

# FDA Additive Manufacturing Workshop

## Perspectives on Pre-Printing Considerations (Metals)

EOS GmbH – Martin Bullemer

October 8<sup>th</sup> 2014



# Agenda

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- **EOS**
- Perspectives on Pre-Printing Considerations (Metals)

- **Family-owned**, founded in 1989,
- Headquartered in Krailling near **Munich, Germany**
- **Integrated solution provider for Additive Manufacturing**
- **Solution portfolio:** Additive Manufacturing (AM) systems, materials (plastics and metals), software and services
- **Complete end-to-end solutions:** from part design and data generation to part building and post-processing
- **EOS enables competitive advantages for a variety of industries**, such as medical, aerospace, tooling, industry, lifestyle products and automotive
- EOS is committed to:  
**Innovation – Quality – Sustainability**

## EOS Management



Christian Kirner

Dr. Tobias Abeln

Dr. Hans J. Langer

Dr. Adrian Keppler

## EOS Headquarters in Krailling, Germany



# Agenda

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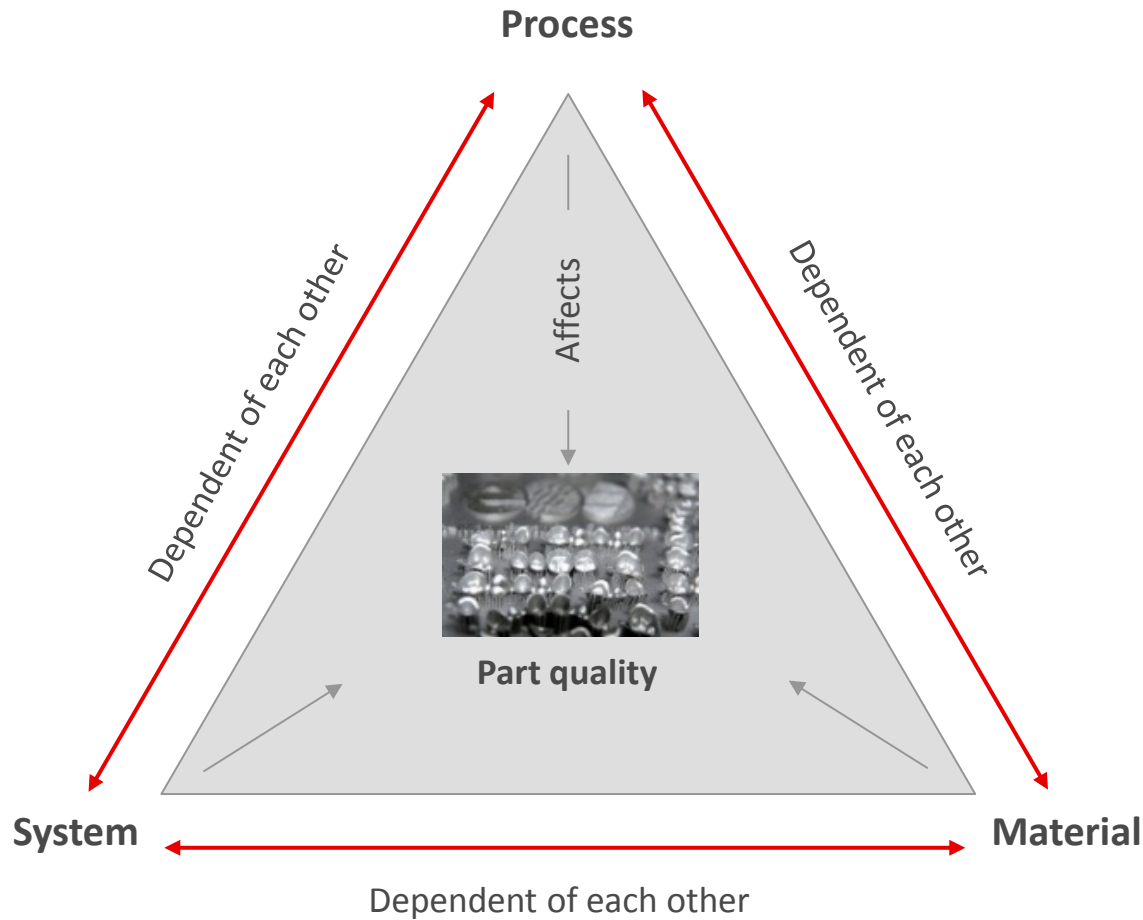
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- EOS – Leader in e-Manufacturing Solutions
- **Perspectives on Pre-Printing Considerations (Metals)**

# The well balanced “Magic” AM Triangle ...



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... will ensure constantly high quality parts!

# Metal Powder Design and Development



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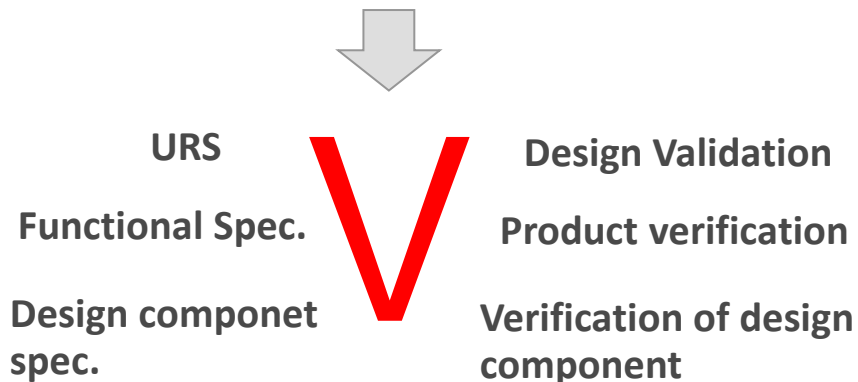
## Metal Powder Development Inputs

- Mechanical properties
- Chemical properties
- Functional performance
- Regulatory requirements
- FMEAs of raw material suppliers procedures
- FMEA of EOS products and processes

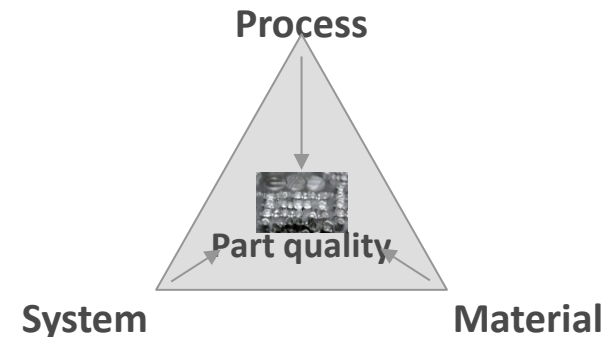
## Metal Powder Development Outputs

- Chemical specification
- Particle size specification
- Powder manufacturing method(s)
- Quality control methods specified

=> Specified in material data sheet (MDS)



**Verification and Validation**

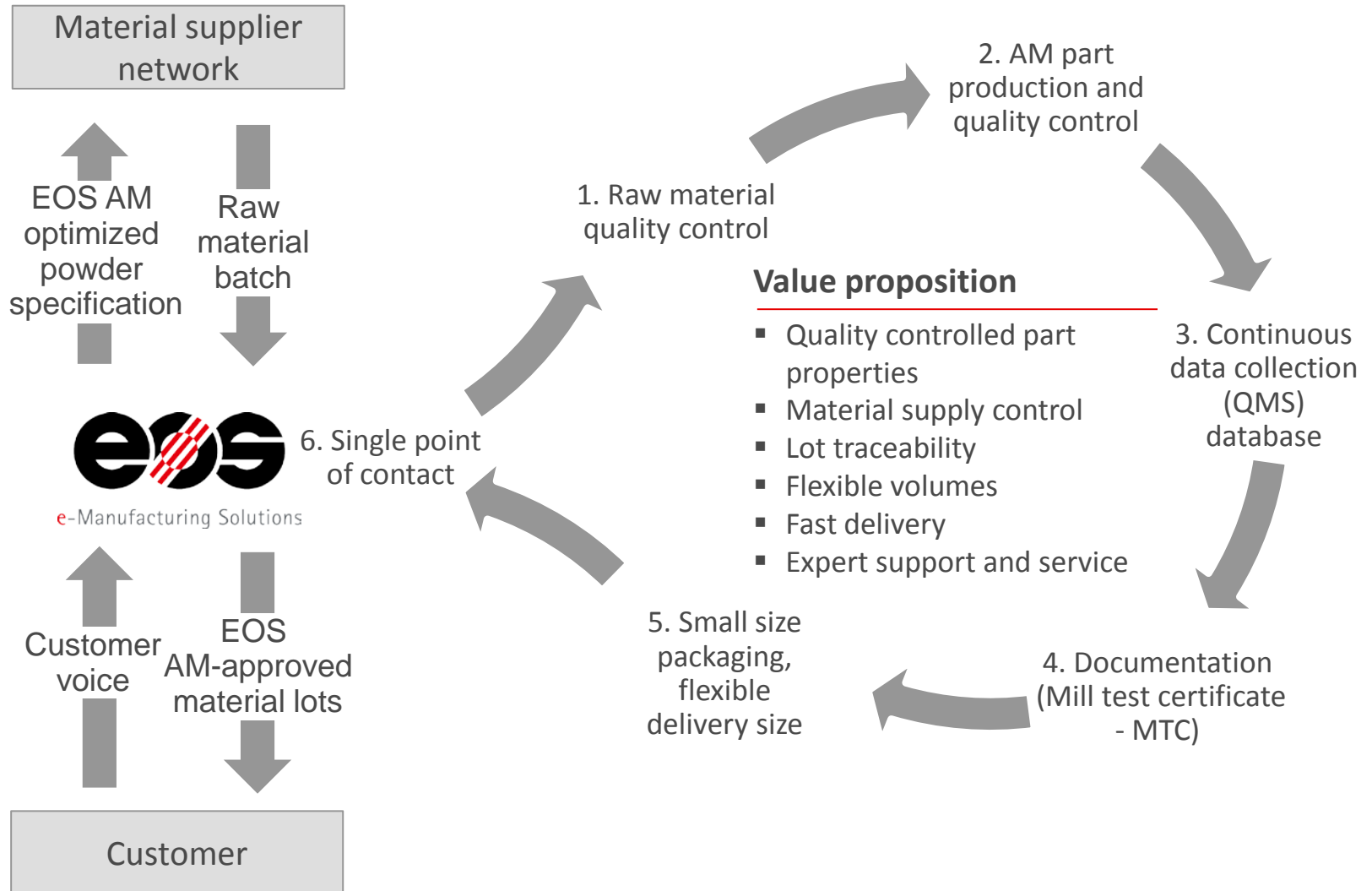


**System, software, parameter and post process specified!**

# Procedures to ensure high material quality suitable for AM<sup>1)</sup>



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# Several procedures are in place to ensure high material quality on a level needed for AM



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## 1. Raw material intake control

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- Selection of suitable raw material supplier
- Detailed definition of powder specification and intake control
- Clear identification numbering of raw material batches and customer released powder lots
- Dedicated storage location for different powder batches

## 4. Documentation (MTC)

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- Material lot specific mill test certificate containing analyses results.
- Delivered with every material delivery in printed and/or digital version

## 2. AM part production and quality control

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- Chemical composition analyses of powder in accredited laboratories
- Part production with defined parameters on qualified system for each material lot
- Test of part material properties to meet specification in material data sheets

## 5. Small size packing and fast delivery

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- Small size packing, as low as 10kg minimum delivery
- Volume agreements for large quantities
- Fast delivery through international warehousing
- Transparent delivery status to inform customer in case of variations ([internal link](#))
- Stock in case of raw material supplier delivery problems

## 3. Continuous data collection (QMS database)

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- Full traceability of materials from customer back to raw material supplier
- Documentation of all quality information for each material lot in database

## 6. Single point of contact

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- Expert support of EOS in case of any variations
- Single point of contact for a continuously increasing variety of materials from different raw material supplier



# The Foundation: Quality Management



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## Quality Management System of EOS Oy

- The Quality Management System of EOS Oy in Finland applies to Design, Manufacture and Sales of Metal materials and processes for EOS Metal – systems.
- EOS Finland has certified quality management system in place in accordance with standard ISO 13485:2003
- In addition, the system meets the requirements of Medical Device directive 93/42/EEC, Annex II for design, manufacture and final inspection



# Manufacturing Insight



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## Production process steps are recorded and signed into a WO traveller

1. Raw material approval
2. Taking QA-sample
  - Building QA-samples
    - Separate WI-record
    - Internal QA-testing
    - Separate measurement protocol
3. QA-approval/issuance of MTC
4. BOM, used lots and amounts
5. Label printing and verification
6. Packing - Preparation work
7. Packing
8. Deviations/NCs
9. Final inspection
10. QA approval for sales

WORK ORDER NO. 236

EOS Travel

Production order reference: 32460

Material	Quantity	Unit	Material	Quantity	Unit
EOSINT M EOS CobaltChrome SP2	2.00	kg			
	2.00	kg			

Material usage table with columns for Material, Quantity, Unit, and Material. Includes handwritten entries for quantities and units.

Signatures: Frank [unclear], [unclear]

WORK ORDER NO. 236

EOSINT M EOS CobaltChrome SP2

Material usage table with columns for Material, Quantity, Unit, and Material. Includes handwritten entries for quantities and units.

Signatures: Frank [unclear], [unclear]

Product label: EOSINT M EOS CobaltChrome SP2, H421201-1, 2014-10, Metal powder EOS CobaltChrome SP2

Barcode: 08100810000009

## Mechanical and chemical testing

- QA –test batch is used for manufacturing of laser sintered QA-samples in qualified EOS Metal machines according to product dependent Work Instructions
  - Product dependent heat treatments are conducted according to relevant Work Instructions
- From the same QA –test batch a small powder sample is sent to external test lab for chemistry analysis
- Mechanical testing of laser sintered QA-samples and chemical testing is conducted by accredited testing lab according to QA-test specifications defined by EOS Finland



Manufacturing procedure for Quality Assurance samples of EOS NickelAlloy HK

SUPPLIER LOT: 12991

AMOUNT (~34kg): ~74 kg

EOS MATERIAL LOT: N151201

EOS MATERIAL NAME: EOS NickelAlloy HK

MACHINE TYPE & S/N: K1200 / S-991

Prep	PAJ	DATE	26.09.2012
Test	ThS	DATE	26.09.2012
Quality	HIA	DATE	26.09.2012

1. Tensile testing according to EN ISO 6893-1:2009

1.1 Rectification of tensile test samples

1.2 Tensile Test Requirements

1.3 Tensile Test Report

2. Hardness Analysis according to EN ISO 6506-1 (Brinell)

2.1 Test Report

# Quality Assurance Insight



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## Internal LAB testing is conducted in EOS Oy's GMP lab

- Measurement protocol and approval by QA of:
  - Sample preparation according to product specific recipes
  - Density measurement
  - Microstructure analysis
- Powder lots meeting the product specifications are being released by QA
- Inspection certificates are issued for every production lot

The collage shows several EOS test certificates and reports. Key elements include:

- Inspection Certificate (top left):** Details a test for 'Mikrostruktur' (Microstructure) with a 'Pass' result.
- Material Certificate (top middle):** Provides technical specifications and test results for a material lot.
- Inspection Certificate (top right):** Details a test for 'Densitet' (Density) with a 'Pass' result.
- Material Certificate (middle left):** Another material test report with a 'Pass' result.
- Material Certificate (middle right):** A third material test report with a 'Pass' result.
- Graph (bottom right):** A line graph titled 'Per Area (Bkg./Total) (Hard Coefficient 0.0)' showing data points across a range of values.

**EOS MII Test Certificate**  
Inspection certificate, according to EN ISO 9001, April 2014

Task name: EOS Material 01 (EOS Oy, 00101001)  
Lot number: 001001  
Manufacturer: EOS Oy, 00101001  
Customer ref code: 00101001

Property	Test method	Units	Specification	Result
Particle size distribution	ISO 4402	µm	100	100
Mean particle size	ISO 4402	µm	100	100

**EOS MII Test Certificate**  
Analysis of powder

Property	Test method	Units	Specification	Result
Particle size distribution	ISO 4402	µm	100	100
Mean particle size	ISO 4402	µm	100	100

**EOS MII Test Certificate**  
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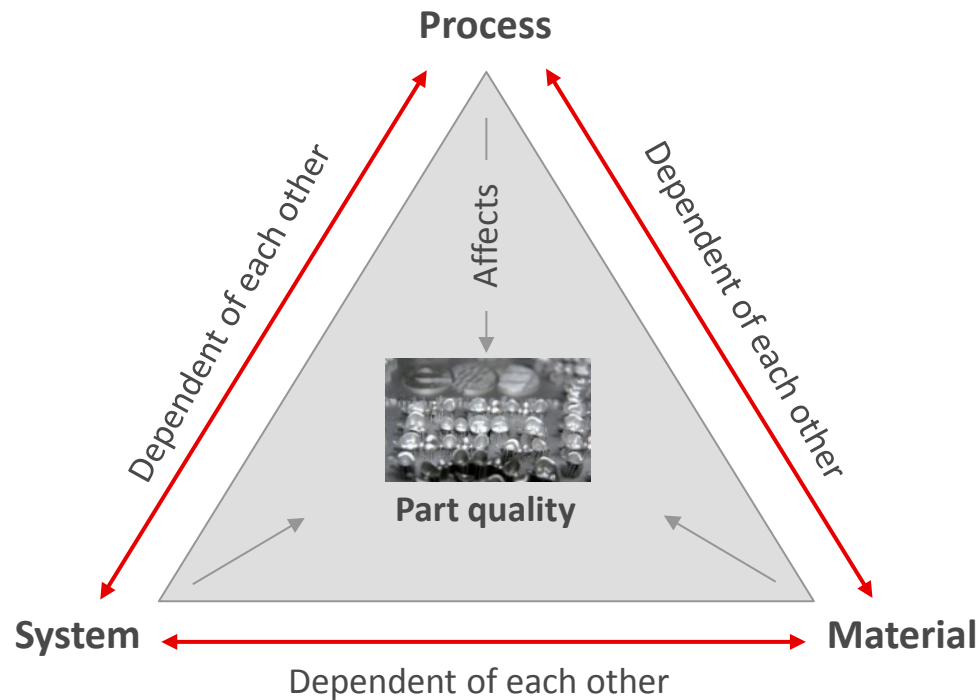
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Manufacturer: EOS Oy, 00101001  
Customer ref code: 00101001

# Summary



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**Materials are an important part of a well balanced high quality part generation!**



**There is nothing „Magic“ – Thank You!**