Proceso de certificación en entornos de Fabricación Aditiva

4 de Diciembre, 2019

Detlef Scholz
EOS/Additive Minds

Introduction

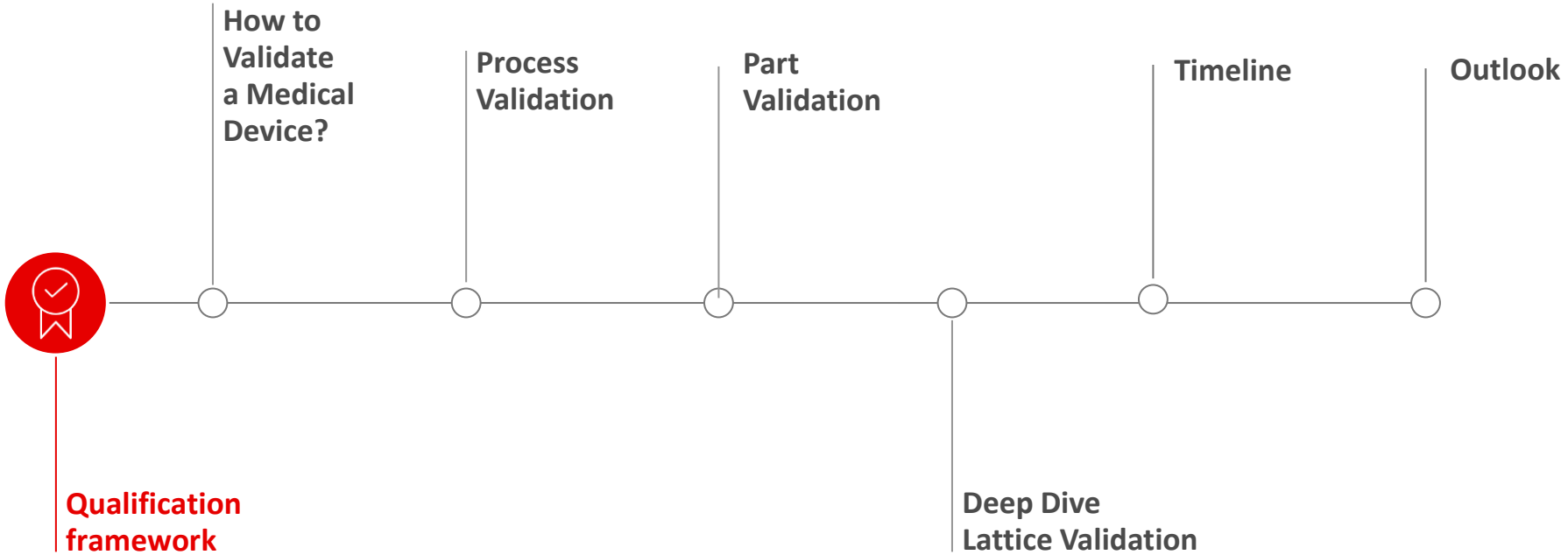
In traditional manufacturing, process qualification refers to tested validation data that ensures a specific manufacturing process can provide a consistent result.

For Additive Manufacturing (AM), **qualifying the process is essential** to create parts that meet specific requirements without adding prohibitive testing and sampling costs.

A validated AM process allows customers to know that their chemical, mechanical, and metallurgical specifications as well as complex geometries can be achieved consistently within specification limits.

The combination of equipment, powder, and process + part and regulatory requirements makes qualification a challenging task due to the high number of input variables.

Today´s Agenda

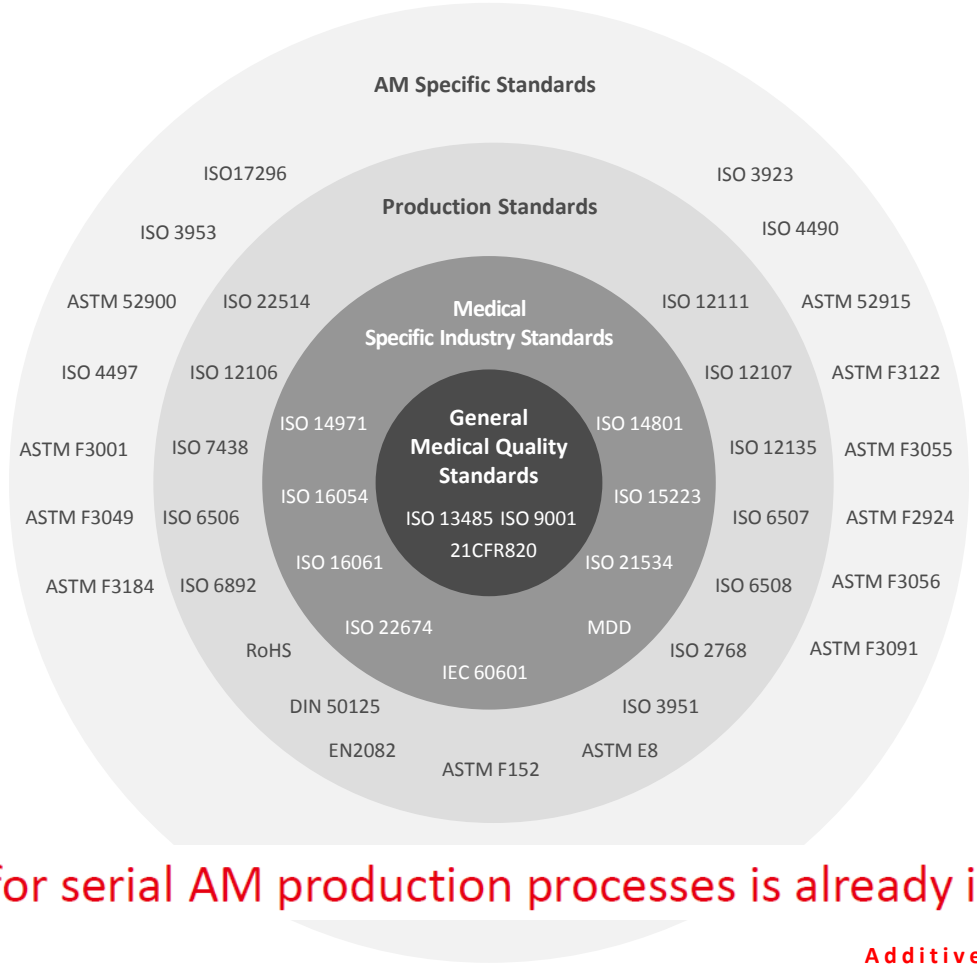


Additive Manufacturing (AM) is spreading into serial production

Application Examples of AM in the Medical Industry

Source: Alphaform, Instrumentaria, plus medica OT, Argen, DePuy Spine, Permedica Orthopaedics

Standard and regulatory framework for AM processes



A quality framework for serial AM production processes is already in place

Latest DIN Norm

Date:2019 December

DIN SPEC 17071

Additive manufacturing — Requirements for quality-assured processes at additive manufacturing centres

Additive Fertigung — Anforderungen an qualitätsgesicherte Prozesse für additive Fertigungszentren

Fabrication additive — Exigences aux processus d'assurance qualité dans les centres de fabrication additive

Source: DIN Deutsches Institut für Normung e. V.

VALIDATION:
A REGULATORY REQUIREMENT ACCROSS THE BOARD

FDA (21 CFR 820):

"Where the results of a process cannot be fully verified by subsequent inspection and test, **the process shall be validated with a high degree of assurance and approved according to established procedures**."

ISO 13485:2016

"The organization shall **validate any processes for production and service provision** where the resulting output cannot be or is not verified by subsequent monitoring or measurement and, as a consequence, deficiencies become apparent only after the product is in use or the service has been delivered".

AS9100D (8.5.1.2)

For processes where the resulting output cannot be verified by subsequent monitoring or measurement, the organization shall **establish arrangements for these processes**

Today´s Agenda

How to Validate a Medical Device?

Process Validation

Global Harmonization Task Force (GHTF)
QMS – Process Validation Guidance
- IQ, OQ, PQ

Part Validation

510(k) submission
PMA submission
Lattice requirements

Timeline

Outlook

Qualification framework

Deep Dive Lattice Validation

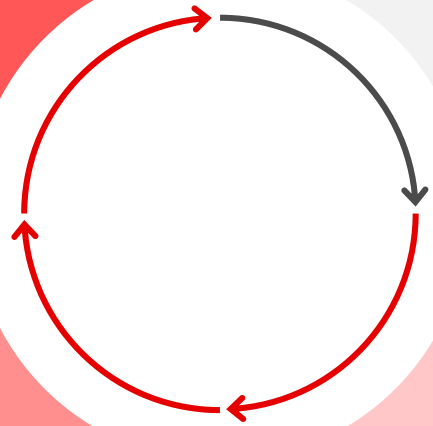
Process for the development of qualified AM processes

Performance Qualification (PQ)

- Reproducibility and repeatability
- Process Quality Monitoring

Factory Acceptance Test (FAT)

- Functional Test
- Conformity Check



Operational Qualification (OQ)

- Process control limits
- Risk Assessments and mitigations
- Material handling requirements

Installation Qualification (IQ)

- Safety features
- Verification of utilities and facility

Installation Qualification (IQ)

… establishes, by objective evidence, that all key aspects of the process equipment and ancillary system installations adhere to the manufacturer’s approved specification and that the recommendations of the supplier of the equipment are suitably considered.
Additionally, IQ determines, through documented evidence, that all **systems and equipment are installed correctly**.

Operational Qualification (OQ)

… establishes, by objective evidence, that the equipment process control limits meet all predetermined requirements by challenging the limits to provide evidence that the predetermined **process output requirements can meet the predetermined requirements**.
Additionally, OQ determines through documented evidence, that the equipment process control limits meet all predetermined requirements.

Operational Qualification (OQ) provides in general the evidence that equipment and processes are working well within the defined ranges

Performance Qualification (PQ)

… establishes, by objective evidence, that a process consistently produces a result and/or product that meets the predetermined requirements (reproducible and repeatable). Additionally, the objective of PQ is to demonstrate that the process will **consistently produce an acceptable product** under normal operating conditions.
Furthermore, PQ testing should always take place at nominal process conditions. Moreover, PQ samples should always be taken from the product lot(s) representative of production.

Performance Qualification (PQ) provides the evidence in special that equipment and process are working well within the defined ranges **and** specific parts under condition of serial production

Requirements for a capable production process

Technology (TRL) Readiness Level

TRL 1: Basic principles observed and reported
TRL 2: Technology concept and/or application formulated
TRL 3: Analytical and experimental critical function and/or characteristic proof of concept
TRL 4: Component and/or breadboard validation in a laboratory environment

TRL 5: Component and/or breadboard validation in a relevant environment

TRL 6: System/subsystem model or prototype demonstration in a relevant environment

TRL 7: System prototype demonstration in an operational environment

TRL 8: Actual system completed and qualified through test and demonstration

TRL 9: Actual system proven through successful mission operations

Requirements for a capable production process

Manufacturing (MRL) Readiness Level

MRL 1: Basic Manufacturing Implications Identified
MRL 2: Manufacturing Concepts Identified
MRL 3: Manufacturing Proof of Concept Developed
MRL 4: Capability to produce the technology in a laboratory environment

MRL 5: Capability to produce prototype components in a production relevant environment

MRL 6: Capability to produce a prototype system or subsystem in a production relevant environment

MRL 7: Capability to produce systems, or components in a production representative environment

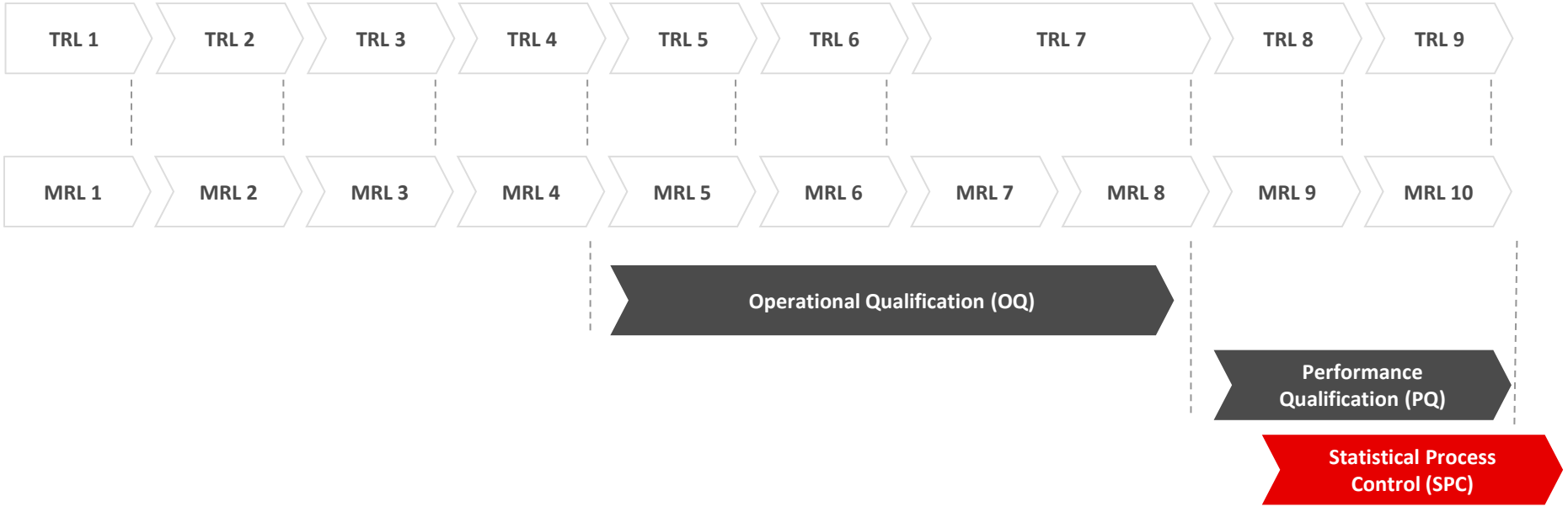
MRL 8: Pilot line capability demonstrated; Ready to begin Low Rate Initial Production

MRL 9: Low rate production demonstrated; Capability in place to begin Full Rate Production

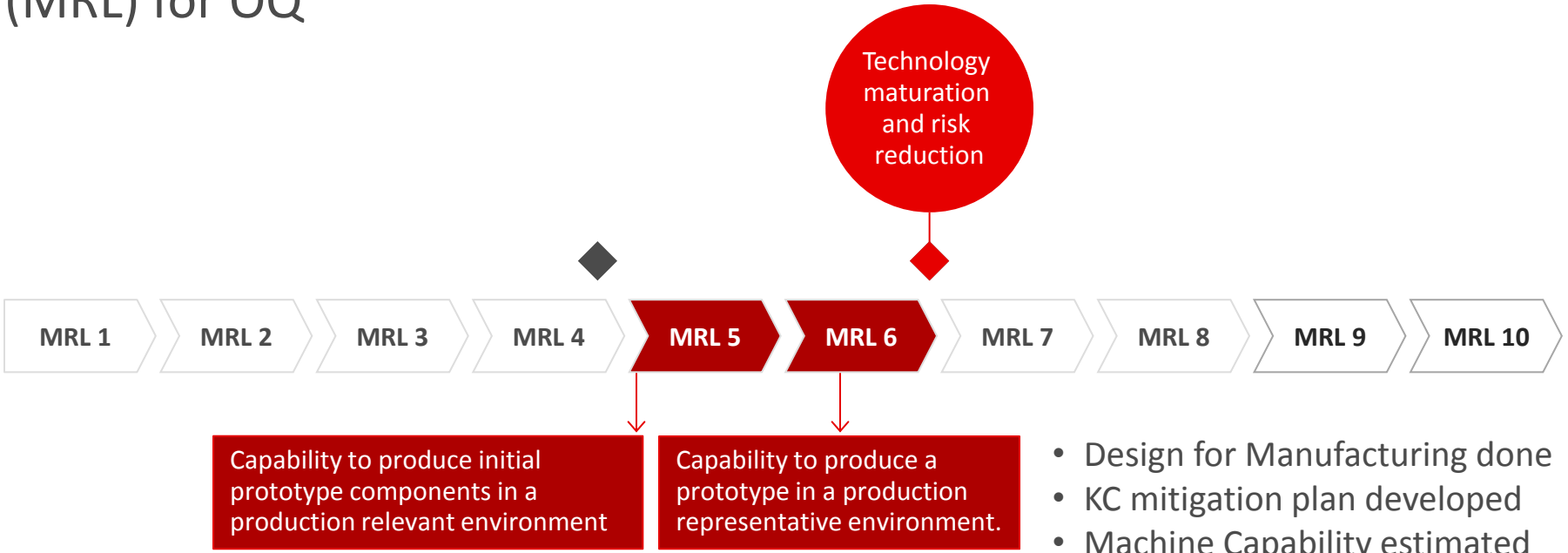
MRL 10: Full Rate Production demonstrated and lean production practices in place

Requirements for a capable production process

Technology (TRL) & Manufacturing (MRL) Readiness Level



Key Requirements of Manufacturing readiness level (MRL) for OQ



- Design for Manufacturing done
- KC mitigation plan developed
- Machine Capability estimated
- Quality metrics identified
- Acceptance tests defined
- Process FMEA done
- Materials specified and validated

Key Requirements of Manufacturing readiness level (MRL) for OQ

- Detailed design completed and frozen
- Test/Inspection equipment proven (MSA)
- Machine Capability Analysis started
- All identified manuf. risks addressed
- Work instructions prepared
- Operators trained
- Materials proven and validated

Key Requirements of Manufacturing readiness level (MRL) for OQ

- All manufacturing risks mitigated
- Machine capability fully proven
- Quality targets fully met
- Quality issues occur rarely and unrepeated
- Maintenance schedule fully implemented
- Controlled processes implemented

How to implement these requirements in an additive manufacturing environment?

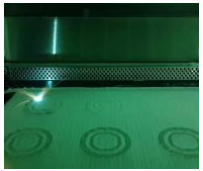
The Building process is one of many steps in an AM process chain

Data Preparation

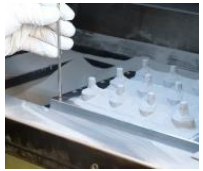
Incoming Inspection
- Quality of gas and powder

Ware-housing
- Powder handling

Machine Setup
- Filling of powder
- Fitting of recoater
- Flooding and Heating



Building Process
- Energy Density
- Oxygen %
- Flow Speed
- Recoating thickness



Unpacking & Cleaning
- Removing of build platform
- Sieving
- Cleaning of machine

Heat treatment
- Tempering
- Isostatic pressing

Post Processing
- Sampling and part testing
- Machining and milling

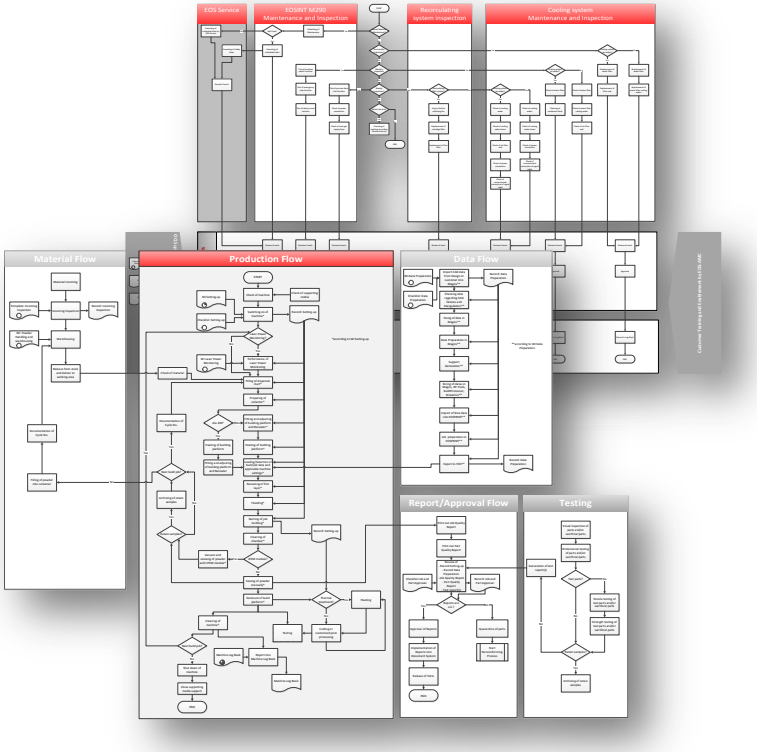
Final Product

Only a throughout assessment of all processes ensures qualified AM products

Source: EOS, Permedica, NMU.edu, Dreamstime.com, sgs.com, accuform, bodycote

Ensuring a qualified AM manufacturing process

1a. Assessment of Process Steps and Flow

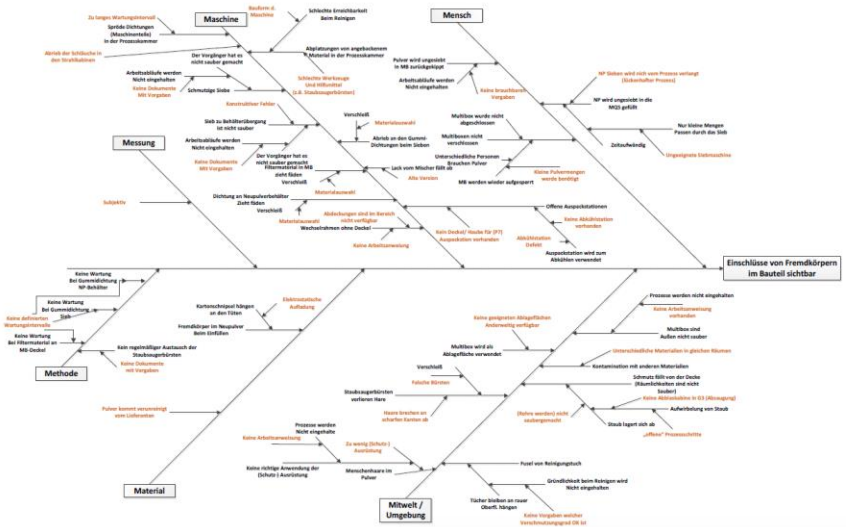


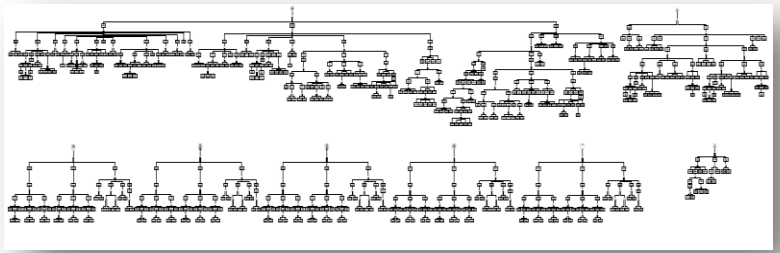
Additive Minds prepare **Process Flow Charts** consisting of

- Raw Material => Specification, Incoming Inspection, Material handling and Storage
- Data Preparation
- Setting-up the machine
- Build Job
- Monitoring
- Cleaning
- Post Processing
- Testing
- Documentation
- Approval
- Maintenance

Source: EOS

Ensuring a qualified AM manufacturing process
1b. Assessment of Key Characteristics



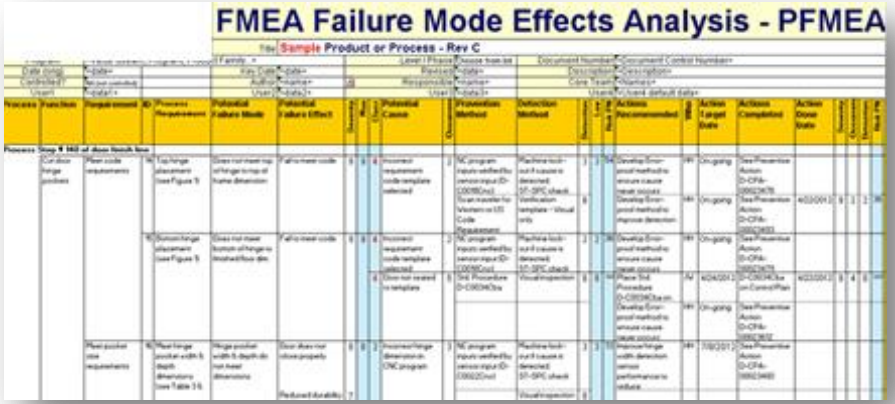


Additive Minds prepared Ishikawa Diagrams and Fault Tree Analysis (FTA) for AM consisting of

- Part does not build
- Part does not met specifications
- No Part traceability
- Health & Safety issues
- Define failures, sub-causes and causes
- Highlight the key characteristics

Source: EOS

Ensuring a qualified AM manufacturing process
2. Prioritise KCs within the AM-process


FMEA Failure Mode Effects Analysis - PFMEA

for Sample Product or Process - Rev C

Additive Minds prepare a Process-FMEA form for AM consisting of

- Linked causes and sub-cause to every failure
- Defined pre-mitigation by EOS
- Initial risk evaluation
- Recommended actions for further risk assessment with responsibilities and due date
- Final risk evaluation
- Pre-defined Control Plan

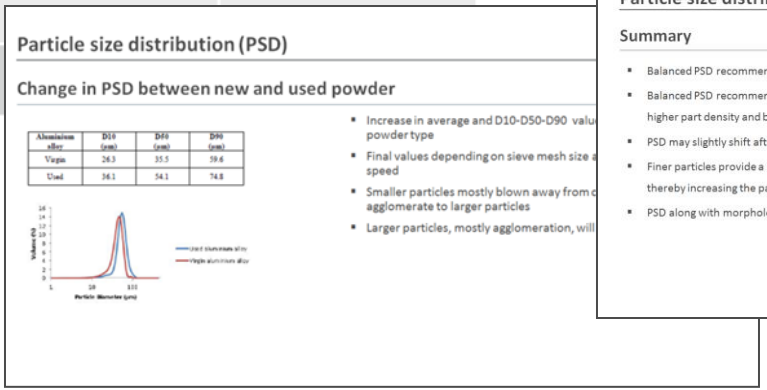
Source: EOS

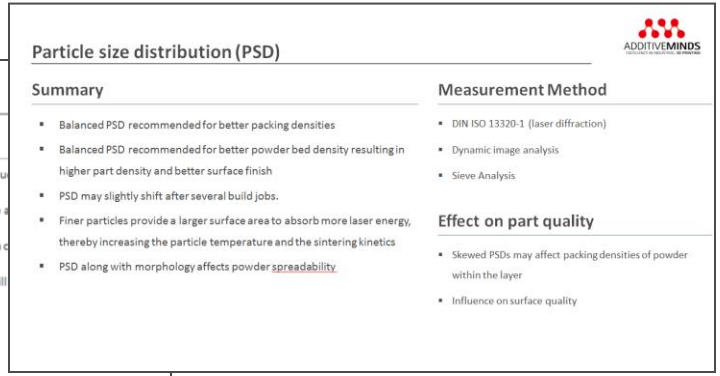
Ensuring a qualified AM manufacturing process
3. Assign Control Methods

Powder characteristics	Existing standard	Criticality to process
Sampling	ASTM B214	4
Chemical composition	AMS/ASTM specs	5
Particle size distribution (PSD)	DIN ISO 13320	5
Powder flowability	ASTM B213-13 (Hall) ASTM B964 (Carney)	2
Apparent Density	ASTM B212-13	3
Tap Density	ASTM B527-15	4
Morphology- SEM	*GOST 25849-13	4
Spreadability		
Other tests (angle of repose etc.)		

Additive Minds conducts a “Critical-to-Quality” Workshop to assess Key Characteristics:

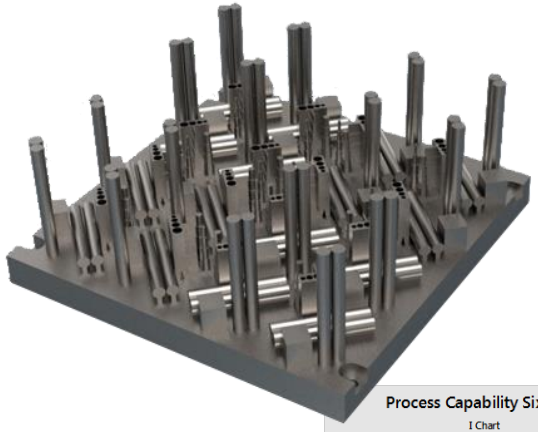
- Priorization of all Key Characteristics according to Additive minds knowhow
- In-depth explanation of all KCs
- Recommended for testing methods and limits

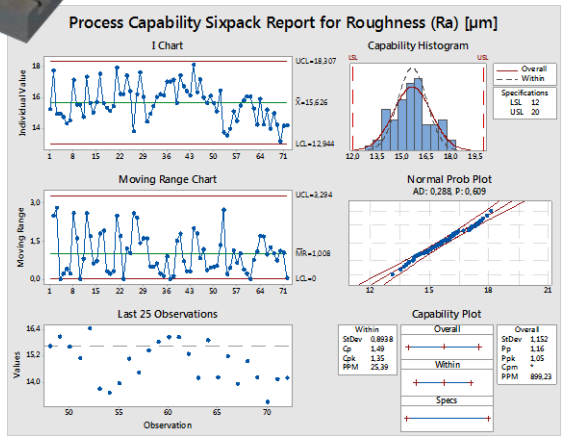




Source: EOS

Ensuring a qualified AM manufacturing process
4. Define Process control limits





Additive Minds develop with the costumer test strategies for serial production based on static mechanical properties (tensile, density, porosity, hardness) and accuracy

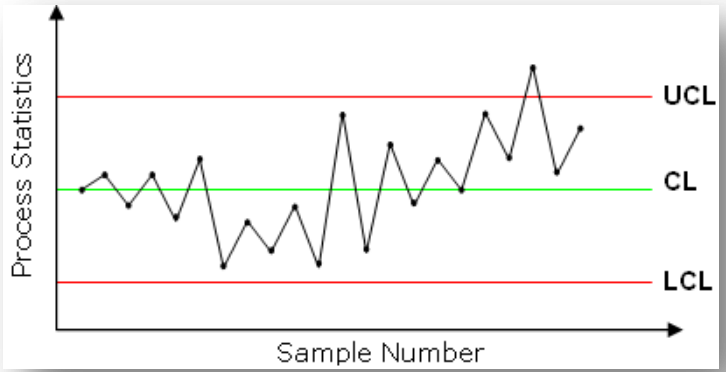
- Serial part geometries
- Serial job layout
- Defined acceptance criteria
- Available measurement tools

Additive Minds prepared a procedure for Process capability

- Pp/Ppk analysis
- Cp/Cpk analsysis

Source: EOS

Ensuring a qualified AM manufacturing process
5. Set required inspection lots (Statistical process control)



Process Limits

Additive Minds develops with the customer a Statistical Process Control (SPC) that consisting of

- Defined control limits (UCL, LCL)
- Defined pre-indications for out-of-control
- Defined sample number
- Defined Accepted-Quality-Level (AQL)

AQL-Level

Source: EOS

Ensuring a qualified AM manufacturing process
6. Control Key Requirements

CONTROL PLAN

Prototype	Prelaunch	Production	Key Contact/Phone	Date(Orig)	Date (Rev.)
Number					
/Latest Change Level			Core Team	Customer Eng. Approval/Date	
escription			Organization/Plant Approval/Date	Customer Quality Approval/Date (if Req'd)	
/Plant		Organization Code	Other Approval/Date (if Req'd)	Sample	If Req'd)

Characteristics					Methods					
Process Name/ Operation Description	Machine, Device, Jig, Tools, for Mfg.	No.	Product	Process	Special Char Class	Product/Process Specification/ Tolerance	Evaluation/ Measurement Technique	Siz	Freq.	Control Method	Reaction Plan
Warehouse			Environmental condition			Temperature/ humidity	sensor	1	daily	xR	NCR
AM Production			Environmental condition			Temperature/ humidity	sensor, internal machine sensor	1	daily	xR	NCR
AM Production			Inert gas pressure			Pressure	visual	1	daily	xR	NCR
AM Production			Pressurised air			Pressure	visual	1	daily	xR	NCR
AM Production	SI XXXX			Laser Power		Process specification	LMK	1	before job	xR	NCR
AM Production	SI XXXX			Laser Power		Process specification	LPM	100%	each job	xR	NCR
AM Production	SI XXXX			Scan Accuracy		Process specification	internal machine sensor	100%	each job	xR	NCR
AM Production	SI XXXX			Build platform temperature		Process specification	internal machine sensor	100%	each job	xR	NCR
AM Production	SI XXXX			Oxygen level		Process specification	internal machine sensor	100%	each job	xR	NCR
AM Production	SI XXXX			Process chamber Humidity/ Temperature		Process specification	internal machine sensor	100%	each job	xR	NCR
AM Production	SI XXXX		AM Part								
AM Production	SI XXXX		AM Part								
AM Production	SI XXXX		AM specimen								
AM Production	SI XXXX		AM specimen								

Additive Minds suport the development of an OQ Test Plan, by

- Asking for evidence of implemented mitigations
- Asking for evidence of implemented documents
- Asking for evidence of training
- Defining build parameter
- Defining qualification build job
- Defining test for built parts

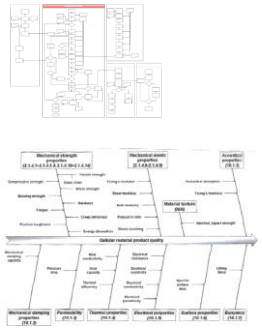
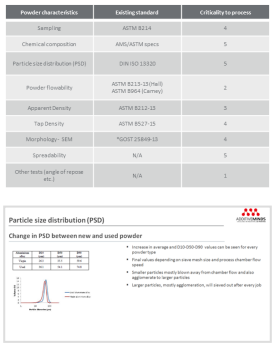
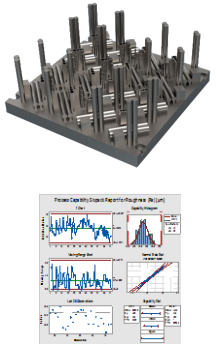
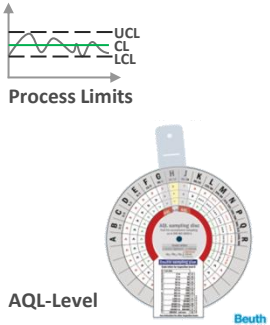
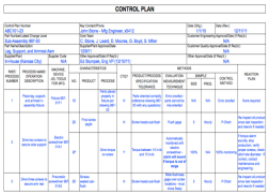
and

- Executing OQ tests according to the Test Plan
- Documenting results of the OQ tests
- Approving the Operational Qualification (OQ)

Source: EOS

Ensuring a qualified AM manufacturing process

Approach for implementation of key characteristics

Assessment of Key Characteristics	Prioritise KCs within AM-process	Assign Control Methods	Define Process control limits	Set required inspection lots	Control Key Requirements
					
Process Map, Ishikawa Diagram, Fault Tree Analysis	Process- FMEA	Critical to Quality Workshop (CTQ)	Machine Capability Analysis	Statistical process control	Control Plan

Source: EOS, Beuth, Rehme

Process specifications for: Powder reuse in AM

Considerations for powder reuse in AM

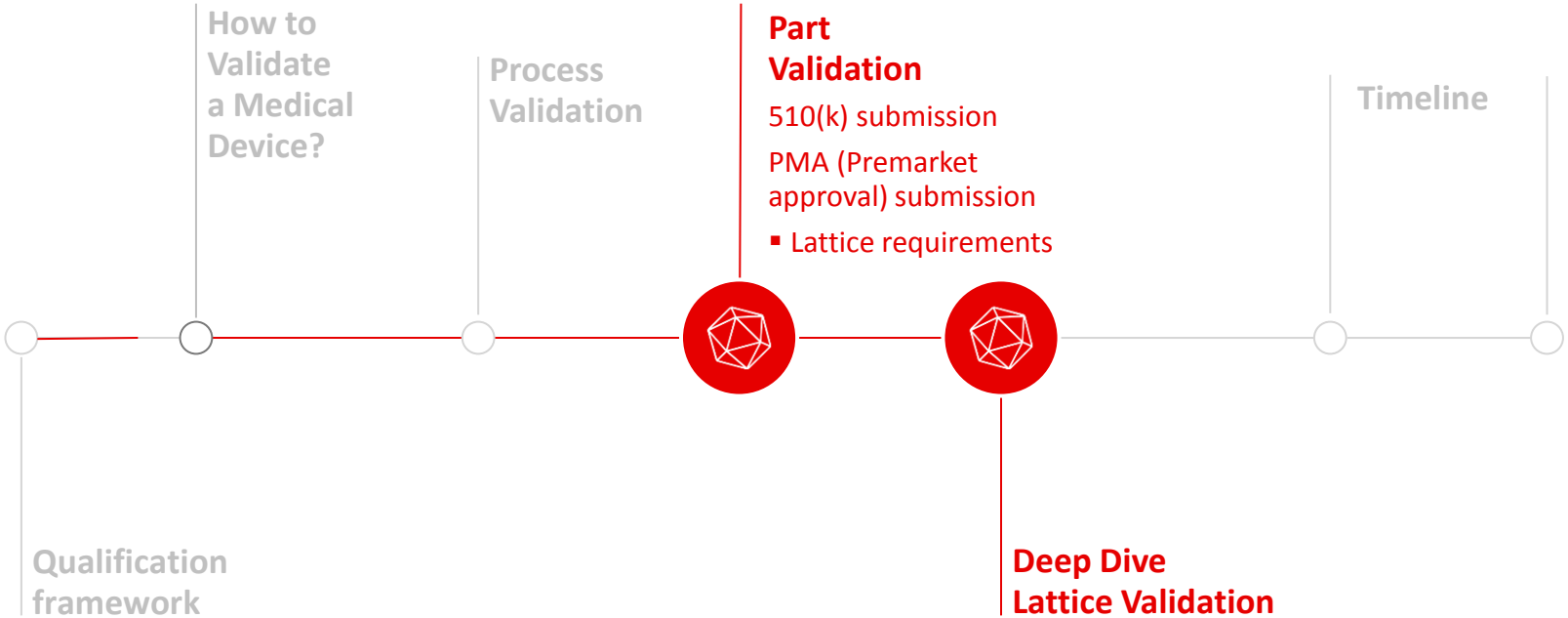
- → Definitions of powder states
- → Key parameter for powder evaluation
- → Blending strategies
- → Definition of limits and test frequencies in serial production
- → Powder storage and shelf live

Requirements for a capable production process

The ISO 13485 requires e.g.:

Controlled part drawings and specifications	MRL 5
Material specification	MRL 5-6
Process Flow Charts	MRL 5-6
Risk Assessment (Process-FMEA)	MRL 5-7
Inspection/ Test procedures (Control Plan)	MRL 5-7
Process specifications	MRL 5-6
Critical Characteristics	MRL 5-6
Standard Operation Procedures (SOP)	MRL 5-6
Trained operators	MRL 5-6
Measurement System Analysis (MSA)	MRL 5-6
Process capability	MRL 6-8
Controlled process	MRL 9-10

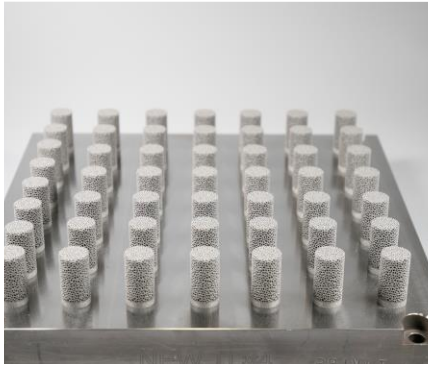
Today´s Agenda



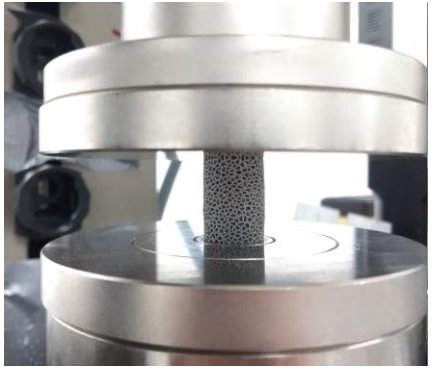
Procedure

Design 1

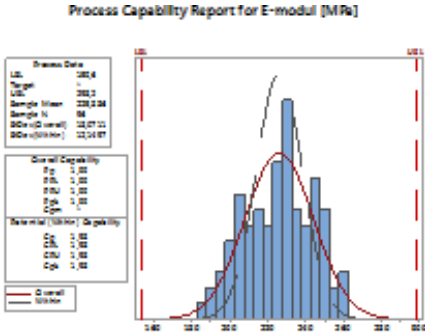
Build 2



Testing 3



Evaluation 4



1 Influence of Energy Input

Strut thickness Z

Part Nr. 3

150 W with 2000 mm/s

Energy input 12,5 J/mm³

Strut thickness X/Y

Part Nr. 13

250 W with 1000 mm/s

Energy input 41,7 J/mm³

2 Build Job

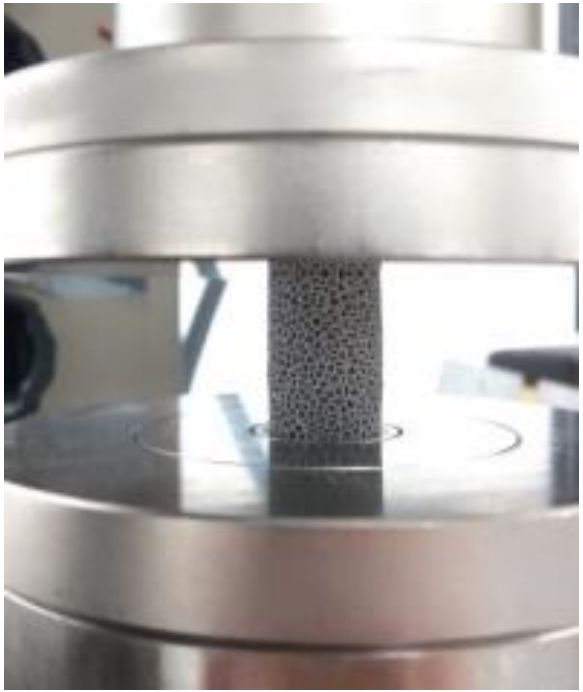
Build Job for capability evaluation

3 Jobs x 56 test coupons per job

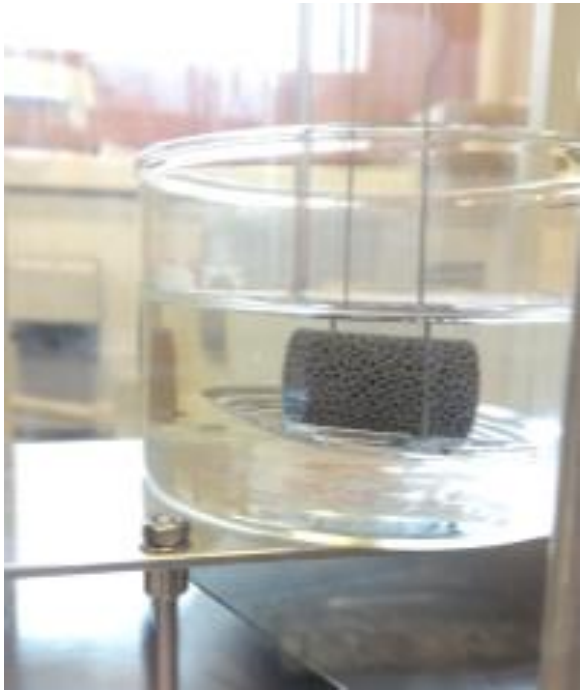
= 168 test coupons

3 Testing

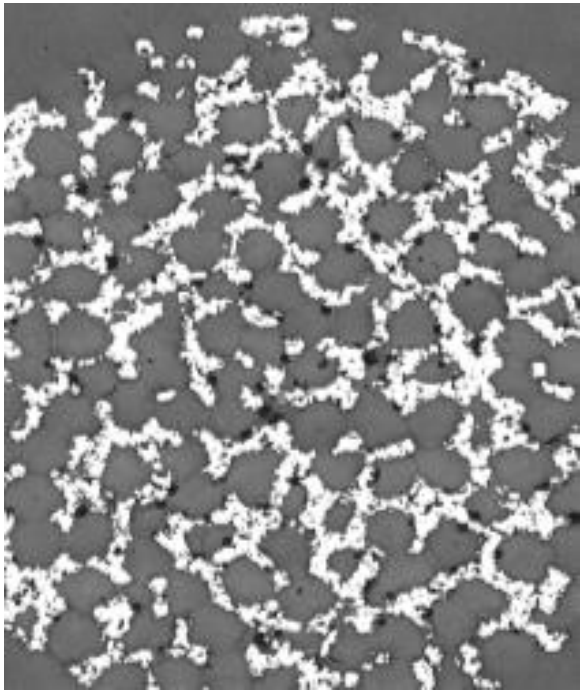
Compression test



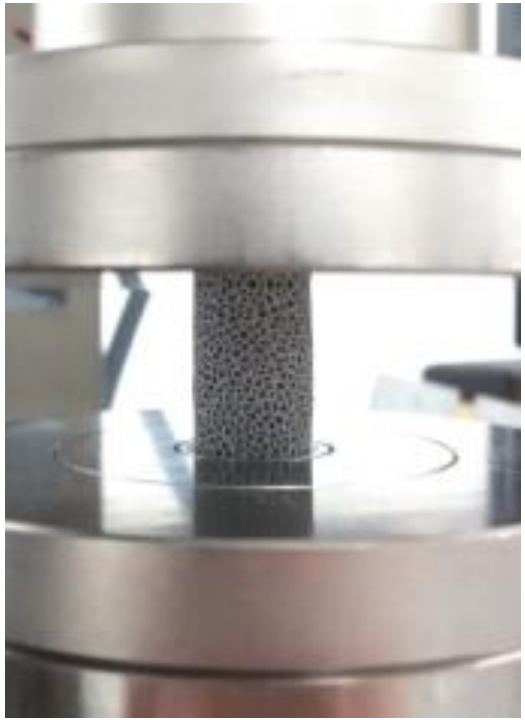
Archimedes principle

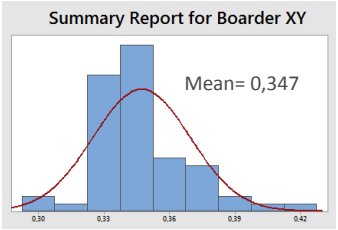


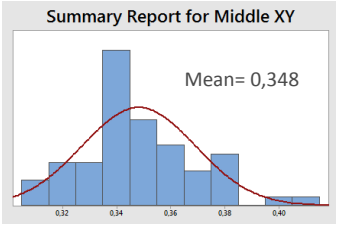
Stereological Evaluation

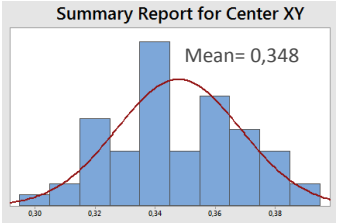


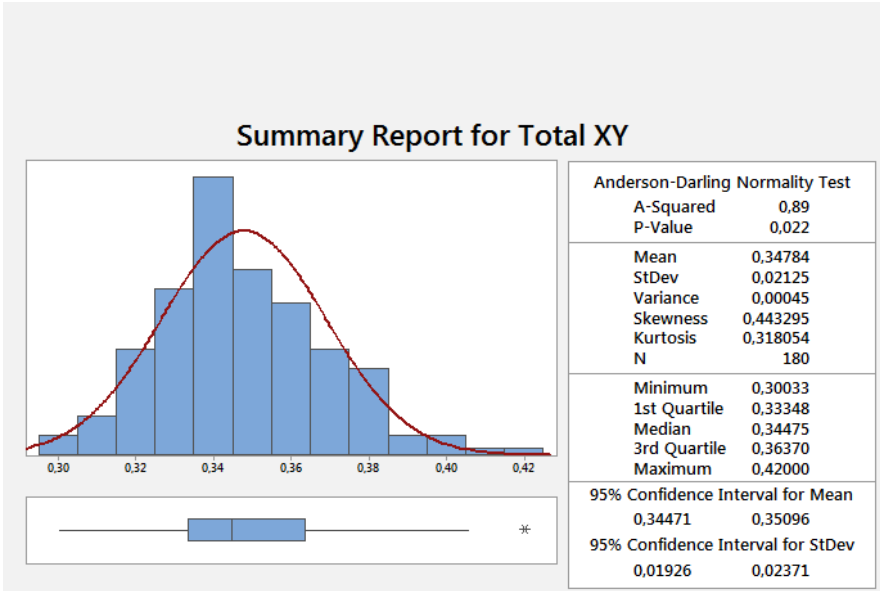
4 Strut thickness X/Y











Mean= 0,347 mm

How Machine/Material Suppliers can support the Industry

- Hand-over Material Data Sheets and Process Parameter Sets that provide validated material data for a given system and process
- Co-develop with customers qualification design of experiments (DOE) that provide the right dataset, crucial to cost and time investment required for a proper process validation strategy.
- Support the qualification of material/machine combinations at OEMs
- Provide end-users with operating instructions, check-list, standard operating procedures, labels etc.
- Support parts manufacturers during the entire qualification process to maximize speed and quality of the certification process

Material Data Sheets

System set-up	EOS M 290
EOS ParameterSet	M 290 Ti64 Grade23 040 V1
EOSPAR name	Ti64_Grade23_040_HiPerM291_100
Software requirements	EOSPRINT 2.5 or newer EOSYSTEM 2.8 or newer
Powder part no.	9011-0046
Recoater blade	EOS HSS blade
Nozzle	EOS grid nozzle
Inert gas	Argon
Sieve	90 µm

Additional information	
Layer thickness	40 µm
Volume rate	6.2 mm³/s
Min. wall thickness	Approx. 0.4 mm

Heat Treatment Description:
120 min (± 30 min) at 800 °C (± 10 °C) measured from the part in vacuum (1.3 x 10-3-1.3 x 10-5 mbar) followed by cooling under vacuum or argon quenching.

Mechanical properties ISO6892-1

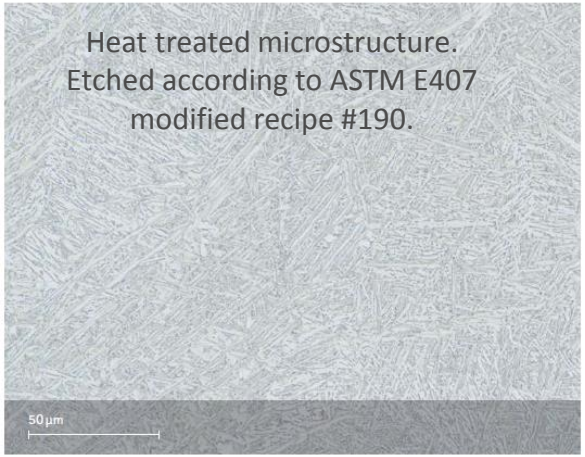
	Yield strength Rp0.2 [MPa]	Tensile strength Rm [MPa]	Elongation at break A [%]	Reduction of area Z [%]	Number of samples
Vertical	980	1050	15	≥ 25	84
Horizontal	940	1050	14	≥ 25	72

Fatigue strength at 1 x 10^7 cycles in heat treated state

Fatigue strength, MPa	589 MPa

Coefficient of Thermal Expansion ASTM E228

Temperature	25 – 100 °C	25 – 200 °C	25 – 300 °C
CTE	11.1 *10^{-6}/K	11.6 *10^{-6}/K	11.9 *10^{-6}/K

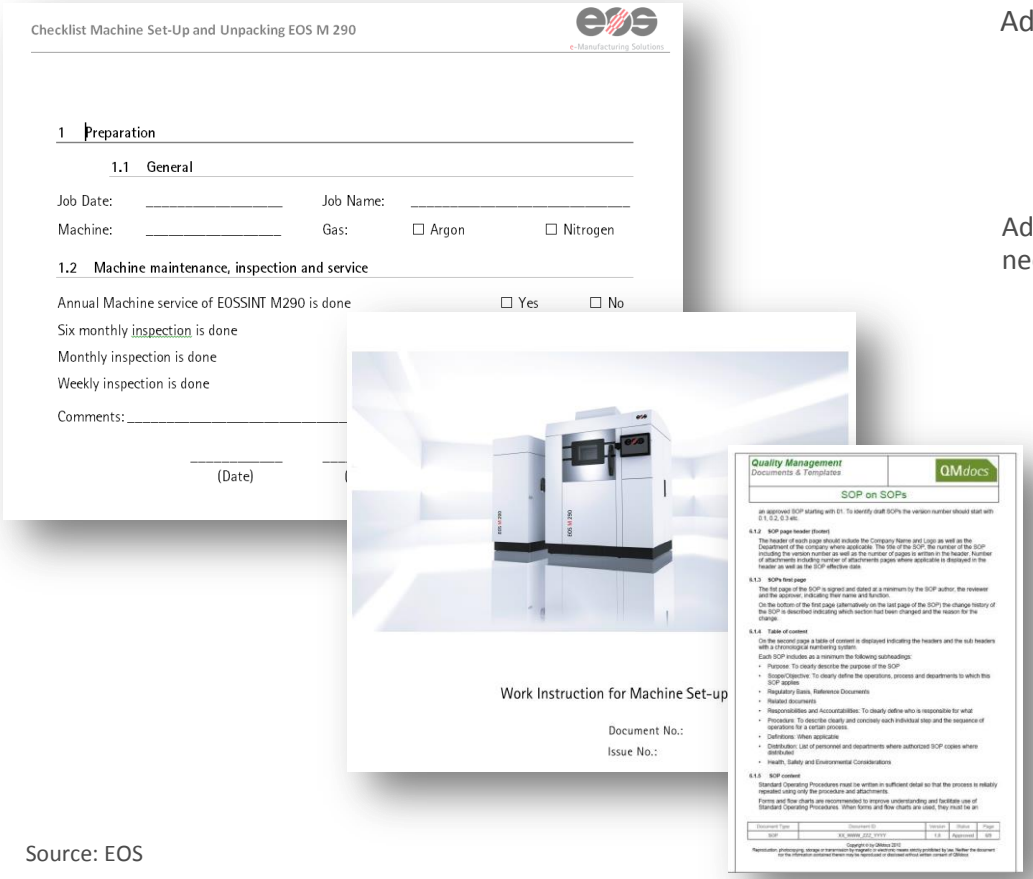


Defects	Result	Number of samples
Average defect percentage	0.01 %	30

Density, ISO3369	Result	Number of samples
Average density	≥ 4.4 g/cm³	10

Source: EOS

Documentation Support



Additive Minds prepared for the AM process all necessary

- Work Instructions
- Checklists
- Labels

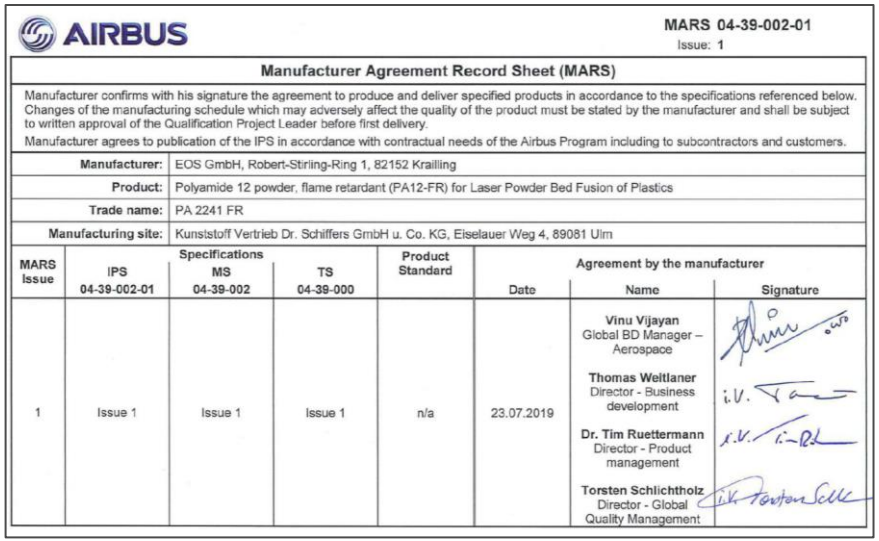
Additive Minds prepared a trainings matrix to visualize the training needs for

- Operators
- Maintenance Staff
- Supplier
- Process Developer
- Responsible person for Data Preparation

Source: EOS

Engineered Polymers : EOS low temp solutions ready

EOS PA 2241 FR Material and EOS P396/P770 process certified by Airbus



AIRBUS

MARS 04-39-002-01
Issue: 1

Manufacturer Agreement Record Sheet (MARS)

Manufacturer confirms with his signature the agreement to produce and deliver specified products in accordance to the specifications referenced below. Changes of the manufacturing schedule which may adversely affect the quality of the product must be stated by the manufacturer and shall be subject to written approval of the Qualification Project Leader before first delivery.
Manufacturer agrees to publication of the IPS in accordance with contractual needs of the Airbus Program including to subcontractors and customers.

Manufacturer:	EOS GmbH, Robert-Stirling-Ring 1, 82152 Krailling
Product:	Polyamide 12 powder, flame retardant (PA12-FR) for Laser Powder Bed Fusion of Plastics
Trade name:	PA 2241 FR
Manufacturing site:	Kunststoff Vertrieb Dr. Schiffers GmbH u. Co. KG, Eiselauer Weg 4, 89081 Ulm

MARS Issue	Specifications IPS 04-39-002-01	Specifications MS 04-39-002	Specifications TS 04-39-000	Product Standard	Agreement by the manufacturer: Date	Name	Signature
1	Issue 1	Issue 1	Issue 1	n/a	23.07.2019	**Vinu Vijayan** Global BD Manager – Aerospace **Thomas Weitlaner** Director - Business development **Dr. Tim Ruettermann** Director - Product management **Torsten Schlichtholz** Director - Global Quality Management	

- Non-structural applications (class 3) of Airbus products
- Suitable for parts which have to fulfil FST requirements, *not* for heat release
- The qualification is valid for Airbus group globally

Example: Serial production of automotive exterior parts

Requirements for indicator inlays

- Withstand Environmental Impacts over Lifetime such as
  - UV Radiation
  - Resistance to Stone Chipping
  - Various Weather Conditions and Moisture
- Homogeneous Distribution of Mechanical Properties over entire Building Area esp. elongation@break
- High Part Accuracy
- High Machine Availability

Challenge: High quality parts in an highly efficient production environment

Source: press.bmwgroup.com

Example: Serial production of customized blinker inlays

Automotive Example

Challenge

Produce serial parts that meet the high-grade plastic qualities in automotive industry

Dyed blinker inlay made of PA 1101

Solution

Additive manufacturing with EOS P 396

Results

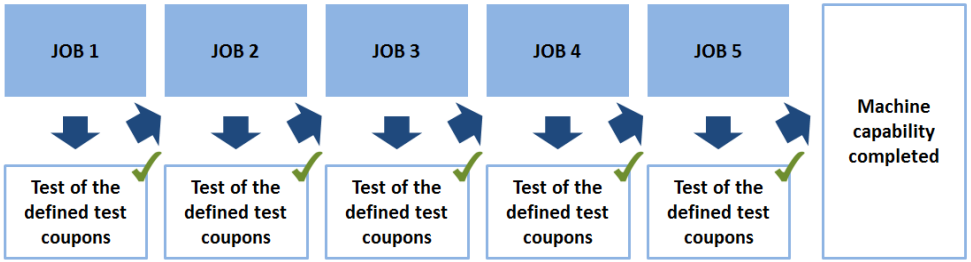
- Freedom of design allows realisation of individual customer wishes
- Short production times enable customized products to be delivered within a few weeks
- Part quality, functionality and safety matches the stringent product-guidelines
- System tailored to serial production

Source: EOS

Example: Serial production of automotive parts

Project Outcome

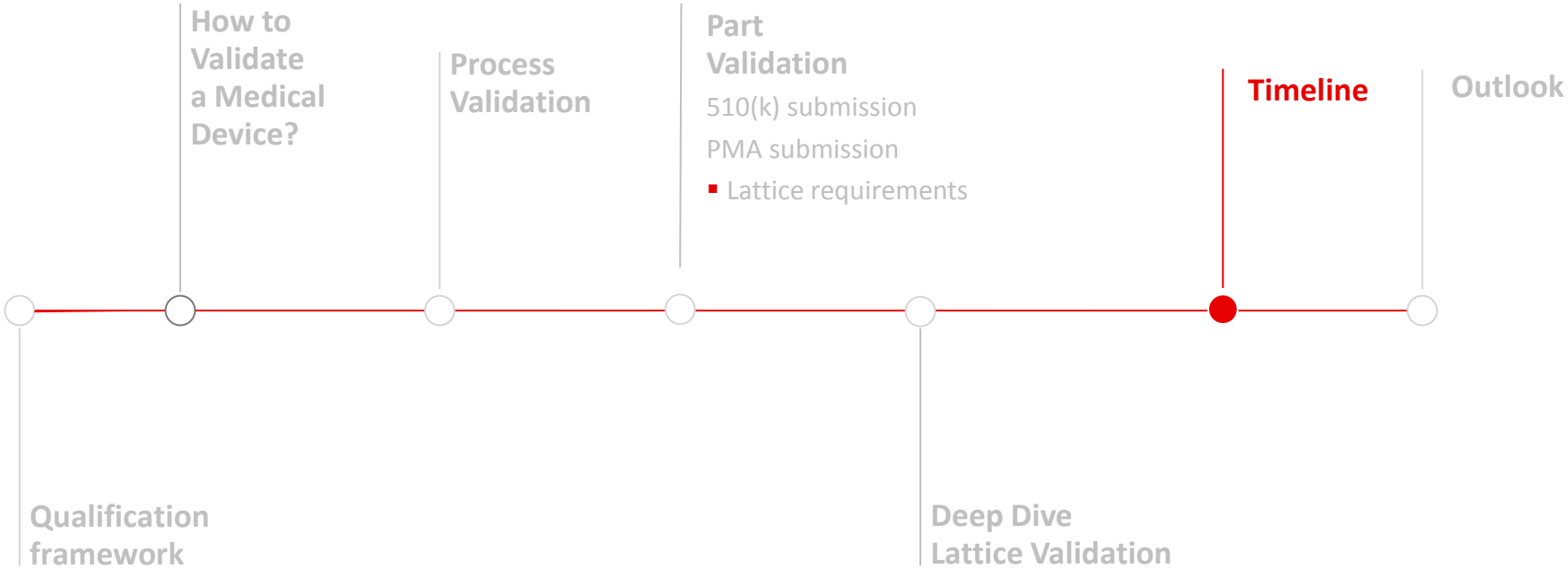
- Used Material for Application: P1101
- Layer Thickness: 120µm
- Proven and stable AM Process with 4 EOS P 396 (successful capability studies: MFU and PFU)
- Start of Serial Production: Q1/2018



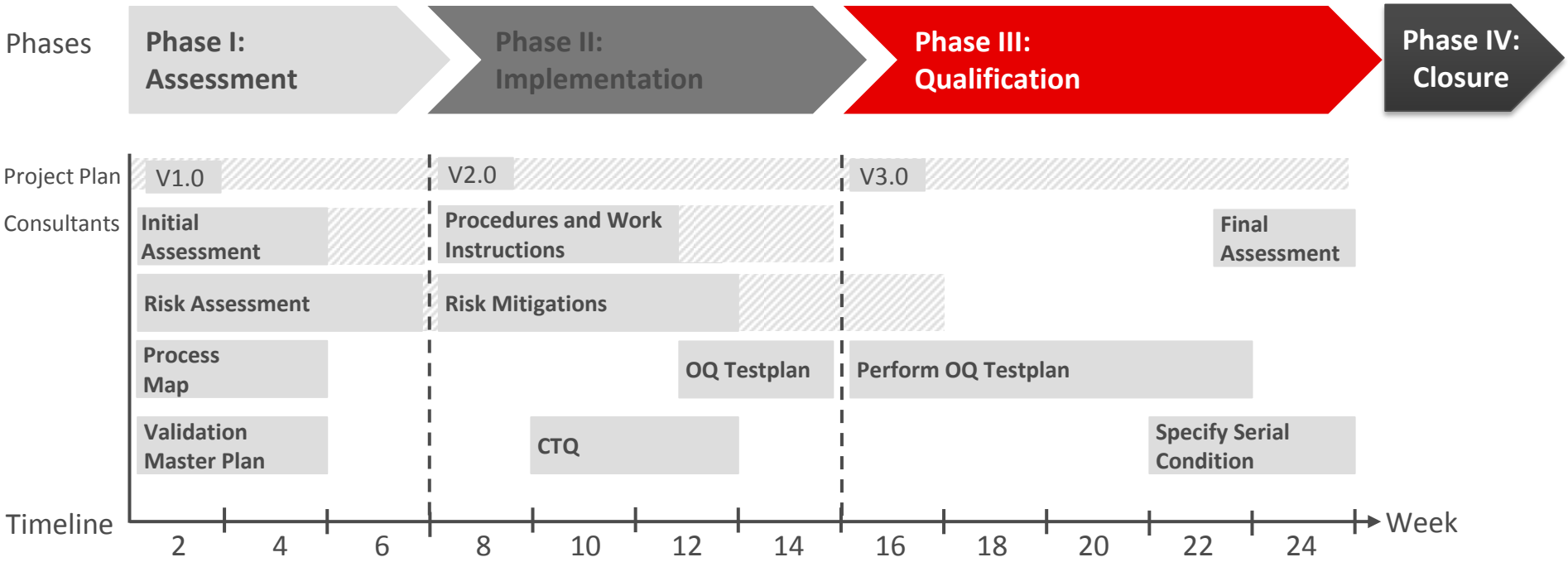
Result: Successful qualification of EOS P 396 into automotive production system

Source: EOS, press.bmwgroup.com

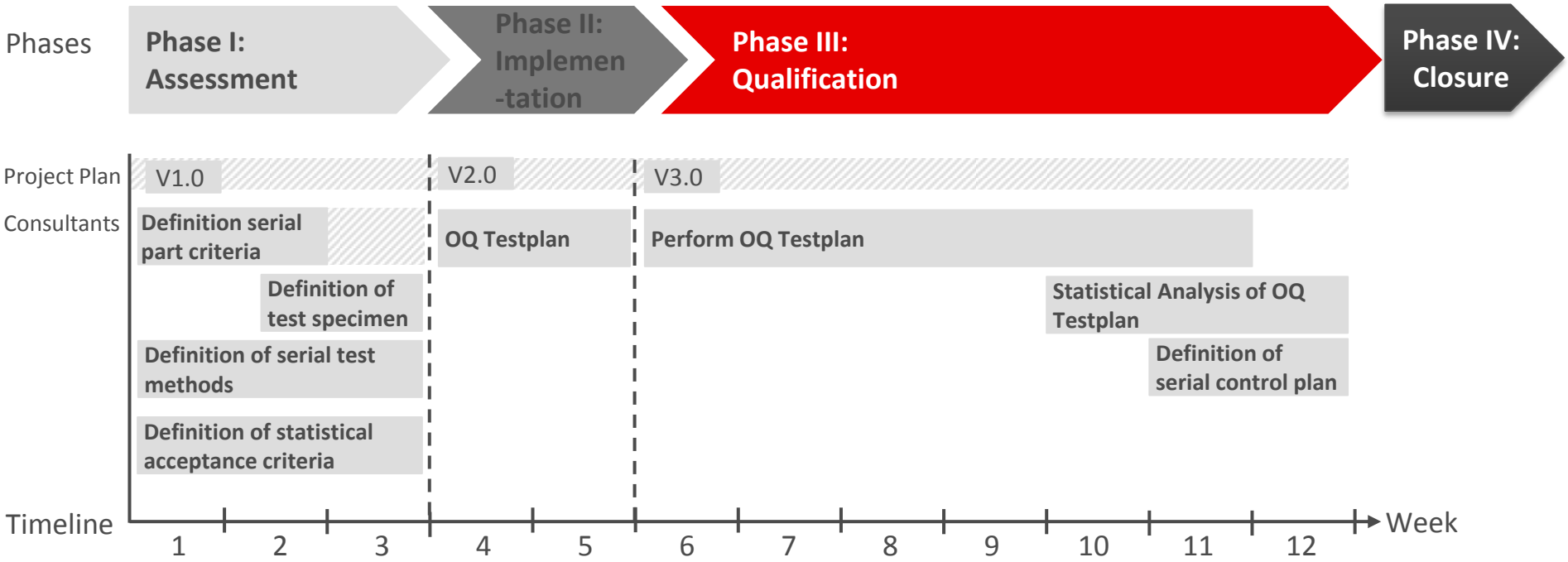
Today´s Agenda



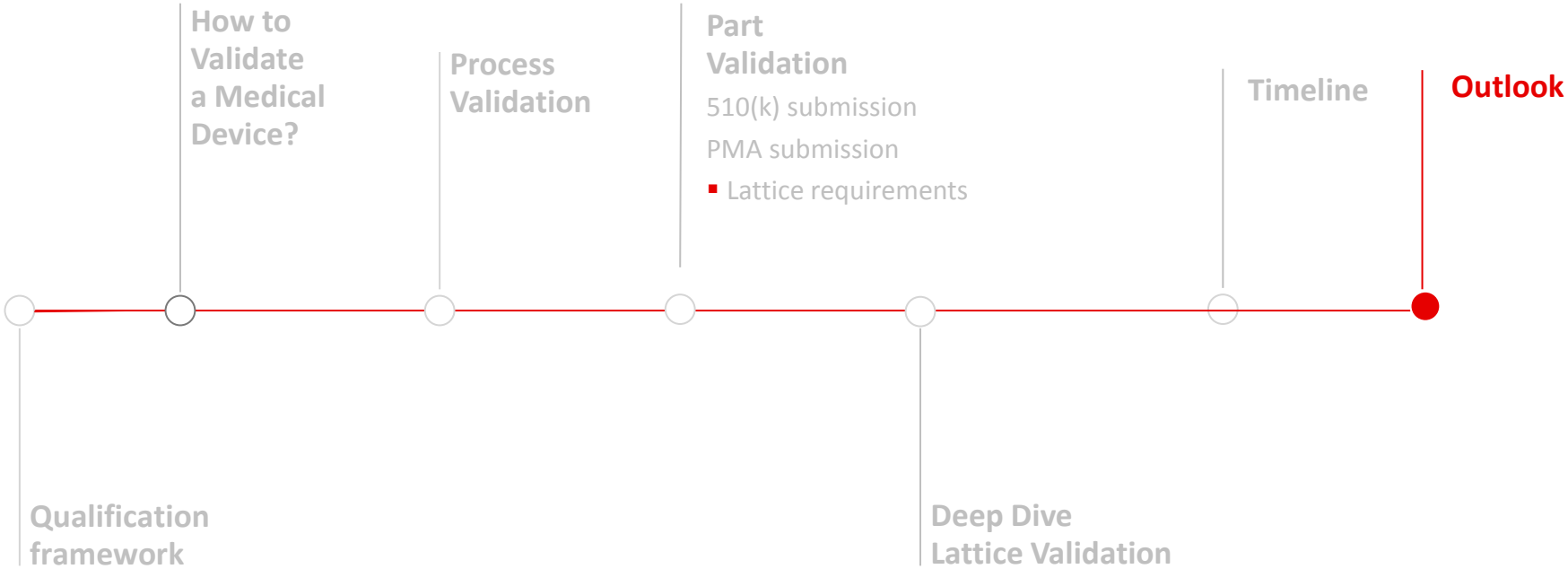
Operational Qualification (OQ) Time Table



Performance Qualification (PQ) and SPC Time Table



Today´s Agenda



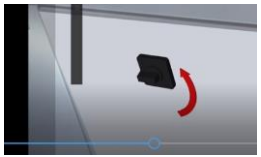
Newest Developments

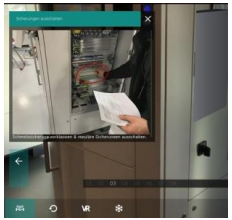
EOS, PTC and Link3D to collaborate on quality assurance for AM using AR

Objective: to help organisations in the AM industry to:

- Use AR technology to **train** the workforce
- Increase production quality with repeatable fixed processes
- Standardise workflows with **guided AR work instructions** for machine setup and maintenance
- Enable an end-to-end **digital thread**
- **Validate processes to adhere to customer regulatory requirements**
- **Generate part certificates of conformance, other quality documentation and data analytics reports**

1) Identify and orientate
2) Find location
3) Show action
4) Provide operator manual





Source: AM Metals Magazine

AM Production Qualification

Summary

1) International standards do exist
2) FAT, IQ, OQ and PQ as well as MRLs provide the framework
3) A throughout assessment of all processes – from design to final part including incoming inspection, warehousing, post-processing, etc. – ensures qualified AM products
4) Many customers have successfully qualified their AM production
5) Suppliers should support qualification efforts on various levels
6) New technologies facilitate Quality Assurance

Additive Minds support organizations to become AM

13 trainings and 17 consulting offerings

7 global technical and Innovation centers

#1 consultancy in AM market

110 AM experts: largest team world-wide

Thank you for your attention

>400 successful customer projects in >25 countries