

# CONCEPT GENERATION & DEVELOPMENT >

1

CONCEPT GENERATION

DESIGN FOR MANUFACTURE

A concept design that “works like” your intended design

WORKS LIKE

2

DESIGN FEASIBILITY

DESIGN FOR MANUFACTURE

A frozen design that “works like and looks like” the final device

WORKS LIKE + LOOKS LIKE

3

DESIGN VERIFICATION & VALIDATION

PILOT MANUFACTURING

Validation that design outputs meet design inputs. Comprehensive product testing including: aging, packaging, transportation, biocompatibility, sterilization

OUTPUTS = INPUTS; SPECIFICATIONS & CLINICAL

4

COMMERCIALIZATION & RAMP

VALIDATION & RAMP

Validations of product and process capability, regulatory approval, transfer to production and line ramp.

FINAL PRODUCT

5

PRODUCT LIFE CYCLE MANAGEMENT

VOLUME MANUFACTURING

Steady state manufacturing of the approved product. Next generation product planning.

<COMMERCIALIZATION