



# Catheter Design & Development Partner Checklist

## 1. Technical Expertise

- Experience across catheter types (neurovascular, EP, structural heart)
- Shaft construction: coil, braid, laser-cut hypotubes
- Steerability and deflection design
- Experience working with multi-lumen extrusions
- Advanced bonding: thermal, RF, adhesives
- Low-friction and hemocompatible coatings

## 2. Prototyping Speed

- In house prototyping/3D Printing
- In-house tooling and fixture development
- Fast iteration cycles (days to weeks)
- Strong material access and vendor network

---

## 3. Manufacturing Scalability

- Low-to-mid volume production capability
- Class 7 cleanroom assembly
- Pilot build readiness
- Flexible assembly lines
- Robust manufacturing engineering support

## 4. Quality & Regulatory Strength

- ISO 13485-compliant QMS
- Design controls (QMSR)
- Biocompatibility guidance (ISO 10993)
- DDF/MDF support
- Full material traceability and documentation

---

## 5. Project Management & Communication

- Dedicated project manager
- Clear timelines and budget transparency
- Regular (weekly) meetings
- Defined Project Plan
- Proactive risk and issue escalation

## 6. Startup-Friendly Approach

- Comfortable with evolving or incomplete specs
- Early design for manufacturability (DFM) input
- Regulatory and testing strategy support
- Flexible engagement models

---

## 7. IP Protection & Confidentiality

- Strong NDAs in place
- Multi-factor authentication
- Secure data management systems
- Clear IP ownership (no shared IP)

## 8. Cultural Fit

- Collaborative, engineering-first mindset
  - Responsive and accountable communication
  - Agility with changing requirements
  - True partner mentality—not just a vendor
-