipment, computer technology, and electronics, but they have grown in popularity in recent years with the advent of AM technology.

In health care, a medical makerspace provides the intellectual capital within an organization, bringing together doctors, nurses, patients, and students and giving them the autonomy and time to develop innovative solutions to enhance the patient experience, improve patient outcomes, or support hospital operations. By harnessing AM technologies, makerspaces can provide health care professionals a palette to turn simple ideas into helpful realities, such as clips for tubing or improved patient call buttons. In 2015, MakerNurse launched the first medical makerspace for health care professionals, known as the MakerHealth™ Space. Medical makerspaces are continuing to grow in popularity and should be a part of any health care organization's playbook when considering how to incorporate AM technologies.

Read *3D opportunity in medical technology* for technical background on producing medical devices via AM.

Medical models

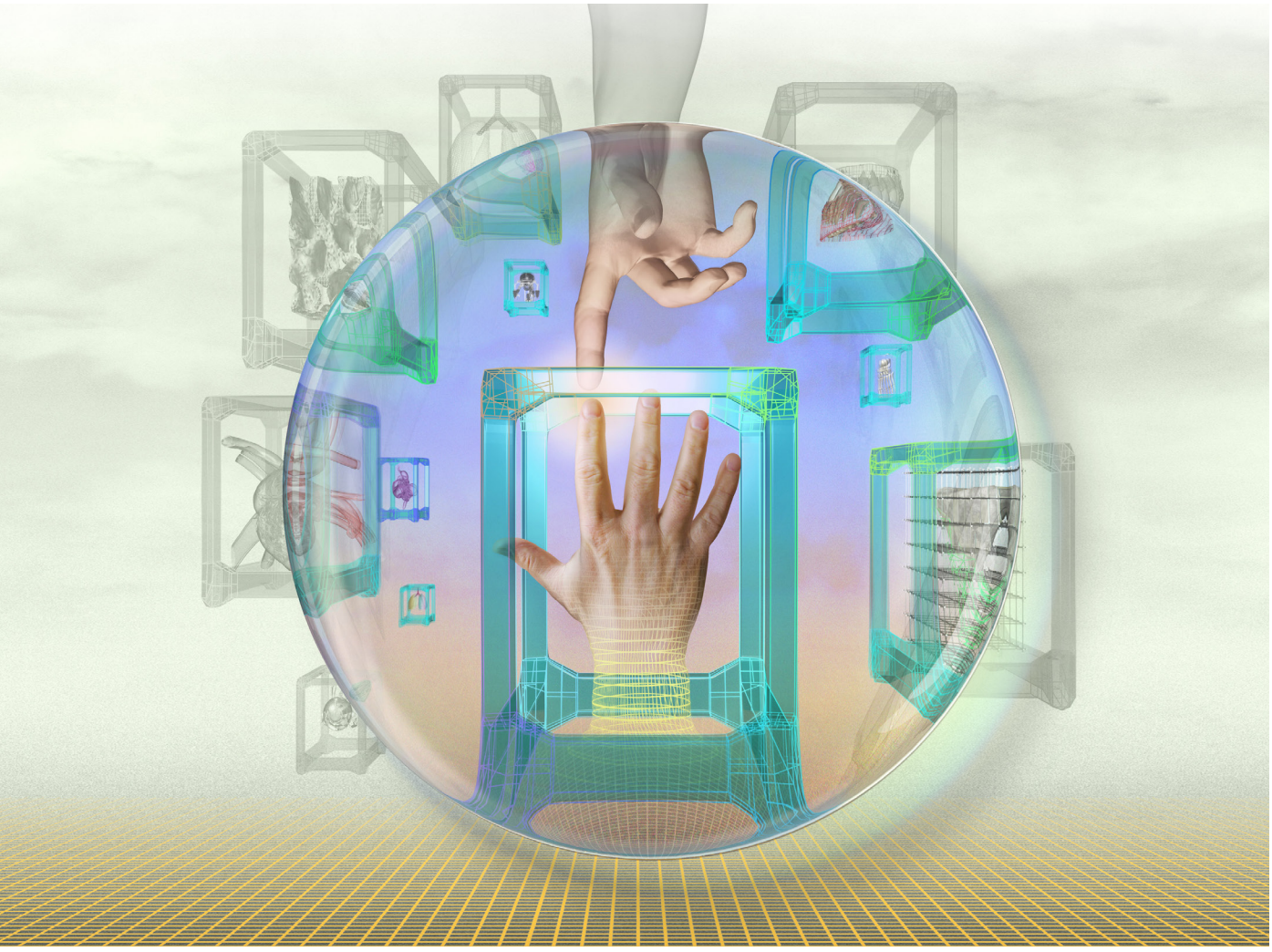
Other types of deregulated applications of AM that organizations can leverage include medical models. Physicians will perform a computerized tomography (CT) scan of a patient's anatomy—perhaps an appendage or organ—that can be converted into a computer-aided design (CAD) drawing that can then be 3D-printed. These medical models can be leveraged by physicians to prepare and plan for surgeries without directly touching the patient.[5]

In April 2016, a five-day-old baby was facing a life-threatening congenital heart defect and required timely surgery. Preparing for the surgery, physicians turned to AM, as standard CT scans alone did not provide surgeons enough visibility. A 3D-printed model of the boy's

heart provided surgeons the visibility they needed to plan for the surgery. It also provided the boy's parents a contextual reference point to ease their concerns leading into the procedure.[6]

Biologics

Organizations are also beginning to use AM to print biological materials in order to better support ethical R&D practices. Pharmacy students at North Dakota State University (NDSU) have developed a system for cloning and 3D-printing patient tumors.[7] The cloned tumors can then be tested to determine the optimal treatment before even touching the patient. Traditional R&D required animal and/or human testing, which can now be eliminated with some forms of AM. In addition, biologic AM solutions like the ones developed at NDSU are occurring on a global scale and have the potential to provide patients with more informed treatments, which can improve patient outcomes.



The way forward for medical devices

THERE is a limit to how much unregulated uses of AM can accomplish in the health care market. Eventually, to directly impact patient care, medical devices are required. Whether made by AM or traditional manufacturing processes, all medical devices that touch the patient are subject to regulatory pre-market and post-market requirements enforced by the FDA.[8]

Table 1. Pre-market pathways

Pathway	Description	Device class	Examples
Pre-market approval (PMA)	Rigorous review where the FDA evaluates scientific data, such as clinical trials and manufacturing processes, to ensure the device is safe and effective	III	Hip-joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis[i]
Pre-market notification (510(k))	Process to determine whether a device to be marketed is safe, effective, and substantially equivalent to a previously marketed device	II and some I	Elbow-joint radial (hemi-elbow) polymer prosthesis[ii]
De novo classification	Risk-based and evidenced-based process to classify a new device into class I or II, where there is no legally marketed predicate device	I or II	Upper-extremity prosthesis, including a simultaneously powered elbow and/or shoulder with more than two simultaneous powered degrees of freedom and controlled by nonimplanted electrical components[iii]
Humanitarian device exemption	Approval of a class III device intended to benefit patients with rare diseases or conditions	III	A device that provides circulatory assistance for up to 14 days in pediatric or adult patients with a body surface area of >= 1.5 m^2 who develop acute right heart failure or decompensation following left ventricular assist device implantation, myocardial infarction, heart transplant, or open-heart surgery[iv]
Emergency use authorization	Provides for the use of a device during national security and public health emergency situations	I, II, III	In vitro diagnostic tests for the detection of the Zika virus[v]

Pathway	Description	Device class	Examples
Expanded access	Provides for device access either in an emergency situation, where there is a life-threatening condition with no alternative and no time for FDA approval, or for compassionate use where an unapproved device can be used, with FDA concurrence, for a serious condition	III	An investigational device used outside a clinical trial to treat a patient[vi]
Custom device exemption	PMA or 510(k) not needed for devices designed to treat a unique pathology or physiological condition that no other device is domestically available to treat; intended to meet the special needs of the prescribing physician in the course of the professional practice of such physician; or intended for use by an individual patient named in such order of such physician. Limited to no more than five units per year of a particular device type.	I, II, III	Artificial cervical disc replacement for reconstruction of the cervical disc following cervical discectomy to treat cervical radiculopathy in a 7-foot, 2-inch male patient[vii]

i. Sec. 888.3330 of FDA Code of Federal Regulations Title 21.

ii. Sec. 888.3170 of FDA Code of Federal Regulations Title 21.

iii. FDA letter to DEKA Integrated Solutions Corporation, May 9, 2014, http://www.accessdata.fda.gov/cdrh_docs/pdf12/DEN120016.pdf.

iv. FDA listing of CDRH humanitarian device exemptions.

v. FDA, "Emergency Use Authorization," http://www.fda.gov/emergencypreparedness/counterterrorism/medicalcountermeasures/mcmlegalregulatoryandpolicyframework/ucm182568.htm.

vi. FDA, "Expanded access for medical devices," http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/ucm051345.htm.

vii. FDA, "Custom device exemption: Guidance for industry and Food and Drug Administration staff," January 14, 2014, http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm415799.pdf.

Determining the pre-market pathway begins with a classification of the device. The FDA classifies medical devices into three categories based on the level of control necessary to ensure the device's safety and effectiveness. These regulatory classifications, which depend on the intended use of the device as well as involved risks, are:

- **Class I**—Devices such as nasal oxygen cannulas, manual stethoscopes, and hand splints represent a low risk to the patient.
- **Class II**—These devices, such as tracheal tubes, bone plates, and elbow joint radial prostheses, are more invasive—typically implanted into the body and requiring surgery or some type of medical intervention to apply—and represent a moderate risk to the patient. A majority of medical devices are class II.
- **Class III**—Devices such as aortic valves, constrained metal hip prostheses, and coronary stents represent the highest risk to the patient.

Each class of device has specific regulatory requirements associated with it. At the lowest level, class I is subject to "general controls," which include requirements for registration, good manufacturing practices, medical device reporting, and, in some cases, pre-market notification. Since they represent the lowest risk, many class I devices can be exempt from certain requirements. For example, 74 percent of class I devices are exempt from pre-market notification.[9] Class II also has general controls, but it must contend with additional special controls, such as specific performance standards, patient registries, or surveillance requirements. Finally, as the most controlled class, class III not only requires general controls but also pre-market approval from the FDA before a product can be sold. Table 1 summarizes the various submission pathways medical devices need to pursue, depending on the device class.

However, the classification of an AM-produced medical device, and therefore the specific path through FDA regulation, will likely change depending on exactly how a company decides to use AM.

THE ADDITIVE MANUFACTURING FRAMEWORK

AM's roots go back nearly three decades. Its importance is derived from its ability to break existing performance trade-offs in two fundamental ways. First, AM reduces the capital required to achieve economies of scale. Second, it increases flexibility and reduces the capital required to achieve scope.

Capital versus scale: Considerations of minimum efficient scale can shape supply chains. AM has the potential to reduce the capital required to reach minimum efficient scale for production, thus lowering the manufacturing barriers to entry for a given location.

Capital versus scope: Economies of scope influence how and what products can be made. The flexibility of AM facilitates an increase in the variety of products a unit of capital can produce, reducing the costs associated with production changeovers and customization and, thus, the overall amount of required capital.

Changing the capital versus scale relationship has the potential to impact how supply chains are configured, and changing the capital versus scope relationship has the potential to impact product designs. These impacts present companies with choices on how to deploy AM across their businesses.

Companies pursuing AM capabilities choose between divergent paths (figure 1):

Path I: Companies do not seek radical alterations in either supply chains or products, but they may explore AM technologies to improve value delivery for current products within existing supply chains.

Path II: Companies take advantage of scale economics offered by AM as a potential enabler of supply chain transformation for the products they offer.

Path III: Companies take advantage of the scope economics offered by AM technologies to achieve new levels of performance or innovation in the products they offer.

Path IV: Companies alter both supply chains and products in pursuit of new business models.

Figure 1. Framework for understanding AM paths and value

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Deciding how to use AM, and to what extent, can be daunting. Several organizations already use AM in different ways, achieving a range of product and supply chain impacts. Here are some examples of these organizations, mapped along Deloitte's AM framework (see the sidebar "The additive manufacturing framework").

Path I: Stasis

AM medical devices that align to path I of Deloitte's AM framework allow for design and rapid prototyping, with no radical changes in either supply chain or products. Companies exploring AM for the first time tend to adopt this path.

Time to market is critical in the highly competitive medical device space, which makes rapid prototyping essential to the design process. Traditional tooling and injection molding for prototyping can be costly and time consuming.[10] By leveraging AM instead, organizations can produce high-quality prototypes rapidly and cost-effectively. Shaving a few days or weeks off the design process can often mean the difference between being first or second to market. In addition, the ability to rapidly prototype allows organizations to react quickly to the needs of patients, which can help support and improve overall patient care.

Kablooe Design, an invention, design, and engineering firm, is an example of an organization that has effectively leveraged AM to rapidly develop prototypes. When asked to develop a device to treat benign prostatic hyperplasia, or enlarged prostate, Kablooe estimated it would require 10 prototypes in

order to develop a minimally invasive working solution. For such a complex design process, Kablooe turned to AM versus traditional prototyping methods. In doing so, Kablooe was able to develop a working prototype, saving $250,000 and 12 weeks of development time.[11]

As with Kablooe Design, most medical device companies are applying AM to support the prototyping process to realize cost and time benefits. Any medical device organization currently adhering to traditional prototyping methods may want to consider incorporating AM in order to stay competitive in the market place.

SPECIFIC REGULATORY CONSIDERATIONS

Because companies on path I are not using AM to introduce any new features to their products or value changes, the regulatory impacts would likely be limited to changes introduced by the AM process itself. For example, AM makes complex geometries possible, leading to objects in previously unseen shapes and configurations. These complex designs can create some new cleaning- and sterilization-related challenges, including porosity, internal voids, twisted pathways, or increased surface area. As a result, when documenting cleaning processes for approval, companies would need to validate cleaning and sterilization procedures to ensure that the complex geometries made possible by AM are adequately cleaned.

PATH I AT A GLANCE

Advantages: Rapid prototyping

Regulations to think about [Quality Systems Regulations (QSR)]:

- Design Controls (21CFR820.30)
- Process Validation (21CFR820.75)
- Production and Process Control (21CFR820.70)

Path II: Supply chain evolution

With vast amounts of specialized supplies and tools, the medical supply chain often represents the second-largest single cost for hospitals after labor.[12] Some AM medical devices can remake that supply chain, allowing for manufacturing at the point of use and introducing new efficiencies and savings. This can provide tremendous flexibility for an organization, allowing for inventory to be managed just in time (JIT) as opposed to just in case. In turn, organizations' overall inventory and costs can be reduced by aligning to this phase.

Recently, researchers have turned this concept into reality. With the goal of making affordable, on-demand surgical equipment for developing countries, they generated a sustainable process to 3D-print sterilized surgical instruments.[13]

The researchers first 3D-print the surgical equipment using polylactic acid filament, which is already approved by the FDA for use in medical devices. Then the printed device is sterilized using glutaraldehyde, which is an active ingredient in various sterilants and disinfectants cleared for marketing via the pre-market notification process by the FDA. It takes about 90 minutes to print a simple medical device. When printing is completed, the end result is a completely sterilized medical device ready for use at a material cost of less than a dollar.[14]

This revelation can now bring affordable medical equipment to developing countries. Yet even in developed counties, hospitals are no longer required to maintain stock rooms of common surgical equipment and concern themselves with the perpetual challenge of sterilization.[15] As hospitals and similar organizations consider cost-saving measures, they can consider using AM to enable JIT inventory.

SPECIFIC REGULATORY CONSIDERATIONS

While companies on path II are not introducing significant changes to the product, the reorientation of the supply chain that AM allows introduces some

specific regulatory challenges. For example, now that products are manufactured at the point of use and not in a central facility, how can final measurements of finished products be taken, and how can consistent, appropriate quality be assured? Recognizing this challenge, the FDA recommends that dimensional tolerances should be specified and measurements of these dimensions taken for each component manufactured via AM due to the variability that may exist with build orientation and build space. Companies should address this variability in process validation, where consistency and reproducibility of the process are determined.[16]

PATH II AT A GLANCE

Advantages: Point-of-use manufacturing

Regulations to think about [Quality Systems Regulations (QSRs)]:

- Design Controls (21CFR820.30)
- Purchasing Controls (21CFR820.50)
- Acceptance Activities (21CFR820.80)
- Process Validation (21CFR820.75)
- Production and Process Control (21CFR820.70)

Path III: Product evolution

AM medical devices that align to phase III of Deloitte's AM framework allow companies to create products that would be difficult or impossible to manufacture traditionally. This can, in turn, lead to improved financial performance and revenue growth.

K2M Inc., a medical device company that specializes in the complex spine, has leveraged this form of product evolution with its Lamellar 3D Titanium Technology™. The designs that can be achieved using AM technology have allowed K2M to design a spinal interbody—once considered unthinkable using traditional manufacturing methods. A spinal interbody replaces the disk space between two vertebral elements and encourages spinal fusion in conjunction with bone-grafting material.[17] K2M's interbody incorporates both a porosity and surface roughness that pre-clinical data have associated with bone growth activity. In addition, the interbody has 70 percent porosity and therefore a decreased radiographic signature, making it easier to work with on X-ray.[18]

This advancement, spurred by the use of AM, can be revolutionary for K2M and the spine industry. Similar organizations and industries within the health care sector can realize similar benefits by exploring the design potential that can be achieved using AM.

SPECIFIC REGULATORY CONSIDERATIONS

Uses of AM to introduce changes to the product offer some novel considerations. Everything from the dimensions to performance to even the materials used in manufacturing should be examined to ensure no harmful effects on patients. As many AM-produced medical devices could be implanted within the human body or used for invasive procedures that greatly impact human health, the purity and properties of materials used for device production are of the utmost importance. Material chemistry information found in certificates of analysis or material safety data sheets will help in identifying the source and purity of the manufacturing material.[19] A description of all material chemistry changes expected during manufacturing—most particularly

PATH III AT A GLANCE

Advantages: Efficient manufacturing of complex geometries

Regulations to think about (PMA, QSR):

- Traceability (21CFR820.65)
- Design Controls (21CFR820.30)
- Purchasing Controls (21CFR820.50)
- Acceptance Activities (21CFR820.80)
- Process Validation (21CFR820.75)
- Production and Process Control (21CFR820.70)

those that affect biocompatibility—should also be considered to understand unexpected changes in chemistry due to material reuse. Material physical properties known to affect interlayer bonding, a cohesion unique to AM, should be defined to address concerns of structural integrity.[20]

Depending on the type of material used for AM, the FDA has issued the following recommendations in its guidance (table 2).

Table 2. FDA recommendations based on material type

Material type	Characterization	Method
Metal or ceramic	Grain size and orientation	Conduct tests to show device performance is not negatively affected by structural inhomogeneity, microstructural voids, or incomplete consolidation.
Polymer	Shore hardness and uniformity	The method used to determine uniformity depends on the type of material used. For instance, the percent cross-linking and degree of curing should be evaluated for polymers. Identify crystalline morphology for crystalline material. Indicate water swelling or water content percentage for hydrogel materials.
Absorbable	Degradation profile	Conduct in vitro degradation testing using final finished devices or equivalents.

Source: FDA letter to DEKA Integrated Solutions Corporation, May 9, 2014, http://www.accessdata.fda.gov/cdrh_docs/pdf12/DEN120016.pdf.

Path IV: Business model evolution

AM medical devices that align to phase IV of Deloitte's AM framework allow for mass customization at the point of use and complete supply chain disintermediation. This type of device can evolve the traditional business model by providing patients with personalized solutions at the point of use. In addition, the commercialization of AM technologies can even empower patients to take part in their own treatment.

Consider the example of Amos Dudley. Amos, a college student at the New Jersey Institute of Technology (NJIT), wasn't happy with his smile. Determined to straighten his teeth without incurring the high cost of name brands, Amos went the do-it-yourself (DIY) route.[21]

First, Amos scanned and 3D-printed models of his teeth. With each model, Amos progressively adjusted and corrected the direction of his teeth to get to his optimal end state. He then molded a nontoxic plastic around each model, forming a set of 12 plastic braces. Amos wore each set of braces, and, over time, his end result was perfectly straight teeth. The cost of name brand braces, such as Invisalign, can be around $8,000.[22] Amos did all this for $60 in material costs and a little help from NJIT.[23]

Amos's DIY solution aligns with the current regulatory environment and is an example of the future to come. As AM technologies become more commercialized, organizations should look to engage patients in their own care. Organizations should consider how they can design personalized medical treatments for patients that can be 3D-printed and administered at home. A clear parallel is prescription drugs, where a patient visits the doctor, and the

doctor prescribes a treatment that the patient then administers; in this case, the prescription is in the form of a personalized CAD drawing.

Whatever AM path you decide to follow, it is critical to thoroughly understand the complex web of regulations and procedures before beginning to develop your AM-produced medical device.

SPECIFIC REGULATORY CONSIDERATIONS

Companies that embark upon path IV are starting on a long path to realizing the greatest potential benefits of AM. However, as with any significant change, there are numerous challenges along the way, and regulation is no exception. Significantly changing both the product and value chain means that companies on path IV must navigate the most significant changes from what they may be used to with traditional manufactured medical devices. For example, even things as seemingly simple as labeling can change. In addition to what is required for non-AM manufactured devices, labeling for AM-produced, patient-matched devices should address:

- Patient identifier
- Details identifying use, such as anatomical location (such as left distal femoral surgical guide)
- Final design iteration or version used to produce the device

PATH IV AT A GLANCE

Advantages: Mass customization at the point of use

Regulations to think about:

- Pre-Market Approval (FDCA515 and 21CFR814)
- Pre-Market Notification (FDCA510(k) and 21CFR807)
- QSRs (21CFR820)
- Labeling (FDCA502 and 21CFR801, 812, 830)

- Expiration date—considering the time lapse between when the patient is imaged and when the final device is used, to account for anatomical changes over time[24]

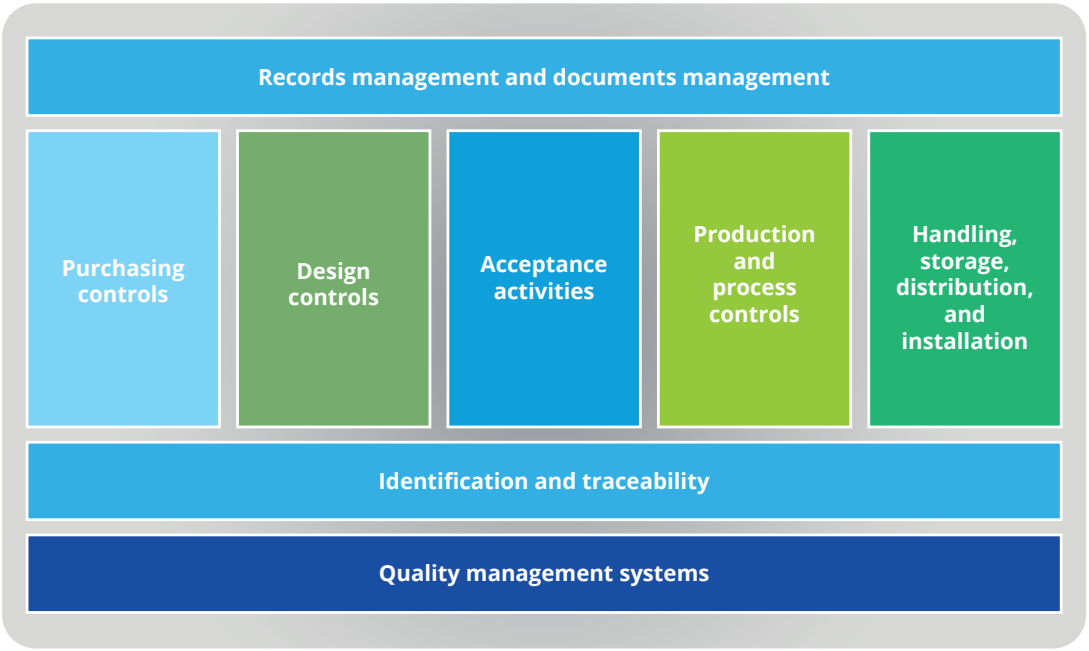
FDA's draft guidance provides timely insight into the agency's thinking on information needed to market AM-manufactured medical devices in the United States. Manufacturers and institutions should have systems in place to compile the information the agency is looking for to minimize submission review time. Agency guidelines are not meant to be a barrier to innovation. Rather, by taking advantage of FDA's recommendations when submitting AM-manufactured products, innovative devices not only get to market quicker but also provide increased treatment options to those with specialized physiologies.

Approval is not the end of the story: Creating a quality system

Regardless of which path a company travels, the ultimate goal is to introduce a truly beneficial medical device to the market. In this respect, simply winning FDA approval is not the end of the story but rather merely the beginning. There are a series of post-market regulatory requirements to which companies must adhere. The goal of these post-market regulations is to ensure that medical devices continue to be created adhering to the same high quality standards demonstrated during their pre-market approval. Therefore companies pursuing AM in health care need to create a robust system of process and management quality controls to ensure the continued quality of approved devices.

The Food Drug and Cosmetic Act (FDCA) grants the FDA the authority to promulgate Current Good Manufacturing Practices (cGMPs) for medical devices. Quality System Regulations (QSRs) are the cGMPs FDA prescribed under this authority. Once a medical device is marketed, compliance with the QSRs is required. Failure to adhere to the QSRs deems the medical device adulterated and thus may subject the responsible person or people to civil and criminal penalties.[25]

Figure 2. Quality system elements



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Since the QSRs apply to devices ranging in complexity from finger splints to aortic heart valves, they provide a framework for manufacturers to implement procedures according to leading-edge manufacturing processes. The QSRs cover the product life cycle from design and development, through manufacturing, testing, distribution, and post-market surveillance. As such, companies need to think about controls across the life cycle of a product. The elements of a quality system required by QSRs and most applicable to AM are listed in figure 2.

Quality controls are typically required at every phase of a product life cycle:

- **Purchasing controls** govern the purchase and procurement of materials for the medical device to ensure they are of sufficient quality.
- **Design controls** are intended to ensure that as AM products are customized, their overall performance remains within tolerances approved in pre-market determinations.
- **Acceptance activities** involve the destructive or nondestructive testing of products to verify quality.
- **Production and process controls** ensure validation of software, processes, process changes, and manufacturing equipment. Procedures need to be in place for calibration, maintenance, environmental controls, material handling, and operating personnel.
- **Handling, storage, distribution, and installation controls** seek to prevent product contamination (via personnel or equipment) and product deterioration.
- **Records management** and **traceability controls** are meant to ensure that in the event

other controls fail and a defect or problem is detected, the root cause can quickly be identified and harm to patients avoided.

- Finally, a **quality management system** represents the integrated business approach to quality by which management and employees ensure adherence to the other quality controls.

The regulatory requirements for quality are merely a starting point. In an industry such as health care, consistent, superior quality can be a strong differentiator for a product.[26] It is important to note, however, that quality exists on a continuum; depending on their intended class, use, and function, not all medical devices will need to be subjected to the same quality demands.[27] By locating their needs and goals within the quality continuum, they can begin to address FDA QSRs in the most appropriate way.

AM is able to produce consistent, customized products time after time. As a result, AM and quality are natural partners.

Conclusion: How to get started

If your organization has ever considered adopting or experimenting with AM, now is the time to embrace it. AM innovations are just being tapped into throughout the health care industry, with many solutions still left to be discovered. AM could provide your organization the freedom to create solutions that can advance patient care as we know it today, with the potential to grow top-line revenue and cut costs. Moreover, starting with AM now can provide a head start on the radical innovations—new designs, processes, and treatments—that AM is likely to introduce in the coming years.

The new processes, materials, and value chains of AM can introduce new regulatory considerations, but they are by no means insurmountable. When considering using AM to create a health care product, following specific actions can help you get started (figure 3).

Regulations can be confusing, but they are no reason to avoid trying potentially game-changing innovations, such as AM. With a little thought and some structure questioning, your company can take advantage of AM, meet all regulatory requirements, and deliver a truly valuable product to patients.

Figure 3. Checklist for getting started with AM and the FDA

- ☑ **Begin with business strategy.**
  How does your company seek to use AM? To redefine product, value chain, or both?
- ☑ **Determine what AM medical device you are making.**
  Is it classified as a regulated medical device or is it unregulated?
- ☑ **If a regulated medical device, determine the level of regulatory classification your product will fall under (class I, class II, or class III) and understand the pre-market regulatory pathways.**
- ☑ **Follow all protocal for submission and approval of your product.**
- ☑ **Understand the post-market FDA regulations for marketing your product.**

ENDNOTES

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