



Regulating the future: Navigating the complexities of 3D Printing in the Pharmaceutical Industry.

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SA02



The difference is in the data.™

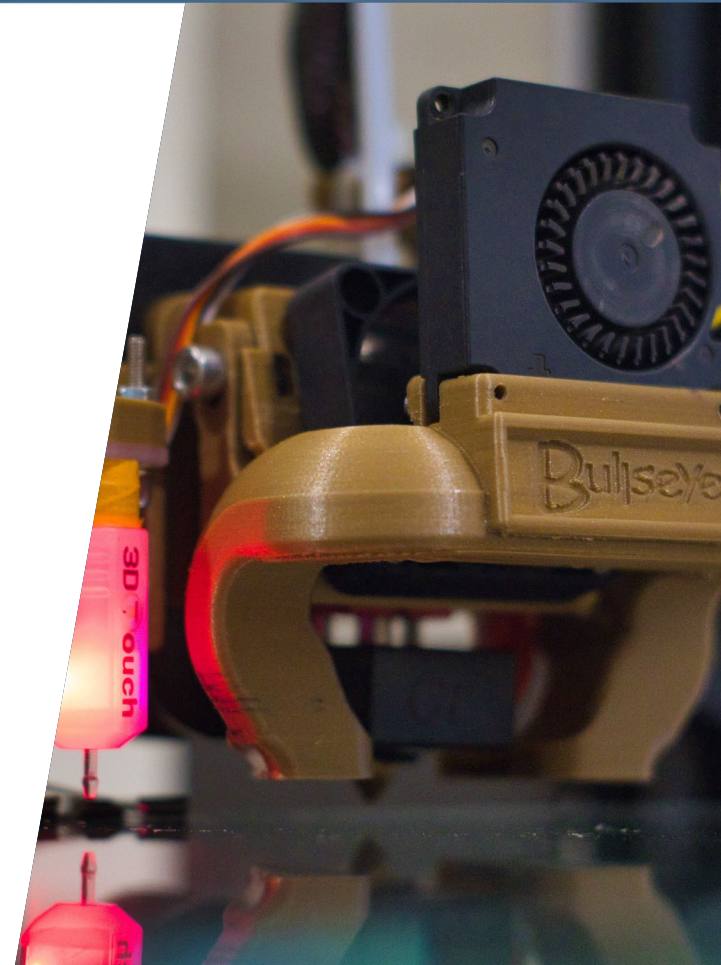
Agenda

- Background
 - Defining 3D printing
 - 3D printing manufacturing process
- Real world application
 - Randomized controlled trial: Personalized Titanium Plates
 - Randomized longitudinal trial: Patient-specific orbital implants
- Health authority conformance
 - Healthcare facilities
 - FDA Guidance
 - EMA and MDR
- Conclusion

Background

Why 3D printing?

- 3D printing -> Personalized Healthcare
- 3D Printing at the point of care



Background

3D printing Definition

3D Object

3D Model

Additive
manufacturing

Background

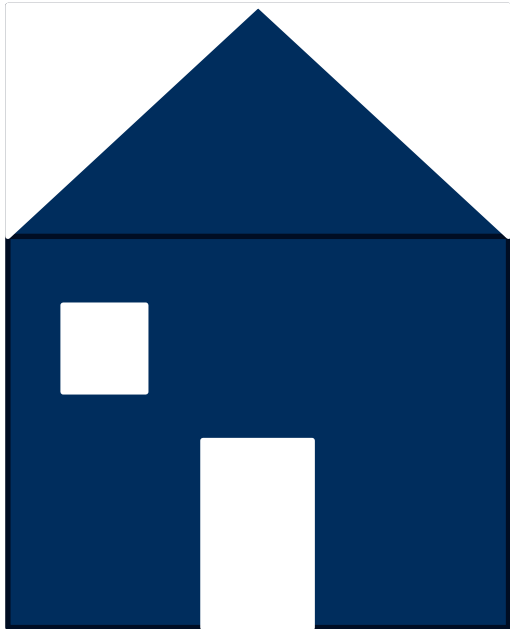
Subtractive (Traditional)



Additive (3D Printing)

Background

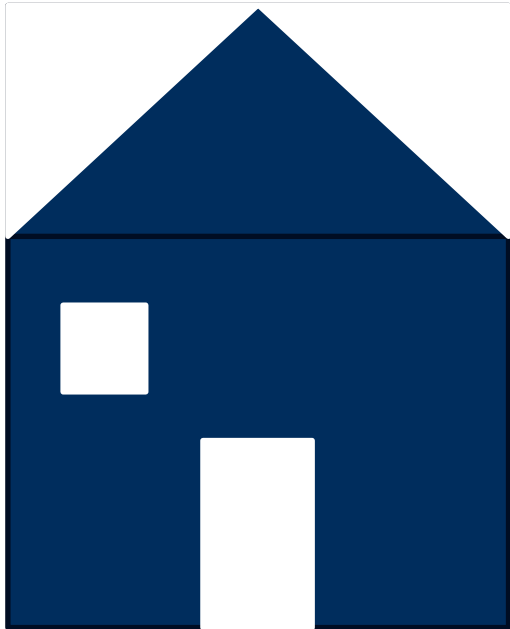
Subtractive (Traditional)



Additive (3D Printing)

Background

Subtractive (Traditional)

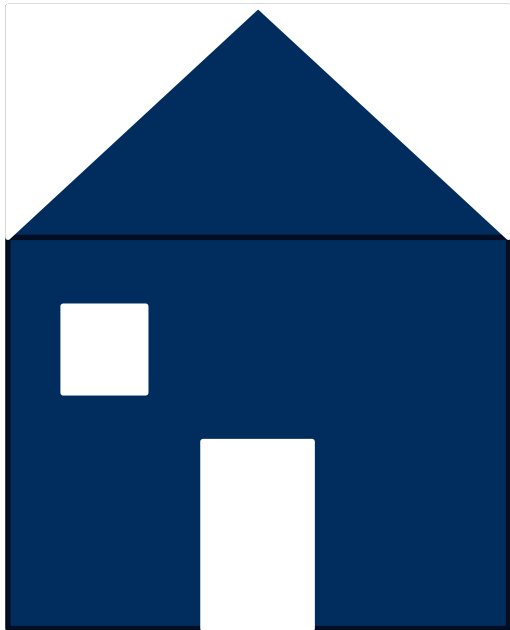


Additive (3D Printing)



Background

Subtractive (Traditional)

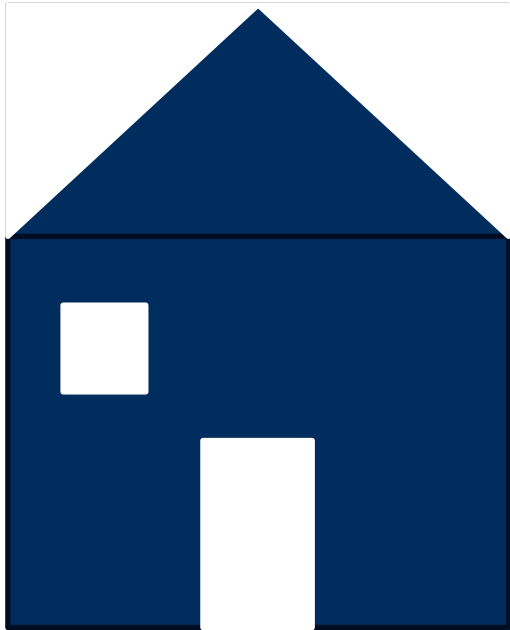


Additive (3D Printing)

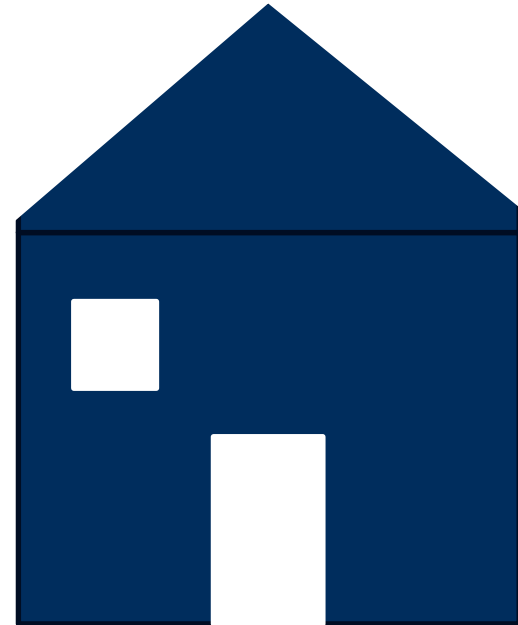


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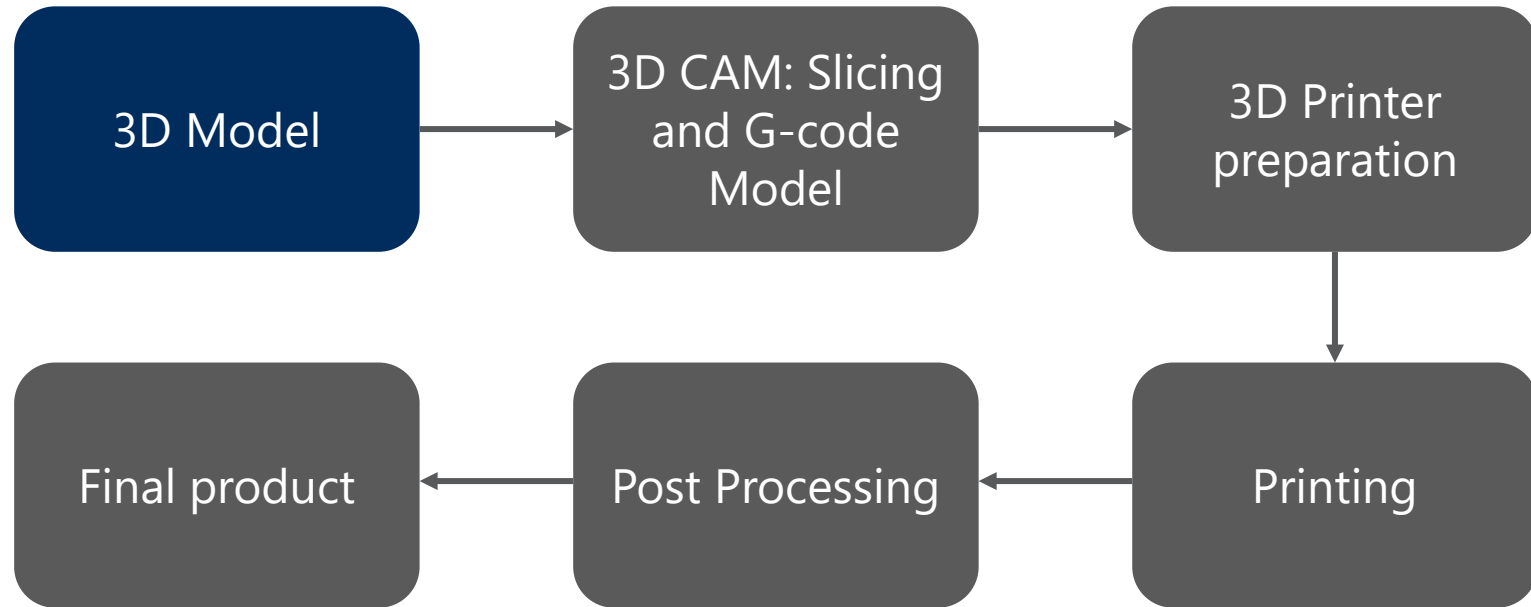
Subtractive (Traditional)



Additive (3D Printing)

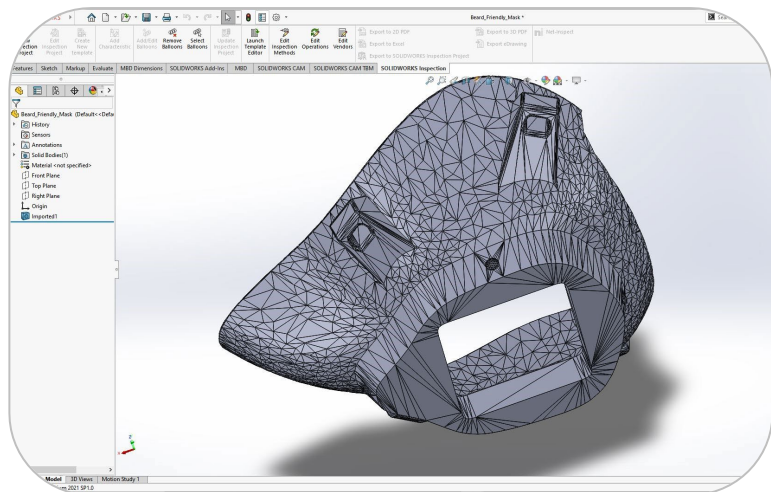


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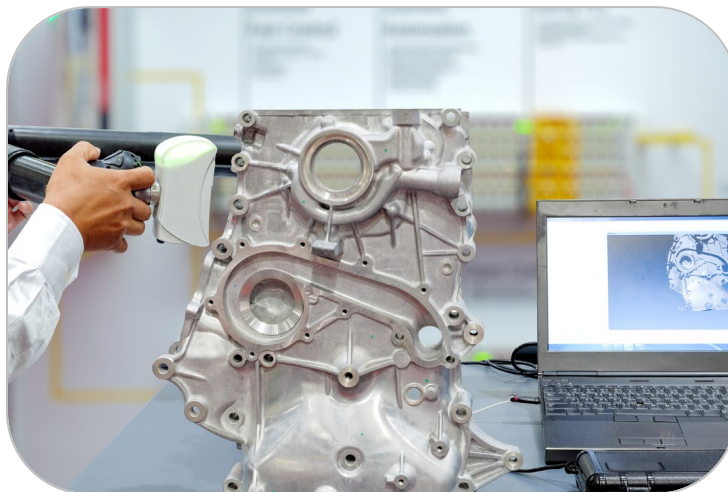


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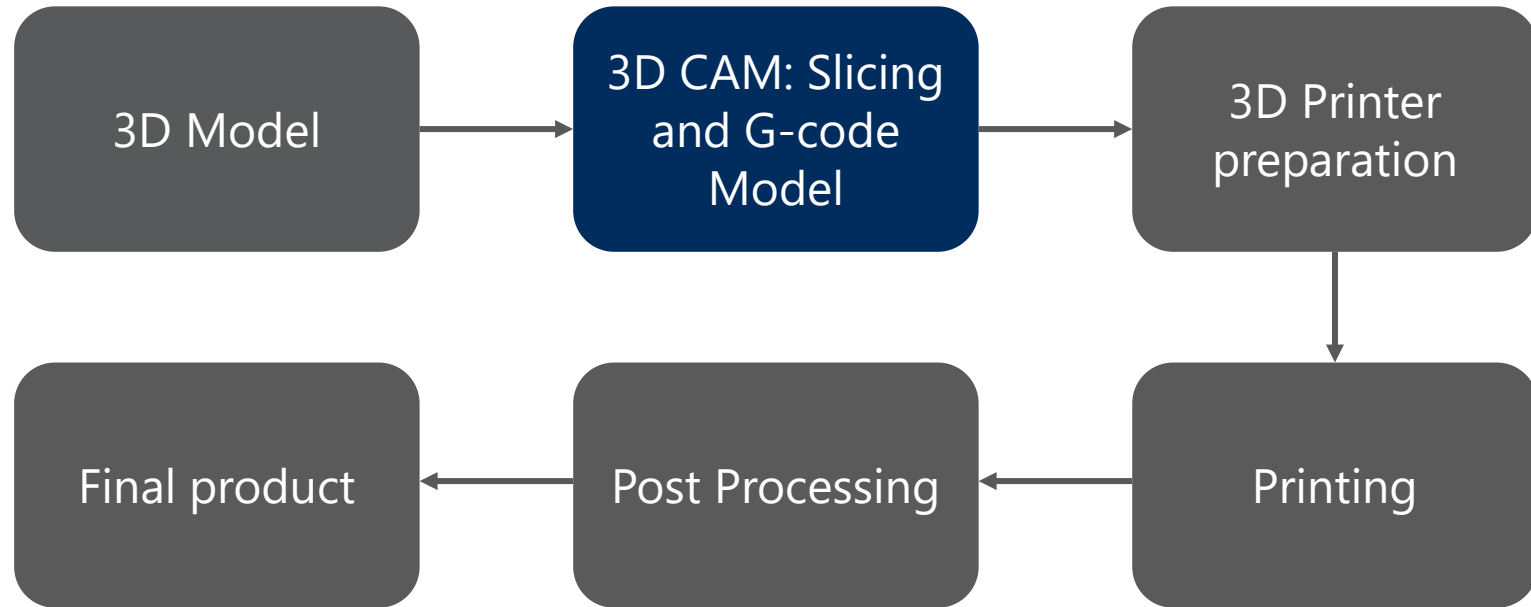
CAD



Scanning

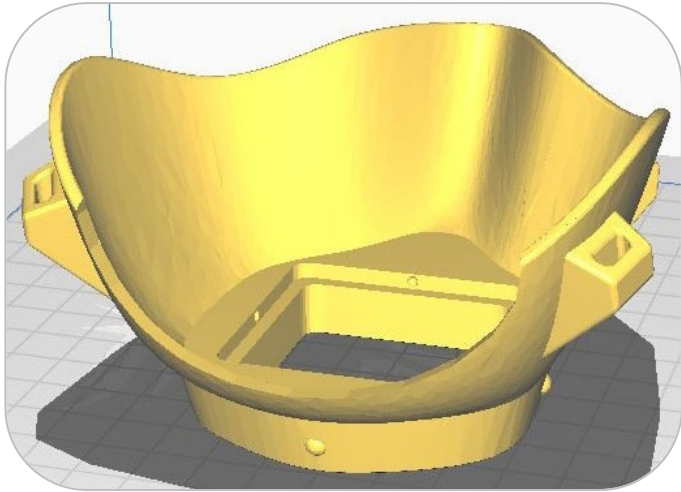


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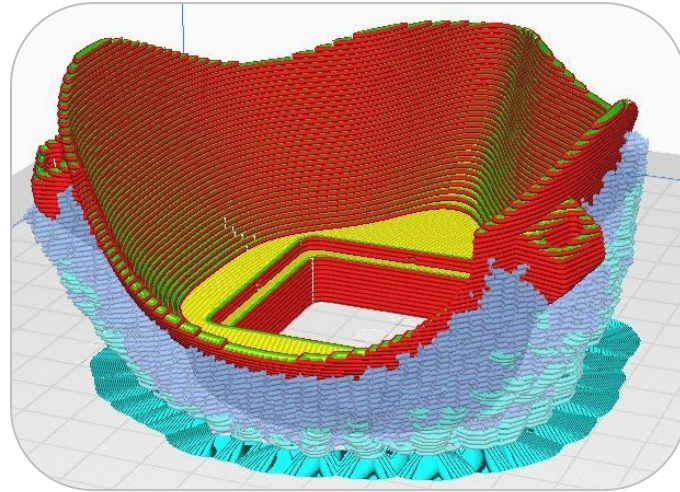


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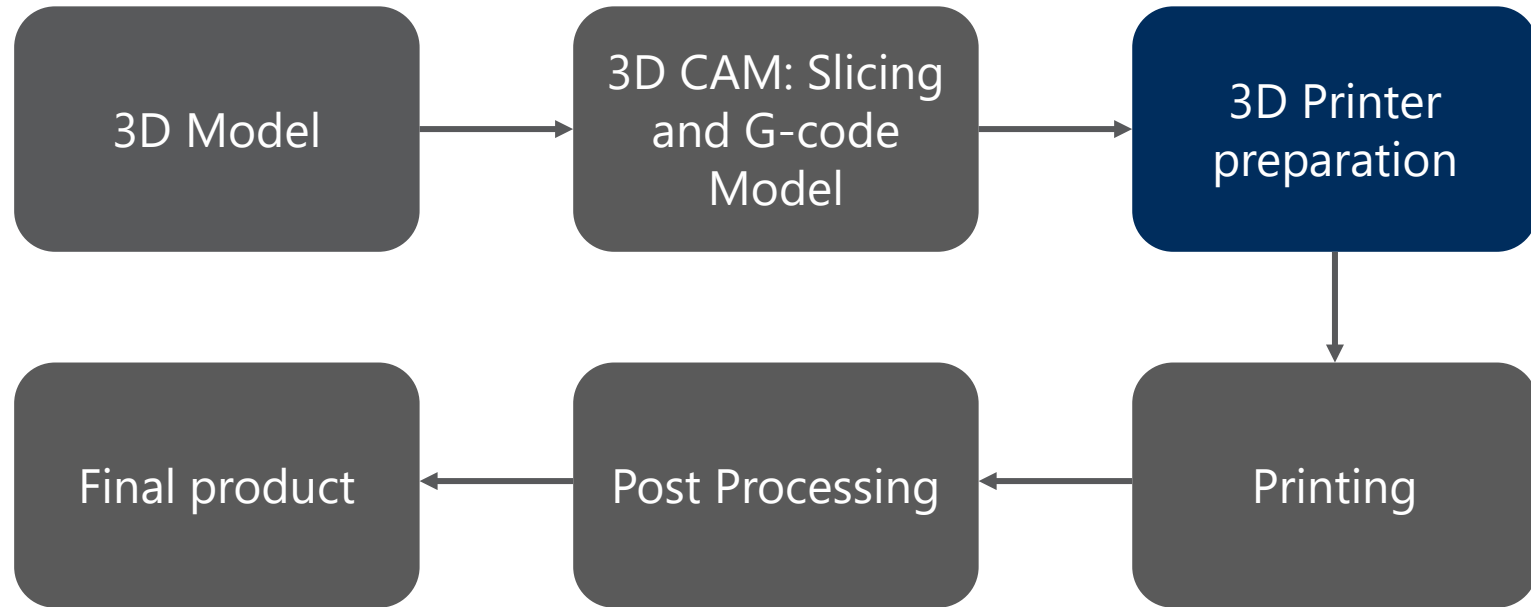
Face mask with filter slot



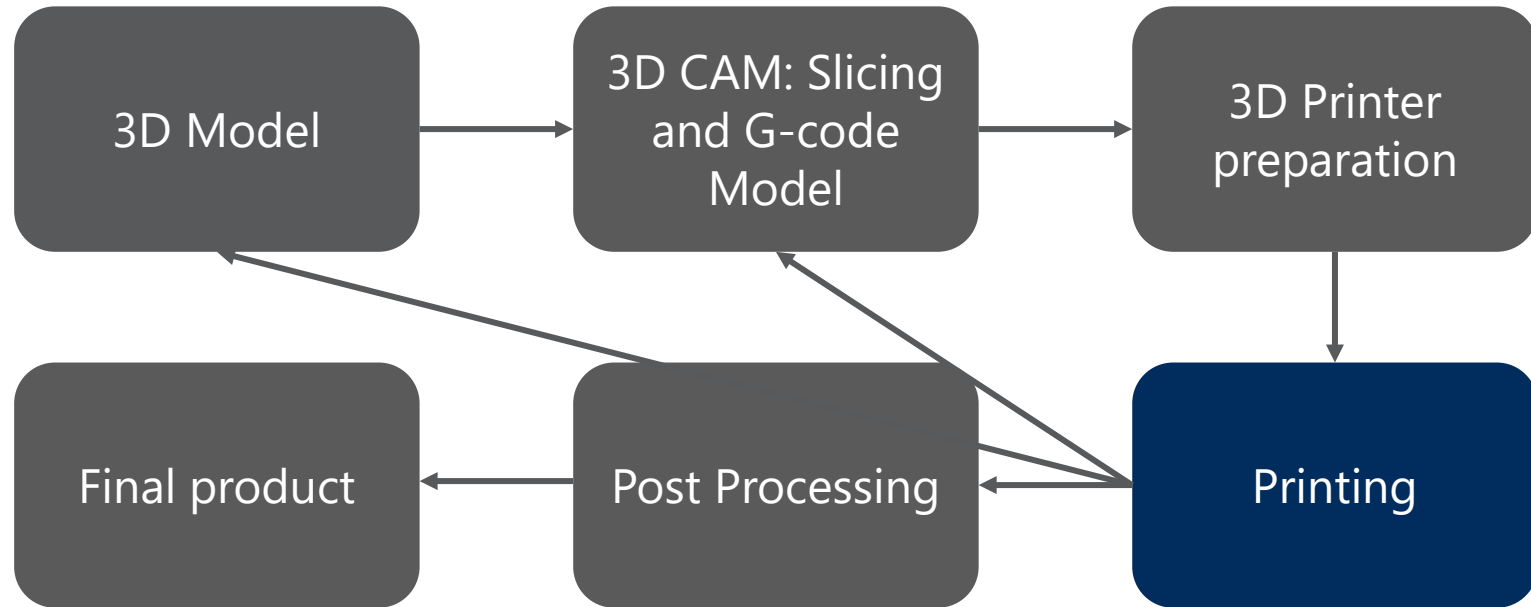
Sliced and supported model



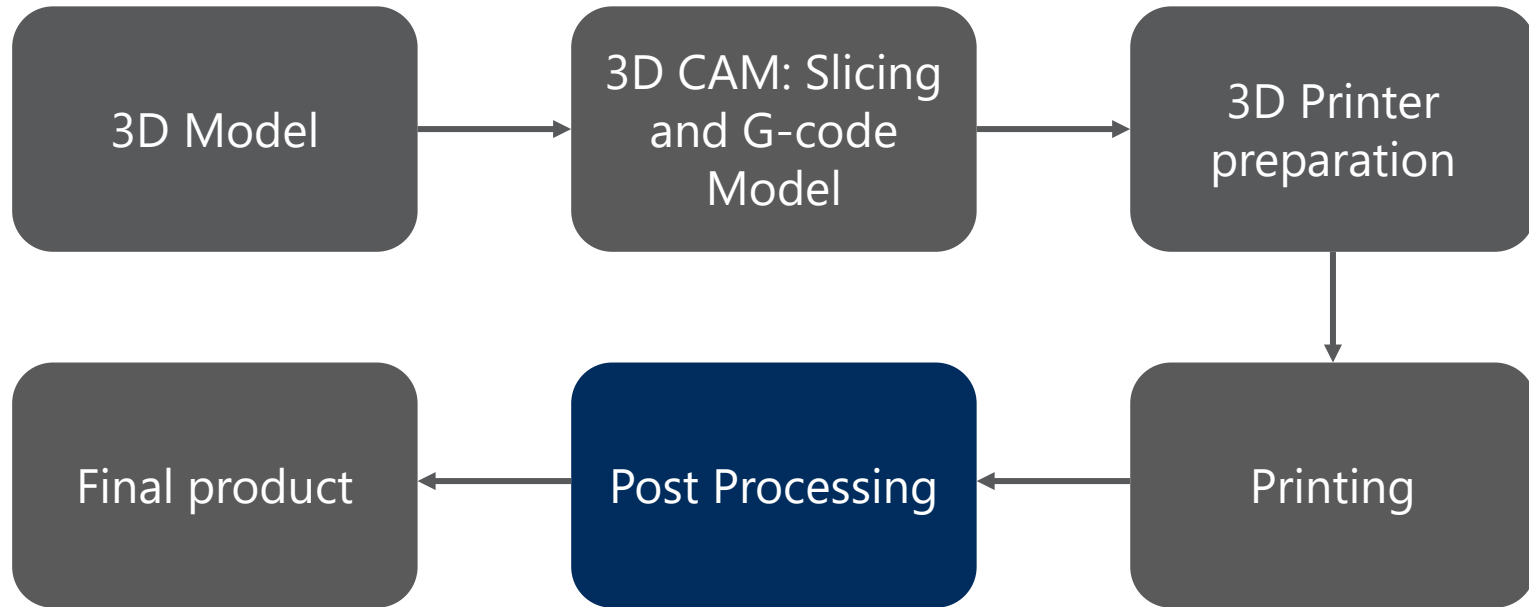
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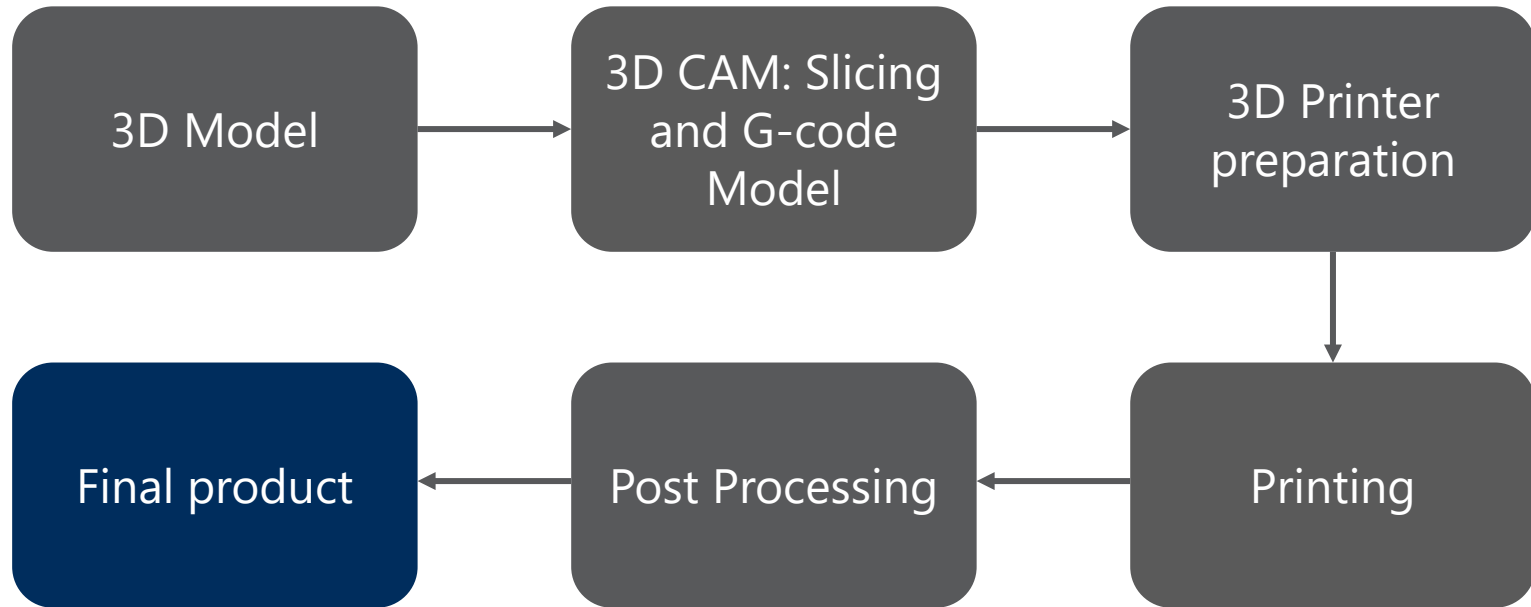
Background



Background



Background





Real World Applications

Study objectives and analysis

- Personalized 3DP Titanium Plates vs Traditional implants
- Primary Objective - Interbody radiographic fusion rate 6 months postoperatively



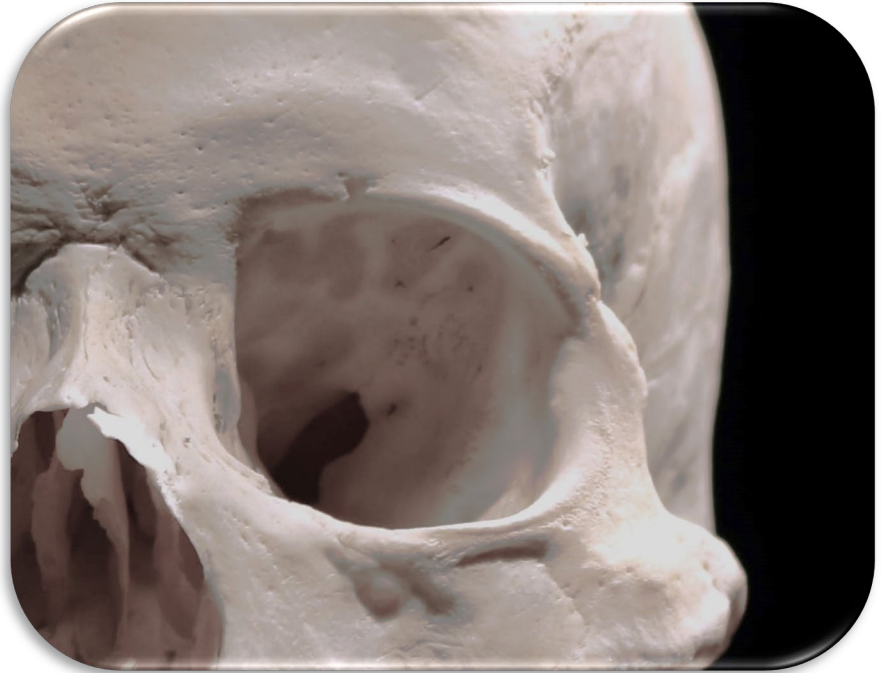
Study objectives and analysis

Arm	3D-printed Titanium Cage	(PEEK) Cage
Participants Analyzed	24	26
Units Analyzed	34	40
BSF Grade 3	27 (79,4)	10 (25,0)
BSF Grade 2	6 (17,6)	24 (60,0)
BSF Grade 1	0 (0,0)	6 (15,0)
Cage Removed	1 (2,9)	0 (0,0)

- Percentages are calculated using the number of units analyzed.

Study objectives and analysis

- Pre-adapted implants vs Non-patient-specific orbital implants
- Primary Objective - Orbital Volume of the Injured Orbit Compared to the Contralateral Uninjured Orbit

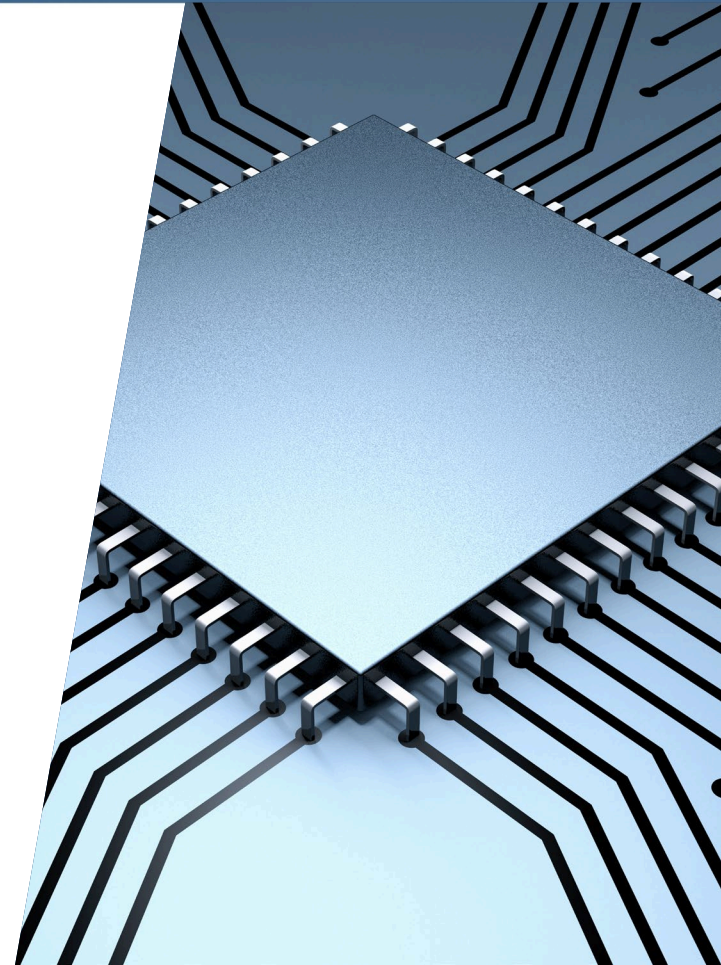


Study objectives and analysis

Arm	Patient-specific (Personalized)	Non-patient-specific (Non-Personalized)
Participants Analyzed	13	12
Uninjured Orbit cm ³	23	22,8
Reconstructed Orbit cm ³	23,5	28,6
Length of surgery	32,6	53,3
Time interval from plate insertion to fixation	15,8	41,4
Total Cost	3602,54	4287,25

Study objectives and analysis

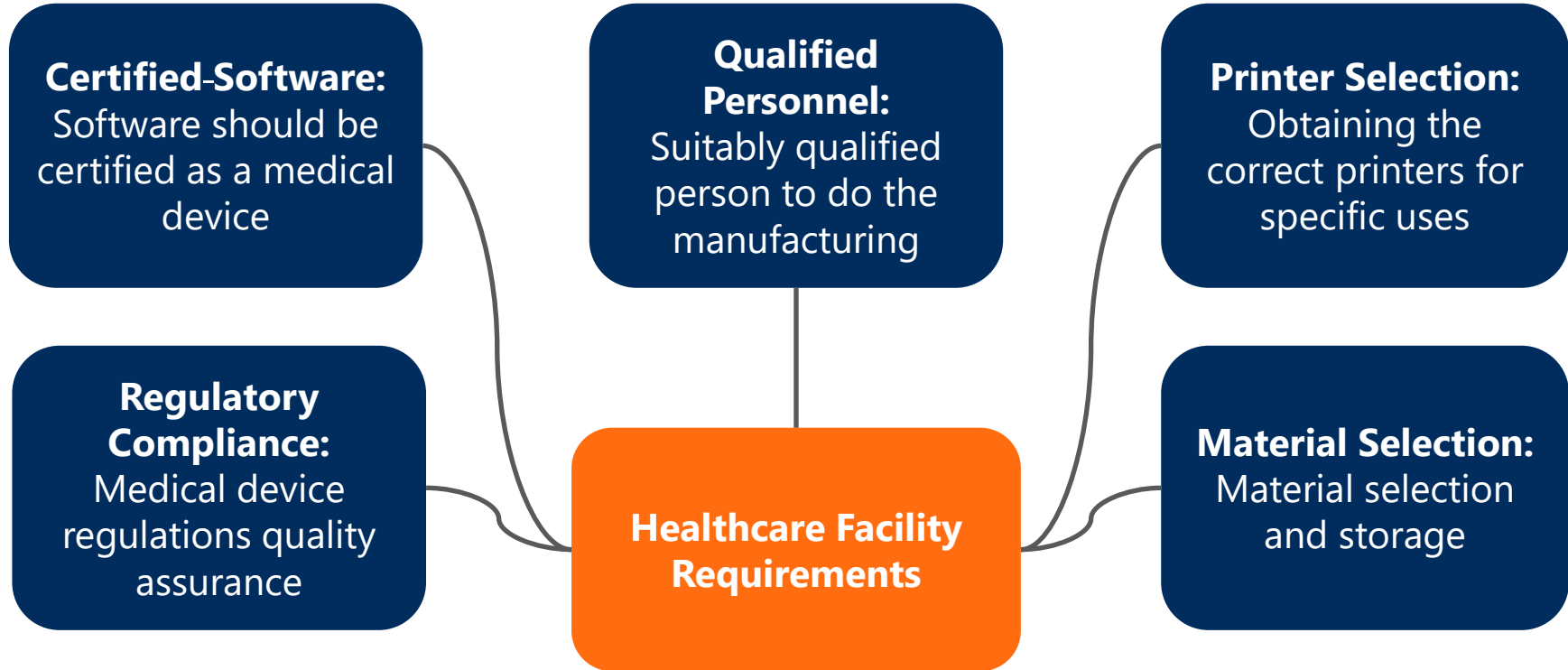
- Heterogeneity with added complexity
- Innovation vs standardization
- Device tolerances and maintenance
- Statistical analysis of individuals





Health Authority Conformance

Health authority conformance



Health authority conformance

**Medical Device
Production System
(MDPS)**

Responsible Party



**POC By
Manufacturer In
The Hospital**

Responsible Party

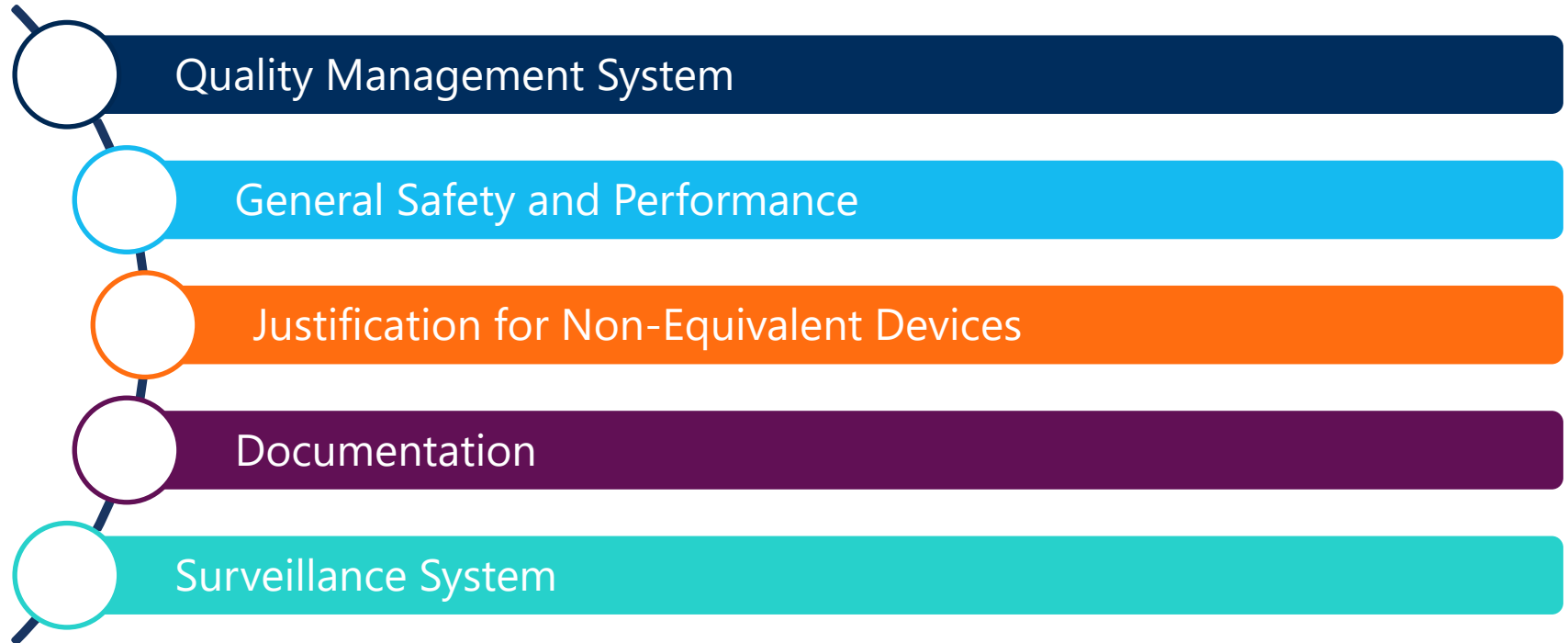


**Hospital As
Manufacturer**

Responsible Party



Health authority conformance





Conclusion





Thank you!
Any questions?

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