**Instructions**

Use this form to qualify suppliers as defined in the Eye Bank SOP. This form may be used for either a desk audit (completed by the supplier) or by the Eye Bank as an on-site audit tool. Attach all relevant supporting documentation.

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| **Organization Information** |
| Organization Name: |  |
| Org. Contact Person: |  | QA Contact Person: |  |
| Address: |  |
| City: |  | State: |  | Zip: |  |
| Phone 1: |  | Phone 2: |  | Fax: |  |
| Website: |  |
| Is the organization a division or a subsidiary of a parent company? | 🞎 Yes 🞎 No |
| If yes; list the name of the parent company: |  |
| Total Organization Employees: |  | Operating Hours: |  |

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| **Description of Products and/or Services Provided by Organization** |
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| **Regulatory Information** |
| FDA FEI: |  | Date of last FDA Inspection: |  |
| Has an FDA 483 been issued in the last three years: | 🞎 Yes 🞎 No |
| If yes, please list dates and a brief summary of findings: |  |
| Has the organization been inspected any State? | 🞎 Yes 🞎 No | If yes, when was the last inspection? |
| List results of last State inspection: |  |
| Has the organization been inspected by EBAA? | 🞎 Yes 🞎 No | If yes, when was the last inspection? |
| List results of last EBAA inspection: |  |
| Is your organization ISO certified? | 🞎 Yes 🞎 No | If yes, list ISO number: |
| Has the organization ever identified a problem which resulted in a product recall? | 🞎 Yes 🞎 No |
| If yes, please attach a brief summary |
| Please attach the following as applicable:* FDA Establishment Registration (🞎 N/A)
* ISO Certification (🞎 N/A)
* Other applicable federal, state, or local registration (🞎 N/A)
* Approval certificates such as UL, CSA, EN46001, or CE (🞎 N/A)
* SOP Table of Contents or Lists of all applicable SOPs (🞎 N/A)
* Mission and/or Quality Statement (🞎 N/A)
* Organizational Chart (🞎 N/A)
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| **Facilities Information** |
| Is the facility size adequate to perform necessary functions? | 🞎 Yes 🞎 No |
| Is routine cleaning performed and documented? | 🞎 Yes 🞎 No |
| Are adequate security measures in place (both physical and electronic)? | 🞎 Yes 🞎 No |
| If no, please list measures not in place: |  |
| Are there any off-site facilities? | 🞎 Yes 🞎 No |
| If yes, please list all off-site facilities and describe the functions performed at each: |  |

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| **Records Information** |
| Are standard operating procedures (SOPs) maintained on-site? | 🞎 Yes 🞎 No |
| Are training records maintained on-site? | 🞎 Yes 🞎 No |
| Is initial and annual training provided – including safety/OSHA training? | 🞎 Yes 🞎 No |
| Please describe the document revision and distribution system (e.g. how are SOPs revised and how is access to old versions limited): |  |
| Are any records maintained electronically? | 🞎 Yes 🞎 No |
| Are electronic records able to be printed as paper copies? | 🞎 Yes 🞎 No |
| Are the following records maintained and for how long: |
| Packaging | 🞎 Yes 🞎 No 🞎 N/A | If yes, how long: |
| Storage | 🞎 Yes 🞎 No 🞎 N/A | If yes, how long: |
| Final Release / Distribution | 🞎 Yes 🞎 No 🞎 N/A | If yes, how long: |
| Purchase Orders | 🞎 Yes 🞎 No 🞎 N/A | If yes, how long: |
| Contracts / Agreements | 🞎 Yes 🞎 No 🞎 N/A | If yes, how long: |
| Shipment / Tracking | 🞎 Yes 🞎 No 🞎 N/A | If yes, how long: |
| Equipment Maintenance | 🞎 Yes 🞎 No 🞎 N/A | If yes, how long: |
| Equipment Calibration  | 🞎 Yes 🞎 No 🞎 N/A | If yes, how long: |
| Environmental Control | 🞎 Yes 🞎 No 🞎 N/A | If yes, how long: |

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| **Quality Assurance Program** |
| Is there a formal Quality Assurance (QA) Program | 🞎 Yes 🞎 No |
| If yes, please describe or attach QA Program: |  |
| Is the individual responsible for the QA Program directly responsible for the performance of operations?  | 🞎 Yes 🞎 No |
| Is there a complaint handling system? | 🞎 Yes 🞎 No |
| Is there a deviation system that documents process deviations? | 🞎 Yes 🞎 No |
| Is there a procedure for handling product deviations? | 🞎 Yes 🞎 No |
| Is there a document control system? | 🞎 Yes 🞎 No |
| Is there a preventative and corrective action (CAPA) system?  | 🞎 Yes 🞎 No |

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| **Supplies Information** | 🞎 *This section is not applicable* |
| Is there a procedure for receiving supplies (including supply specifications)? | 🞎 Yes 🞎 No |
| Are incoming supply records reviewed upon receipt? | 🞎 Yes 🞎 No |
| Are sterile supplies ordered / received? | 🞎 Yes 🞎 No |
| Do you maintain Certificates of Analysis for all sterile supplies? | 🞎 Yes 🞎 No |
| Are supplies quarantined by inspection status? | 🞎 Yes 🞎 No |
| Is a FIFO philosophy used to ensure adequate stock rotation of supplies? | 🞎 Yes 🞎 No |
| Is there a supplier evaluation / qualification system? | 🞎 Yes 🞎 No |
| Are suppliers evaluated and qualified prior to utilization? | 🞎 Yes 🞎 No |
| Are audits performed on supplier facilities? | 🞎 Yes 🞎 No |
| Are nonconforming supplies controlled, identified, segregated, and trends analyzed? | 🞎 Yes 🞎 No |

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| **Other General Requirements** | 🞎 *This section is not applicable* |
| If new information concerning the quality of a supply shipment becomes available, describe how this information will be communicated to the Eye Bank: |  |
| Do you have an exposure control plan? | 🞎 Yes 🞎 No | Do you have a post-exposure plan? | 🞎 Yes 🞎 No |

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| **Processing Information** | 🞎 *This section is not applicable* |
| Describe the processing environment (cleanroom or flow hood, classification, etc.) |  |
| Describe any contamination control programs for the processing environment (environmental monitoring, cleaning schedule, etc.) |  |
| Are all processing methods validated? | 🞎 Yes 🞎 No |
| Is there traceability of materials used in the manufacturing process? | 🞎 Yes 🞎 No |
| Are systemic or random inspections performed during and after manufacturing | 🞎 Yes 🞎 No |
| If yes, describe the sampling plan: |  |
| Is there a final review of product records before they are shipped? | 🞎 Yes 🞎 No |

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| **Equipment Information** | 🞎 *This section is not applicable* |
| Do you have procedures for the following, please attach copies as applicable: |
| Calibration of Equipment | 🞎 Yes 🞎 No 🞎 N/A |
| Preventative Maintenance of Equipment | 🞎 Yes 🞎 No 🞎 N/A |
| Cleaning of Equipment | 🞎 Yes 🞎 No 🞎 N/A |
| Equipment Failure (Lock Out / Tag Out, Removal from service until repaired) | 🞎 Yes 🞎 No 🞎 N/A |

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| **Person Completing This Form** |
| The signature below is to verify that all elements within the scope of the audit, including the notes and evaluation of objective evidence were completed and reviewed by the auditor below. The audit represents a fair and accurate evaluation of the applicable audit elements within the scope of the audit. Due to the limited scope of the audit, this audit tool may not identify all deficiencies or non-compliances within the audited organization.

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| *Lead Auditor – Name* |  | *Lead Auditor Title* |  | *Lead Auditor – Signature* |  | *Date* |

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| **Eye Bank Use Only** |
| **🞎 Supplier is APPROVED** | **🞎 Supplier is REJECTED** | **🞎 Supplier is CONDITIONALLY APPROVED** |
| If conditional, list conditions for approval: |
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| **Name – Eye Bank Quality Assurance** |  | **Signature** |  | **Date** |

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