Executive Brief

How to Bring on Metal AM as a Validated Process for Certified Parts in Highly Regulated Industries
## Contents

<table>
<thead>
<tr>
<th>Page</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>03</td>
<td>Accelerating Innovation with Metal AM</td>
</tr>
<tr>
<td>04</td>
<td>Unlocking the Value of Metal AM in Critical Applications</td>
</tr>
<tr>
<td>05</td>
<td>Overcoming the Knowledge Gap: the Primary Challenge of Implementation</td>
</tr>
<tr>
<td>06</td>
<td>Partnering to Establish and Qualify a Production AM Workflow</td>
</tr>
<tr>
<td>09</td>
<td>Advanced DMP Process Training</td>
</tr>
<tr>
<td>10</td>
<td>Scaling with Metal Additive Manufacturing</td>
</tr>
</tbody>
</table>
Accelerating Innovation with Metal AM

The design and fabrication freedoms of additive manufacturing (AM) technology unlock new opportunities for companies and organizations to advance their products, processes, and bottom lines.

As metal AM continues to prove itself in the production of high value, critical parts, players in regulated industries like healthcare, aerospace, and energy are looking for ways to access AM’s unique benefits while mitigating the risks inherent to change. Matters of workforce readiness, quality assurance, validation, and process control are hot topics, all leading to the same question of how to accelerate the implementation of metal AM to jumpstart innovation.

In this Executive Brief you will learn how 3D Systems helps customers obtain high quality, repeatable, certifiable metal printed parts, and qualify and control their metal AM processes at all stages to eliminate months from implementation, achieve their goals faster, and adopt best practices sooner. This is made possible through the teams of experts at our global Customer Innovation Centers (CICs), which are facilities where we both manufacture parts and offer customer training and engineering services.
Unlocking the Value of Metal AM in Critical Applications

Additive manufacturing is a high value-add process that lends tremendous competitive advantages to those who properly implement it. The freedom from conventional design and manufacturing limitations which AM enables, offers new opportunities to achieve superior performance parts, lighter weights and increased efficiencies. All of which can translate to improved function or economics.

For these reasons, metal AM is increasingly being used in regulated industries to produce complex parts and assemblies. In defense and space sectors, conventional assemblies are being consolidated to reduce manual labor and limit or eliminate former joining areas. In healthcare, AM is helping medical device companies create optimized orthopedic products designed to enable improved bone in-growth.

To achieve optimized parts using AM, the best design approach begins with the end in mind and works backwards to identify and implement effective strategies to achieve that goal. These strategies optimize not only for the part's final function, but for the AM process and post-processing as well. Creating a successful metal printed part requires taking into consideration all aspects that impact final outcomes, such as part feature sizes, part orientation, and the technology being used. Learning the ins and outs of designing for AM is a process in and of itself, but the benefits it imparts bring new functionality, productivity, and innovation to your application.
Overcoming the Knowledge Gap: the Primary Challenge of Implementation

Separate from the part design process is the process of validating and qualifying an AM production workflow. If this introduction is overwhelming, it is likely due to a knowledge gap within your organization stemming from little-to-no experience with metal AM. Such gaps are common and are slowing the integration of an otherwise highly compelling and empowering capability.

Many rightly feel that before investing in a new technology, they need to know it will work for them and know they will be able to understand, control and validate their processes. Given the perceived newness of additive manufacturing, this creates a tricky Catch-22: before using AM, you must understand it, but you can’t understand it until you use it.

Fortunately, there is a systematized way to onboard this technology and reduce the friction of implementation. This is through knowledge and technology transfer facilitated by a collaborative partnership between an AM novice and an AM expert. By choosing this route, it is possible to accelerate the path to innovation by bridging the gap between interest and capability.

3D Systems’ background as an industry pioneer means we have years of experience with process characterization, risk management, risk analyses, and best practices for process control. Over the past decade and counting, we have not only engineered our Direct Metal Printing (DMP) machines to ensure the highest optimization of workflows and processes, but we have built up our in-house knowledge and manufacturing experience by producing hundreds of thousands of validated metal parts for use in highly regulated environments such as healthcare, aerospace, and energy. Our team of seasoned AM experts have developed an effective equipment qualification protocol for all stages, and we offer application development, advanced training and engineering services to our customers through our CICs.

3D Systems’ CICs are global, certified facilities that exist to help our customers answer the specific and exacting demands of their application. The first step of any 3D Systems CIC engagement is to deeply understand our clients’ requirements and intentions. From there, we are able to recommend and help implement design and infrastructure protocols to enable better outcomes, a faster time-to-market, and a faster time-to-profit.

You can engage with 3D Systems’ CICs however best suits your needs: from using us to fulfill design feasibility studies or volume manufacturing orders, to getting up to speed on best practices in your own facilities through knowledge and technology transfer. Our constant work on and support of customer applications ensures our engineers and processes are as up-to-date and productive as possible.
Partnering to Establish and Qualify a Production AM Workflow

Setting up an AM process that can be validated is far faster and more straightforward when you can leverage data captured over a decade plus of full-scale metal additive manufacturing.

This streamlining enables significant time savings, which translates to money saved, and money faster earned. 3D Systems is accustomed to playing a variety of roles, from expert consulting and production using our own facilities, to fully collaborative application development and technology transfer to your facilities. In other words: We can help you go from zero exposure to AM to full confidence with a trained workforce, or anywhere in between.

Using a risk-based, phased approach, working with a 3D Systems CIC means gaining access to industry knowledge with expert guidance to develop process controls and characterization. Through technology transfer, 3D Systems’ engineers collaborate with you to design a validation strategy and test campaign to support and accelerate your AM onboarding experience.

The CIC approach to implementing AM uses 3D Systems’ defined and proven production protocol to take the guesswork out and facilitate a streamlined path to qualified AM parts. This protocol is broken down into the following phases:

1. Developing & controlling a process flow
2. Process validation
3. Product-specific validation
4. Production
1. Developing & Controlling a Process Flow

During the initial implementation phase with 3D Systems, our team of experts work with you to establish and control your process.

This phase includes fundamental aspects like calibration, maintenance, and operational training, as well as critical aspects of the AM process such as powder handling, powder mixing, and process characterization. Analyzing and managing risk is also part of this phase, and is underscored throughout all phases that follow. Because this workflow is digital, software validation is also a key step to ensure proper and predictable functionality of all software features used.

2. Process Validation

Process validation is built around three core qualifications: installation, operational, and performance.

**IQ**

During installation qualification (IQ), 3D Systems ensures your machine is properly installed to pass both SAT and FAT, as well as to ensure aspects such as training, work instructions and maintenance are in place.

**OQ**

Operational qualification (OQ) is a thorough challenging of your process to confirm you are producing the expected result at your process parameter highs, lows, and in-betweens. OQ also includes a design of experiment, in which we help you develop a deep understanding of how the different process parameters interact with each other and what variations might be expected, and how to control them, in normal production.

**PQ**

Lastly, performance qualification (PQ) ensures repeatability of the expected result over a series of unique builds.
3. Product-Specific Validation

After process validation, 3D Systems can assist with product-specific validation, or part qualification. This is where we verify that the established AM process delivers a useable part based on the application requirements.

How a part is verified can vary based on its end use, as well as the details of its design and build.

3D Systems takes a quality by design approach on all the applications we develop and help to develop. Using this approach, risks for the part are defined and addressed upfront from a design, application and process point of view. When executed to the thorough and proven standard of 3D Systems’ expert teams, this strategy typically leaves only performance testing and non-destructive testing for the part validation phase. Destructive testing can also be performed as needed based on the part requirements and production volumes.

4. Production

Once the process and part have been validated and verified, the application is ready for production or submission to the applicable regulatory agency.

Over the past decade 3D Systems has helped hundreds of customers qualify parts that stand up against regulatory scrutiny across industries.

Following certification, there are several ways to launch production. In cases where a low volume of parts is required, the application is still in the proof-of-concept phase, or a company is otherwise not ready to invest in its own equipment and workforce, 3D Systems or a certified partner can fulfill production. If or when a company is ready to bring operations under its own roof, 3D Systems’ team of experts enables that process through technology transfer to get the internal team trained and up to speed.
Advanced DMP Process Training

To support and enable your adoption of metal AM, 3D Systems offers various advanced training options that include both practical and theoretical sessions using our DMP printers.

Training options include:

- **New User Training**, comprised of two main modules: (1) 3DXpert™ Software Training; and (2) Application and Operator Training. The objective of these sequenced trainings is to familiarize new users with the capabilities of 3D Systems’ all-in-one additive manufacturing software, 3DXpert, and provide an opportunity to apply that knowledge while diving deeper into machine architecture, operational safety, machine operations, and post-printing operations.

- **Advanced DMP Process Training**, designed to deliver a breakdown of the different parameters that affect the DMP process, and how to control them.

- **DMP DfAM (Design for Additive Manufacturing) Training**, for fundamentals and technical concepts pertaining to metal AM, and how the DMP process affects design and manufacturability. This training also includes hands-on, application-based workshops that give trainees the opportunity to receive feedback on applied engineering.

- **Quality and Regulatory Training**, designed to impart a detailed understanding of the fundamental considerations behind introducing additive manufacturing to an organization’s quality system. Regulatory aspects and current industry landscapes are also reviewed to ease the path to certification by leveraging proven quality and regulatory strategies.
Scaling with Metal Additive Manufacturing

Metal AM is supported by a digital workflow, which enables efficiency and repeatability. Because the build file holds all of the necessary parameter information, you can perform the same job on any machine and get the same outcome.

Additionally, new developments in machine architecture are enabling increased productivity through partially and fully modular systems. Modularity creates new opportunities to use metal AM for scalable production, and is moving the technology beyond the realm of low volume production runs.

3D Systems’ metal printers are high-performance systems that are developed for high quality and productivity, and are tested and enhanced on an ongoing basis. A feedback loop between 3D Systems’ application engineers and 3D Systems’ machine engineering group fuels constant refinement of 3D Systems’ software, hardware, materials and process for better outcomes and a better user experience. 3D Systems’ DMP printers feature a unique vacuum chamber to reduce argon gas consumption and deliver best-in-class oxygen purity (<25ppm). This results in exceptionally strong parts of high chemical purity.

The expertise of 3D Systems’ engineers is built into each component of its solutions, from the print parameters of the materials, to the tools within the software, to the printers themselves. For the DMP Flex 350, partial modularity in the form of quick-swap build modules enables flexibility for R&D projects as well as scalability for volume production. Print jobs, materials, settings and maintenance are managed on a central server to enable 24/7 productivity, and the platform design of 3D Systems’ DMP line makes it simple to transition from the DMP Flex 350 to the DMP Factory 350 as production needs evolve.

3D Systems’ DMP Factory 500 is a primary example of a fully modular system, and is comprised of function-specific modules to handle printing, powder management, movement from one module to another, and temporary docking, with a removable print module that migrates among them to keep printer uptime high. This system’s 500mm x 500mm build platform enables the production of large single parts or multiples of smaller parts, which opens new opportunities in aerospace and defense sectors, as well as for larger batch builds in healthcare.

The DMP Factory 500 was developed by 3D Systems in partnership with GF Machining Solutions to deliver robust AM that integrates with traditional manufacturing for a mixed factory environment. The DMP Factory 500 features GF Machining Solutions’ System 3R referencing and clamping system to help operators save time and money in the production of high-quality metal printed parts. Zero point clamping enables optimal positioning of the build plate to facilitate a quick transition from 3D printer to post-processing steps. This feature reduces set-up times and enhances flexibility by making it possible to quickly transition the build plate from the additive process to downstream subtractive operations.
3DXpert Software

All of 3D Systems’ metal additive machines also include 3DXpert software to handle the entire AM workflow from design, to manufacturing, to post-processing.

Key features within the software enable users to optimize printing strategies for faster print times and enhanced part quality, as well as run simulations on prints to minimize trial and error.

LaserForm® Material Portfolio

3D Systems DMP printers operate using the LaserForm® material portfolio comprised of ready-to-run metal materials that have been extensively tested and fine-tuned for optimal performance on 3D Systems’ DMP systems.

Even without taking advantage of 3D Systems’ consultation services, 3D Systems’ expertise is baked into its solutions to advance your outcomes.
With decades of experience spanning everything from application development and front-end engineering, to equipment validation, process validation, part qualification and production, 3D Systems’ CICs can help companies of all experience levels accelerate innovation through additive technology.

Get in touch today - we’ll be right with you.