SUPPLIER QUALIFICATION ASSESSMENT

Name of Supplier: _____

Mailing Address: _____

Number and street or PO Box

_____

City *Province/State* *Postal/Zip Code*

Remittance Address: ☐ ***Same as above or***

_____

Number and street or PO Box

_____

City *Province/State* *Postal/Zip Code*

Type of Supplier: ☐ **Manufacturer** ☐ **Distributor** ☐ **Machine Shop**

☐ **Broker/Agent** ☐ **Service** ☐ **Calibration**

Type of Product or Service Provided:

Quality Contact: _____ **Sales Contact:** _____

Quality Telephone: _____ **Sales Telephone:** _____

1. **Do you have a documented Quality Assurance System in accordance with a national / international model, such as ISO 9001, API Q1, QS 9000, AS 9000, CLIA Certification, FDA Regulations, Health Canada, AATB, EBAA, etc.?**

   ☐ **Yes** ☐ **No**

   If "Yes", which standard? _____

   Date of Certification: _____ **Certificate No:** _____

   Registrar: _____

2. **If you are not certified to a recognized Quality Assurance Standard, do you plan to achieve certification?**

   ☐ **Yes** ☐ **No**

   If "Yes", what is your target date for certification? _____

IMPORTANT:

A) If you <u>are certified</u> to a recognized Quality Assurance Standard, please return a copy of your certification and <u>do not</u> complete the remainder of this Survey.

B) If you <u>are not certified</u> to a recognized Quality Assurance Standard, please complete the remainder of this survey and return it to:

Trillium Gift of Life Network
Attention: Quality Assurance Department
483 Bay Street South Tower, 4th Floor
Toronto, Ontario M5G 2C9
Phone: 416-363-4001
Fax: 416-363-4002

Management Responsibility and Quality Management System

3. **Does your organization have an organizational chart or similar document that defines responsibilities within the organization?**
   ☐ **Yes** ☐ **No**
4. **Does your organization have a Quality Manual?**
   ☐ **Yes** ☐ **No**
5. **Are documented Quality procedures in place to ensure the quality of goods and/or services provided?**
   ☐ **Yes** ☐ **No**
6. **Does your Quality Manual establish the authority and responsibility for assigned quality personnel to adequately implement and enforce it?**
   ☐ **Yes** ☐ **No**
7. **Do Management Responsibility procedures specify a Management Review of the Quality System for suitability and effectiveness?**
   ☐ **Yes** ☐ **No**

Design Control and Prototype Verification

8. **Does your company have procedures that control the design of products to ensure that requirements are correctly translated into specifications, drawings and procedures?**
   ☐ **Yes** ☐ **No**

9. **Does your organization maintain detailed records of all test and test results of prototype verification**
   ☐ **Yes** ☐ **No**

Document and Data Control

10. **Do you have established document control procedures to ensure that the latest revision of documents are available at the locations where operations essential to the quality system are performed?**
    ☐ **Yes** ☐ **No**

11. **Are documented Quality procedures periodically reviewed and updated?**
    ☐ **Yes** ☐ **No**

    By whom? _____

    At what intervals? _____

Purchasing Controls

12. **Does your organization have established procedures to ensure that all purchased or otherwise received products and services conform to specified requirements?**
    ☐ **Yes** ☐ **No**

13. **Do you have documented procedures for the evaluation and selection of sub-contractors?**
    ☐ **Yes** ☐ **No**

14. **Do you maintain quality records of subcontractors (do you have an Approved Supplier List?)**
    ☐ **Yes** ☐ **No**

Product Identification and Traceability

15. **Do you maintain procedures for suitable means of unit, lot or batch traceability of product from receipt and through all stages of production and delivery?**
    ☐ **Yes** ☐ **No**

16. **Do you maintain procedures to facilitate recall of units, lots or batches due to defects or non-conformance to specified requirements?**
    ☐ **Yes** ☐ **No**

Please feel free to add any additional comments below (feel free to add additional pages if necessary):

_____

_____

Submitted by: _____ **Date:** _____
Please print clearly

Title: _____