GENEPRO DX Making Precision Medicine Certain	**Form:** **Supplier Qualification Questionnaire**	**Document:** SOP Q006.F3
		Revision: 1.0
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Supplier Information	
Vendor Name:	Website Address:
Address:	
City:	State: Zip:
Telephone:	Email Address:
Supplier Contact Name:	Supplier Contact Title:
Telephone:	Email Address:
Quality Assurance Contact:	Title:
Telephone:	Email Address:
Type of Facility: ☐ Material Supplier ☐ Manufacturing ☐ Service ☐ Distributor ☐ Other _____	
Description of Primary Products or Services:	
Is this the site the material or product is manufactured or service is performed? ☐ Yes ☐ No If No, please provide the address for the site below:	
How long has your company been in business?	
How many people does your company employ?	
What is the square footage of your facility? OFFICE MFG/DISTRIBUTOR	
Are you a global, national or regional supplier?	
Have you ever operated under a different name and/or declared bankruptcy?	

Part A
General Questionnaire (All Suppliers):

1. Have you been certified to ISO 13485:2016, ISO 9001:2015 or GMP? ☐ Yes ☐ No

*If yes, please **provide a copy of the certificate** issued by the registrar.*

2. Have you been accredited under another recognized quality standard? ☐ Yes ☐ No

If yes, what standard have you been accredited under? _____

3. Is this facility registered with the FDA? ☐ Yes ☐ No

If yes, please provide the FDA Registration Number: _____

4. Has the FDA inspected this facility? ☐ Yes ☐ No

If yes, please provide the last inspection date:_____

5. **Manufacturers/Subcontractors/Distributors:** Does your company have experience manufacturing, specifying, or distributing medical devices, or components used in medical devices?
☐ Yes ☐ No ☐ N/A

Service Providers: Does your company have experience in providing services in the medical device or regulated industry? ☐ Yes ☐ No ☐ N/A

Please provide a brief description of the company's experience in the medical device area or company's relevant experience in other related areas.

6. Can your organization accommodate on-site or desktop quality system audits? If so, how much advance notification would you require?

7. Do you agree to notify GeneproDx of changes to products or services that may impact product quality, or the ability of the product or service to continue to provide safe and effective products and treatments, or other? ☐ Yes ☐ No

***NOTE:** Changes must be communicated to GeneproDx with sufficient notice to allow an assessment by GeneproDx of the impact of a change before any such change is implemented.*

Please attach any additional supporting information, such as a Company brochure, PowerPoint Presentation, or Organizational Chart that would help GeneproDx familiarize ourselves with your organization. Please list attachments:

NOTE: If your company is ISO certified, please provide the company's ISO Certificate with this questionnaire and do not complete Part B.

If you are providing a software service, including SaaS, software development, software engineering please complete Part C.

Part B

Questionnaire: Quality System Evaluation (Non-ISO Certified Suppliers Only) ☐ NA

1. Do you have formal documented policies, procedures and instructions for managing quality and quality related issues?

   ☐ Yes ☐ No ☐ NA

2. Does Executive Management periodically and formally review the effectiveness of your quality system?

   ☐ Yes ☐ No ☐ NA

   If yes, how frequently?

3. Do you have a system for controlling quality related documents to prevent unauthorized use of uncontrolled or outdated documents?

   ☐ Yes ☐ No ☐ NA

4. Do you have a system for controlling quality related records providing evidence of conformance to requirements?

   ☐ Yes ☐ No ☐ NA

5. Have personnel whose work may impact quality been trained in basic good manufacturing practices, and in the impact of defects on product quality?

   ☐ Yes ☐ No ☐ NA

6. Are suppliers evaluated to ensure they are capable of meeting your requirements for delivery and quality?

   ☐ Yes ☐ No ☐ NA

7. Is the manufacturing/production process described in a plan documenting required equipment, maintenance, instructions, materials, personnel, process flow, inspections, tests, and records?

   ☐ Yes ☐ No ☐ NA

8. Are facilities and equipment appropriate to meet GeneproDx requirements for quality?

   ☐ Yes ☐ No ☐ NA

9. Is test and measurement equipment maintained in a calibrated state against authorized standards?

   ☐ Yes ☐ No ☐ NA

10. Are products withheld from shipment until all requirements have been completed and approved?

☐ Yes ☐ No ☐ NA

11. Are products identified with a control number, and is traceability maintained throughout all stages of production, storage, and distribution?

☐ Yes ☐ No ☐ NA

12. Is product found not to conform to requirements identified, segregated, and disposed as nonconforming product?

☐ Yes ☐ No ☐ NA

If nonconforming product is allowed to be repaired, re-classified, re-inspected, or to be used under concession, describe the process below or on an attached sheet.

13. Is there a formal system for receiving and resolving customer complaints?

☐ Yes ☐ No ☐ NA

*Who is the contact for initial communication of complaints?*_____

14. Is there a formal system for corrective action, preventive action, and continual improvement activity?

☐ Yes ☐ No ☐ NA

15. Are process results and trends analyzed statistically to identify negative trends or opportunities for improvement?

☐ Yes ☐ No ☐ NA

If yes, what key quality indicators are analyzed? Examples include but are not limited to things such as: on-time delivery, number of complaints and non-conformances, percentage of orders filled

Part C Questionnaire **Software Service (Includes SaaS, Software Development, Software Engineering)** ☐ NA
Software Development Lifecycle
1. Please provide a high-level overview of the SDLC.
2. Does the SDLC include an assessment of the regulatory and compliance requirements of a system, including: ☐ GxP ☐ 21 CFR Part 11 ☐ HIPAA ☐ GDPR
3. Does the SDLC include the following activities/deliverables for the system/product, where warranted: ☐ Business Requirements ☐ System Design Specification? ☐ Configuration specification? ☐ Validation Plan? ☐ Installation Testing Script? ☐ Configuration Verification Testing Script? ☐ Unit, Integration, Regression, Functional, System Testing Scripts? ☐ Traceability Matrix? ☐ Validation Summary Report?
4. What other documentation is produced as part of a product/system: ☐ Installation Guide? ☐ Administration Guide? ☐ Database Design/Schema ☐ User Guide?
5. Is the SDLC documentation for the products/services available for review? ☐ Yes ☐ No
6. How is source code managed and controlled?
7. Do you have defect tracking and customer issue reporting processes in place? ☐ Yes ☐ No
8. Please confirm that company has a tested, documented backup procedure in place to protect client data from loss in the event of a system or application failure.
9. Is the quality organization independent from the IT organization? ☐ Yes ☐ No
10. Does the Quality group perform periodic audits of system quality, documentation, and procedural compliance? ☐ Yes ☐ No

11. Do formal coding standards and/or guidelines exist? ☐ Yes ☐ No
Software Change Control
1. Describe your Change Control process.
2. Is there a requirement for a quality and/or independent approval of change requests? ☐ Yes ☐ No
IT Environment
1. Provide a high-level overview of the IT environment that the product is hosted/served from.
2. What monitoring admin-reporting capabilities are available for system usage and license management?
3. How does the company mitigate the risks of computer viruses?
4. a. How does the company securely exchange documents and data with customers (i.e. Secure Web Portal, VPN, etc.)? b. How do you manage remote access to your corporate network?
5. Is support available internationally? ☐ Yes ☐ No
6. Describe the frequency of product releases. What is the current version of the proposed products?
7. What monitoring admin-reporting capabilities are available for system usage and license management?

8. Please explain the physical measures takes to protect any network or server infrastructure used to process or store Client data.

   a. Does the company regularly conduct penetration testing on computer systems?

   ☐ Yes ☐ No

   b. Does the company regularly conduct vulnerability scanning on computer systems?

   ☐ Yes ☐ No

   c. Please explain how the company keeps all computer systems updated and patched on a regular basis.

9. How do you assess the security of the software that you develop and acquire?

10. How does the company securely exchange documents and data with customers (i.e., Secure Web Portal, VPN, etc.)?

   a. Please explain how the company uses encryption to protect data at rest and in transit.

   b. Do you offer multi-factor authentication?

   ☐ Yes ☐ No

   c. Does the company support single sign-on with SAML 2.0?

   ☐ Yes ☐ No

11. Provide a high-level overview of the IT environment that the product is hosted/served from.

   a. Do you own the servers and space?

   ☐ Yes ☐ No

   b. What software packages are used? Are there any cloud based service providers?

   c. If cloud based service providers are used, have they been qualified and approved as a vendors?

   ☐ Yes ☐ No

12. What monitoring admin-reporting capabilities are available for system usage and license management?

13. Please confirm that the Company has technical, physical and organizational measures, including policies, procedures, processes, controls and training programs, that meet industry standards, in place to safeguard and back up data, whether stored on a server, in the cloud or on a mobile device, including personal data, and that the Company keeps the data confidential.

Business Continuity Plan and Recovery

1. Does the company have formal Business Continuity and Disaster Recovery Plans?
☐ Yes ☐ No

2. Is your Business Continuity Plan approved by executive management?
☐ Yes ☐ No

3. In the event of a regional disaster or crisis, will the plans allow for the recovery of all critical business products and services?
☐ Yes ☐ No

4. Is your Business Continuity Plan formally reviewed and updated on a routine basis?
☐ Yes ☐ No

5. Is your Business Continuity Plan tested on a routine basis?
☐ Yes ☐ No

6. Describe your data backup policy, backup procedures, data recovery capabilities, backup technology and data retention policy

EU General Data Protection Regulation (GDPR)
1. Is your company in compliance with GDPR? ☐ Yes ☐ No If yes, describe the process you used to ensure compliance. If no, describe the actions you are taking and provide a date when you will become compliant.
2. Please attach the GDPR compliance statement that you are providing to your clients?
3. List your data classifications including specific classifications for Personal Data?
4. If you are collecting or receiving personal data, describe the systems and data-stores where this data resides (Database, email, fileshares, etc.)?
5. Where is personal data physically located (hosted)? Provide third party vendor that may apply and include physical address and country
6. Why is personal information being collected and how is it being used?
7. List third party entities that personal information is or has been shared with
Security
1. Do you have a dedicated security officer? ☐ Yes ☐ No If so, please describe their role in the organization?
2. Does the company carry at least $2 million in cybersecurity insurance coverage? ☐ Yes ☐ No
3. Provide a high-level overview of the company's physical security system and cybersecurity framework?

4. Are there formal, written information security policies and procedures?

☐ Yes ☐ No

5. Does the company require all employees and subcontractors to comply with all security policies and customer agreements?

☐ Yes ☐ No

7. Does the company have a formal breach procedure?

☐ Yes ☐ No

a. In the event of a breach, does the company have a tested, documented incident response procedure in place to follow?

b. How will company notify and communicate with customers in the event of an information security incident?

8. Do you have a dedicated training process related to Security and Privacy?

☐ Yes ☐ No

8. What is the contingency plan if systems are temporarily unavailable?

9. Please explain how the company segregates client data from other customers' data in their computer systems.

9. Are highly privileged accounts (such as administrator accounts) periodically audited?

☐ Yes ☐ No

11. Please confirm that the company will agree to respond and cooperate during an information security investigation/assessment or audit.

12. Are systems and applications protected by individual user IDs and passwords?

☐ Yes ☐ No

13.	Are user accounts access to information periodically reviewed? ☐ Yes ☐ No
14.	Please confirm that the company has documentation that describes how, in the event of a termination of the customer agreement, upon the successful return or destruction of all client data present on servers and other redundant storage locations will be certified as deleted.
15.	Are the development and manufacturing facilities adequately secured against unauthorized entry? ☐ Yes ☐ No Is there a documented authorization list? How is access authorized? ☐ Yes ☐ No

Completed By:

Please check all parts completed:

☐ Supplier Information (**Required)**

☐ Part A Supplier General Questionnaire **(Required)**

☐ Part B Supplier (**Required if not ISO Certified)**

☐ Part C Software Service (**Required if providing a type of software service)**

Printed Name:	**Title:**
Signature:	**Date:**

This Section is Completed by <u>GeneproDx Only</u>

Review and Approval:

Additional Actions Required ☐ Yes ☐ No

If Yes, list actions required:	☐ N / A

Disposition: ☐ Accept ☐ Reject

If Reject, provide reason:	☐ N / A

GeneproDx Quality:	
Printed Name:	Title:
Signature:	Date: