|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **SUPPLIER PROFILE** | | | | | | |
| 1. **GENERAL INFORMATION** | | | | | | |
| **Company Name** |  | | | | | |
| **Address** |  | | | | | |
| **Contact Name** |  | | | | | |
| **E-mail Address** |  | **Phone Number** | |  | | |
| **Public or Private** |  | **Years in Business** | |  | | |
| **Number of employees** |  | **% Capacity Utilization** | |  | | |
| **Product, materials and services offered** | | | | | | |
|  | | | | | | |
| **FDA registered device manufacturer number or N/A** | | | | | | |
|  | | | | | | |
| **Is your company registered to any recognized quality standards? (ISO 13485, 17025, 9001)** | | | | | | |
| * **If yes, please send a copy of your registration and skip to section III.** * **If no, are you pursuing ISO registration?** | | | | | | |
|  | | | | | | |
| **Is there anything else you would like us to know about your company?** | | | | | | |
|  | | | | | | |
| **Please provide a copy of the Organizational Chart.** | | | | | | |
| **SUPPLIER SURVEY** | | | | | | |
| 1. **QUALITY MANAGEMENT** | | |  | |  |  |
| **Question** | | | **Yes** | | **No** | **Comment** |
| **Do you have an established Quality Management System manual?** | | |  | |  |  |
| **Is there a company quality statement?** | | |  | |  |  |
| **Do you have an established procedure for the control of quality records?** | | |  | |  |  |
| **Do you have documented training programs, including effectiveness evaluation, for personnel?** | | |  | |  |  |
| **Do you have a documented procedure for corrective and preventive actions?** | | |  | |  |  |
| 1. **MATERIALS** | | | | | | |
| **Question** | | | **Yes** | | **No** | **Comment** |
| **Is there an "approved supplier list" which ensures all suppliers (vendors, distributors and subcontractors) meet quality standards, undergo periodic surveillance and auditing, and provide products in accordance with applicable quality standards?** | | |  | |  |  |
| **Do you have a documented inspection process?** | | |  | |  |  |
| **Do you have written procedures controlling sampling plans?** | | |  | |  |  |
| **Are your sampling inspection plans based on a statistically valid source?** | | |  | |  |  |
| **Do you have a documented procedure for receiving inspection?** | | |  | |  |  |
| **Do you have a documented procedure for identifying and controlling non-conforming material?** | | |  | |  |  |
| **Do you have disposition procedures for acceptance and rejection of purchased goods or services upon receipt?** | | |  | |  |  |
| **Do you maintain traceability of your material from receiving to delivery?** | | |  | |  |  |
| **Do you have an established procedure for handling and distribution of products?** | | |  | |  |  |
| **Do you incorporate Materials Requirements Planning (MRP)?** | | |  | |  |  |

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| **SUPPLIER SURVEY (cont)** | | | | | | |
| 1. **MANUFACTURING CAPABILITIES** | | | | | | |
| **Question** | | **Yes** | | **No** | **Comment** | |
| **How do you maintain, communicate and ensure compliance to customer specifications?** | |  | |  |  | |
| **Do you use written manufacturing process instructions to assure process repeatability?** | |  | |  |  | |
| **Are your manufacturing processes validated following the requirements of 21 CFR 820 Quality System Regulation and ISO 13485?** | |  | |  |  | |
| **Do you have a written maintenance schedule where maintenance of equipment is necessary to assure manufacturing specifications are met?** | |  | |  |  | |
| **Is the Preventive Maintenance work documented and records maintained?** | |  | |  |  | |
| **Do you control tool life per the manufacturer’s specifications?** | |  | |  |  | |
| **Do you have the capability to make tools?** | |  | |  |  | |
| **Do you have documented and approved procedures or controls that prevent the cross-contamination of lots?** | |  | |  |  | |
| 1. **FACILITIES AND EQUIPMENT** | | | | | | |
| **Question** | | **Yes** | **No** | | | **Comment** |
| **Do you have procedures for removal of hazardous materials?** | |  |  | | |  |
| **Security - Does the supplier have adequate protection for burglary, fire, etc.?** | |  |  | | |  |
| **Do you have a disaster back-up plan?** | |  |  | | |  |
| **Is inventory adequately stored, controlled, and supervised?** | |  |  | | |  |
| **Is there a tool and equipment calibration program which includes; all tools and tooling which require calibration, frequency and due date of calibration, personal tools, and a system to prevent the use of tools out of calibration?** | |  |  | | |  |
| **When processes/equipment are revised/changed are these revisions/changes documented and processes re-validated?** | |  |  | | |  |
| **Do you have an established procedure for storage of products?** | |  |  | | |  |
| **Is material with limited shelf life identified and controlled?** | |  |  | | |  |
| **SUPPLIER SURVEY (cont)** | | | | | | |
| **The information contained in this questionnaire is true and correct at the time of issue. Any major changes to key personnel, business address, company approvals or product lines will be reported if and when they occur.** | | | | | | |
| **Signed** |  | | | | | |
| **Title** |  | | | | | |
| **Date** |  | | | | | |

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| --- | --- | --- |
| **For Internal Use Only: Decision** | | |
| **Survey Results Acceptable:** | **Conditional Approval:** | **Survey Results Unacceptable:** |
| **Comments:** | | |
| **Approved by/Date:** | | |