



# Quality in Additive Manufacturing

Best practices for  
quality management in  
Additive Manufacturing

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## INSIGHTS GAINED:

- Best practice for machine qualification
- Quality requirements in aviation
- Standardization of Additive Manufacturing
- State of the industry

Vol. 4

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“Many business cases for Additive Manufacturing with laser beam powderbed fusion technology are in regulated industries such as aviation or medical. However, the current lack of standards and knowledge on AM qualification increases the threshold for companies to adapt the technology. Therefore Ampower partnered with Trumpf to conduct an extensive study and present a comprehensive qualification approach and best practices to establish a qualified production environment.”

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DR. ERIC WYCISK  
Managing Partner at Ampower

“In the field of Additive Manufacturing, TRUMPF sees great opportunities not just for itself but for German industry overall. Qualification, however, proves to be a challenging issue for the end-user. By demonstrating the qualification process on TRUMPF’s 3D printer TruPrint 3000 and sharing best practices for standardization, the study we conducted with Ampower assists end-users to successfully apply Additive Manufacturing in their production and contributes to the ongoing technological development in general.”



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DR. THOMAS FEHN  
General Manager  
Additive Manufacturing at TRUMPF

# Insights gained

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Best practice for machine qualification  
Quality requirements in aviation  
Standardization of Additive Manufacturing  
State of the industry

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## Management summary

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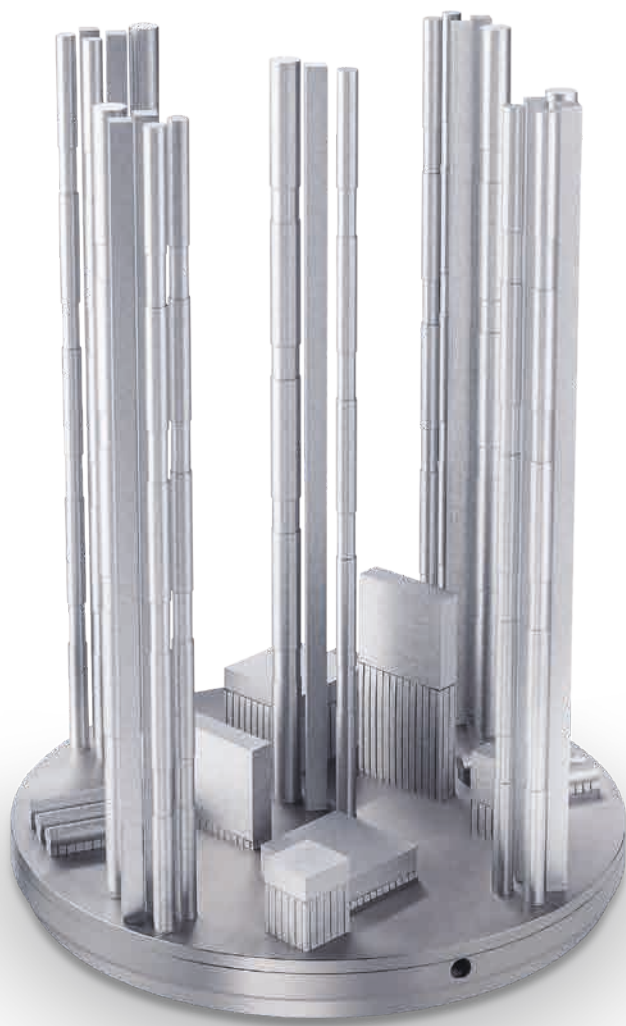
Additive Manufacturing is entering industrial serial production. Especially in regulated industries such as aviation and medical, the need for internationally accepted standards and proven practices for machine qualification is continuously growing. To meet this demand, Ampower Insights Vol. 4 presents a comprehensive approach and best practices to establish a qualified production environment and gives an overview on standardization efforts and published standards.

A thorough machine qualification is the essential foundation for a successful implementation of manufacturing systems in regulated industries. Due to the pioneering role of medical applications, the methodologies from the Global Harmonization Task Force for machine qualification including Installation, Operational and Performance Qualification (IQ, OQ, PQ) have been widely adapted in the AM industry. Ampower Insights presents the requirements as well as documentation and testing efforts for each of the qualification steps and highlights best practices for a successful implementation of Additive Manufacturing.

Ampower Insights highlights the current landscape of existing AM standards and committees responsible for standardization. To illustrate this the route to developing international standards within the framework of the ISO TC 261 and ASTM F42 committees is described. Furthermore, a detailed look on quality management in Additive Manufacturing shows that additionally to existing quality management certifications such as EN/AS 9100 and ISO 13485, the industry is demanding and developing AM specific certifications such as the NADCAP certificate.

The study closes with representative statements of AM experts from an early adopter medical company to a high-volume automotive manufacturer on the state of qualification and standardization in their respective field. The aggregated results suggest that a strong personnel and monetary commitment and focus is required to successfully implement a qualified AM production. Ampower Insights Vol. 4 gives a comprehensive view on qualification methodologies and the state of standardization for Additive Manufacturing technologies.

Download this study at [www.am-power.de/insights](http://www.am-power.de/insights)



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## About Ampower

Ampower is the leading consultancy in the field of industrial Additive Manufacturing. Ampower advises their clients on strategic decisions by developing and analyzing market scenarios as well as compiling technology studies. On operational level, Ampower supports the introduction of Additive Manufacturing

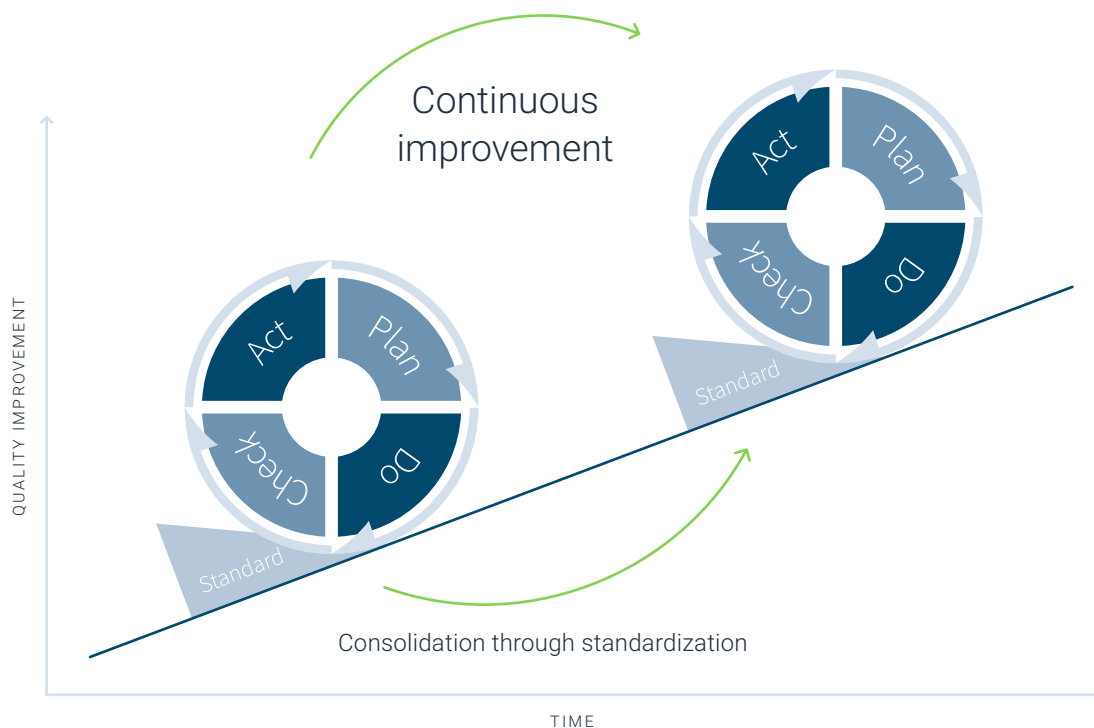
through targeted training program as well as identification and development of components suitable for production. Further services include the setup of quality management and support in qualification of internal and external machine capacity. The company is based in Hamburg, Germany.

The image shows a stack of several books with dark covers and thick pages. The books are arranged vertically, with the spines facing left. A large, dark blue geometric shape, consisting of several overlapping triangles, is positioned on the right side of the image, partially covering the books. The overall color palette is monochromatic, featuring shades of blue, grey, and black.

# Introduction

# Quality management

Continuous improvement of the product quality and customer satisfaction is the fundamental concept of quality management. The minimum requirements for the quality management system are defined in ISO 9001. However, many industries have established their own quality management standards with additional requirements important for their respective field of application.



Quality management refers to all organizational measures that serve to improve the internal processes and ultimately the product quality. The instated quality management system therefore should enable its creator to continuously monitor and improve its internal processes and meet the customers requirements and enhance their satisfaction. Through standardization, requirements are defined to which the management system has to comply.

The ISO 9001 is the most common quality management standard and defines the minimum requirements an industrial quality management system has to fulfill. In 2015 the ISO 9001 was revised and a more process focused approach introduced. With this revision the structure of the norm was adapted to the PDCA-cycle, which describes the iterative cycle for learning and improvement by the four steps: Plan – Do – Check – Act.

In addition to the general quality management certification according to ISO 9001 many industries have developed a specific set of standards for quality management in their respective field. The most prominent are IATF 16949 for automotive, ISO 13485 for medical and EN/AS 9100 for aviation industry. All standards are based on ISO 9001 and have adapted the process oriented quality management, established in the newest revisions.

The EN/AS 9100, for example, has over 100 additional requirements to the ISO 9001. These mainly focus on issues regarding risk management, supplier and delivery requirements, project management and management of critical and counterfeit parts. To be eligible as an AM supplier to the aviation industry the successful ISO 9100 certification is almost always a strict prerequisite.



EN/AS 9100



IATF 16949



ISO 13485





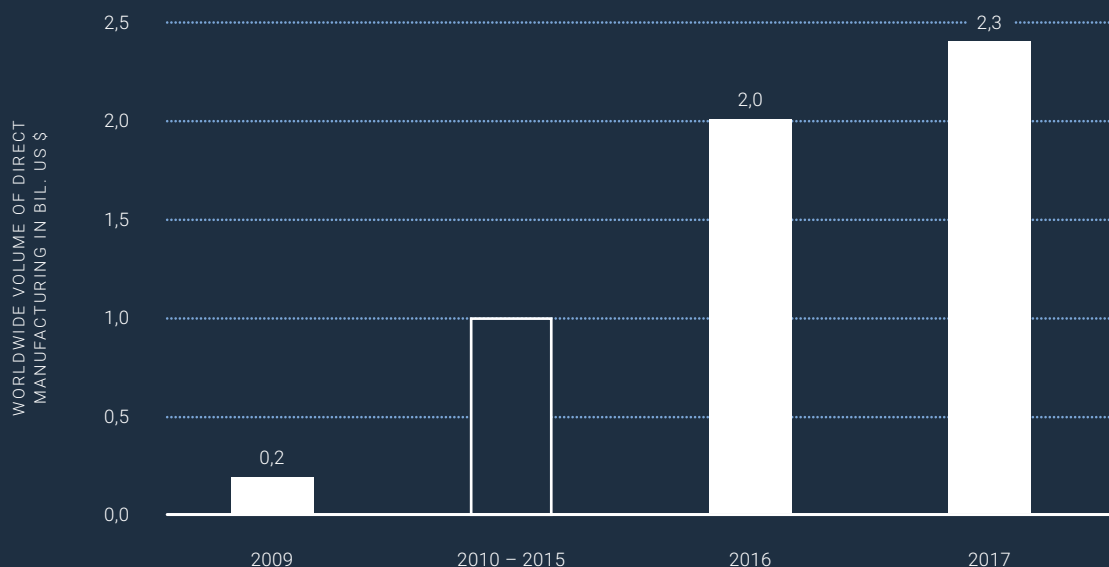
# Route to international AM standards

Additive manufacturing technologies developed to an industrial production technology during the last years. As a result of this technology maturity, the current lack of international standards became obvious. Therefore, committees ISO TC261 and ASTM F42 on a international level, in close cooperation with VDI on a German national level, provide a powerful platform to deliver the standards needed.

Additive manufacturing technologies have gained significance as production technologies during the last years. In 2017 the worldwide volume in the field of Direct Manufacturing (cf. VDI3405 for Terminology) was 2,3 billion USD. A detailed summary of industry forecasts is provided by Seidel and Schaetz in Pei et al. (ed.) "Additive Manufacturing – Developments in Training and Education" (Springer, 2018). Based on this reference, a compound annual growth rate of 31 % until the year 2020 appears to be the

most probable forecast for the development of the total additive manufacturing market volume.

In order to reach these high growth rates year-by-year, increasingly more industrial AM applications need to be exploited. In contrast to Rapid Prototyping applications, Additive Manufacturing use cases require larger lot sizes and will therefore significantly increase total market volume growth. In order to enable and foster the application of AM in industrial scenarios, there is a strong need for standards.



Source: Wohlers Report, Fraunhofer IGCV

To avoid competing international standards, ISO TC261 and ASTM F42 joined forces in 2011 and decided to develop standards together. The so called PSDO agreement (“Partner Standards Developing Organization”) provides the organizational frame. The spirit that drives this unique partnership is best described by a slogan from the current Chairman of ISO TC 261 Joerg Lenz “One world – one standard!”. The process to publication of an ISO/ASTM standard starts with a demand typically expressed by industry representatives to either ISO TC261 or ASTM F42. An expert group decides on the target document type, which suits best for the expressed demand.

Typical document types include ISO/ASTM standards or ISO/ASTM Technical Reports. Subsequently, a Joint Working Group (JG) is installed comprising both ISO and ASTM experts and ensuring an efficient work environment. Web meetings are used to ease international collaboration. Once the JG has completed the document it is submitted to both ISO and ASTM for balloting. For several months, the AM community has the opportunity to review the developed documents and to submit editorial, general and technical comments. Every comment has to be discussed and processed by the JG before the standard can finally be published.



On the German National Level, VDI committees 105.X drive the development of guidelines for AM. Not surprisingly, VDI guidelines often serve as an input for international standards, such as ISO/ASTM DIS 52911-1 and ISO/ASTM DIS 52911-2. Typically, VDI activities are seamlessly geared with the ISO/ASTM activities in order to avoid a duplication of work. This is also relevant as the usual evolution of an ISO/ASTM standard is to become a European EN ISO/ASTM standard via adoption by CEN committee 438. According to the so called “Vienna agreement”,

once it is a European standard it needs to become a German National DIN EN ISO/ASTM standard. Following high-level agreements between VDI and DIN, a VDI guideline has to be withdrawn as soon as a German National standard with identical scope is available.

AM standardization is on a very promising path. Especially in 2017 and 2018, the AM community got together and agreed on streamlined procedures to develop the standards needed to foster Additive Manufacturing applications.

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## Guest author

### Dr.-Ing. Christian Seidel

Christian Seidel is an internationally recognized expert for Additive Manufacturing and appointed in several national (VDI, DIN) and international (ISO) steering committees for AM. Since 2014, he has been working with Fraunhofer IGCV where he serves as Director for Strategy and Institute Development and Head of AM. Furthermore, he gives lectures on AM at the Technical University of Munich and the Munich University of Applied Sciences. Since 2014, he has also been a Freelance Management Consultant for AM. He has enjoyed a Mechanical Engineering education at Technical University of Munich and had the chance to gather experience at MTU Aero Engines in Munich before he started his Fraunhofer career.



# From national to international standards in Additive Manufacturing

National content generation



Coordination and collection of input



Development of international standard



Publication of international ISO/ASTM standard



Regular revision and revoking process



# Existing AM standards

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Due to early efforts of the VDI and DIN on German and ASTM on US side there are existing standards concerning different aspects of the AM technology. Since the harmonization phase on ISO level started, the standardization progresses even faster. A complete overview of the existing norms and standards in devel-

opment can be viewed on the homepage of ISO or DIN under the working groups ISO TC 261 and DIN NA 145-04-01 AA respectively. With most published standards focusing on the overview of the technology as well as terminology, the standards in development target AM specific process steps or characteristics.

## ISO/ASTM WD 52942

[Under development] Qualification principles – Standard guideline for qualifying machine operators of powder bed based laser beam machines in aerospace applications

## ISO/ASTM WD 52941

[Under development] System performance and reliability – Standard test method for acceptance of powder-bed fusion machines for metallic materials for aerospace application

## ISO/ASTM WD 52916

[Under development] Data formats – Standard specification for optimized medical image data

## ISO/ASTM 52901:2017

General principles – Requirements for purchased AM parts

## ISO/ASTM DIS 52907

[Under development] Technical specifications on metal powders

## ISO/ASTM CD 52905

[Under development] General principles – Non-destructive testing of additive manufactured products

## ISO/ASTM 52900:2015

General principles – Terminology

## ISO/ASTM 52910:2018

Design – Requirements, guidelines and recommendations

## ISO/ASTM WD 52932

[Under development] Environmental health and safety – Standard test method for determination of particle emission rates from desktop 3D printers using material extrusion

# AM FACTORY

## Application specific standards and guidelines

ISO/ASTM WD 52942  
 ISO/ASTM WD 52941  
 ISO/ASTM WD 52916



**Feedstock**

**Process & equipment**

**Finished parts**

ISO/ASTM 52901:2017  
 ISO/ASTM DIS 52907  
 ISO/ASTM CD 52905

**Feedstock characteristic**

- **Material properties**
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- 
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**Process technology**

- **Process material combination**
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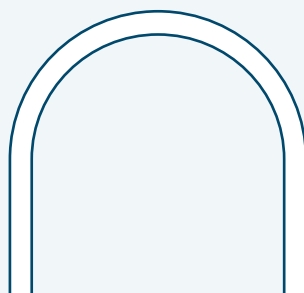
**Testing methods**

- **Material properties**
- 
- **Post processing**
- 
- 
- 

ISO/ASTM 52900:2015  
 ISO/ASTM 52910:2018  
 ISO/ASTM WD 52932

## Base standards

Terminology Design guidelines Safety Inspection Qualification ...



# Challenging requirements in aviation

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The fast adaption of Additive Manufacturing has forced the aircraft and turbine OEMs to develop their own specifications and standards for manufacturing and supplier qualification. In addition to EN/AS 9100 and Nadcap certification, aviation suppliers have to fulfill the detailed and challenging requirements defined by the OEMs.

The qualification documentation designed by the aviation OEMs includes detailed material and process specifications and instructions. The severity of requirements vary depending on part criticality and qualification method (part or process qualification). To define these specifications the OEMs are developing deep process knowledge to understand limitations and risks in their respective R&D departments. Laser powder bed fusion ist the most researched AM technology in aviation and therefore on the forefront of the qualification process. The areas of interest for defined requirements are, amongst others, the process strategy, machine technology, quality insurance, testing intervals, non-destructive testing and personnel requirements.

The defined specifications have to be fulfilled by the in-house production facility or the supplier depending on the chosen supply chain model. Aviation giant Airbus, for example, outsources the Additive Manufacturing to its strategic tier 1 suppliers, that must fulfill the extensive and challenging specifications to receive production approval. In the future the tier 1 supplier may in turn subcontract to further suppliers, while being responsible for the sub-supplier qualification.





This connector from B/E Aerospace Systems GmbH represents one of the first qualified metal parts in aviation for military application. The connector is being produced by AM specialist Robert Hofmann GmbH since 2006. The component is part of the pilot's oxygen system of an Eurofighter vessel and has to withstand gas pressures of over 600 bar.

## Nadcap Certification

The National Aerospace and Defense Contractors Accreditation Program (Nadcap) is a global cooperative accreditation program initiated by and focused on the aviation industry. Through the Performance Review Institute (PRI) the Nadcap program provides independent certification for manufacturing processes. Nadcap was one of the first certification

institutions to develop an audit and certification program especially for powder bed fusion technologies. The audit criteria by Nadcap comply closely to established qualification approaches for AM by the medical industry. However, additionally they put a strong focus on the powder handling and recycling procedures.





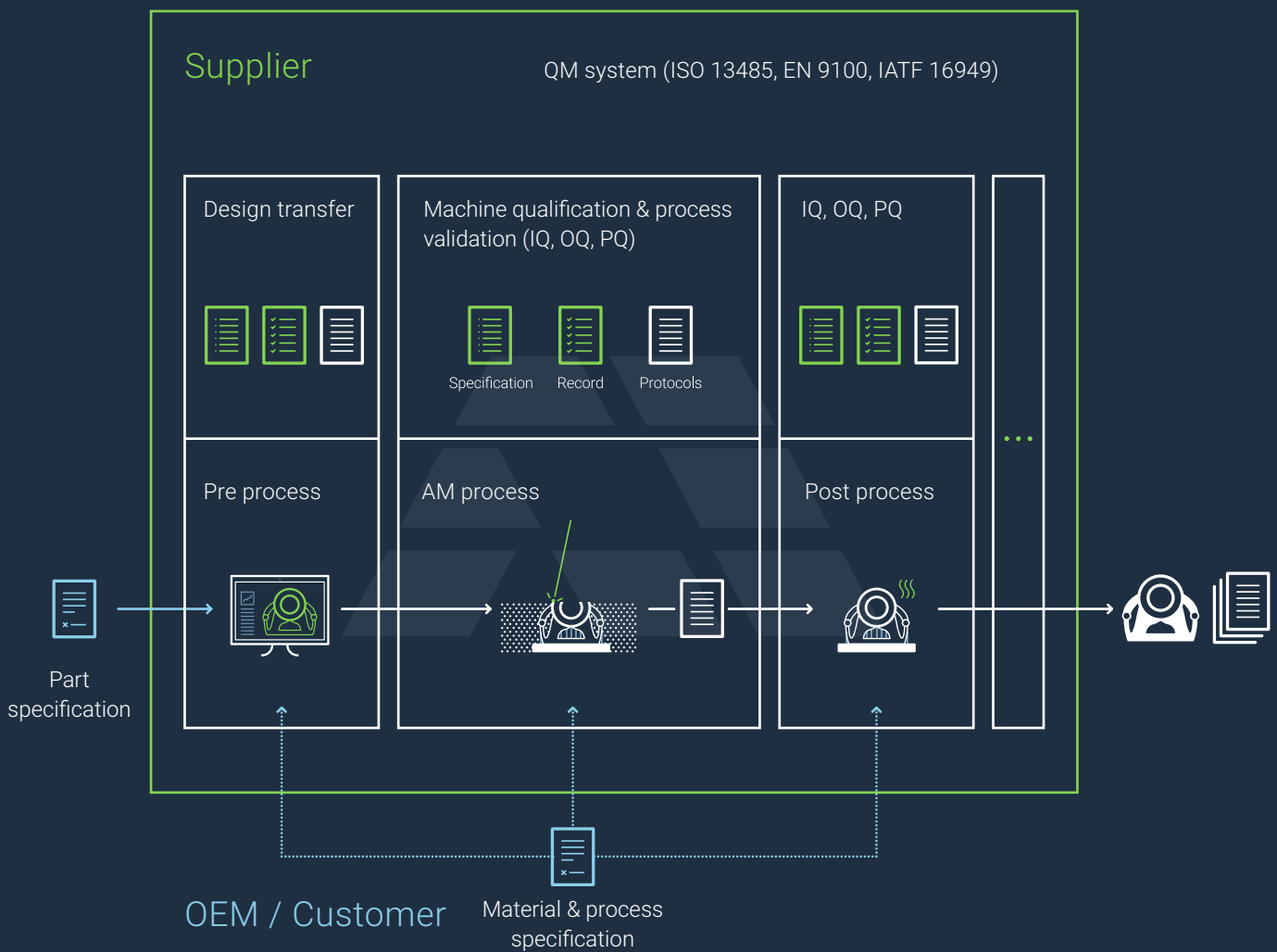
TruPrint 3000

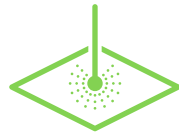
Qualified  
production



# Qualified production

A qualified production in regulated environments requires a validated process of which the machine qualification is a significant component. Furthermore, a detailed specification and documentation of each process step ensures reproducible execution. Continuous and gapless reporting guarantees full traceability of all critical process parameters and the material flow.





## Machine qualification

The machine qualification is a series of inspections and tests to objectively verify that all necessary requirements for the final product quality are fulfilled. This includes procedures and documentation for the installation, operation and maintenance of the machine. The requirements are typically derived from industrial standards, manufacturer and customer specifications.

Since medical applications have been one of the first regulated industrial AM applications, the methodologies from the Global Harmonization Task Force for machine qualification have been widely accepted in the AM industry. The method of installation, operational and performance qualification (IQ, OQ, PQ) has been proven to be well suitable for AM systems.



## Specifications and records

Additionally to the standard operational procedures and working instructions required for the general quality management, the machine qualification requires detailed working instructions and standard

forms on each critical process step. Furthermore protocols for production, maintenance and quality assurance have to be established.



## Process validation

In regulated environments, a machine qualification must be performed for each single system in the process chain. In Additive Manufacturing this includes at least the AM machine and heat treatment oven and must be expanded to processes of hot isostatic pressing, milling and others, if relevant to the manufacturing of the final product.

If the qualification of each system is successful, the whole process chain can be validated by the "first part qualification" or "first article inspection", where parameters for production are defined and the final product passes through the complete process chain while complying to all given requirements.

# Machine acceptance

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The machine acceptance verifies that the installed system fulfills all requirements defined in the technical specification. The final machine acceptance during the site acceptance test can be combined with the installation and operational qualification.

The machine acceptance is performed to determine, if all requirements from the technical specification are met by the AM system at delivery. Typically the machine acceptance is divided into two separate events. First the factory acceptance test (FAT) at the supplier site has to be passed before the customer allows shipment to his own site. After the machine installation at the customer site, the successfully performed site acceptance test (SAT) shows the conformity of the AM system with the predefined machine requirements.

Promoted by the aviation industry, the German Institute of Standardization (DIN) published “DIN 35224 Welding for aerospace applications – Acceptance inspection of powder bed based laser beam welding machines for additive manufacturing” to unify and regulate the minimum criteria for the acceptance of laser powder bed fusion systems. Within the standard the main system components and characteristics required for inspection and their respective acceptance criteria are defined.

## Installation qualification (IQ)

The installation qualification ensures that the installed AM system complies with the requirements and critical installation requirements are verified. This includes verification of critical documentation, service and calibration protocols and the ambient atmosphere at the installation site.

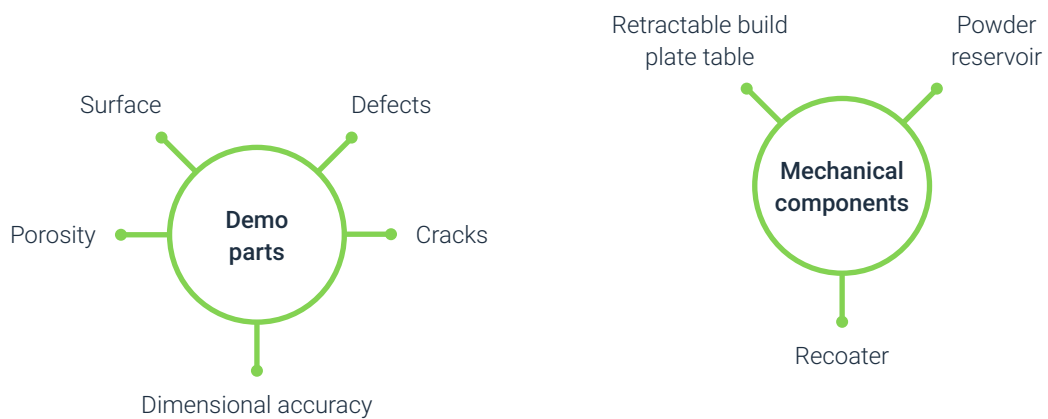
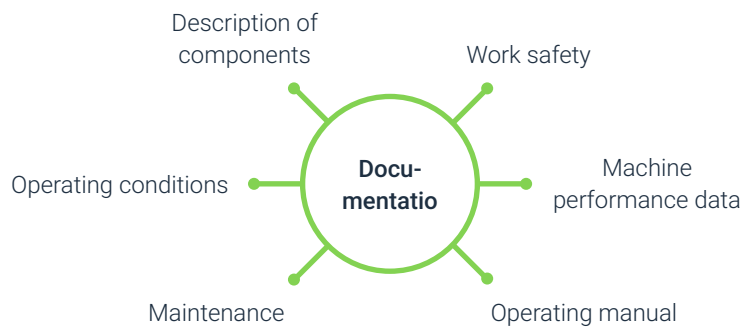
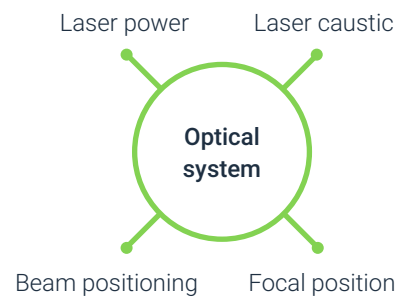
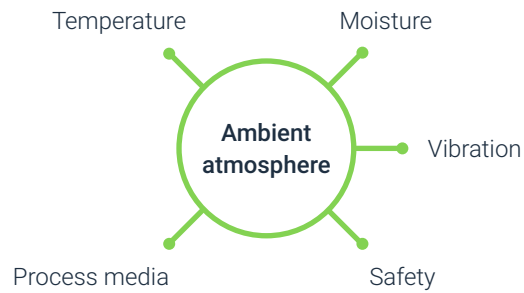
## Operational qualification (OQ)

The operational qualification ensures that the installed AM system complies with the requirements and critical operational requirements are verified. The OQ consist of a series of tests challenging critical operational requirements such as alarms, safety mechanisms and build performance. The duration of tests should be adequate to ensure the machine capability while experiencing variations that might occur during normal use. The range of testing should include conditions at the upper and lower operation limits.

Although the final IQ and OQ is performed at the customer site, preferably during the SAT, it is recommended to check all critical IQ and OQ requirements

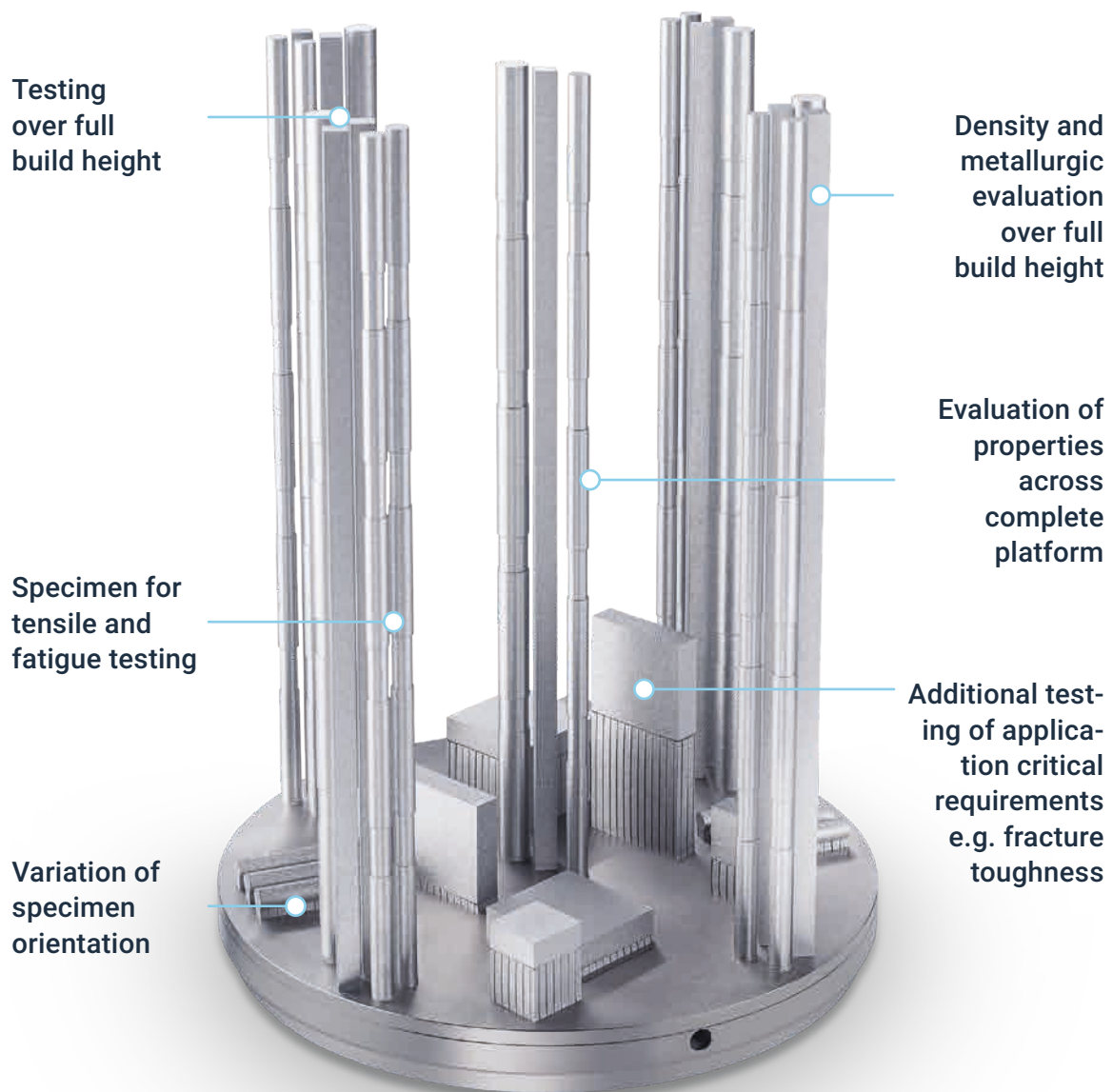
during the FAT to identify any deviations as early as possible. In the end the IQ and OQ protocols can also function as part of the machine acceptance protocol.

## Minimum inspection and documentation efforts for the machine acceptance in accordance to DIN 35224



# Machine acceptance build job

The machine acceptance build jobs allow the evaluation of required material properties as well as geometrical capabilities and dimensional accuracy. The evaluation should consider the full build volume.



The machine acceptance build job contains test specimens for the most relevant material requirements of the planned product portfolio. This typically includes density, microstructure and tensile properties in different building orientations and positions. For demanding applications additional specimens are added to evaluate fracture toughness or fatigue properties.

It is advisable to choose testing methods that facilitate a quick evaluation of results. Especially for fracture mechanical values, such as fatigue or

fracture toughness, test methods such as alternating deformation behavior or Charpy impact testing accelerates the evaluation of the results and reduces testing cost.

It is highly recommended to determine the material properties across the full build volume or at least the intended build envelope. The acceptance build job should be manufactured during the FAT and SAT. If time or cost constraints prohibit this, it is recommended to build the individual acceptance job at least during the SAT to evaluate the machine performance.

## Demonstrator parts

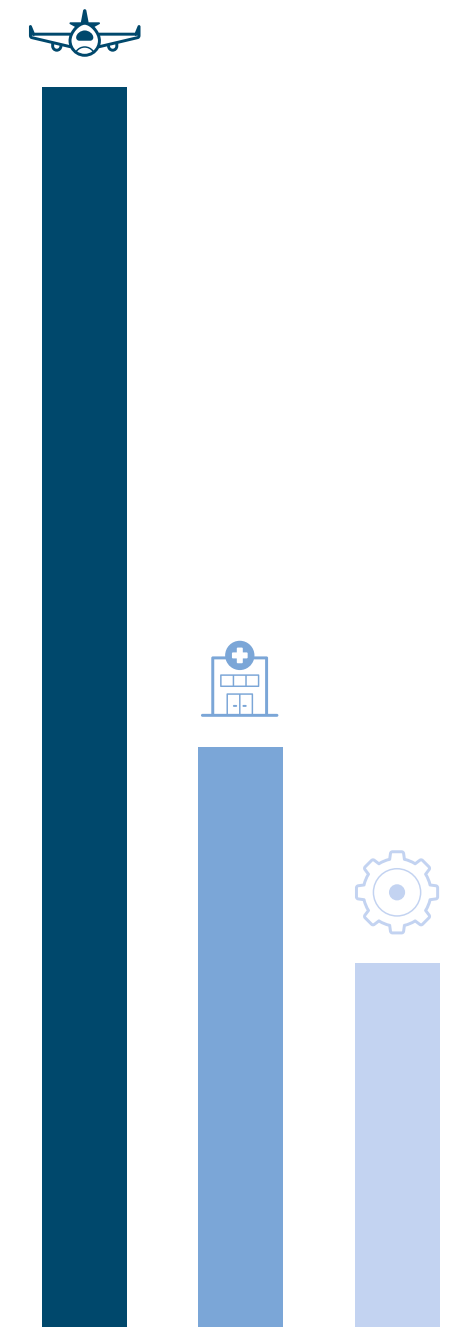
Additional to generic geometrical test specimens to determine shrinkage and beam offset, demonstrator parts for evaluation of geometrical capability and dimensional accuracy are manufactured during the machine acceptance. It is advised to choose part geometries, that represent the product portfolio that will be produced on the AM system. Typical design features such as lattice structures on hip cup implants, fluid channels in hydraulic components or complex 3D freeform surfaces of turbine blades should be represented in a demonstrator part.



# Performance Qualification

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The technical or performance qualification uses a large sampling size to demonstrate the consistent performance of the system and to verify the long term fulfillment of the product quality requirements.



After a successful IQ and OQ the performance qualification (PQ) is the last step in the machine qualification. It involves an extended monitoring and sampling program to demonstrate the system performance and to verify that the requirements towards product quality are fulfilled in a long term view. In aviation the extended sampling of material properties is often referred to as the technical qualification.

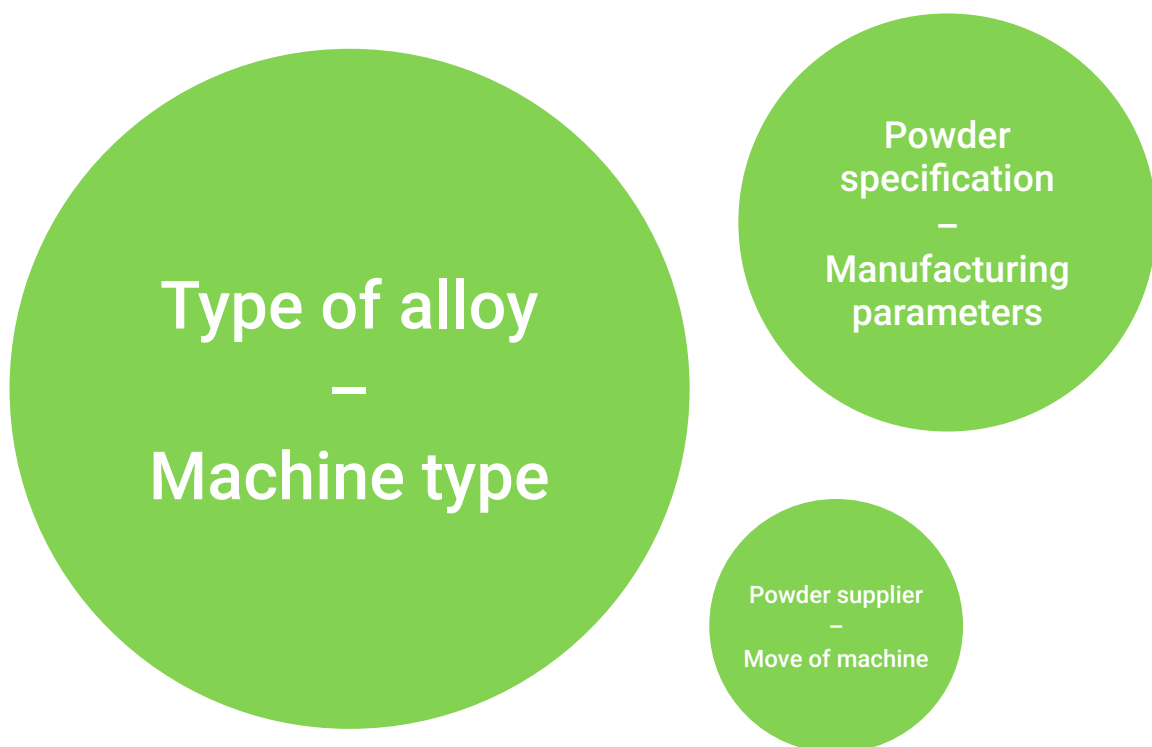
Efforts for the initial performance qualification can vary greatly depending on application, material, industry and customer specific requirements. Applications in civil aviation represent the largest efforts. The specifications require testing of several hundred specimens to determine tensile, fatigue, fracture toughness and crack propagation properties as well as additional NDT testing. For medical applications cost driver of the PQ can be test requirements regarding fatigue properties, lattice structures and cleaning operations. For low demanding applications the test efforts can be scaled down significantly and consist of only a few build jobs with a small amount of density and tensile specimen.



# Requalification

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Significant changes of process relevant factors will revoke the qualification status of the affected machine. A requalification process is needed to regain the status. The efforts for requalification vary greatly depending on severity of the change and are defined by the customer specification or have to be determined by the manufacturer by impact analysis.



● ● ● Requalification effort after a change

During qualification all process relevant factors are frozen and cannot be changed. This includes machine settings and manufacturing parameters as well as ambient settings and material specifications. Any changes during the production revoke the qualified status of the machine. It is important the personnel is made aware of the restrictions of a qualified environment and trained to uphold the defined status. Particular focus is to be laid on supervising external service personnel to prevent service updates which will account for a process relevant change.

If changes occur, for example process performance improvements or material supplier change, a requalification has to be performed to regain the qualified machine status. Requalification efforts are either defined in the customer specification or have to be defined by the supplier based on an impact analysis. Most common reasons for requalification are: change of material supplier, move of machine to new location, improved manufacturing parameters for enhanced performance or significant software and hardware updates.

# Personnel qualification

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Only qualified personnel enables the successful implementation and qualification of the highly complex AM process in industrial “serial” production.

## AM machine operator qualification

The significance of personnel qualification for Additive Manufacturing will grow in the near future. Therefore, the aviation industry, prime example for demanding and high-risk applications, defined prerequisites for operators of laser powder bed fusion systems. This led to the German national standard DIN 35225

*“Welding for aerospace applications – Qualification testing of operators for powder bed based laser beam machines for additive manufacturing”* published in June 2017. It includes topics of theoretical and practical testing, intervals of testing and additionally physical requirements of the operator such as eyesight.

## General personnel qualification

To successfully implement a qualified AM production and create viable business cases AM expertise has to be propagated throughout the whole company. Involving departments of R&D, engineering and design,

production and procurement as well as general management ensures commitment and creates the mindset for a successful AM implementation and qualification.

## Training program by Ampower



The BASIC training Additive Manufacturing teaches the fundamentals of the technology, from understanding the process and material properties to the process chain and design guidelines. The training is the basis for a screening for Additive Manufacturing.



The DESIGN training Additive Manufacturing consists of the BASIC module and a subsequent design workshop. The aim is to transfer selected customer components from screening into additive concepts. The result are 3D printing concepts.



The PILOT PROJECT includes the BASIC training, an internal screening for Additive Manufacturing and the DESIGN workshop. Subsequently, a selected design is transferred to CAD data, manufactured additively and post processed to the finished part. A detailed final report rounds off the PILOT PROJECT Additive Manufacturing.



# Quality assurance

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To maintain the defined part quality and monitor any deviations in material, part and process properties a continuous and comprehensive quality assurance has to be established. The quality assurance steps have to be included in the process validation and their measures must be able to detect and evaluate the defined properties. Possible quality assurance measures are check of protocols, analysis of powder composition, geometrical measurement, testing of tensile properties and NDT testing.



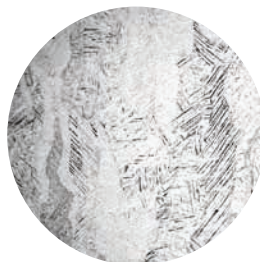
**Material analysis  
(porosity)**



**Powder analysis**



**NDT testing**



**Material analysis  
(microstructure)**

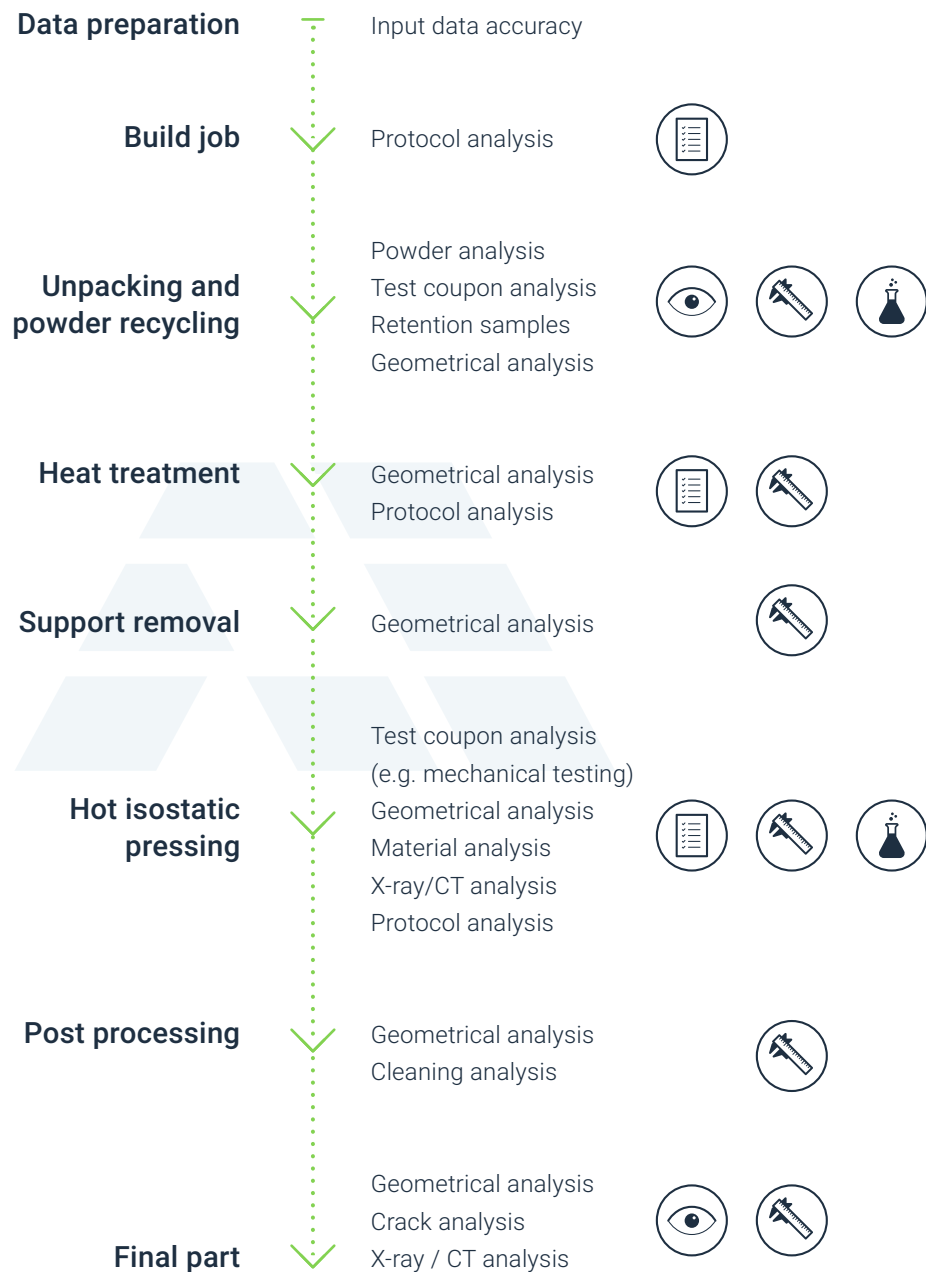


**Geometrical analysis**



**Tensile testing**

# Quality assurance along the manufacturing route





Resume



## Voices of the industry

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“Lima Corporate is recognised as an industry forerunner for off the shelf orthopaedic implants produced via AM. With rapidly evolving regulatory and industrial scenarios in the medical field, we recommend to build up a robust validation architecture following the GHTF guidance, and to tailor the process parameters on each AM machine to achieve reliable results.

Moreover, it is important to understand and qualify the entire AM chain: from powder characterization and regeneration protocols to software workflow validation. This route is also suggested by the new FDA guidance and ASTM standards.

Lima believes in the internal verticalization of the AM process in the actual framework due to better cost and process control. Nevertheless, it is also fundamental to expand the flexibility of the supply chain with suppliers well-aware of the regulations and to support data-driven process optimization. These conditions will enable a true standardized AM Medical industry.

In a market that is moving to mass customization, an important challenge will be the shift from a qualified output for a standard product to a qualified output for an envelope of possible designs.”



DR. ING. MICHELE PRESSACCO

Director Research & Development, Limacorporate S.p.A.

RICCARDO TONINATO, PHD

Manager Additive Manufacturing, Limacorporate S.p.A.



“General standards are of considerable importance for further industrialization of additive manufacturing, since industrial users rely on clear rules and guidelines for the implementation in their own company. At Deutsche Bahn, we realized early on that, in the context of AM, there is a need for action, especially on the subject of our own supplier qualification. As early as in the beginning of 2016, we started to develop a DB-internal standard for the qualification of AM suppliers, involving external competence. In close cooperation with a large certification company, a cross-industry manufacturer certification program was created, which is currently being piloted with four companies. Ultimately, the clear recommendation to all users and service providers is to deal intensively with the topic of standardization and internal specifications.”



FLORENS LICHTÉ  
Head of Additive Manufacturing,  
DB Fahrzeuginstandhaltung GmbH



“The quality management framework described in ISO 9001, VDA Vol. 4&5 and IATF 16949 is the basis for our internal material and process specifications. At the BMW Group, we developed internal guidelines and regulations for LB-PBF technology based on existing standards such as casting. If possible and applicable, we evaluate a reference to Additive Manufacturing ISO standards. However the complexity of LB-PBF and the lack of know-how in the field brought us to develop proprietary requirements that leave little gaps for deviation.”



DR.-ING. MAXIMILIAN MEIXLSPERGER  
Head of Additive Manufacturing Metal,  
BMW Group



“Lufthansa Technik (LHT) has long standing experience in qualification of additive technologies based on the history of using AM technologies for turbine repairs. However, with powder bed and further AM technologies emerging such as cold gas spray new internal specifications and qualification methods are in development. Due to MRO locations all over the world it is of utmost important for LHT that international and industry wide accepted standards for qualification and quality assurance of Additive Manufacturing are developed. Therefore LHT is engaging in the combined efforts of the European Aviation Safety Agency (EASA) and aviation OEMs to develop appropriate requirements, standards and certifications routes which helps to deploy these on an international level.”



SIMON FEICKS  
Project Manager Additive Manufacturing,  
Lufthansa Technik AG



# Resume

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1.

## Separation

Especially service bureaus with large share of prototyping should separate and clearly mark application development and prototyping processes from the qualified machines in the production environment.

2.

## Investment

Machine qualification and process validation, especially for aviation applications, require substantial monetary investments. Therefore, the full dedication and support of top management is essential to successfully establish a production environment for regulated industries.

3.

## Focus

For highly regulated industries such as aviation or implant manufacturing a focus on one material and/or product type accelerates the qualification process.

4.

## Mindset

Often today's Additive Manufacturing teams have a strong background in R&D or prototyping. The transformation into a production environment for regulated industries requires a complete change of mindset: from machine operator to management.

# About the authors

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## Dr.-Ing. Maximilian Munsch

Since 2007, Maximilian Munsch is a professional user of Additive Manufacturing. After finishing his dissertation on reduction of residual stresses in metal Additive Manufacturing in 2012, he acquired extensive hands-on experience with metal powder bed based Laser and Electron Beam Melting processes in industry. His focus is on the full Additive Manufacturing process chain required for industrial production. Max has successfully planned, implemented and qualified multiple Additive Manufacturing productions for regulated applications.



## Matthias Schmidt-Lehr

Matthias Schmidt-Lehr successfully managed countless projects in Additive Manufacturing with focus on part screening, business case development, AM design optimization and production in both metal and plastic materials. With a history in the consulting business, he is committed to customer satisfaction, project management and controlling. In his former positions Matthias gathered experience in business development, customer relationship management, as well as marketing and sales.



## Dr.-Ing. Eric Wycisk

Eric Wycisk can look back on 10 years in Additive Manufacturing with a focus on metal, especially titanium alloys. In his former affiliation, he was team leader and Key Account Manager for aviation applications and light weight design. He managed multiple projects concerning topology optimization and light weight design, process development and optimization as well as industrial implementation of Additive Manufacturing. The research in Eric's dissertation focuses on fatigue properties of laser beam melted Ti-6Al-4V.

## Missed out on our previous Issues?



### **Vol.1: Additive Manufacturing – Make or Buy**

Additive Manufacturing became a game changer in many industries. Especially for SMEs, however, high part costs are still the main restriction for further wide-spread adoption of this production technology.

Ampower Insights Vol. 1 gives a detailed calculation of production costs and introduces the ratio of cost per unit of volume for an easy comparison of technologies and materials.



### **Vol.2: Additive Manufacturing of Automotive Components**

Medical and Aerospace companies count among the early adaptors of metal Additive Manufacturing. The usually highly innovative automotive industry, however, so far struggles with the high manufacturing cost of Additive Manufacturing. An exception are high performance cars with low production volumes and demand for customization.

In the second issue Ampower Insights provides a deep dive into the manufacturing route of high performance automotive components.



### **Vol.3: Metal Additive Manufacturing with sinter-based technologies**

In this study, Ampower presents an objective and independent view on the current capabilities of sinter-based AM technologies compared with LB-PBF and metal injection molding (MIM). By analyzing over 50 specimens from 9 different system suppliers, Ampower is revealing the characteristics of the different technologies.

Download **Ampower Insights Vol. 1, 2 and 3**  
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