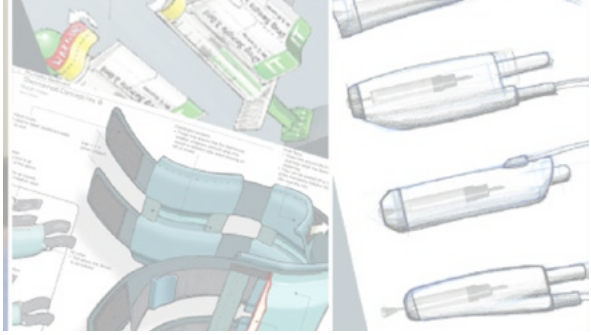

StarFish MEDICAL

PATHFINDER MEDICAL DEVICE INITIAL REVIEW QUESTIONS

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.

Technology

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

User Requirements

- [ ] *Target users identified*
- [ ] *User interviews conducted and documented at more than 2 sites*
- [ ] *Use environment documented and adequately considered*
- [ ] *User interface requirements documented*

Workflow / Industrial Design / Human Factors

Workflow

- [ ] *Procedures observed and documented*
- [ ] *Frequently used functions identified*
- [ ] *Workflow mapped and possible solutions defined*
- [ ] *Reasonably Foreseeable and Routine Violations misuse identified*

Industrial Design

- [ ] *Focus groups evaluated possible solutions before detailed design*
- [ ] *Marketing Brand adequately represented in solutions*
- [ ] *Client expectations*

Human Factors

- [ ] *Relevant anthropometric size ranges reviewed and documented*
- [ ] *Ergonomic testing using mockups by real target users*
- [ ] *Usability engineering in compliance with ISO62366*

IP Status

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

Data/Connectivity

- [ ] *Report generation considered?*
- [ ] *On board database required - HIPAA adequately considered?*
- [ ] *Connectivity required? Appropriate standard identified?*
- [ ] *Wireless required? Communication standard identified?*

Value Chain

- [ ] *COGs target understood*
- [ ] *Target price identified*
- [ ] *Gross margin target determined*
- [ ] *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*
- [ ] *ISO 13485 certification planned or in place (for Canada/EU sales) and/or FDA-compliant Quality Management System in place and being followed*
- [ ] *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*
- [ ] *Project risks identified*

Design for Manufacturability and Test

- [ ] *Manufacturing processes identified for all significant components*
- [ ] *Tight tolerances identified and repeatable achievable*
- [ ] *Critical components are reliably obtainable in right quality*

Design for Service

- [ ] *Service method identified*
- [ ] *Shippability 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?*

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*