



**Validation** *solved.*  
**Manufacturing** *ready.*  
**Launch** *accelerated.*

Accelerating the most demanding phase of  
device development.



# You've already moved further than most teams do.

The device works. Verification is underway. The path forward is clear.

What's left is the most constrained phase of development:

***design validation & preparation for manufacturing.***

IMM engages with you after verification and before full manufacturing—to complete validation, refine DFM, and prepare programs to scale.

**Manufacturing-ready when programs are built to move.**

# Validation

IMM steps in after verification to accelerate validation, ensuring devices are ready for regulatory submission and scalable under real-world conditions.



## Validation Support:

1

### **Functional performance testing**

Flow rate, pressure, leak, burst, pull, torque, snap-fit, and other performance characteristics required to demonstrate readiness for manufacturing.

2

### **Biocompatibility evaluation and testing strategy**

Defined plans aligned to device use, materials, and regulatory expectations.

3

### **Packaging validation (ISO 11607-1 / -2)**

Including aging and shelf-life studies to support distribution, storage, and submission requirements.

4

### **Sterilization process validation**

EO and Gamma, executed to meet regulatory and production needs.

# Design for Manufacturability (DFM)

IMM aligns designs to the realities of production—so programs are built to scale *without rework*.

## DFM Support:

1

### **Define Critical-to-Quality (CTQ) Characteristics**

Establish CTQs and acceptance criteria so requirements are measurable, testable, and locked before tooling decisions are made.

2

### **Surface Cost and Yield Risks Early**

Identify sensitivity to variation, yield loss, and process instability before they become production constraints.

3

### **Design for Repeatable Production**

Refine designs, materials, and supplier controls to support repeatability, reliability, and stable production performance at scale.



**When designs stabilize early,  
they scale smoothly.**

# What this Level of Detail Signals

## **Engineering-led scope definition**

*Work defined by requirements, evidence, and execution—not sales narratives.*

## **Clear ownership of critical stages**

*Validation and manufacturability handled deliberately, without ambiguity.*

## **Early alignment between validation and manufacturing**

*So decisions made here hold up in production, not just on paper.*

**Manufacturing-ready when  
programs are built to move.**

# IN THEIR OWN WORDS

Feedback from partners across validation, DFM, and scaled production.



IMM is by far our most **reliable**, **consistent**, and **dependable supplier**.

– Taylor  
Manager of Manufacturing



Quality and delivery of product is **consistent** and **excellent**. Feedback and assistance are **fast** and **reliable**.

– Brenda  
Materials Manager



The IMM team has been a **great partner** for exploring new products and **consistently executing** on existing ones.

– CEO, Medical Device Company





# Built for Precision. Designed for scale.

We take medical device teams from validation to production at scale.

*Manufacturing-ready when programs are built to move.*



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