

# Design & Development Transfer



This checklist is intended to capture and guide the roles and responsibilities associated with the design transfer process. Part 1 of this document will be used to assign transfer responsibilities. Part 2 of this document tracks progress.

Client: \_\_\_\_\_ Program Name: \_\_\_\_\_ Review Date: \_\_\_\_\_

|   |                          |                    |       |
|---|--------------------------|--------------------|-------|
| <b>Name of Assembly/ Device:</b>                  |                          |                    |       |
| Brief Description:                                |                          |                    |       |
| <b>Top Level Part Number of Assembly/ Device:</b> |                          |                    |       |
| <b>Revision of Assembly/ Device at Transfer:</b>  |                          |                    |       |
| <b>Type of Transfer:</b>                          | Transfer to Mfg. Partner | Transfer to Client | Other |
| <b>Summary of Transfer Intent:</b>                |                          |                    |       |

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## Transfer Planning Part 1

**Key**  
 R=Responsible S=Support  
 N/A = Not Applicable

| Primary Responsibilities During Transfer Planning: |  | Sunrise Labs | Client | Mfg. Partner |
|--|--|--------------|--------|--------------|
| Pre-Transfer Phase                                 | Maintain and control drawings, specifications    |              |        |              |
|  | Maintain and control DHF and BOM                 |              |        |              |
|  | Update DFM and DFMA                              |              |        |              |
|  | Select Mfg. Partner and supply chain             |              |        |              |
|  | Build clinical, pre-pilot units                  |              |        |              |
|  | Create and maintain DMR/ build record            |              |        |              |
| Transfer Phase                                     | Maintain and control drawings                    |              |        |              |
|  | Maintain and control DHF and BOM                 |              |        |              |
|  | Maintain and control tooling                     |              |        |              |
|  | FAI's resolution                                 |              |        |              |
|  | PCB circuit test and fixtures                    |              |        |              |
|  | In-process and final acceptance tests            |              |        |              |
|  | Release pilot material released to Mfg. Partner  |              |        |              |
|  | Create work instructions                         |              |        |              |
| Transfer Completion Phase                          | Maintain and control drawings                    |              |        |              |
|  | Maintain and control DHF and BOM                 |              |        |              |
|  | Conduct IQ-OQ-PQ                                 |              |        |              |
| Post Launch Phase                                  | Maintain and control drawings, ECO's             |              |        |              |
|  | Maintain and control DHF and BOM                 |              |        |              |
|  | Conduct market surveillance/ sustaining/ support |              |        |              |

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# Transfer Review Part 2

Key

R=Responsible S=Support N/A = Not Applicable

| Primary Responsibilities and Status:  | Sunrise Labs | Client | Mfg. Partner | Status |
|---|--------------|--------|--------------|--------|
| Project plan up-to-date and approved  |              |        |              |        |
| Design and Development Transfer Plan up-to-date and approved (required to begin the process)                              |              |        |              |        |
| Essential outputs defined and approved, including all drawings, specifications and product software                       |              |        |              |        |
| Servicing requirements reviewed with Mfg. Partner   |              |        |              |        |
| Product BOM(s) released to Mfg. Partner   |              |        |              |        |
| Manufacturing and test requirements reviewed with Mfg. Partner  |              |        |              |        |
| Risk analysis complete and approved   |              |        |              |        |
| Design verification results approved  |              |        |              |        |
| Agency testing complete and report available  |              |        |              |        |
| Mechanical custom components first article inspection (identify components or reference list here)                        |              |        |              |        |
| Electronics design package release checklist (SLI730410-ckl completed and reviewed (identify PCBs or reference list here) |              |        |              |        |
| Labeling including service and operation manuals  |              |        |              |        |
| Perform specialized testing, including sterilization, and bio-compatibility   |              |        |              |        |
| Review of BOM with Mfg. Partner   |              |        |              |        |

Notes:



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# Transfer Review Part 2

Key

R=Responsible S=Support N/A = Not Applicable

| Activity Checklist  | Sunrise Labs | Client | Mfg. Partner | Status |
|---|--------------|--------|--------------|--------|
| Mfg. Work Instructions, assembly, test reviewed with Mfg. Partner   |              |        |              |        |
| Complete and review DHF and any additional Mfg. process equipment   |              |        |              |        |
| Complete preventative maintenance and servicing requirements and procedures   |              |        |              |        |
| Sunrise designed assembly or test equipment validated   |              |        |              |        |
| Mfg. process to install product software coordinated with Mfg. partner, released and validated  |              |        |              |        |
| Supplier list reviewed with Mfg. Partner  |              |        |              |        |
| Transfer of any inventory from Sunrise to Manufacturer  |              |        |              |        |
| Completion and disposition of any MRB items (from inspection activity)<br>PFMEA from Mfg. Partner reviewed against device system hazards analysis. Essential requirements traceable into mfg. process. Documented as a design review. |              |        |              |        |
| Review in-process and final acceptance test with Mfg. Partner   |              |        |              |        |
| IQ-OQ-PQ of manufacturing and test equipment including software   |              |        |              |        |
| Training of Mfg. Partner personnel  |              |        |              |        |
| Quality agreement between Sunrise and Client approved   |              |        |              |        |
| Support or Maintenance Plan approved  |              |        |              |        |
| Design review for completion of Design and Development Transfer activity  |              |        |              |        |
| Other   |              |        |              |        |

Notes:



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