The Importance of Qualification and Certification for Additive Manufacturing

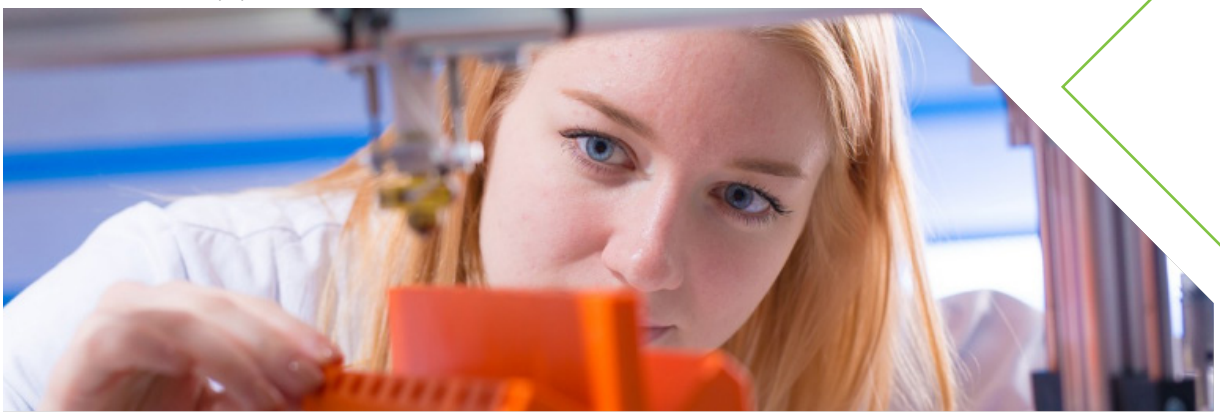
By Brett Lyons, Chief Engineer, Jabil Additive

> *It's exciting when new processes find their way into manufacturing, especially when they offer so much potential, like Additive Manufacturing (AM). But it is important to understand that a great deal lies between a cutting-edge technology and a robust industrial process that can be qualified, validated and certified for use on a large scale and in multiple industries. Indeed, some of the industries where Additive Manufacturing can offer the greatest benefit are the industries that have the greatest qualification requirements and need for compliance.*

Take for example the aerospace industry. Additive Manufacturing has the potential to create lighter parts that reduce the aircraft weight, and in turn improve efficiency. Additive Manufacturing also enables spare parts to be manufactured and deployed close to the airports where the parts are needed. But, all solutions that offer great value to the user also require approvals and compliance to important regulations. And rightly so. Other sectors like transportation and medical also have much to gain from Additive Manufacturing and its capability to create customized and personalized parts. However, these too require compliance to government regulations.

Additive Manufacturing or 3D Printing isn't a new technology. It has been in commercialized form since the early 1990s. It was initially used to make one-off items such as models, prototypes and fixtures. They were accurate emulations of finished products, but they did not require the same functionality. The early 2000s saw the first niche, high-cost manufacturing applications in ducting for aircraft, custom hearing aids and medical tooling, demonstrating an important move into the category of production parts.

Fast forward to the present day and we find ourselves at a tipping point where Additive Manufacturing is reaching a broader range of manufacturing applications. The technology readiness and cost models for Additive have matured to the point where lot sizes from 1 to 100,000 are worth considering for an Additive Manufacturing approach.



Everything Begins With Understanding the Customer's Requirements

Figure 1. End-to-End Evaluation and Approval Process

Jabil's unique insight into the use of Additive Manufacturing comes from an intimate relationship with hundreds of brands that operate in just about every vertical market. Those brands are seeing the potential of Additive Manufacturing but need to ensure the technology is ready for mass production and fully complies with regulation in the same way as traditional manufacturing processes. In this way, Additive Manufacturing is similar to any other manufacturing process. It requires the same level of engineering rigor to ensure it is reliable, repeatable, robust and meets the needs of the market.

The qualification of a process is nothing new; it is something that has been undertaken every time a new manufacturing technique reaches the critical level to make it viable for widescale production. The same engineering rigor must be applied to Additive Manufacturing that is applied to every other process and likewise to every other finished product or solution. This rigor applies not only to the finished goods produced using Additive Manufacturing, but also to the machines they are made on, the processes they use and, of course, the materials. Being intimately involved with supply partners who provide machines and materials technology affords Additive Manufacturing solution providers, like Jabil, insight to integrate processing expertise and bring the customer a complete Additive Manufacturing solution that meets the specifications of a specific application. This is a solution we refer to as "MPM" (Materials, Processes and Machines) at Jabil.

Qualification and Certification Process

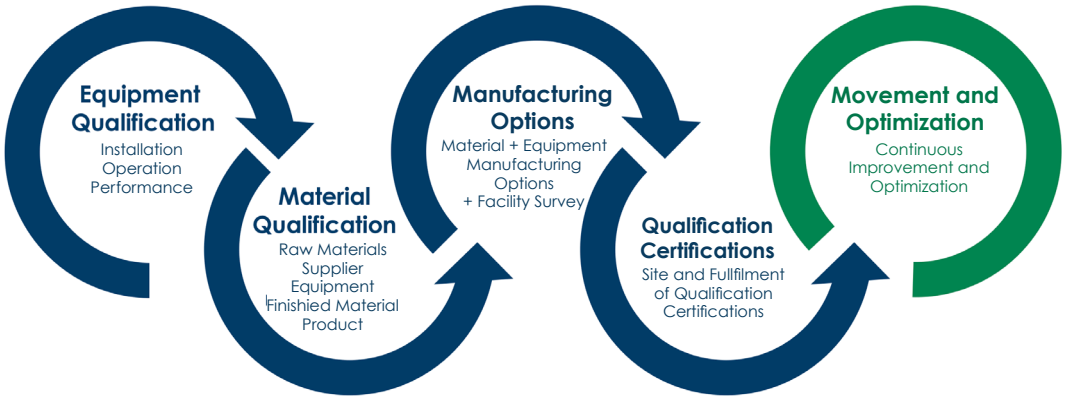


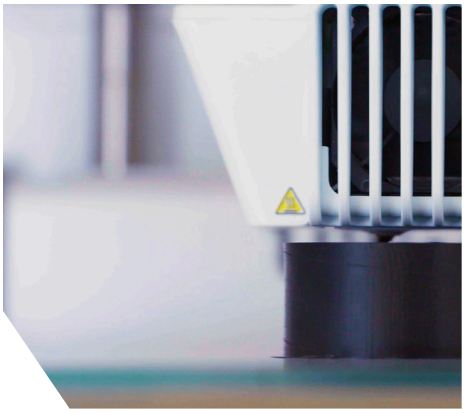
Figure 2. Qualification Process

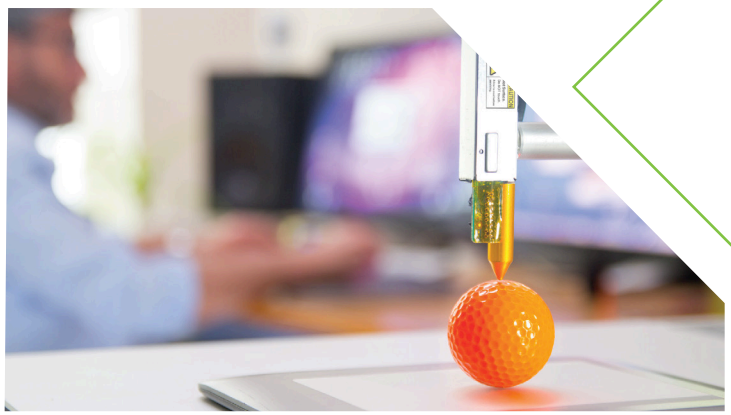
Qualification, like certification, begins at the materials, processes and machine level, but the ultimate goal is to produce qualified parts that can be used in these mission-critical environments and markets. This is true in every market where Additive Manufacturing is appropriate, and both brands and consumers benefit from its cost, speed and flexibility. Authorities like the FDA, FAA and NHTSA operate in the industries where Additive Manufacturing will likely be used. To ensure success, a product standards framework is needed. The framework will give our customers and regulatory authorities the comfort required to ensure that the materials, processes and machines in use are stable, repeatable and fit for the application they are applied to.

Industry	Quality Standards	Oversight Agency
Transportation	IATF 16949 / ISO 9001	NHTSA
Aerospace	AS 9100 / ISO 9001	FAA
Medical	ISO 13485 / ISO 9001	FDA
Consumer Products	ISO 9001 / UL / ASTM F963 among others…	CPSC

Table 1. Applicable Industry Standards and Certifications

Pending industry standards from ANSI include ASTM D20 (Plastics) and ASTM F42 (AM). There are also SAE committees developing standards for both metals and polymers. It is also important to understand traditional standards from SAE, ISO, UL, ASTM, etc. As well as monitor work being done at other Standard Development Organizations for Additive Manufacturing.





A Digital Thread to Ensure Connectivity and Traceability

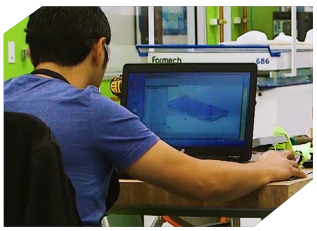
The digital thread plays an essential role, providing the control over the data that is required to manufacture, as well as the standards and qualifications. One of the true benefits of Additive Manufacturing is the ability to move data, rather than materials or parts, closer to the point of consumption, so data management plays an even larger and more pivotal role. This data is connected to all materials, process and machine elements.

Additive Manufacturing does not operate in isolation. It forms part of a more complex build and supply chain, so interoperability also has a role to play. Standards must reflect this, and manufacturing systems will need to consider when parts are made using more than one technology, or even where the manufacturing methodology could be interchanged. This could and should mean the ability to deliver multiple solutions to customers, rather than a single solution.

There are a great many moving parts when it comes to Additive Manufacturing and a great many players in the marketplace. Like every manufacturing process that has gone before, and those that will follow, it must be robustly engineered, fully compliant, and completely traceable. The digital thread combined with engineering experience and manufacturing rigor – according to industry specifications and standards - enables this to happen and will support the full industrialization of Additive Manufacturing.

Jabil Additive has combined a powerful set of industry experts from Aerospace and other highly regulated vertical segments to support the compliance requirements of its customers when it comes to Additive production. Leveraging a disciplined combination of machines, processes and materials, Jabil is uniquely equipped to help customers introduce Additive parts at scale and to the standards set by the governing bodies assigned to ensure safety and compliance.

Learn more and see how at Jabil Additive is transforming the way things are made.



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