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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** [x]  |
| 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:  |