**\*\* Return to GT Medical via email \*\***

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| **Supplier Information** | | |
| Supplier Name: | | Address of site being qualified: |
| Web page: | |
| Federal Tax ID: | Parent Company: |

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| **Criticality**  ***Supplier:*** *Do not complete this* | Critical[[1]](#footnote-1) | If Critical, complete SECTION 1 and 2 |
| Non-critical | If Non-critical, complete SECTION 1 only |

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| **Supplier Contacts** | **Name** | **Role** | | **Phone** | **E-mail** |
|  | Operations | |  |  |
|  | RAQA | |  |  |
|  | Accts Payable | |  |  |
|  | Sales/C. Service | |  |  |
| *<Add others if needed>* |  | |  |  |
| **Type of Material/Product/Service Supplied** | | | | | |
| Calibration  Components  Computer services  Facility equipment/service  Packaging  Printed material  Manufacturing equipment | | | Outsourced manufacturing services  Translations  Consulting  Service provider *(describe services)*:  Other *(describe)*: | | |

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| **SECTION 1 – Overall Business**  *Please answer the following questions.  Explanations or details may be included in the provided space.* | |
| **Question** | **Response** |
| What portion of your business does our company represent? |  |
| What portion of your business is in FDA-regulated products/services? |  |
| What is your current capacity? |  |
| How many years has your company been in business? |  |
| What is your company’s status (private, public)? |  |
| Approximate annual sales |  |
| How many employees currently work for your company? | Quality:  Production:  Development:  Clinical:  Administration/Other:  Total: |
| Do you monitor on-time deliveries? How are you performing? |  |
| How many shifts are you currently running? |  |

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| **SECTION 2 – Supplier Process Controls**  *If the supplier can provide evidence of a quality management system compliant to 21 CFR 820 and ISO 13485 ,* ***this section may be left blank****. Evidence of compliance must be included/referenced in the COMMENTS space at the bottom.*  *Otherwise, please answer the following questions. Explanations or details may be included in the COMMENTS space at the bottom.* | | |
| Are your Quality Assurance responsibilities and authorities clearly defined in writing? | | Yes No N/A |
| Is QA given the authority to hold items/services that have not yet met acceptable quality standards? | | Yes No N/A |
| Does QA have direct access to appropriate levels of company management for quality problems? | | Yes No N/A |
| Is there a Quality Assurance Manual? If yes, please furnish a copy. | | Yes No N/A |
| Is there a Document Control program in place to maintain and issue revision updates to drawings, documentation, change orders, etc.? | | Yes No N/A |
| Does QA prepare and issue periodic reports and maintain quality records? | | Yes No N/A |
| Is there a system for quality evaluations and approval of potential suppliers? | | Yes No N/A |
| Do purchase orders specify specifications and/or acceptance criteria? | | Yes No N/A |
| Does your Quality Assurance system require that your own sub-suppliers have a Quality Assurance program? | | Yes No N/A |
| Do you perform periodic audits of your critical suppliers? | | Yes No N/A |
| Do you perform receiving inspections? | | Yes No N/A |
| Are inspectors provided with documented instructions? | | Yes No N/A |
| Do you notify your customer when you intend to or have made changes to materials or process parameters? | | Yes No N/A |
| Do you have a control process for items with a limited shelf-life? | | Yes No N/A |
| Is there an in-process inspection activity performed according to written instructions? | | Yes No N/A |
| Do you maintain a system that identifies and prevents the unauthorized use of materials that have not yet been inspected? | | Yes No N/A |
| Are finished goods/services inspected or tested according to written instructions to ensure that requirements have been met? | | Yes No N/A |
| Do you maintain control of material/services to ensure that uninspected /untested parts/processes are not shipped/implemented? | | Yes No N/A |
| Are shipping inspections conducted? | | Yes No N/A |
| Is product packaged to prevent contamination and/or damage? | | Yes No N/A |
| Do you maintain a formal calibration program traceable to national or international standards? | | Yes No N/A |
| Is there a documented system for handling nonconforming material where nonconformance reports regularly prepared and reviewed by management for action? | | Yes No N/A |
| Does the corrective action system prevent repetitive discrepancies and allow for prompt remedial actions? | | Yes No N/A |
| Is there a control process to prevent mix-up during manufacturing and labeling operations? | | Yes No N/A |
| Is training and/or certification/re-certification documented and records maintained for personnel? | | Yes No N/A |
| Upon encountering customer complaints and reports of product nonconformities is corrective action taken and communicated to the customer? | | Yes No N/A |
| If you manufacture medical components/products, when was the last time your facility was inspected by the FDA?  Date: | | Yes No N/A |
| How many form 483’s did your company receive during the last FDA inspection? | | Yes No N/A |
| Is a copy of the results of the FDA inspection available for review? If available, please attach. | | Yes No N/A |
| Is your facility ISO certified? If so, to which standard/ revision?\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Attach a copy of the certification. | | Yes No N/A |
| When was your last certification audit? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Please provide a copy of the audit report. | | Yes No N/A |
| Is product identified by lot/batch number? | | Yes No N/A |
| Are expiration dates assigned based on average shelf life determinations? | | Yes No N/A |
| Do you maintain records on product shipments with positive traceability to all raw materials? | | Yes No N/A |
| Is there a regularly scheduled Management Review meeting to assess the overall effectiveness of the quality management system? | | Yes No N/A |
| **COMMENTS (add any additional information regarding the questions above):** | | |
| **Supplier Qualification Checklist completed by:** | | | |
| Name and Title: | Signature & Date: | | |

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| --- | --- | --- |
| ***SUPPLIER APPROVAL***  *GT Medical use only.* ***Supplier:*** *Do not complete this section.* | | |
|  | *Conditionally Approved* | *If conditionally approved, specify conditions:* |
| *Approved By (Print Name and Title):* | *Signature & Date:* |
| *Approved* |  |
| *Approved By (Print Name and Title):* | *Signature & Date:* |
| *Not Approved* | *If Not Approved, state reason:* |
|  | *Determined By (Print Name and Title):* | *Signature & Date:* |
|  | *Disqualified* | *If Disqualified, state reason:* |
|  | *Determined By (Print Name and Title):* | *Signature & Date:* |

*This form may be input electronically for legibility purposes. Electronic input may result in multiple pages.*

1. Supplier delivering materials, components, or services that may directly and/or significantly influence the safety and performance of the product. [↑](#footnote-ref-1)