Medical Device NPI: Best Practices for OEM's

In the fast-evolving medical device landscape, the ability to bring innovative products to market quickly and compliantly is essential. For Original Equipment Manufacturers (OEMs), selecting a contract manufacturing partner with a disciplined, proven New Product Introduction (NPI) framework can mean the difference between a successful launch and costly delays. At EPTAM Precision, with eight advanced U.S.-based facilities, our NPI program, led by Mary Jo Sysko, VP of Commercial Development, enables seamless transitions from concept to commercialization.

This white paper outlines the best practices in NPI for contract manufacturers and the OEMs they support, and details how EPTAM's structured, cross-functional approach reduces risk, accelerates development, and ensures market readiness.

The Importance of an NPI Framework in MedTech

In an industry governed by stringent regulations and fast-paced innovation, a strong NPI framework ensures that medical devices are safe, effective, and brought to market efficiently. With FDA regulations (21 CFR Part 820), ISO 13485:2016 compliance, and increasing scrutiny over traceability and validation, OEMs must adopt a methodical approach to development.

Additionally, product complexity is rising. Devices are smaller, more interconnected, and often combine mechanical, electrical, and software elements. Meanwhile, market pressures demand shorter product life cycles. A robust NPI program mitigates regulatory, design, and production risks early—reducing costs, ensuring design intent, and accelerating time to market.

For OEMs, the right contract manufacturer becomes an extension of their development team, embedding compliance and manufacturability into every step.

EPTAM's NPI Center of Excellence

Led by **Mary Jo Sysko,** EPTAM's VP of Commercial Development, the NPI Center of Excellence brings deep industry insight and rigorous execution across our eight manufacturing sites. Our team's mission is simple: streamline the path from innovation to production with discipline, transparency, and speed.

The Center of Excellence employs a hub-and-spoke model—centralized NPI leadership with site-specific execution teams. Weekly program reviews, standardized phase gate checkpoints, and real-time reporting tools ensure that every project stays aligned.

Key strengths include:

- Cross-functional expertise in engineering, quality, supply chain, and automation
- Integrated quality planning and early design input
- Strong customer onboarding protocols
- Experience across hundreds of complex, highly regulated device launches

EPTAM's 5-Phase NPI Methodology

At each phase, progression is formally reviewed by a cross-functional Decision Gate Committee to ensure alignment with business goals, compliance, and project performance.

1. Kickoff & Chartering

Initiate program based on customer award. Define scope, assign project leadership, and establish baseline assumptions and risk factors. Create formal project charter.

- Conduct internal handoff between Business Development and Project Management
- Define customer requirements, part numbers, forecasts, and assumptions
- Assign cross-functional team roles and responsibilities
- Establish initial project goals, risk profile, and communication plan
- Launch project in EPTAM's centralized program management system
- Hold formal Decision Gate review to authorize full project start

2. Planning

Align cross-functional teams on resource plans, facility needs, tooling, materials, and project milestones. Develop risk registers and communication plans. Prepare for validation and early builds.

- Define capital equipment and facility requirements
- Integrate project into site capacity planning
- Align on supplier readiness and initiate sourcing activities
- Initiate Design for Manufacturability (DFM) reviews
- Develop quality, staffing, and material readiness plans
- Build resource-loaded timeline with risk-based countermeasures
- Establish baseline KPIs and identify scope changes if applicable

3. Development

Execute process planning, layout design, PFMEA, and validation protocols. Install equipment, develop manufacturing and inspection documents, and prepare for process qualification.

- Finalize process flow diagrams, inspection plans, and work instructions
- Procure and install equipment, tooling, and fixtures
- Create component specifications and metrology requirements
- Perform incoming material qualifications and safety assessments
- Draft validation protocols (IQ, OQ, PQ) and align with customer input
- Begin staff training and internal documentation reviews
- Monitor and update project risks, scope, and timeline as needed

4. Validation

Complete installation (IQ), operational (OQ), and performance qualifications (PQ). Finalize training, documentation, and regulatory readiness. Deliver first articles for customer review.

- Complete final calibration, equipment qualification, and validation reports
- Execute First Article Inspection (FAI) and document regulatory compliance
- Finalize Device Master Record, traceability plans, and QA release processes
- Conduct hiring and training for production team
- Ensure material traceability and system alignment for production launch
- Confirm customer acceptance of validation builds and readiness for go-live

5. Launch & Handoff

Transition ownership from project to operations. Track key performance metrics, close out risks, and document lessons learned. Validate supply continuity and long-term sustainment.

- Transfer process ownership to operations and quality control teams
- Confirm alignment on supply chain, manufacturing, and regulatory readiness
- Monitor post-launch metrics including scrap, yield, and throughput
- Complete close-out of project risks and open actions
- Document lessons learned for continuous improvement
- Finalize long-term quality and commercial agreements as needed

Capabilities and Technologies That Enable NPI Success

EPTAM's technical breadth enables seamless scalability and faster time-to-market for complex devices. These include:

Plastics Machining: Expertise in high-performance medical polymers like PEEK, PPSU, and UHMWPE for implantables and surgical components

Metal Machining: Precision CNC machining of titanium, cobalt-chrome, and stainless alloys for implants, spinal fixation, housings, and surgical instruments

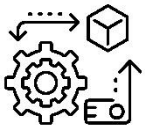
Liquid Silicone Rubber (LSR): ISO Class 7 cleanroom molding with advanced overmolding for drug delivery and diagnostics

Laser Processing: High-precision cutting, drilling, welding, and marking for guidewires, hypotubes, & delivery systems

Micro-Machining: Micron-level precision for MIS, RAS, and structural heart devices, enabling complex geometries and consistent performance.

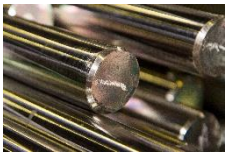
Automation Integration: Custom automation strategies that improve consistency, reduce cycle times, and enable lights-out manufacturing where applicable

Secondary Operations: Cell-based, lean manufacturing supported by cleaning, color anodization, passivation, and both sterile and non-sterile packaging.



Rapid Prototyping: Quick-turn development capabilities for iterative product refinement and faster design feedback loops

Material Selection Expertise: Guidance on balancing biocompatibility, performance, regulatory compliance, and cost to ensure optimal material choices



Full-Scale Manufacturing Support: Infrastructure, staffing, and quality systems that support smooth ramp-up from pilot to full-rate production

Post-Launch Technical Support: Infrastructure, staffing, and quality systems that enable smooth, reliable ramp-up from pilot builds to full-scale production.

Industries We Serve

EPTAM supports top-tier OEMs across a range of high-growth medical sectors, offering precision manufacturing, regulatory alignment, and scalable production from prototype through commercialization. Our domain expertise allows us to serve as both a manufacturing partner and technical problem-solver throughout the product lifecycle. Our expertise spans:

- **Orthopedic Spine & Trauma:** Components for joint replacement systems, fixation hardware, spinal spacers, and bone plates made from titanium, stainless steel, and PEEK. We also support trauma implants, including humeral and radius plates and screws.
- **Interventional & Structural Heart:** Ultra-precise components for catheter-based cardiovascular procedures, including vascular, congenital, and structural heart devices. Our expertise in tight-tolerance micro-machining, laser processing, and cleanroom-ready assemblies helps enable life-saving valve delivery platforms and structural heart implants.
- **Robotic-Assisted Surgery:** End effectors, actuation elements, and miniature assemblies enabling precise, sensor-integrated surgical tools. We help OEMs rapidly iterate designs and scale robotic platforms with repeatable, validated manufacturing.
- **Minimally Invasive Surgery (MIS):** Tight-tolerance laparoscopic and endoscopic tools, including graspers, cutters, electro-cautery, vessel sealer, implants, and more. Our ability to fabricate complex subassemblies in mixed materials supports growing demand for disposable and reusable surgical devices.
- **Molecular Diagnostics & Life Sciences:** Plastic and metal components for test cartridges, assay plates, micro-fluidics, and diagnostic components. We support cost-effective, scalable production for consumables in biopharma, R&D, and point-of-care testing.
- **Biopharmaceutical Delivery Systems:** Enclosures, pump housings, and combination device components manufactured in cleanroom settings. We maintain biocompatibility and dimensional integrity for safety-critical drug delivery applications.
- **Implantable Devices:** High-precision machining and molding of implantable-grade polymers and metals for spine, sports medicine, and cardiovascular use. We maintain sterile processing protocols to support patient-ready devices.

This industry expertise allows EPTAM to not only deliver critical components, but also guide OEMs through technical challenges, regulatory expectations, and volume transitions across the product lifecycle.

Best Practices for OEMs Working with Contract Manufacturers

Successful New Product Introduction (NPI) programs depend on more than technical execution—they require active, aligned collaboration between OEMs and contract manufacturing partners. To ensure your next launch stays on track and meets both performance and compliance goals, consider these proven strategies:

- **Engage Early** Involve your manufacturing partner during the design feasibility phase. Early collaboration enables DFM input, tooling planning, and early identification of regulatory or material risks—saving time and cost later.
- **Define Scope Clearly** Set clear expectations around deliverables, tolerances, volumes, and timelines. Aligned scope and commercial terms reduce change orders, delays, and confusion as the project scales.
- **Maintain Documentation Discipline** Use revision-controlled CAD files, BOMs, specifications, and test protocols. Strong documentation control supports traceability, compliance, and effective design transfer.
- **Use Structured Communication** Establish a consistent cadence of project reviews, dashboards, and issue-tracking tools. These frameworks keep teams synchronized and allow for faster resolution of blockers.
- **Foster Agility with Accountability** Iteration is inevitable—especially with complex or evolving devices. Choose partners who can adapt quickly while maintaining rigorous controls and documentation discipline.
- **Prioritize Risk Management** Conduct joint PFMEA sessions and develop aligned control plans to proactively address potential failure modes. Early mitigation strengthens validation and downstream quality.
- **Process Validation:** Comprehensive validation support including IQ/OQ/PQ protocols, PPAP documentation, Gauge R&R studies, SPC monitoring, and all required evidence to ensure stable, compliant, and repeatable manufacturing.
- **Leverage Digital Systems** Integrated tools like eQMS, MES, and ERP provide real-time visibility, streamline compliance, and help manage complexity across phases and facilities.

By building the right foundation of communication, planning, and shared accountability, OEMs can accelerate NPI timelines, control risk, and increase their likelihood of a smooth and successful product launch. Choosing a manufacturing partner who actively enables these best practices can make all the difference.

Case Studies and Outcomes

Each outcome shows what's possible when NPI is driven by speed, precision, and purpose. From surgical platforms to implants and drug delivery, EPTAM helps OEMs launch with confidence.

Micro-Machining – Inner Body Spacer

A customer had completed an Alpha launch with a supplier unable to support their production ramp. EPTAM partnered early to identify manufacturing improvements, stabilize the process, and accelerate time to market while ensuring scalable volume capability.

→ **Outcome:** Accelerated design transfer and full production volumes achieved ahead of schedule.

Metal Machining – Trauma Implantable

An orthopedic OEM engaged EPTAM to advance the design and development of a trauma implant. Through iterative technical development, engineering samples, and targeted DFM feedback, EPTAM supported the customer through design maturation and design freeze.

→ **Outcome:** Customer completed a successful commercial launch while meeting performance goals and beating target pricing.

Liquid Silicone Rubber – Treatment for Calcified Arterial Disease

EPTAM partnered with the OEM early in the development phase of their ultrasonic pressure-wave system for fracturing calcified plaque. The customer needed to reduce cycle time and scrap, and their legacy glued assembly limited throughput and consistency. EPTAM identified and validated an overmolding solution that simplified production 10% and improved reliability.

→ **Outcome:** 4× reduction in cycle time and significantly reduced scrap, enabling a stronger, more scalable production process.

Liquid Silicone Rubber – Blood Transfer device

A customer faced high scrap rates and inconsistent quality from an overseas supplier. EPTAM collaborated with their engineering team to provide DFM recommendations and transitioned the design to injection molding, improving manufacturability and long-term stability.

→ **Outcome:** Product now exceeds quality expectations with negligible scrap and dependable, scalable capacity.

Precision Molding – Surgical Evacuation System

To support a late-stage development effort, EPTAM coordinated multiple capabilities across several facilities and delivered design samples for test builds. Feedback from these builds informed mold-design refinements that improved processing efficiency and achieved aggressive cost targets.

→ **Outcome:** Successful product launch, with automated operations helping the customer meet an aggressive launch schedule while beating pricing goals.

A Smarter Path from Concept to Commercialization

To lead in today's medical device market, OEMs must elevate New Product Introduction (NPI) from a functional task to a strategic discipline. *NPI excellence* means integrating design for manufacturability, regulatory alignment, rapid iteration, and cross-functional execution — all while accelerating speed to market without compromising quality.

EPTAM Precision delivers this level of execution through a dedicated NPI team, led by Mary Jo Sysko, ensuring agility, discipline, and accountability from the earliest concept stages through full-scale production. With seven U.S.-based manufacturing sites, deep domain expertise, and proven success with complex Class II and III devices, EPTAM is not just a contract manufacturer — we are your strategic partner for bringing innovations to life.

Ready to advance your next device with confidence?

Let's start building it together.

Contact us Today to Learn More

Acknowledgments

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Industries
Implants
Ortho-Trauma
Interventional & Structural Heart
BioPharma
Molecular Diagnostics
Robotics
Minimal Invasive Surgery

Certifications
ISO:13485:2016 Certified
ISO 9001:2015 Certified
FDA #3005144609 Registered
21 CFR 820 Compliant
CAGE Code: 1TYA1
ITAR, DDT Registered
FDA #3011302692 (West/Metals)

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