|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Supplier:** |  | **Website:** |  | **Supplier Survey Status:** |  |
| **Contact:** |  | **Email:** |  | **Date Approved:** |  |
| **Phone:** |  | **Fax:** |  | **Approved By:** |  |

|  |
| --- |
| **CM Capability Assessment Survey** |
| **Instructions**1. This survey is intended to assess and document your capabilities as a contract manufacturer.
2. This survey contains open-ended questions. Please respond to each question as completely as possible.
3. Please return the completed survey within 15 business days.
4. Please direct any questions to the contact provided below.

Name/Title:Phone #: Email: Website:Address: |

## Supplier Contact Information

|  |  |
| --- | --- |
| Question | Response |
| List primary location (s), address(es), and contact information: |  |

## Certifications

| Question | Response |
| --- | --- |
| Is your company ISO 13485: 2016 certified?If yes, how long have you held/maintained certification. \*Please attach a copy of your certification |  Yes | No |
| Does your company plan to seek ISO 13485:2016 certification? |  Yes | No  |
| Is your company ISO 9001:2015 Certified?If yes, how long have you held/maintained certification? \*Please attach a copy of your certification |  Yes | No |
| Does your company plan to seek ISO 9001:2015 certification? |  Yes | No  |
| List any other type of certifications: Type (Standard) – Notified Body – Date of Certification:\*Please attach a copy of your certification |  |

## Regulatory Bodies

|  |  |
| --- | --- |
| Question | Response |
| Are you currently inspected by any local, state, or federal agencies (OSHA, EPA, etc.) ?If yes, please describe.  |  Yes | No |
| Are you registered with the FDA to manufacture finished medical devices\* ?*\*as defined by 21CFR 820.3 (l)*If yes, please provide your registration number:  |  Yes | No  |

## General Business

|  |  |
| --- | --- |
| Question | Response |
| What industries do you serve?  |   |
| What are products that your company specializes in? |  |
| Describe your manufacturing capacity (e.g., # of production lines that can be run simultaneously, number of production shifts, volume/per mos. of product that can be produced., etc.) |  |
| What metrics does your company use to qualify a client? Do you consider forecasted volume, revenue, technology, or other criteria? Will you manufacture prototypes as well as high volume units? |  |

## Business Management

| Question | Response |
| --- | --- |
| Schedule Management - Describe how your organization manages and communicates schedule.  |   |
| Program Risk Management - Describe your organization's process for managing program risks, if any. |  |
| Procurement and Inventory Management (suppliers, vendors) - Describe your organization's process for managing suppliers, vendors, and inventory. |  |
| Cost Management - Describe how your organization manages and communicates the financial status of the project. |  |
| Documentation Management - Describe your organization's preferred process for management/control of documents between you and the client. |  |
| Data Security: Describe your organization's practices for the protection of data. Note if you are using data encryption in transit and/or data encryption at rest. |  |

## Manufacturing Services

| Question | Response |
| --- | --- |
| PCB Assembly & Test - Does your organization offer PCB Assembly & Test services (in-house, or sub-contracted)? If yes, please describe and identify any specialized equipment used. | Yes | No |
| Cable Assembly – Does your organization offer Cable Assembly services?If yes, please describe and identify any specialized equipment used. | Yes | No |
| Mechanical Assembly - Does your organization offer Mechanical Assembly services? If yes, please describe and identify any specialized equipment and processes used. | Yes | No |
| System Level Assembly - Does your organization offer full System Assembly services (electrical, mechanical, firmware, software)?If yes, please describe and identify any specialized equipment and processes used. | Yes | No |
| NPI Engineering Services – Does your organization offer NPI services? If yes, please describe services offered. | Yes | No |
| Cleanroom – Does your organization offer cleanroom assembly? If yes, please describe your capabilities, and note cleanroom classification. | Yes | No |

## NPI/Process Development

|  |  |
| --- | --- |
| Question | Response |
| DFMA Review Process - Describe your organization's process for Design for Manufacturability and Assembly. |  |
| Tool Development - Describe your organization's manufacturing and test tool development capabilities. |  |
| Process Development – Describe your organization's method for process development (work instructions, etc.) |  |
| Process Validation - Describe your organization's method of process validation. |  |
| Tool Validation - Describe your organization's methods of tool validation (HW and SW). |  |

## Process Controls Services

|  |  |
| --- | --- |
| Question | Response |
| Process Optimization - Describe your organization's method of process optimization. |  |
| Process Stability and Capability: Describe your organization's method of establishing process stability and capability. |  |
| Failure Investigation Process - Describe your organization's process for failure investigation. |  |
| Return Manufacture Authorization (RMA): Describe your organization's handling of RMAs. | li |
| Risk Management - Describe your organization's methods for process risk, assessment, if any (e.g. Process FMEA, Risk Analysis). |  |
| Process Controls - Describe your methods for process control. |  |
| Environmental Controls: Describe the type and extent of environmental controls in place for your production/test areas (e.g. ESD Controls, temperature/humidity, etc.). |  |

## Inspection and Test

|  |  |
| --- | --- |
| Question | Response |
| Inspection Capabilities: Describe your organization's inspection processes and equipment (e.g., GD&T expertise, metrology lab, CMM, CMM programming expertise, other inspection equipment, etc.) |  |
| Test Capabilities: Describe your organization’s test processes and equipment (e.g., test lab, environmental chamber, failure analysis lab, Instron, etc.) |  |

## Specialty Services

|  |  |
| --- | --- |
| Question | Response |
| Sterilization Services – Does your organization offer any sterilization services?If yes, please describe and identify any specialized equipment used. | Yes | No |
| Packaging Services – Does your organization offer any packaging design and/or assembly services?If yes, please describe and identify any specialized equipment used. | Yes | No |
| Regulatory Services – Does your organization offer any regulatory services?If yes, please describe. | Yes | No |
| Customer Fulfillment Services – Does your organization offer any customer fulfillment services?If yes, please describe. | Yes | No |
| Warranty and Repair Services – Does your organization offer any Warranty and Repair Services? If yes, please describe. | Yes | No |
| Other Services – Please let us know of any other specialty service(s) that you provide. |  |