FDA Additive Manufacturing Workshop

Perspectives on Pre-Printing Considerations (Metals)

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Agenda

- EOS

- Perspectives on Pre-Printing Considerations (Metals)
EOS

- **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**
Agenda

- EOS – Leader in e-Manufacturing Solutions
- Perspectives on Pre-Printing Considerations (Metals)
The well balanced “Magic” AM Triangle ...

... will ensure constantly high quality parts!
Metal Powder Design and Development

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$^1$)

1. Raw material quality control
2. AM part production and quality control
3. Continuous data collection (QMS) database
4. Documentation (Mill test certificate - MTC)
5. Small size packaging, flexible delivery size
6. Single point of contact

Value proposition
- Quality controlled part properties
- Material supply control
- Lot traceability
- Flexible volumes
- Fast delivery
- Expert support and service

Material supplier network
- EOS AM optimized powder specification
- Raw material batch
- EOS AM-approved material lots

Customer voice
- Customer

1) Additive Manufacturing
Several procedures are in place to ensure high material quality on a level needed for AM

1. **Raw material intake control**
   - 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

2. **AM part production and quality control**
   - 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

3. **Continuous data collection (QMS database)**
   - Full traceability of materials from customer back to raw material supplier
   - Documentation of all quality information for each material lot in database

4. **Documentation (MTC)**
   - Material lot specific mill test certificate containing analyses results.
   - Delivered with every material delivery in printed and/or digital version

5. **Small size packing and fast delivery**
   - 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

6. **Single point of contact**
   - 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

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

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
Quality Assurance Insight

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
Quality Assurance Insight

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
Summary

There is nothing „Magic“ – Thank You!

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