BIOMERICS

DESIGN & DEVELOPMENT PROCESS

UNDERSTANDING OUR INTERNAL PROCESSES FOR DESIGNING AND DEVELOPING MEDICAL DEVICE PRODUCTS THAT MEET AND EXCEED CUSTOMERS NEEDS AND REQUIREMENTS

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SCIENTISTS STUDY THE WORLD AS IT IS; ENGINEERS CREATE THE WORLD THAT HAS NEVER BEEN.

-THEODORE VON KARMAN

ABOUT US

Biomerics has roots in Utah dating back to 1994, where the company first started as a leading custom injection molding facility, within the Intermountain West. In 2009, the company went through a re-branding initiative to reflect a new focus to become a vertically integrated contract manufacturer for the medical device industry known as "BIOMERICS." Biomerics' strategic direction to grow organically and through acquisitions came with a vision to become a mid-market medical device manufacturer that specialized in the design, development, and production of medical devices for interventional procedures and markets in cardiovascular, structural heart, cardiac rhythm management, electrophysiology, neurovascular, vascular access, and gastrointestinal/urology. Biomerics focuses its wide range of capabilities into seven "Centers of Excellence" including injection molding, materials, metals processing, extrusion, machining, balloon and balloon catheters, as well as shafts, sheaths and steerables.

Today, Biomerics has experienced exponential growth and executes on its strategic direction as a fully vertically integrated contract manufacturer. Biomerics recently merged with a metal processing facility in Monroe, Conn., to expand its capabilities in laser machining, swiss machining, and metal finishing. It now operates eight facilities in five states including, Costa Rica. All facilities are ISO-13485:2016 compliant, and the company employs over 1300 people.

INTRODUCTION

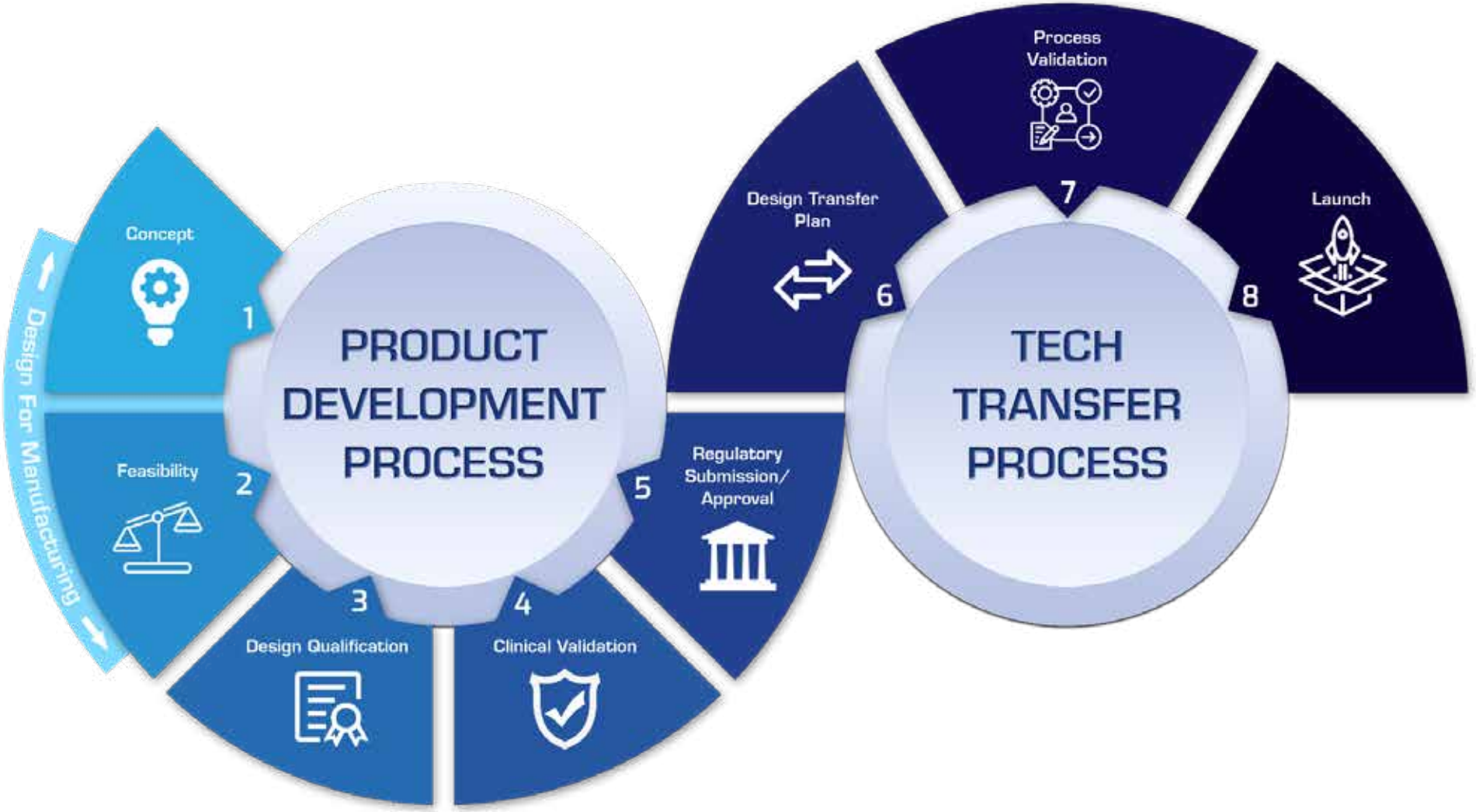
THE PROCESS

This document is designed to assist current and future customers of the process we follow to design and develop medical device products in the life sciences industry. This process is tightly aligned with our internal quality management system and offers in-depth information as to what to expect during the entire process or other stages within the full program itself. This document explains each step with its accompanying procedures and expectations between our clients and us. It offers high-level purposes and outcomes, and the results each part of the process will deliver. By using this process, we intend to create a product that meets and exceeds our customers' needs and expectations while building a product that solves a problem in the healthcare industry.

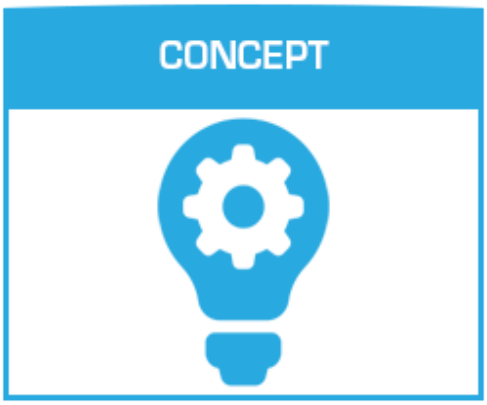
THE 8 DESIGN DEVELOPMENT PROCESS STAGES

- CONCEPT
- FEASIBILITY
- DESIGN QUALIFICATION
- CLINICAL VALIDATION
- REGULATORY/ SUBMISSION APPROVAL
- DESIGN TRANSFER PLAN
- PROCESS VALIDATION
- LAUNCH

D&DP DIAGRAM


Concept
1
Feasibility
2
Design Qualification
3
Clinical Validation
4
Regulatory Submission/ Approval
5
Design Transfer Plan
6
Process Validation
7
Launch
8
Design For Manufacturing
PRODUCT DEVELOPMENT PROCESS
TECH TRANSFER PROCESS

CONCEPT



Purpose:

Transform an idea, thought, or sketch into a design with a working and functioning prototype that mimics the intended device and prospective use in the market.

High-Level Outputs:

- Execute agreements and open DHF
- Concept development ideas in place
- Prototyping & performance testing initiated.
- Project teams assess the manufacturability of a concept device.
- Cost modeling scenarios completed.
- Initiate risk management plan
- Regulatory strategy

Result:

Concept Prototypes are constructed and reviewed before moving on to the next step.

FEASIBILITY

Purpose:

Establishes “design freeze” that presents a working engineering level sample with initial evidence supporting design feasibility.

High-Level Outputs:

- Design & Development Plan – Full optimization
- Equipment & Process development
- Packaging design outlined.
- Risk management & Regulatory plan refined
- Product feasibility sample
- Any include animal trials
- Bill of materials and product cost review

Result:

Design is frozen, and all aspects of the project will follow as described in documented drawings.

DESIGN FOR MANUFACTURING

Configured within the Concept & Feasibility Stages

This process and deliverable function in both the Concept and Feasibility stages. It is a methodology used to continuously alter and refine a design each time it goes through a development and prototype process to ensure the product is manufacturable as intended. As an outcome of this constant refinement, the intention is satisfying all of the customer's requirements to:

- Provide more cost-effective pricing options,
- Bring clarity to the specifications needed in materials,
- Proper scheduling of the product through the manufacturing process. Additional Outputs for this result ensure the product meets the required quality and cost targets, that assembly lines are configured and prepared, identifies other high-risk design features, and proposes a process to mitigate risk and quality costs overall.

DESIGN QUALIFICATION

Purpose:

Provide needed data points and information to verify and validate the device. The device should work like, look like and be made like a production product, as well as meet the customers original design intent (requirements/inputs). Design verification must be representative of production parts.

High-Level Outputs:

- Build production like qualification product
- Design verification testing & reports
- Complete device master record (DMR)
- Execute biocompatibilitysStrategy
- Full risk management plan is organized
- FMEA
- IFU review
- Biocompatibility testing
- Packaging and sterilization validation
- Regulatory submission preparation

Results:

Quality Test Reports Completed, Regulatory Submission of Device (filing)

CLINICAL VALIDATION

Purpose:

Establish objective evidence that device specifications conform to user needs and intended uses.

High-Level Outputs:

- Source, create and develop relationships with key opinion leaders (KOLs) in industry
- Interviews with KOL's
- Product evaluations
- Substantiated evidence accepted by authoritative professionals, with guidelines, consensus, or evidence-based sources received.
  - May involve first in man study
  - May involve a clinical study

Result:

Design Validation Report

REGULATORY SUBMISSION /APPROVAL

Purpose:

Achieve regulatory approval for a medical device project.

High-Level Outputs:

- 510(k) file
- Technical file/Design dossier (CE Mark)
- Medical Device Reporting (MDR) methodology determined.
- Reports submitted to regulatory bodies as required.
- Complaint handling

Results:

Authorized documentation clears either FDA or EU governing bodies.

DESIGN TRANSFER PLAN

Purpose:

Develop an execution plan to prepare for full-scale manufacturing while ensuring both yield and quality throughout the project. These activites start during the Feasibility phase.

High-Level Outputs:

- Create Process Flow Chart
- Define Manufacturing Cell Layout
- Transferred to Manufacturing for Review.
- Quality Management System Documentation begins (Includes: 2-D Prints and Drawings, Bill of Materials (BOM), Test Methods, Labels, Work Instructions, DHR Suppliers, and Vendors selected.)
- Initialize Sterilization Plan
- Design is transferred to process manufacturing team for production

Results:

Plan for manufacturing is created, and adequately assigned to necessary production teams.

PROCESS VALIDATION

Purpose:

Consists of the collection and evaluation of data, from the process design stage throughout the production. It establishes scientific evidence that a process is capable of consistently delivering quality products.

High-Level Outputs:

- Process Validation (IQ, OQ, & PQ) finalized
- Quality inspection plans are in place
- Packaging and labeling procedures configured
- Final risk management plan in place

Results:

Generalized acceptance that product can be manufactured within targeted measures and provide consistent results.

LAUNCH

Purpose:

This stage reflects the devices' compliance with regulatory bodies and the continuous monitoring and management of the device in its reflected market.

High-Level Outputs:

- Build lauch quantities
- Review manufacturing performance
- Continuous improvement
- Commercialization plan is activated
- Complaint handling
- Regular analysis and performance review of product in the Market.

Results:

Proper shipment of products to Distributors, Healthcare Providers, Physicians, and Technicians as it relates to market

BIOMERICS

6030 W HAROLD GATTY DR.
SALT LAKE CITY, UT 84116
888-874-7787

LOCATIONS:

SALT LAKE CITY, UT
BROOKLYN PARK, MN
ATHENS, TX
MONROE, CT
INDIANAPOIS, IN
CARTAGO, COSTA RICA