Design and Validation

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- **How does process validation for general 3D printing/proto-typing need to be adapted, taking into account the nature of medical devices that may be:**
  - **implantable or non-implantable,**
  - **load bearing or non-load bearing,**
  - **and patient matched or prescribed stock sizes?**

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- **How is the software used in 3D printing different or the same as the software used in other automated manufacturing processes?**
  - **Are new considerations necessary for validating the interoperability/compatibility of software programs and versions for use with different file types, printers, and other accessories to produce safe and effective medical devices?**

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- **What process parameters should be considered to be established during process validation and subsequently monitored? How are the parameters in process validation evaluated to be predictive of devices that conform to established specifications?**

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- **What non-destructive testing methods are available for device validation or verification (e.g. volumetric subsurface imaging like micro-CT, optical coherence tomography)? What quantitative validation metrics can imaging provide?**

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- **How do you approach reproducibility (1) across printers (2) at different locations of the printer bed within the same run?**

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