

# Pathfinder Medical Device Initial Review Questions

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These 50 questions are meant for novel products in the conceptual development stage. They are by no means comprehensive. We hope you find them useful at identifying the strengths and weaknesses of your project to date. You may wish to score your readiness with a point for every 'yes' answer, and compare with the suggested actions at the end.

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## **TECHNOLOGY**

- Proof of concept demonstrated
- Durability/Robustness and Sensitivity to Environmental conditions acceptable
- IEC60601-1 – Basic safety of medical electrical equipment adequately considered
- General IEC60601-1-2 medical electrical equipment Electromagnetic Compatibility
- Product Specific standards considered

## **USER RESEARCH**

- Target users identified
- Key Opinion Leaders (KOL) and Subject Matter Experts (SME) interviews conducted and documented
- Use environment identified and adequately considered

## **WORKFLOW / INDUSTRIAL DESIGN / HUMAN FACTORS**

### **WORKFLOW ANALYSIS**

- User interface requirements documented
- Procedures observed and documented
- Frequently used functions identified
- Procedural workflow mapped

### **MARKETING REQUIREMENTS**

- Focus groups / market surveys been conducted
- Voice of customer understood
- Value proposition clear and documented

### **HUMAN FACTORS**

- Relevant anthropometric factors and size ranges documented
- Formative usability testing using mockups by KOLs conducted

### **IP STATUS**

- Core IP filed
- Claims cover critical innovations and are protective
- Competitive prior art identified and Freedom to Operate considered

### **DATA/CONNECTIVITY**

- Report generation considered
- Connectivity required? Appropriate standard identified
- Wireless required? Communication standard identified
- Cloud-based storage - HIPAA & cybersecurity considered

### **VALUE CHAIN**

- Target price identified
- Gross margin target determined
- COGs target understood
- Manufacturing costs allowed for

### **REIMBURSEMENT**

- Existing reimbursement identified
- Reimbursement advisors identified (if necessary)
- Reimbursement strategy defined

## REGULATORY COMPLIANCE

- Risk Class identified for FDA and CE Marking
- FDA-compliant Quality Management System in place and being followed
- ISO 62366 compliance for human factors
- ISO 62304 compliance for software
- ISO 13485 certification planned or in place (for Canada/EU sales) and/or
- Detailed specification exists (each spec referenced in verification test plan)
- Relevant FDA guidance documents considered

## RISK MANAGEMENT

- Preliminary Hazard Identification/Risk Assessment performed
- Preliminary Risk of harm to patient or operator quantified in accordance with ISO14971 (2007 or 2012 as applicable)
- Adequate mitigation of critical risks demonstrated
- Program risks identified

## DESIGN FOR MANUFACTURABILITY AND TEST

- Manufacturing processes identified for all significant components
- Critical components are reliably obtainable in right quality

## DESIGN FOR SERVICE

- Service method identified
- Shipability of service components considered
- On board/remote diagnostics considered

## DISPOSABLES STRATEGY

- Disposable/consumable component(s) identified and justifiable to end user
- Process Validation planned for? (e.g. sterilization, microfluidic injection molding)
- Disposables margins appropriate for business model

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## SCORING

The questionnaire is primarily intended as a sanity check to identify strengths and weaknesses of your project to date. However, a simple scoring rationale could be apportioned as shown below:

**35 OR MORE:** Almost Ready for Product Realization and Detailed Design, some tweaking may be required.

**18 – 34:** Review Pathfinder white paper and consider which remaining questions are required before detailed design can begin.

**UP TO 17:** Early in the realization process. Consider a free Pathfinder consultation with StarFish to prioritize key questions which will progress project to next stage.