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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Vendor Company Name:** | | | | | | | | |  |
| **Supplier Site Address:** | **Supplier Business Address (if different):** | | | | | | | |  |
| Phone No: | Phone No: | | | | | | | |  |
| Fax No: | Fax No: | | | | | | | |  |
| E Mail: | E Mail: | | | | | | | |  |
| **Material or Service supplied to Integrated DNA Technologies, covered by this questionnaire:** | | | | | | | | |  |
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| **Is the Company a division/subsidiary of another corporation?** | | | | **Yes** | | | **No** | | **N/A** |
| **If Yes, Please Specify:** | | | | | | | | |  |
| **This questionnaire was completed by:** | | | | | | | | | |
| Name: | | | | | | | | | |
| Job Title: | | | | | | | | | |
| Date: | | | | | | | | | |
| Signature: | | | | | | | | | |
| **For “Yes” / “No” answers; Please tick the box for the one which applies, or select “N/A” (Not Applicable)** | | | | | | | | | |
| **Management Responsibility** | | | | | | | | | |
| Is an organization chart available? If yes, please enclose a copy. f | | **Yes** | | | **No** | | | **N/A** | |
| Are there any written job descriptions defining each individuals responsibilities? | | **Yes** | | | **No** | | | **N/A** | |
| How many shifts of operation are there in the Production Area? How many shifts of operation are there in QC Laboratory? | | | | | | | | | |
| Approximately how many employees do you have?  -Site total: | | | | | | | | | |
| -QA/QC: | | | | | | | | | |
| -Production: | | | | | | | | | |
| To whom does the QA/QC Manager report? | | | | | | | | | |
| Does the company have a policy on EHS (Environmental, Health & Safety)? | | **Yes** | | | **No** | | | **N/A** | |
| Does the company have a policy on Quality? | | **Yes** | | | **No** | | | **N/A** | |
| **Who is responsible for contacts with Integrated DNA Technologies with regards to the following areas:**  Quality:  Technical:  Commercial: | | | | | | | | | |
| Are subcontractors (if used), used for significant steps or components in Preparation of IDT’s products? The term subcontractors includes both contracted operations within Production and the Laboratory | | **Yes** | | | **No** | | | **N/A** | |
| **If “Yes”, please list and explain:** | | | | | | | | | |
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| Can you please provide full Supply chain(s) for the referenced material(s) (i.e. Manufacturer, Testers, Providers of C of A / C of C, Packers / Re-packers and Storage & Distribution) | | **Yes** | | | **No** | | | **N/A** | |
| **If “Yes”, please list & explain:** | |  | | |  | | |  | |
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| **Quality Management System** | |  | | |  | | |  | |
| Does your company have a documented Quality Management System?  If your company has a Quality Manual, please provide a copy. | | **Yes** | | | **No** | | | **N/A** | |
| Is your company ISO 9001 registered (or equivalent)?  If “Yes”, please enclose a copy of the certificate. | | **Yes** | | | **No** | | | **N/A** | |
| If “No”, does your company intend on pursuing registration within the next 12 months? | | **Yes** | | | **No** | | | **N/A** | |
| Is your company registered with the FDA?  If “Yes”, please provide the registration number: | | **Yes** | | | **No** | | | **N/A** | |
| Have any regulatory agencies inspected your facility in the last five years? | | **Yes** | | | **No** | | | **N/A** | |
| If “Yes”, by whom, when and what were the results? | |  | | |  | | |  | |
| Is formal document control utilized in your company processes that includes revision level controls and date affectivity? | | **Yes** | | | **No** | | | **N/A** | |
| Are there approved product specifications that include materials, packaging and label requirements, and manufacturing and inspection instructions? | | **Yes** | | | **No** | | | **N/A** | |
| Are procedures in place that control changes/deviations to material, manufacturing processes, test methods, and/or product specifications? | | **Yes** | | | **No** | | | **N/A** | |
| Are QA/QC responsibilities well defined and independent? | | **Yes** | | | **No** | | | **N/A** | |
| Is your company capable of identifying changes/deviations that may impact IDT’s use of the product, and subsequently provide notification to IDT prior to implementation and shipment? | | **Yes** | | | **No** | | | **N/A** | |
| How is a batch (standard quantity) defined? | |  | | |  | | |  | |
| What is the batch numbering system? (Please explain in detail) | |  | | |  | | |  | |
| Do you assign shelf/expiry/retest-lives for all materials (incoming & produced)? | | **Yes** | | | **No** | | | **N/A** | |
| If “Yes”, please provide details*.* | |  | | |  | | |  | |
| Which department reviews and approves production procedures? | |  | | |  | | |  | |
| Are reference samples retained? | | **Yes** | | | **No** | | | **N/A** | |
| If “Yes”, for how long? | |  | | |  | | |  | |
| For how long are records retained? | |  | | |  | | |  | |
| Is there a self-audit program? | | **Yes** | | | **No** | | | **N/A** | |
| **Exclusively *Service* companies may proceed directly to**  **The ‘Social Responsibility’ section, found on page 7.** | | | | | | | | | |
| **Incoming Goods** | | | | | | | | | |
| Is a list of approved suppliers used? | | **Yes** | | | **No** | | | **N/A** | |
| Is there a documented procedure for approval of suppliers? | | **Yes** | | | **No** | | | **N/A** | |
| Does this include the auditing of suppliers? | | **Yes** | | | **No** | | | **N/A** | |
| If bulk tankers are used, are they dedicated? | | **Yes** | | | **No** | | | **N/A** | |
| If not, is a cleaning certificate required? | | **Yes** | | | **No** | | | **N/A** | |
| Is there a system for monitoring or reviewing suppliers’ performance? | | **Yes** | | | **No** | | | **N/A** | |
| Are there documented procedures for:  -Inspecting material | | **Yes** | | | **No** | | | **N/A** | |
| -Testing material | | **Yes** | | | **No** | | | **N/A** | |
| Are established Purchase Specifications used? | | **Yes** | | | **No** | | | **N/A** | |
| What is the basis for acceptance of raw materials, i.e. testing, receipt of suppliers C of A or both? | | | | | | | | | |
| Is a sampling plan in place? | | **Yes** | | | **No** | | | **N/A** | |
| Is a testing plan in place? | | **Yes** | | | **No** | | | **N/A** | |
| **Warehouse** | |  | | |  | | |  | |
| Are storage facilities/equipment/ rented or personnel contracted? | | **Yes** | | | **No** | | | **N/A** | |
| If “Yes”, please provide details. | |  | | |  | | |  | |
| Are receipt and release procedures documented? | | **Yes** | | | **No** | | | **N/A** | |
| Is the supply chain documented? | | **Yes** | | | **No** | | | **N/A** | |
| How is material status controlled? (i.e. Physical, system or labeling) | |  | | |  | | |  | |
| How is rejected material controlled? (i.e. Physical, system or labeling) | |  | | |  | | |  | |
| Is there an identified sampling area? | | **Yes** | | | **No** | | | **N/A** | |
| Are all containers identified? | | **Yes** | | | **No** | | | **N/A** | |
| Is a First-In-First-Out or First-Expiry-First-Out system in use? (Identify) | | **Yes** | | | **No** | | | **N/A** | |
| Are shelf life/expiration dates used? | | **Yes** | | | **No** | | | **N/A** | |
| Is Temperature (T°), controlled and documented? | | **Yes** | | | **No** | | | **N/A** | |
| Comments: | |  | | |  | | |  | |
| Is Relative humidity (RH %), controlled and documented? | | **Yes** | | | **No** | | | **N/A** | |
| Comments: | |  | | |  | | |  | |
| **Production** | | |  | |  | | |  | |
| Is there more than one site or plant used for the manufacture of the specified material(s)? | | | **Yes** | | **No** | | | **N/A** | |
| If “Yes”, please provide details*.* | | |  | |  | | |  | |
| Is there a formal product release procedure that includes review of batch records? | | | **Yes** | | **No** | | | **N/A** | |
| Does your company have non-conforming materials & process deviation controls? | | | **Yes** | | **No** | | | **N/A** | |
| Are critical processes validated? | | | **Yes** | | **No** | | | **N/A** | |
| Does process documentation include:  -Process instructions | | | **Yes** | | **No** | | | **N/A** | |
| -Cleaning instructions | | | **Yes** | | **No** | | | **N/A** | |
| -Cleaning records | | | **Yes** | | **No** | | | **N/A** | |
| -Area clearance | | | **Yes** | | **No** | | | **N/A** | |
| Are cleaning processes validated? | | | **Yes** | | **No** | | | **N/A** | |
| Is there traceability throughout the process? | | | **Yes** | | **No** | | | **N/A** | |
| Is there an in-process monitoring system? | | | **Yes** | | **No** | | | **N/A** | |
| Is there an equipment use log? | | | **Yes** | | **No** | | | **N/A** | |
| Are all critical instruments calibrated? | | | **Yes** | | **No** | | | **N/A** | |
| Is there a preventative maintenance program? | | | **Yes** | | **No** | | | **N/A** | |
| Is reprocessing allowed? | | | **Yes** | | **No** | | | **N/A** | |
| Is there a non-conformance procedure? | | | **Yes** | | **No** | | | **N/A** | |
| Is the yield checked against defined limits? | | | **Yes** | | **No** | | | **N/A** | |
| Are different grades of material produced? | | | **Yes** | | **No** | | | **N/A** | |
| If “Yes”, how and at what stage are these differentiated/selected? | | | | | | | | | |
| Is the plant dedicated or multi-purpose? | | | | | | | | | |
| If the plant is multi-purpose, what other types of materials are produced in the unit(s)? | | | | | | | | | |
| Please list any hazardous materials that are manufactured on your site, e.g. herbicides. | | | | | | | | | |
| **Packing** | |  | | | |  | |  | |
| Are packing operations segregated from production? | | **Yes** | | | | **No** | | **N/A** | |
| Are barcode readers in use? | | **Yes** | | | | **No** | | **N/A** | |
| Are areas labeled with the product being packed? | | **Yes** | | | | **No** | | **N/A** | |
| Are re-usable containers used? | | **Yes** | | | | **No** | | **N/A** | |
| Are cleaning procedures in place? | | **Yes** | | | | **No** | | **N/A** | |
| Are controlled procedures used for issuing labels and labeling? | | **Yes** | | | | **No** | | **N/A** | |
| Are label details checked? | | **Yes** | | | | **No** | | **N/A** | |
| Are there label reconciliation procedures? | | **Yes** | | | | **No** | | **N/A** | |
| Are there label disposal procedures? | | **Yes** | | | | **No** | | **N/A** | |
| How are containers security sealed? | |  | | | |  | |  | |
| Is material clearly labeled, including waste and reject material? | | **Yes** | | | | **No** | | **N/A** | |
| **Computerized Systems** | |  | | | |  | |  | |
| Do you have a list of the Computerized systems used by this facility? | | **Yes** | | | | **No** | | **N/A** | |
| If “Yes”, do you identify the Computerized systems that are considered to have an impact on Quality of Product, or Service offered? | | **Yes** | | | | **No** | | **N/A** | |
| If “Yes”, how is this documented? | |  | | | |  | |  | |
| Does your Quality system cover the quality of Computerized systems? | | **Yes** | | | | **No** | | **N/A** | |
| Do you have procedures in place for disaster recovery and restoring of data archives? | | **Yes** | | | | **No** | | **N/A** | |
| Do you have access security levels for the Computerized systems? | | **Yes** | | | | **No** | | **N/A** | |
| Do your procedures for validation cover the Computerized systems? | | **Yes** | | | | **No** | | **N/A** | |
| Do you have anti-virus protection? | | **Yes** | | | | **No** | | **N/A** | |
| Does the Change Control procedure include Computerized systems? | | **Yes** | | | | **No** | | **N/A** | |

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| **Laboratories, QA & QC** |  | | |  |  |
| Is an equipment use log in place? | **Yes** | | | **No** | **N/A** |
| Are all instruments qualified (IQ, OQ, PQ)? | **Yes** | | | **No** | **N/A** |
| Are all instruments calibrated? | **Yes** | | | **No** | **N/A** |
| Is there a preventative maintenance program? | **Yes** | | | **No** | **N/A** |
| Are there documented procedures for:  -Sampling? | **Yes** | | | **No** | **N/A** |
| -Sample handling? | **Yes** | | | **No** | **N/A** |
| -Sample labeling? | **Yes** | | | **No** | **N/A** |
| -Re-testing / Re-sampling? | **Yes** | | | **No** | **N/A** |
| -Specification generation? | **Yes** | | | **No** | **N/A** |
| -Analytical method generation? | **Yes** | | | **No** | **N/A** |
| -Control and review of analytical methods? | **Yes** | | | **No** | **N/A** |
| -Investigation of rejected material? | **Yes** | | | **No** | **N/A** |
| -Product complaints? | **Yes** | | | **No** | **N/A** |
| -Handling out of specification results? | **Yes** | | | **No** | **N/A** |
| Are manual calculations checked by a second person? | **Yes** | | | **No** | **N/A** |
| Are data transcriptions checked by a second person? | **Yes** | | | **No** | **N/A** |
| Is all raw-data retained? | **Yes** | | | **No** | **N/A** |
| Are all standards traceable to their preparation and the reagents used? | **Yes** | | | **No** | **N/A** |
| Are analytical methods validated? | **Yes** | | | **No** | **N/A** |
| Do you perform stability testing on materials and/or products? | **Yes** | | | **No** | **N/A** |
| Are all standards traceable to their preparation and the reagents used? | **Yes** | | | **No** | **N/A** |
| Are analytical methods validated? | **Yes** | | | **No** | **N/A** |
| Do you perform stability testing on materials and/or products? | **Yes** | | | **No** | **N/A** |
| If so, what shelf life / retest dates are available for the referenced product(s)? | |  |  | |  |
| Do you perform annual product reviews or campaign reviews on products? | **Yes** | | | **No** | **N/A** |

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| **Material Release** |  |  |  |
| Is the decision to release/reject product made by a person or function independent from production? | **Yes** | **No** | **N/A** |
| Is the final status recorded? | **Yes** | **No** | **N/A** |
| Are certificates issued for each batch? | **Yes** | **No** | **N/A** |
| Are certificates signed by QA/QC? | **Yes** | **No** | **N/A** |
| If not, who signs certificates? |  |  |  |
| Is shelf life or retest dates or expiry date provided on the “C of A “ OR “C of C” | **Yes** | **No** | **N/A** |
| Is there a documented recall procedure? | **Yes** | **No** | **N/A** |
| **Social Responsibility** |  |  |  |
| Does your company have a sourcing policy with respect to Conflict minerals? | **Yes** | **No** | **N/A** |
| Has your company verified that minerals used in your product are from “Conflict free” mines? | **Yes** | **No** | **N/A** |
| If “no”, to either of the two preceding questions, what steps are you taking to verify sourcing of the above mentioned minerals is “Conflict free”? | | | |
| Does your company have a system to ensure compliance with the minimum working age prevailing standard(s)? | **Yes** | **No** | **N/A** |
| Does the company’s site(s) have the accurate system to measure the hours worked by employees to ensure conformance with applicable wage and hour labor laws? | **Yes** | **No** | **N/A** |
| Does the company have a process in place to ensure compliance with applicable laws concerning discrimination in hiring and employment practices? | **Yes** | **No** | **N/A** |
| **Facilities & Housekeeping** |  |  |  |
| Are there procedures for health and hygiene? | **Yes** | **No** | **N/A** |
| Are rest/change/wash facilities separated from production areas? | **Yes** | **No** | **N/A** |
| Are access restrictions implemented as needed? | **Yes** | **No** | **N/A** |
| Do any production areas have special containment needs? | **Yes** | **No** | **N/A** |
| Are waste disposal systems in place? | **Yes** | **No** | **N/A** |
| Are there procedures documenting a pest control program? | **Yes** | **No** | **N/A** |
| Are material Safety Data Sheets maintained? | **Yes** | **No** | **N/A** |
| **Training** |  |  |  |
| Is there a written training program? | **Yes** | **No** | **N/A** |
| Are job-training needs evaluated? | **Yes** | **No** | **N/A** |
| Is completed training evaluated and approved? | **Yes** | **No** | **N/A** |
| Are there completed written training records for all employees? | **Yes** | **No** | **N/A** |
| **Comments:** |  |  |  |

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| **The following sections are to be completed by Integrated DNA Technologies staff only**  Method(s) of supplier assessment [check all that apply, explain in ‘Comments’ below and provide evidence in supplier file]:  □ IDT Supplier Self-Audit Questionnaire □ ISO 9001 registered (or equivalent standard)  □ On-site visit / audit by IDT □ QMS or process control documentation  □ Past job reference/performance analysis □ Other (specify):  □ First Article Submission (i.e. material sample(s)) □ Additional information required?  (product manufacturing/test plan specifications,  certificate of analysis, batch record/process history, etc.)  Comments:  **Supplier Classification/Product Category:** □ **Class A** □ **Class B** □ **Class C**  **Supplier Accepted:** □ **Yes/Prequalified** □ **Yes/Approved** □ **Yes/Conditional** □ **No/Disqualified** |
| Purchasing:  Printed Name Signature Date: |
| Quality Assurance:  Printed Name Signature Date: |
| Purchasing Approver:  Printed Name Signature Date: |