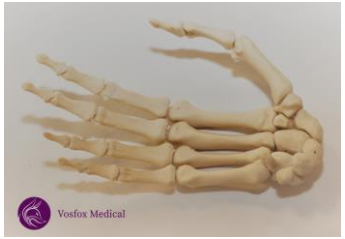
Vosfox Medical

3D printer validation for medical applications, where do you start?

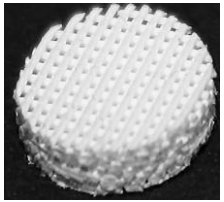
Sandra de Vos

Introduction Vosfox Medical



Contract manufacturing of medical devices and pharma

- Small scale production
  - Production, assembly, packaging, sterilization
  - Support packaging/sterilization design
  - Validations
- 3D Medical Printing
  - Bioprinters, SLA, FDM
  - Cleanroom
  - ISO13485 - GMP



Validation, why should I?

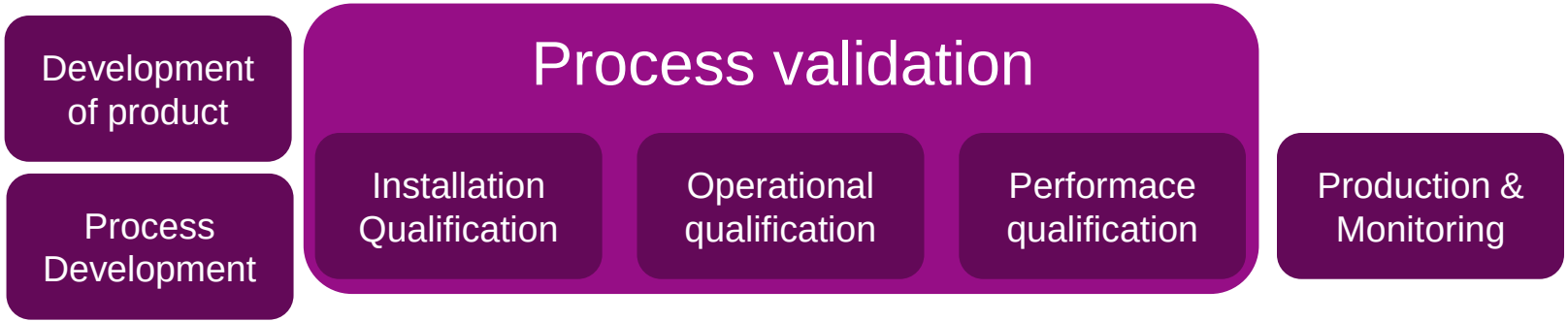
- To show process is under control.
- When verification is not possible

Validation of the production process of product X

Which processes to validate

- Production/software processes
- Cleanroom / Sterilization / Packaging / Transport
- Test methods
- Cleaning

Validation process overview



Development of product

Development

- Design & Development process
  - URS, Input, Output, Verification, Design Reviews, Validation
- One output: Product specification
  - Drawing with dimensions (criticality) and tolerances
  - QC testing (dimension, functionality, GPC, HPLC)
  - Material, packaging, sterilization requirements
- User Requirement specification 3D printer
  - Functional requirements (Temp,speed, etc.) – Mandatory or Beneficial
  - Software/HM interface requirements
  - Safety and cleaning requirements

Process Development

Installation Qualification

New equipment or change

- Did the supplier deliver as he has promised
  - URS requirements fulfilled
- Implement equipment into quality system
  - identification, maintenance, calibration, safety features, work instructions etc.
- Functional testing according to manufacturer specifications
- Software validation
  - Firmware
  - Slicer
  - CAD

Operational qualification

Control your process

- Process Development
  - Engineering study protocol and report
  - Define critical parameters (UV power, time, temperature location buildplate)
  - Define roughly process window
  - Test influence of (critical) parameters on outcome of product
- Design of Experiment
  - Define interaction between different critical parameters
  - set your process parameter boundaries
- Verification Run
  - Test different settings in process window (centre and near boundaries).
  - Low, nominal and high setting

Operational qualification

ISO-ASTM 52920

Additive manufacturing — Qualification principles — Requirements for industrial additive manufacturing sites

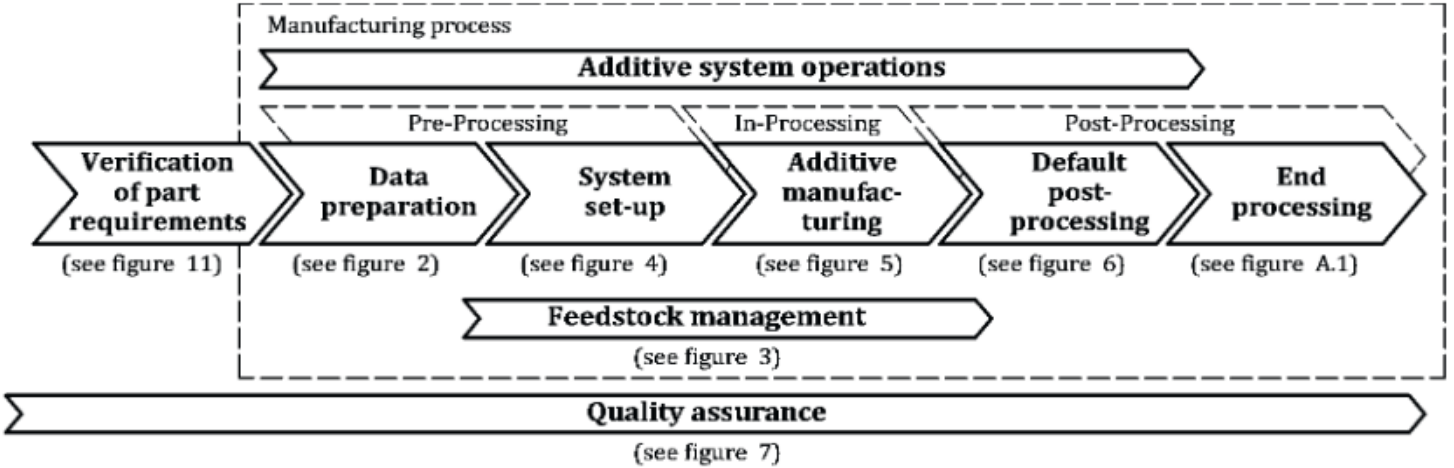
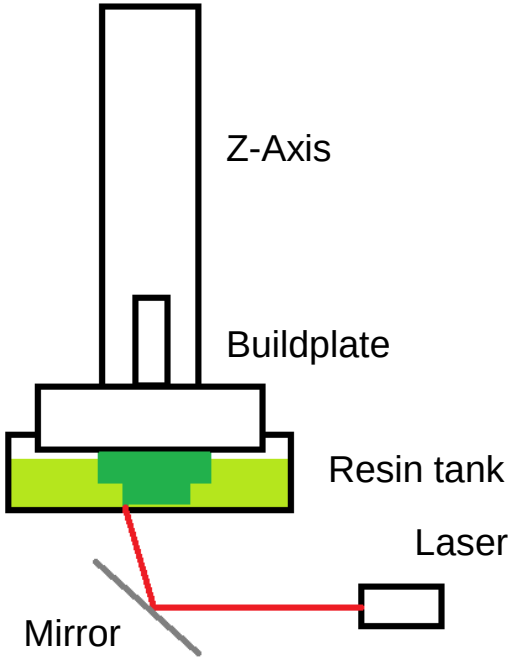


Figure 1 — Quality ensured process in an additive manufacturing production site

Example engineering study SLA

Understand your 3D printing process.

- Materials
  - Viscosity, accuracy possible
- Technical aspects
  - Type of SLA → Spot size
  - Calibration
  - Material build plate
- Post-printing
  - Washing
  - Curing
  - Removing support



Operational qualification

Critical parameters for SLA printing:

- Print process
  - Creation .stl/Gcodes → dimension
  - Layer height → resolution
  - Build plate location → Dimensions
  - Laser power → crosslinking
  - Laser spot size → resolution
  - Exposure time → crosslinking / layer adhesion
  - Resin temperature → crosslinking
  - % virgin resin → irregularities in part
- Post-print process
  - Washing time → uncured resin / leachables
  - Renew IPA → contamination, efficacy
  - Drying time → dimensions compromised
  - Post-curing time → strength / leachables
  - Post-curing temperature → strength

Production

Performace qualification

Production & Monitoring

- PQ runs
  - 3 batches sufficient?
  - Batch versus builds
  - Can be used for clinical evaluation
- Monitoring
  - Periodically review if process is in validated state
  - QC data analysis
  - Change control

Personalized 3D printing

Personalized is not always custom-made

- Mass-produced devices which need to be adapted to meet the specific requirements of any professional user shall not be considered to be custom made devices (MDR 2017-745)

Truly custom made products cannot be validated

Mass produced adapted products must be valdiated

- Define product families with similar characteristics and define boundaries.
- Test a representative (e.g. worst case, most difficult, largest, smallest)

So where do you start?

- Know your product
- Define the requirements for your equipment
- Understand your production process
- Then extensively test your equipment and product

Good Luck!

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Thank you

Questions?

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