LifeNet Health®
Saving Lives. Restoring Health. Giving Hope.
1864 Concert Drive, Virginia Beach, VA 23453

SUPPLIER SELECTION QUESTIONNAIRE

(Additional Information may be attached, as necessary)

1. GENERAL INFORMATION

1a) Supplier Name: Website:

Mailing Address: City: State: Zip:

Remit To Address: City: State: Zip:

Type of Product/Service: Type of Ownership: (LLC, Corp, etc.)

1b) Billing Contact Name and Title: Available hours:

Fax No.: E-mail: Telephone No.:

1c) Customer Service Contact Name and Title: Available hours:

Fax No.: E-mail: Telephone No.:

1d) Primary Quality Contact Name and Title: Cell Phone:

Fax No.: E-mail: Office Phone:

Reports-to Name and Title: Cell Phone:

Fax No.: E-mail: Office Phone:

1e) Primary Sales Contact Name and Title: Cell Phone:

Fax No.: E-mail: Office Phone:

Reports-to Name and Title: Cell Phone:

Fax No.: E-mail: Office Phone:

1f) Is the supplier a division or subsidiary of another company: ☐ Yes ☐ No If marked "Yes", provide name:

1g) Please provide any of the following optional documents:
Company History, Mission/Vision/Guiding Principles/Quality Policy, List of available Products/Services, Locations, Org Chart, Company Brochures

1h) ARIBA Network ID (If available):

2. FINANCIAL INFORMATION

2a) Tax ID or EIN:

2b) Date Company Started / Founded:

2c) D-U-N-S (D&B) No.:

2d) Accept Payments via Credit Card: ☐ Yes ☐ No ☐ N/A

2e) Financial References:

Name	Address	Contact	Phone No.

3. PERSONNEL

3a) Operational schedule: Hours: Shifts: Days / Week:

3b) Please list any planned down time for production (holidays, maintenance, inventory, etc., list scheduled dates):

3c) What is your current number of employees? Full time: ____________ Part time: ____________

4. QUALITY INFORMATION

4a) Check all of the following that exist and are available for customer review:

Documents	Exists	Available (***if available, please provide copies***)
Standard Operating Procedures (SOPs)	☐	☐
Quality Manual	☐	☐
Other (Describe):	☐	☐

4b) What Federal and State Regulatory requirements are applicable to the supplier and services/product?

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4. QUALITY INFORMATION, Continued

4c) Certifications and Registrations (***Attach evidence with submission of this form***):

- ☐ ISO Standard No. ____________ Date Registered: ____________
- ☐ CE
- ☐ FDA
- ☐ CLIA Lab Standard
- ☐ Other (Briefly describe and specify qualification to applicable laboratory standards):

4d) How many of your products were recalled in the last 4 years?

4e) How much notice is required prior to a Quality audit from LifeNet Health?

	Question		
4f)	Does your company employ receiving, in-process and final inspection?	☐ Yes	☐ No
4g)	Is there a Corrective Action system established to address complaints and non-conforming products?	☐ Yes	☐ No
4h)	Does your company have a Quality records retention policy?	☐ Yes	☐ No
4i)	Does your company have a supplier performance management policy in place?	☐ Yes	☐ No
4j)	Is there a segregated / access restricted area for non-conforming or quarantined items?	☐ Yes	☐ No
4k)	Is there a "Change Control" system in place for documents and products?	☐ Yes	☐ No
4l)	Is there a formal or documented Product Development System in place?	☐ Yes	☐ No

4m) Are internal quality audits performed? ☐ Yes ☐ No If marked "Yes", frequency of audits?:

4n) Has supplier been audited by the FDA? ☐ Yes ☐ No If marked "Yes", audit date(s): ____________

List major Findings/Comments:

Have all findings been satisfactorily resolved? ☐ Yes ☐ No

4o) Has supplier been inspected by any other Regulatory Agency(s) within the past 5 years? ☐ Yes ☐ No If marked "Yes", date of inspection: ____________

List major Findings/Comments:

Have all findings been satisfactorily resolved? ☐ Yes ☐ No

5. BUSINESS CONTINUITY PLANNING

	Question			
5a)	Does your company have a written and active Business Continuity Plan (BCP)?	☐ Yes	☐ No	If yes, provide a copy of your plan with your SSQ submission.
5b)	Do you review, exercise, and update your BCP at least annually?	☐ Yes	☐ No	Use Remarks section, if necessary.
5c)	Do you request customer feedback on updates to the plan?	☐ Yes	☐ No	Use Remarks section, if necessary.
5d)	Are you registered (certified) to any recognised Business Continuity Standard for the full range of products, services and works you provide?	☐ Yes	☐ No	Use Remarks section, if necessary.
5e)	Do you identify and mitigate risks or threats to the business operations from specific events such as local/regional events, warnings of heavy weather or localised flooding, power outages etc.?	☐ Yes	☐ No	Use Remarks section, if necessary.
5f)	Have you assessed the risks or threats to your critical activities and are essential for your delivery of the full range of your products, services and works?	☐ Yes	☐ No	Use Remarks section, if necessary.
5g)	Does your business continuity strategy account for people, premises, technology, information, suppliers and stakeholders?	☐ Yes	☐ No	Use Remarks section, if necessary.
5h)	Have you consulted your suppliers, service, and utilities providers during the preparation of plans, and regularly confirmed that they will be able to continue service to you, even in the event of their having an incident?	☐ Yes	☐ No	Use Remarks section, if necessary.
5i)	Do you encourage your suppliers/partners to have BCPs?	☐ Yes	☐ No	Use Remarks section, if necessary.

5j) Remarks:

6. ADDITIONAL INFORMATION REQUIRED

Supplier Category	Additional forms to be completed
Service / Consulting Providers	Attachment "A"
Distributors	Attachment "B"
Manufacturers	Attachment "C"
All Suppliers	Attachment "D"

NOTE: Suppliers seeking qualification under multiple categories must complete each corresponding attachment for the appropriate supplier category (i.e. a company seeking qualification as a distributor and manufacturer must complete both Att. "B" and "C".)

7. SIGNATURE

The undersigned warrants and represents the data provided is accurate. Questionnaire prepared by:

Signature: ____________

Print Name: ____________

Title: ____________

Date: ____________ **Phone:** ____________

E-Mail: ____________

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ATTACHMENT "A" - Service / Consulting Providers

1. **ALL SUPPLIERS.** For all suppliers providing on-site services, provide Certificates of Insurance for General Liability, Employers Liability, and Excess Umbrella coverage.

1a) Are customers notified if significant process changes are implemented that may affect your service? ☐ Yes ☐ No (If no, explain in Box Ie)

1b) Are customers notified 90-days in advance of any changes or discontinuance to services or products ordered? ☐ Yes ☐ No (If no, explain in Box Ie)

1c) As required per FDA 21 CFR 820.50(b), does your company agree to provide advance notification to LifeNet Health of any changes to the form, fit, function, formulation or material composition of the service and/or items provided to LifeNet Health or any changes in testing, repair parts, specification standards or other service related items? ☐ Yes ☐ No (If no, explain in Box Ie)

1d) Do you outsource any part of the services to be provided to LifeNet Health? ☐ Yes ☐ No If yes, provide details on outsourced processes / products and how quality oversight is maintained for the process in Box 1e.

1e) Remarks (attach additional page(s) if necessary):

Scope of Services Provided (check all that apply):

☐ 2. **DISTRIBUTION**: Complete Attachment "B".

☐ 3. **TRAINING**: Provide copies of Training Qualifications and proof of proficiency (Freq / Number of past training provided).

☐ 4. **CONSULTING**: Provide copies of documented qualifications, experience, and results.

☐ 5. **CLEANING**: Provide copies of applicable technical qualifications and Certificates of Insurance. If Clean Room Certified, provide evidence.

☐ 6. **IRRADIATION**: Provide documentation as specified by LifeNet Health Quality Systems (QS).

☐ 7. **LABORATORY**: Provide copies of Lab Certification, per Section 4c.

☐ 8. **CERTIFICATION SERVICES**: Provide copies of qualification certifications. If providing on-site services, also provide certificates of insurance.

☐ 9. **CLINICAL TRIALS**: Provide copies of documented qualifications, experience, and results.

☐ 10. **PREVENTATIVE MAINTENANCE**: Provide evidence of applicable certifications and certificates of insurance.

10a) Primary technician's name and city located:	Phone:	Cell:
	E-mail:	Pager:
10b) Supervisor's name:	Phone:	Cell:
	E-mail:	Pager:

10c) Can a copy of technician's certification be provided? (i.e. HVAC certification, etc.) ☐ Yes ☐ No

10d) What are company's normal business hours for service? Please include time zone

10e) Is documentation explaining service/repair left with customer? ☐ Yes ☐ No

10f) Can technician(s) provide documentation for PMs and calibration at the time of service call? ☐ Yes ☐ No

10g) Is documentation available on-line? ☐ Yes ☐ No

10h) Can the supplier provide service coverage 24x7 - 365 days a year? ☐ Yes ☐ No
State extra charges, if any:

10i) Are service technician(s) employee(s) of service supplier? ☐ Yes ☐ No
If marked "No" state name of the other company(s):

10j) Service request response time:

	By Phone	On-site
Average		
Guaranteed		

☐ 11. **CALIBRATION SERVICES**: Provide evidence of applicable technician and equipment certification(s) and certificates of insurance.

11a) Primary technician's name and city located:	Phone:	Cell:
	E-mail:	Pager:
11b) Supervisor's name:	Phone:	Cell:
	E-mail:	Pager:

11c) Can a copy of technician's certification be provided? (i.e. HVAC certification, etc.) ☐ Yes ☐ No

11d) Company's normal business hours for service:

11e) Is documentation explaining service/repair left with customer? ☐ Yes ☐ No

11f) Can technician(s) provide documentation for PMs and calibration at the time of service call? ☐ Yes ☐ No

11g) Is documentation available on-line? ☐ Yes ☐ No

11h) Can the supplier provide service coverage 24x7 - 365 days a year? ☐ Yes ☐ No
State extra charges, if any:

11i) Are service technician(s) employee(s) of service supplier? ☐ Yes ☐ No
If "No", state name of the other company(s):

12. **FACILITIES (ALL SUPPLIERS)**

12a) What are the primary service points for the following LifeNet Health Zip Codes? 23453: 98057:

12b) How many service centers?

12c) From what location(s) will our services be provided?

12d) Laboratory? ☐ In- house ☐ Sent out for testing ☐ N/A

12e) Briefly describe and specify qualification to applicable laboratory standards:

13. **OTHER COMMENTS:**

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SUPPLIER SELECTION QUESTIONNAIRE

(Additional Information may be attached, as necessary)

ATTACHMENT "B" - Distributors / Material & Equipment Providers

1. Are customers notified if significant process changes are implemented that may affect the final product? ☐ Yes ☐ No (If no, explain in Box 3)

2. Are customers notified 90-days in advance of any changes or discontinuance to services or products ordered? ☐ Yes ☐ No (If no, explain in Box 3)

3. Remarks (attach additional page(s) if necessary):

4a. What is the delivery time to zip code 23453 Standard: Expedited:

4b. What is the delivery time to zip code 98057 Standard: Expedited:

5. Do you substitute products? ☐ Yes ☐ No Note: LifeNet Health must approve ALL substitutions prior to delivery

6. Explain procedures followed to ensure customer approvals of substitute products (attach extra pages, if needed):

7. Is a restocking fee charged: ☐ Yes ☐ No If yes, please explain:

8. Do you email order acknowledgements to customers within (1) business day of order receipt? ☐ Yes ☐ No If no, will you agree to email order acknowledgements within (1) business day? ☐ Yes ☐ No

9. The order acknowledgements include (check all that apply): ☐ Ship date ☐ Expected delivery date ☐ Back order status

10. How are certificates of compliance, analysis, sterility, etc. issued with product (if applicable)?

10a) Please list those applicable to LifeNet Health:

10b) How are certificates available: ☐ Email ☐ Online ☐ Attached with Shipment ☐ Other:

10c) How long are they maintained?

10d) Are they issued with ☐ Every new lot ☐ Every shipment ☐ Other mechanisms:

10e) Are proofs of deliveries maintained? ☐ Yes ☐ No

If yes, for how long?:

If no, please explain:

11. **FACILITIES.**

11a) What are the primary distribution points for the following LifeNet Health Zip Codes? 23453: 98057:

11b) How many distribution centers?

11c) From what location(s) is our product going to be warehoused and shipped?

11d) Laboratory? ☐ In- house ☐ Sent out for testing ☐ N/A

11e) Briefly describe and specify qualification to applicable laboratory standards:

12. **OTHER COMMENTS:**

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SUPPLIER SELECTION QUESTIONNAIRE

(Additional Information may be attached, as necessary)

ATTACHMENT "C" - Manufacturers

1. Are lot numbers printed on finished product containers? ☐ Yes ☐ No
2. Are customers notified if significant process changes are implemented that may affect the final product? ☐ Yes ☐ No (If no, explain in Box 10)
3. Are customers notified 90-days in advance of any changes or discontinuance to services or products ordered? ☐ Yes ☐ No (If no, explain in Box 10)
4. As required per FDA 21 CFR 820.50(b), does your company agree to provide advance notification to LifeNet Health of any changes to the form, fit, function, formulation or material composition of the items provided to LifeNet Health or any changes in testing, repair parts, specification standards or other service related items? ☐ Yes ☐ No (If no, explain in Box 10)
5. Do all raw materials and products have written specifications? ☐ Yes ☐ No
6. Is stored raw material adequately identified to ensure traceability? ☐ Yes ☐ No
7. Is there a process to ensure that manufacturing equipment is on a routine maintenance schedule? ☐ Yes ☐ No
8. Do you outsource any part of the manufacturing process for products to be provided to LifeNet Health? ☐ Yes ☐ No If yes, provide details on outsourced processes / products and how quality oversight is maintained for the process in Box 10.
9. Laboratory? ☐ In- house ☐ Sent out for testing ☐ N/A
10. Remarks (attach additional page(s) if necessary):

11a. What is the delivery time to zip code 23453 Standard: Expedited:

11b. What is the delivery time to zip code 98057 Standard: Expedited:

12. Do you substitute products? ☐ Yes ☐ No Note: LifeNet Health must approve ALL substitutions prior to delivery
13. Explain procedures followed to ensure customer approvals of substitute products (attach extra pages, if needed):

14. Is a restocking fee charged: ☐ Yes ☐ No If yes, please explain:

15. Do you email order acknowledgements to customers within (1) business day of order receipt? ☐ Yes ☐ No If no, will you agree to email order acknowledgements within (1) business day? ☐ Yes ☐ No
16. The order acknowledgements include (check all that apply): ☐ Ship date ☐ Expected delivery date ☐ Back order status
17. How are certificates of compliance, analysis, sterility, etc. issued with product (if applicable)?
    - 17a) Please list those applicable to LifeNet Health:
    - 17b) How are certificates available: ☐ Email ☐ Online ☐ Attached with Shipment ☐ Other:
    - 17c) How long are they maintained?
    - 17d) Are they issued with ☐ Every new lot ☐ Every shipment ☐ Other mechanisms:
    - 17e) Are proofs of deliveries maintained? ☐ Yes ☐ No

      If yes, for how long?: ____________________

      If no, please explain: ____________________
18. **FACILITIES.**
    - 18a) What are the primary manufacturing points for the following LifeNet Health Zip Codes? 23453: 98057:
    - 18b) How many manufacturing facilities?
    - 18c) How many distribution centers?
    - 18d) From what location(s) is our product going to be warehoused and shipped?
    - 18e) Laboratory? ☐ In- house ☐ Sent out for testing ☐ N/A
    - 18f) Briefly describe and specify qualification to applicable laboratory standards:
19. **OTHER COMMENTS:**

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ATTACHMENT "D" - Small Business Self-Certification

☐ **Not Applicable (Other Than Small Business/Non-Profit)**

1) I certify that my business is a(n) [you may check more than one]: *

- ☐ Small Business
- ☐ Small Disadvantaged Business
- ☐ Certified by SBA as a HUBZone Small Business
- ☐ Women-Owned Small Business
- ☐ Veteran-Owned Small Business
- ☐ Service-Disabled Veteran-Owned Small Business
- ☐ Historically Black College/University or Minority Institution
- ☐ Alaskan Native Corporation
- ☐ Indian Tribe
- ☐ Other: Specify ______________________

2) If you are self-certifying as a Small business, fill out the information below for the work you have been contracted to perform:

NAICS Code (for work being contracted): ______________________

3) If you are self-certifying as a Small Disadvantaged Business, fill out the information below:

Primary NAICS Code: ______________________

* You may wish to review the definitions for the above categories in the Federal Acquisition Regulation 19.7 or 52.219-8 (Acquisition.gov). If you have difficulty ascertaining your size status, please refer to SBA's website at www.sba.gov/size or contact your local SBA office.

Under 15 U.S.C. 645(d), any person who misrepresents its size status shall (1) be punished by a fine, imprisonment, or both; (2) be subject to administrative remedies; and (3) be ineligible for participation in programs conducted under the authority of the Small Business Act.

If your size status changes, you agree to notify LifeNet Health within thirty (30) days.

4)

______________________ ______________________
Signature Company Name

______________________ ______________________
Title Date

****** Internal Use Only*****

HUBZone Status sas been verified in the Central Contractor Registration (CCR) Dynamic Small Business Search Database or the System for Award Management (SAM)

as of ____ / ___ / ______. LifeNet Health Representative Signature: ________________________