NISSHA
MEDICAL TECHNOLOGIES

SUPPLIER QUALIFICATION AND APPROVAL FORM

SUPPLIER QUESTIONAIRE

Supplier Information

Supplier Name	
Address	
Website	
State	Zip
Phone	Fax

Contacts

President/Owner	_____	E-mail	_____
Operations Manager	_____	E-mail	_____
Quotations	_____	E-mail	_____
Expediting	_____	E-mail	_____
Quality	_____	E-mail	_____
Accounting	_____	E-mail	_____
Engineering	_____	E-mail	_____
Purchasing / Materials	_____	E-mail	_____
Sales	_____	E-mail	_____

Business Information

Type of business ownership: _____

Products and/or Services Supplier Provides:

_____

Attach Supplier capability listing or line card to this form.

Number of years in business: _____ Number of shifts run? _____

Number of Employees: _____ Building Square Footage? _____

Annual employee turnover: ☐ <1% ☐ 1-5% ☐ 6-10% ☐ 11-20% ☐ >20%

Suppliers current annual Sales: Year_____ $ _____

Suppliers projected Sales Growth in the next year? $_____ 2 yrs: $_____ 5 yrs: $_____

NISSHA
MEDICAL TECHNOLOGIES

Largest Customers

1. Company Name: _____

Industry _____ Percentage of Sales: % _____

Contact that may be called on: _____ Phone Number: _____

2. Company Name: _____

Industry _____ Percentage of Sales: % _____

Contact that may be called on: _____ Phone Number: _____

General

What is Supplier's typical planned capacity utilization? %_____

Capital Equipment Re-investment in %: Last year_____ Next Year_____

Human Resources investment in %: Last year_____ Next Year_____

Percentage of complete work that is Sub-contracted %_____

Supplier has insurance covering sub-contractors or requires sub-contractor to carry insurance covering Raw Material, WIP, and Finished Goods? _____

Customer Service

Supplier provides value added sub-assembly capabilities? _____

Supplier can read electronic files of engineering prints? Solid Works, etc. (Circle file types that are applicable or list additional types)

_____

Supplier utilizes a formal customer design review process? ◯ **No** ◯ **Yes**

Supplier's on time delivery to all customers is? % _____

Supplier's percentage of customer returns is? % _____

Supplier's typical quotation turnaround time is? _____ **Days**

General lead times for; Prototype _____ Production _____

Production Tooling _____

Supplier is familiar with and utilizing demand pull delivery systems (Kanban)? _____

Supplier is using bar-coding technology? _____

FACILITY PROFILE	Yes	No	Comments
Is the facility registered with the FDA?	☐	☐	
If yes, registration number:			
If yes, date of last inspection by the FDA:			
Were there any findings during the audit?	☐	☐	
If yes, were recalls involved?			
If yes, what was recalled?			
Is the facility in compliance with RoHS guidelines?	☐	☐	
If yes, provide accompanying documentation. Approved RoHS material declaration documents include: - IPC-1752 Materials Declaration - Raw Material Data Sheet (RMDS) - Laboratory Analysis Report (LAR) - X-Ray Fluorescence Analysis Report (XRF) - Manufacturer's published data sheet indicating RoHS Compliance (MPDS) - Part Assembly RoHS Certification (PARC)			
Do your products contain BPA, DEHP?	☐	☐	
- Please provide declaration / statement on BHA/DEHP			
Do your products contain latex?	☐	☐	
- Please provide declaration / statement on latex			
Is the facility ISO certified?	☐	☐	
If yes, certification number and certificate copy			
List other special certifications:			

If ISO Certified, stop here skip to last page to complete.

(PLEASE REMEMBER TO INCLUDE A COPY OF YOUR ISO CERTIFICATE(S))

A	MANAGEMENT RESPONSIBILITY	Yes	No	Procedure Number	Comments
1	Is there an organization chart that identifies elements responsible for quality efforts? If yes, please provide a copy.	☐	☐		
2	Is there a formal Quality Control/Assurance department?	☐	☐		
3	Do personnel performing the quality function have the responsibility and freedom of action to identify, quarantine and evaluate quality problems?	☐	☐		
4	Does company management approve a documented Quality Manual?	☐	☐		
5	Are personnel performing the quality function trained in the procedures, instructions and methods identified in the quality manual?	☐	☐		
6	Is there a system providing for training all personnel regarding quality philosophies?	☐	☐		
7	Is there a system to capture and analyze quality costs?	☐	☐		

B	DOCUMENT CONTROL	Yes	No	Procedure Number	Comments
1	Is there a formal Document Control System?	☐	☐		
2	Is there a formal Change Control System?	☐	☐		
3	Is there revision control to ensure the current document status?	☐	☐		
4	Are the latest specifications available at the manufacturing location?	☐	☐		
5	Are records maintained?	☐	☐		
6	Is their documented record retention policy?	☐	☐		
7	Is a system in effect to control customer furnished specifications?	☐	☐		

C	NEW PRODUCT DEVELOPMENT	Yes	No	Procedure Number	Comments
1	Is there a formal design control process and team for new products?	☐	☐		
2	In the pre-production process, are quality characteristics selected for a product based on their relative importance?	☐	☐		
3	Are potential sources of manufacturing problems and control of-quality problems identified and eliminated prior to start of manufacture?	☐	☐		
4	Are revised specifications reviewed prior to acceptance?	☐	☐		
5	Are process capability studies performed?	☐	☐		
6	Are quality costs analyzed when evaluating proposed changes to methods, materials, personnel, and equipment?	☐	☐		

D	PURCHASING	Yes	No	Procedure Number	Comments
1	Are product requirements clearly identified on Purchase Orders?	☐	☐		
2	Are there controls to ensure that purchased materials meet requirements such as: - Receipt of statistical data verifying conformance to specifications? - Receipt of Certificates of Analysis or Compliance? - Receiving inspections or tests?	☐	☐		
3	Is corrective action related to supplier products prompt and effective?	☐	☐		
4	Is there an effort to know and understand supplier's quality systems through the use of: - Periodic audits performed at source locations? - Supplier rating system? Supplier qualification program?	☐	☐		
5	Will Suppliers agree to not change materials or design without notice to GC?	☐	☐		

E	PRODUCT IDENTIFICATION	Yes	No	Procedure Number	Comments
1	Are there procedures that ensure adequate product identification?	☐	☐		
2	Is the status of all products clearly identified?	☐	☐		
3	Is product traceability maintained throughout all phases of manufacturing?	☐	☐		
4	Does product identification provide traceability to individuals performing inspection?	☐	☐		

F	PROCESS CONTROL	Yes	No	Procedure Number	Comments
1	Is product produced following documented instructions or control plan?	☐	☐		
2	Are documents containing specific manufacturing and inspection instructions available and utilized during production?	☐	☐		
3	Are process adjustment and shutdown limits clearly established?	☐	☐		
4	Is product traceability maintained throughout production?	☐	☐		
5	Do Supplier have a formal, documented environmental control system?	☐	☐		
6	If yes, what level of cleanliness is maintained in production?	☐	☐		
7	Are GMP policies enforced in the manufacturing areas?	☐	☐		
8	Can traceability be maintained throughout the manufacturing process?	☐	☐		
9	Are there documented housekeeping and pest control procedures?	☐	☐		

10	Are manufacturing processes documented?	☐	☐		
11	Are manufacturing processes validated?	☐	☐		
12	Are there written procedures for packaging and labeling?	☐	☐		

G	IN-PROCESS INSPECTION	Yes	No	Procedure Number	Comments
1	Are in-process inspections performed per documented instructions?	☐	☐		
2	Is product inspected, measured or tested after process set-up and after process changes to ensure that product consistently meets requirements?	☐	☐		
3	Is product inspected, measured or tested during processing to assure continuous conformance to requirements?	☐	☐		
4	Is sampling performed per documented sample plans?	☐	☐		

H	RECEIVING INSPECTION	Yes	No	Procedure Number	Comments
1	Is product inspected to ensure conformance to requirements prior to production use?	☐	☐		
2	Is product that has been accepted on the basis of test reports or certificates subjected to periodic verification?	☐	☐		
3	Is product pending inspection, accepted product and nonconforming product identified and segregated?	☐	☐		
4	Is sampling performed per documented sample plans?	☐	☐		
5	Is there a sample retention policy?	☐	☐		

I	FINAL INSPECTION	Yes	No	Procedure Number	Comments
1	Is sampling performed per documented sample plans?	☐	☐		
2	Are there documented procedures for use during inspection, test and measuring which include reference to visual aids, sample plans and equipment?	☐	☐		
3	Are there documented procedures to assure that nonconforming product is clearly identified and segregated?	☐	☐		
4	Is responsibility and authority for final disposition of nonconforming product defined?	☐	☐		

J	INSPECTION, MEASURING AND TEST EQUIPMENT	Yes	No	Procedure Number	Comments
1	Is there a system in effect for calibrating inspection, measuring, and test equipment used to verify product conformance to requirements?	☐	☐		

2	Are inspection, measuring and test equipment identified to show: - Date calibrated and calibration due date? - Person who performed calibration? - Device identification?	☐	☐		
3	Are calibration records maintained?	☐	☐		
4	Do calibration records reflect: - Device identification? - Calibration method? - Master Standard reference? - Calibration date? - Calibration frequency? - Person who performed calibration? - Deviation from standard? - Acceptance criteria? - Corrective action on device found to be out of calibration?	☐	☐		
5	Is there a system to validate product inspected, measured or tested during the time a device was found out of calibration?	☐	☐		
6	Is inspection, measuring and test equipment identified and removed from the system when found out of calibration?	☐	☐		
7	Are standards calibrated with certified masters traceable to the National Institute of Standards and Technology (NIST) or its international equivalent?	☐	☐		
8	Are laboratory reagents and other chemicals identified and tested?	☐	☐		
9	Is preventive maintenance performed on production equipment?	☐	☐		
10	Are maintenance and service records available for production equipment?	☐	☐		

K	CORRECTIVE ACTION	Yes	No	Procedure Number	Comments
1	Is there a corrective action system in place that provides for prompt identification and correction of conditions adverse to product quality?	☐	☐		
2	Is non-conforming product data analyzed to determine cause and extent of quality problems?	☐	☐		
3	Is the responsibility and authority for final implementation of corrective action defined?	☐	☐		
4	Is follow-up action performed to verify the effectiveness of corrective action?	☐	☐		
5	Are customers notified when non-conforming product may have been inadvertently shipped?	☐	☐		
6	Do corrective action activities emphasize prevention?	☐	☐		
7	Are suppliers required to meet or exceed internal corrective action requirements?	☐	☐		
8	Is there a system to handle customer rejected or returned goods that includes reporting corrective and preventative action to the customer?	☐	☐		

L	PRODUCT STORAGE, HANDLING, PACKAGING, DELIVERY	Yes	No	Procedure Number	Comments
1	Are storage facilities adequate to safeguard product from damage, contamination or loss?	☐	☐		
2	Is there a system for handling product to prevent damage, contamination, or loss?	☐	☐		
3	Is status of all products clearly identified?	☐	☐		
4	Are product storage areas restricted to authorized personnel?	☐	☐		
5	Is product traceability maintained during storage and handling?	☐	☐		
6	Is there a stock rotation system?	☐	☐		
7	Are procedures in place covering packaging, shipping?	☐	☐		
8	Do procedures meet appropriate government agency guidelines (DOT or EPA for example)?	☐	☐		
9	Are procedures in place to ensure that containers and bulk trailers are clean prior to filling?	☐	☐		

M	RECORDS	Yes	No	Procedure Number	Comments
1	Is there a documented policy for identifying and maintaining quality records?	☐	☐		
2	Do quality records identify: - Characteristics to be measured? - Number and description of non-conformities? - Acceptance criteria? - Reference the action taken? - Disposition of inspected material? - Inspector identification? - Date of inspection?	☐	☐		
3	Is there a system to assure review of quality records?	☐	☐		

N	INTERNAL AUDITS	Yes	No	Procedure Number	Comments
1	Is there an internal audit system in place for assessing effectiveness of the quality system and to assess compliance with documented procedures and instructions?	☐	☐		
2	Do internal audits include the evaluation of activities, processes, work areas, services, and systems as well as written procedures, instructions and other quality system documentation?	☐	☐		
3	Is responsibility for the internal audit system independent from the responsibility for the performance of manufacturing and quality functions?	☐	☐		
4	Are timely corrective actions taken on audit non-conformances?	☐	☐		
5	Are internal auditors trained?	☐	☐		

O	STATISTICAL PROCESS CONTROL	Yes	No	Procedure Number	Comments
1	Are appropriate means used to determine whether processes are in statistical control, using critical quality characteristics?	☐	☐		
2	Is there evidence that critical quality characteristics are used to determine whether processes continue to be in statistical control?	☐	☐		
3	Is corrective action taken on processes found to be out of statistical control?	☐	☐		
4	Are process capability studies performed and utilized?	☐	☐		
5	Are critical quality characteristics predictably distributed?	☐	☐		
6	Is a system in place to reduce inherent variability or move the process average to target?	☐	☐		
7	Is inspection, measuring and test equipment analyzed for capability, precision and accuracy prior to purchase and use?	☐	☐		
8	Is there a system to correlate internal inspection, measuring and test equipment with customer results?	☐	☐		

GENERAL NOTES OR COMMENTS:

COMPLETED BY:

_____ **Date:** _____

TITLE:

_____

NISSHA
MEDICAL TECHNOLOGIES

For Graphic Controls use only:

Critical Supplier? ☐ **Yes** ☐ **No**

PURCHASING

Supplier Scorecard? ☐ **Yes** ☐ **No**

Comments		☐ Approved ☐ Rejected
Name	Signature	Date

ENGINEERING

Required on Critical Suppliers only

Comments		☐ Approved ☐ Rejected
Name	Signature	Date

QUALITY

1st Article? ☐ **Yes** ☐ **No**
Part Qualification? ☐ **Yes** ☐ **No**

Required on Critical Suppliers only

Comments		☐ Approved ☐ Rejected
Name	Signature	Date