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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **1. Company Details:** | | | | | | | | | | | | | | | | | | |
| Company Name: | |  | | | | | | | | | | | | | | | | |
| Address: | | | | | | | | | | | | Telephone: | | | | | | |
| Fax: | | | | | | |
| e-mail: | | | | | | |
| Materials or Services Provided: | |  | | | | | | | | | | | | | | | | |
| Part Number(s)  N/A: | |  | | | | Supplier Part Number(s)  N/A: | | | | | | | | | | | | |
| **2. Organization:** | | | | | | | | | | | | | | | | | | |
| # Of Employees: | | |  | | | | | | | Years in Business: | | | | |  | | | |
| **3. Management:** | | | |  | | | | | | | | | | | | | | |
| Operations Representative: | | | |  | | | | | | | | | | | | | | |
| Quality Representative: | | | |  | | | | | | | | | | | | | | |
| **4. Supplier Selection Criteria:** | | | | | | | | | | | | | | | | | | |
| 1. Is company in conformance with ISO 13485? | | | | | Yes | |  | No |  | | Part 820 (FDA QSR) | | |  | | Yes |  | No |
| If yes; | Certification Body: | |  | | Registration Number: | | | | | | | |  | | | | | |
| Include copy of certificate, and Quality Policy, as possible. | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | |
| 1. Is company in conformance with ISO 9001? | | | | | Yes | |  | No |  | | ISO 17025 | | |  | | Yes |  | No |
| If yes; | Certification Body: | |  | | Registration Number: | | | | | | | |  | | | | | |
| Include copy of certificate, and Quality Policy, as possible. | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | |
| 1. Professional Licenses/Accreditations? | | | | | Yes | |  | No |  | |  | | |  | |  | |  |
| If yes; | Certification Body: | |  | | License Number: | | | | | | | |  | | | | | |
| Include copy of Service Provider/Contractor Curriculum Vitae/Resume. | | | | | | | | | | | | | | | | | | |

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| **Supplier Selection Justification** | | | | | | |
| Comments: | | | | | | |
| **Supplier Evaluation and Approval** | | | | | | |
| **Supplier Level: 1 2 3 4** | | | | | | |
| **Evaluation Criteria used for Approval:** | | **Onsite Audit**  **Survey**  **Other:** | | **ISO 13485 Cert**  **FDA registration** | | |
| **Does Supplier perform processes requiring validation to ensure quality requirements have been met?**  No Yes  (if yes, review and list appropriate validations) | | **Validations Reviewed:** | **Are the Validations Acceptable? Yes**  **No** | | | |
| **Approved:**  *(Approved Suppliers to be added to ASL)* | | **Conditional Approval:**  *(list requirements for full approval in comments section)* | | | **Debarred:**  *(Supplier to not be added to ASL or removed from ASL)* | |
| **Comments:** | | | | | | |
| **Quality Approval:** |  | | | | | **Date:** |
| **Operations Approval:** |  | | | | | **Date:** |