Initial considerations to 3D print in a certified MedTech environment.

researchXchange Seminar / IEEE
MedTech Additive Manufacturing

Example of Metallic Use Cases

<table>
<thead>
<tr>
<th>Individualization (lot size one)</th>
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</thead>
<tbody>
<tr>
<td>Short Lead Time</td>
</tr>
<tr>
<td>Manufacturing of Complex Shapes</td>
</tr>
<tr>
<td>Anatomical Shape</td>
</tr>
<tr>
<td>Improved properties and functionalities</td>
</tr>
</tbody>
</table>

**Opportunities**

- Removable denture
- Spine cages
- Bone reamer
- Acetabulum cup
- Custom cranial implant

**Challenges**

- Adapted design strategy
- Control of process parameters
- Surface finishing and cleaning
- Initial Investments
Acetabulum Cup

Acetabular cup with lattice structure used in total hip replacement (THR) surgeries or hip revision surgeries. The polyethylene or ceramic inlay is fixed in the inner cup geometry.

Material: Ti-6Al-4V Grades 5 and 23 (ELI), ASTM F136
Process: Electron Beam or SLM, post processing
Regulatory Pathway: Non-active implant class III
Implant functionality: Load carrier and bone ingrowth promoter
Some Considerations
ISO 13485

ISO 13485 is a standard defining the aspects of a Quality Management System (QMS) for medical devices.

Depending on the service you are providing is specific to the medical device industry, ISO 13485 might appropriate to be implemented. It is also about building trust in the MedTech Industry.

Ref: https://www.avanti-europe.ch/who-needs-to-get-certified-according-iso-13485/
Production under ISO 13485
End to End process chain.

ISO 13485:2016

Qualified Suppliers

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Manufacturing MedTech AM Route

AM has to be integrated into a supply chain under a defined QMS

1) Powder inspection  
2) Data preparation  
3) Build job (Additive Manufacturing)  
4) Unpacking / (de-powdering)  
5) Heat treatment / Pressing  
6) Support removal / post machining  
7) *(Hot isostatic pressing)*  
8) Sand blasting / vibration grinding  
9) Surface treatment / Polishing  
10) Laser marking  
11) Cleaning  
12) Sterilization

Quality Management System: ISO 13485  
Internal and external processes

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Starting from a bar of metal, we use a CNC equipment to remove material until we obtain the right dimensions. The subtractive process is well known, the risks as well. Mitigation measures are in place.

For 3D printing, everything is built from a powder. What is inside the part cannot be inspected. The remaining questions are: “Did the laser power really melted the metal on all the layer? Is this reliable and reproducible?”

Validation activity should now see the process in a different way than a CNC process. The parameters are different and the risks are also different.
Unpacking / Depowdering…

Free powder

Semi fused powder

Medical device surface
Production Qualification

1) Machine Qualification
IQ: Installation Qualification
OQ: Operational Qualification
PQ: Performance Qualification

2) Working Instruction
Personnel Qualification
SOP: Standard Operating Procedures
Checklists

3) Process Validation
AM
Post-processing
...


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V&V and ISO 13485

In the MedTech filed, validation is part of the Norm ISO 13485.

Under the clause 7.5.6, EN ISO 13485 mandates that organizations validate those processes for which verification is not possible.

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OQ / PQ Runs @ m4m

OQ Build Jobs
8 worst case runs
Min / Max investigation

PQ Build Jobs
30 nominal runs
Consistency / powder degradation

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OQ Runs: Min / Max Definition

- Scan velocity (mm/s): 200, 100, 300
- Layer thickness (um): 1.8, 2.5, 0.5 (defocused), 3.2
- Gas flow velocity (m/s): 13, 5, 11, 5, 80, 0, 0.5 (defocused), 2.5, 3.2
- Laser focus (mm): 135, 5, 115, 5, 80, 0, 0 (focused)
- Laser power (W): 135, 20
- Leak rate (ppm/h): 18, 855, 905, 955
- Job cross section (mm²): 800, 300

Minimum energy density
Maximum energy density
### Acceptance Criteria

<table>
<thead>
<tr>
<th>Acceptance Criteria</th>
<th>Topic</th>
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</thead>
<tbody>
<tr>
<td>ASTM B348-B348M</td>
<td>Material (Ti64)</td>
</tr>
<tr>
<td>ASTM F136</td>
<td>Material (Ti64)</td>
</tr>
<tr>
<td>ASTM F899</td>
<td>Material (SST)</td>
</tr>
<tr>
<td>ISO 10993</td>
<td>Biocompatibility</td>
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<td>...</td>
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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.
Material Qualification

Energy density is used as base for material qualification. Density and mechanical performance are defined as testing criteria.

\[ E_d = \frac{P_{\text{laser}}}{v_{\text{scan}} \Delta h_{\text{hatch}} h_{\text{layer}}} \left[ \frac{J}{m^3} \right] \]

Energy Density \( E = L/(v \times \Delta y \times \Delta z) \)

Build Rate: \( V = v \times \Delta y \times \Delta z \)
Material Qualification

Energy density is used as base for material qualification. Density and mechanical performance are defined as testing criteria.
Machine Acceptance Build Job
Biocompatibility Assessment

Testing to make sure the 3D printed materials are safe to use in conjunction with the human body and medical procedures.
# Medical Device Classification (MDR)

<table>
<thead>
<tr>
<th>Class</th>
<th>Examples</th>
<th>Notified body</th>
</tr>
</thead>
<tbody>
<tr>
<td>CLASS I</td>
<td>Wheelchair, Otoscope, Scalpel, Plaster</td>
<td>Reprocessed Measuring function, Delivered sterile, Syringe, Teeth implant, X-Ray device, Tracheotomy tube, Blood bag, Implantable plate, Condoms, Drug coated stent, Spinal disc cage, Breast implants, Pacemaker</td>
</tr>
<tr>
<td>CLASS IIa</td>
<td>CLASS I special function</td>
<td></td>
</tr>
<tr>
<td>CLASS IIb</td>
<td>M, R, S</td>
<td></td>
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<tr>
<td>CLASS III</td>
<td>High</td>
<td></td>
</tr>
</tbody>
</table>

**Risk Levels:**
- **Low:** Self
- **High:** Notified body
MD Classification (MDR)

Classification of a medical device will depend upon a series of factors, including:

- how long the device is intended to be in continuous use
- whether or not the device is invasive or surgically invasive,
- whether the device is implantable or active
- whether or not the device contains a substance, which in its own right is considered to be a medicinal substance and has action ancillary to that of the device.
MD Classification (MDR)
ASTM F42 / ISO TC 261

21 PUBLISHED ISO STANDARDS * under the direct responsibility of ISO/TC 261

33 ISO STANDARDS UNDER DEVELOPMENT * under the direct responsibility of ISO/TC 261
Do you have any questions?

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