*Company CDE is currently looking for new suppliers of materials and services.*

*In order to assess your overall capabilities and suitability we would like you to complete the following questionnaire.*

*After completing the questionnaire, please also provide copies of documents that will help us to successfully complete our further evaluation.*

*Thank you for your cooperation and look forward to building a successful business relationship.*

**General information**

|  |
| --- |
| **Contact details** |
| Name of company, type of company:  | Click or tap here to enter text. |
|  |  |
| Company address (legal entity):  | Street:           ​ Click or tap here to enter text.Postal Code: Click or tap here to enter text.PO-Box:         ​ Click or tap here to enter text.City/Country:     Click or tap here to enter text. |
| Company address (facility):  | Street:           ​ Click or tap here to enter text.Postal Code: Click or tap here to enter text.PO-Box:         ​ Click or tap here to enter text.City/Country Click or tap here to enter text. |
| Contact person:  | Name:           Click or tap here to enter text.Function:      Click or tap here to enter text.Phone:          Click or tap here to enter text.Fax:               Click or tap here to enter text.E-Mail:          Click or tap here to enter text. |

| **Business area**  |
| --- |
| **Manufacturer** | **Yes** | **No** | **Service provider** | **Yes** | **No** |
| API |[ ]  [ ]  | Contract manufacturing operations |[ ]  [ ]  |
| Excipients |[ ]  [ ]  | QC testing Laboratory |[ ]  [ ]  |
| Intermediate products |[ ]  [ ]  | Equipment/utilities technical maintenance |[ ]  [ ]  |
| Primary packaging materials |[ ]  [ ]  | Calibration |[ ]  [ ]  |
| Secondary packaging |[ ]  [ ]  | Qualification/Validation |[ ]  [ ]  |
| High complexity equipment |[ ]  [ ]  | IT services / Computerised systems |[ ]  [ ]  |
| Equipment |[ ]  [ ]  | Storage (materials, products) |[ ]  [ ]  |
| Other\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |[ ]  [ ]  | Storage (documentation) |[ ]  [ ]  |
| API |[ ]  [ ]  | Cleaning/sanitizing |[ ]  [ ]  |
| Pharmaceutical excipients |[ ]  [ ]  | Regulatory affairs |[ ]  [ ]  |
| Intermediate products |[ ]  [ ]  | Personal training |[ ]  [ ]  |
| Primary packaging materials |[ ]  [ ]  | Transportation |[ ]  [ ]  |
|  |  |  | Other\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |[ ]  [ ]  |
| Do you handle substances of high activity and/or toxicity such as ß-lactams, other antibiotics, cytotoxins, or pesticides on the site?If yes specify: \_\_\_\_\_\_\_\_\_\_\_ |[ ]  [ ]  |

| **Certification details** |
| --- |
| Certifications (please attach a copy of the certificates): | **Yes** | **No** |
| GMP for medical products (EU, FDA, TGA, MHRA, PIC/S members, etc) |[ ]  [ ]  |
| Quality Management System ISO 9001 |[ ]  [ ]  |
| Quality Management System ISO 13485 |[ ]  [ ]  |
| Risk and safety OSHAS 18001 |[ ]  [ ]  |
| Environmental ISO 14001 |[ ]  [ ]  |
| Energy management ISO 50001 |[ ]  [ ]  |
| Others\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |[ ]  [ ]  |

[**NOTE:** If there are no critical compounds manufactured in your facility, and you have a valid ISO-Certification + valid GMP certificate you may stop here, otherwise please continue.

This questionnaire is complete and can be modified according to Company CDE needs and expectations.

The level of detail of the proposed questions depends on whether the potential supplier is reliable and well-known.]

| Personnel, Training, and Education |
| --- |
|  | Do you have written job descriptions for all personnel? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Do you have written procedures that document how you perform training? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Is there a training policy for both temporary and permanent employees (on-the-job training)? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Do you maintain training records including dates, times, subject matter, course outline, instructor, etc.)? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Does the Training Program in place have the following elements: |
|  | Formal Introduction to Regulatory Guidance (GMP, ISO, etc.) | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | New Hire Program | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Specific training e.g. clean room or handling toxic, infectious or sensitizing materials? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Periodic assessment of practical effectiveness? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Periodic refresher training programs for established employees? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Training at the start of new product manufacturing? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Training when new methods are used? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Quality techniques training for production personnel? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Are smoking, eating, drinking, chewing, and the storage of food, drinks, and personal medication prohibited in the manufacturing, storage, and laboratories area? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Does your training program emphasize? |
|  | Product integrity? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Hygiene? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Cleanliness? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Other? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Please specify: Enter text |  |  |  |

| Facility and Utilities |
| --- |
|  | Were the premises designed or adapted for the present use? | [ ]  designed | [ ]  adapted |
|  | Are there separate areas for: |
|  | Handling of starting materials? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Manufacturing? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Quarantined finished products or are other control systems in place? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Approved finished products? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Packaging and dispatch? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Rest and eating? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Does the present design prevent: |
|  | Chemical contamination? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Physical contamination? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Microbial contamination? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Do you have fully dedicated processing rooms with dedicated air-handling systems to the manufacturing processes of these products? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Do you have dedicated equipment to the manufacturing processes of these products? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Are your working-rooms: |
|  | Of proper size for the intended functions? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Satisfactorily lighted, air-conditioned? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Clean and cleaned-up? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Designed to avoid (cross-) contamination? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Supplied with security and fire protection measurements? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Do you have written Good House Keeping Procedures? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | If yes, do you maintain follow- up records of these procedures? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Do your manufacturing locations follow Good Manufacturing Practices? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Are your sites inspected by authorities? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Are plant supply pipelines identified and labelled? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Do you monitor the quality of the water used to prepare standards and reagents? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Do you monitor the quality of the water used during the manufacturing process? | Yes [ ]  | No [ ]  | N/A [ ]  |

| Machines and Equipment |
| --- |
|  | Is the production line multi-purpose or single-purpose? | [ ]  multi | [ ]  single |
|  | lf multi, what other products do you manufacture there? |       |
|  | Is there a maintenance and preventative maintenance program for all pieces of equipment? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Do you have written maintenance and calibration procedures for critical inspection, weighing, and measuring equipment (e.g. thermometer, manometer, stirrer speed)? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Can all critical apparatus and devices easily be recognized as such, e.g. by calibration stickers? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Are these calibrations traceable back to national standards? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Do you retain records of calibration as evidence of control?  | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Is there a cleaning plan/procedure for production machines, and equipment? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Are there cleaning procedures in place for each manufacturing/packaging area | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Are there cleaning procedures in place for each piece of manufacturing/packaging equipment? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Do you mark the status of your manufacturing/packaging equipment and environment (e.g. „cleaned“, „calibrated“, „in use”)? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Do main pieces of equipment used in the production bear identification labels, (e.g. stating lot number, material name etc.)? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Have the cleaning and sterilization processes been validated? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Is any manufacturing equipment software controlled? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Do you have a documented procedure for the validation of all testing and measuring equipment used to demonstrate the conformance of the product to the specified requirements? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Do you retain records of validation as evidence of control? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | If yes,  | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | * Is the software validated?
 | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | * Are modifications of software (or its use) implemented by manufacturing personnel?
 | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | * Is there a procedure concerning the change of software and its copying?
 | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | * Is the security of software controlled?
 | Yes [ ]  | No [ ]  | N/A [ ]  |

| Production and Process Control |
| --- |
|  | Is your manufacturing process validated? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | If not, do you have plans to do so? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | If you do: what is your target date for completion? |       |
|  | How do you define your lot/batch? |       |
|  | How and by whom are lot/batch numbers assigned? |       |
|  | What is your normal lot/batch size? |       |
|  | Does each lot/batch have an identification number? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | If, for capacity reasons, you combine material coming from more than one particular piece or part of process equipment into one lot/batch: |
|  | Is the lot/batch being homogenized prior to packaging? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Is the homogenization operation validated? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Do you manufacture according to a written procedure for each product supplied to the market? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Are these procedures approved by QA? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Do you have a batch record for each batch/lot manufactured? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | If yes, do the batch records detail the following: |
|  | * Description, Lot Number & Quantities of Material used?
 | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | * Processing Conditions (e.g., Temperature, Times)?
 | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | * The identification of the Person who performed the particular step?
 | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | * Results of any In-process tests?
 | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | * All deviations from standard conditions?
 | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | * All cleaning operations carried out before & after batch manufacture?
 | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | If yes, are these records formally checked and approved by QA? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Do you maintain lot separation during | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | * Manufacturing?
 | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | * Packaging?
 | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | * Storage?
 | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Do you maintain records of use, and maintenance for process equipment, in order to demonstrate the traceability in batches, product processed, and personnel? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Are computers used to store records of manufacture, testing, storage, or distribution for the product you supply? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | If yes, have these computer systems been validated (i.e.. have the complete life cycles of the systems been assessed and documented including stages of planning, specifications, programming, testing, commissioning, documentation, operation, monitoring, and modifying)? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Do all product containers bear identification labels, e.g. stating batch/lot number, product name etc.? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Is there expiry or retest dates defined for all material? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Is there storage conditions defined for all material? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Is the product identifiable throughout the manufacturing process? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Is traceability of all raw materials used, maintained throughout manufacture? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Is there a procedure in place to prevent cross-contamination? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Are line clearances undertaken between product changes during manufacturing and labelling? (i.e. Where a variety of products are manufactured on one site, do you carry out an independent, recorded check, immediately prior to a production run to verify the areas are free from previous starting materials, products documentation and waste and that it is fit for use)? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Is testing or inspection performed between processes or manufacturing stages? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Is testing or inspection performed on finished products? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Are rejected lots identified as such and separated? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Do you perform a failure investigation in case of a reject? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Is reprocessing of rejected lots documented? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Do you have a procedure covering rework/reprocessing or recovery of material? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Is the process for reprocessing or reworking of material validated and registered? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Are the goods returned from the market re-used? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Do you have a procedure for handling returned goods? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Is non-conforming final product ever blended with conforming product to bring it into specification? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Is there a documented procedure that clearly defines when blending of non-conforming product is allowed? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | How long do you keep the analytical and production records (number of years)? |       | Years |
|  | Do you have plant shutdowns (holidays, maintenance)? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | If yes, which one(s)? | [ ]  main | [ ]  hol |

| Materials Control |
| --- |
|  | Do you have an approved supplier list? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Do you have agreements in place with all your suppliers that require them to notify you of any change in raw material or the manufacturing process of the product supplied? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Do you have written specifications for all incoming raw material? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Who is responsible for establishing and approving the specifications of raw materials? |       |
|  | Do you require a manufacturer’s certificate of analysis for all material received in the company? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Are Certificates of Analysis routinely compared against a written specification? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Do you routinely test receipted materials to verify conformance with the supplier certification? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Are receipt and release procedures documented? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Is the supply chain documented? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Is a First-In-First-Out or First-Expiry-First-Out system in use? (Identify) | FIFO [ ]  | FEFO [ ]  | No [ ]  |
|  | Is Temperature (T°), controlled and documented (Warehouse)? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Is Relative humidity (RH %), controlled and documented (Warehouse)? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Do you have procedures for the control of raw materials? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Are records kept that show the full traceability of raw materials? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Do you maintain information records for raw materials which include the following: |
|  | * Your lot Identity?
 | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | * Suppliers Lot No?
 | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | * Date of Receipt?
 | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | * Quantity?
 | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | * Suppliers name?
 | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | * Shelf Life?
 | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | * Test Results?
 | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | * Specification?
 | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | * Accepted/Rejected?
 | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | * Retained Sample?
 | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Please describe how material is issued from stock: |       |
|  | Do you have defined areas for Receipt, Identification, Sampling and Quarantine of incoming materials? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Are scheduled stock checks performed? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Do you have a rework/reprocess policy? | Yes [ ]  | No [ ]  | N/A [ ]  |

| Quality Control |
| --- |
|  | Is Quality Control (QC) independent of Production? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Please describe the QC laboratory facilities and the tests these laboratories are capable of performing: |       |
|  | Are records kept of all samples that are submitted to the laboratories? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | If so, do these records include the following: |
|  | Date sample received? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Identity of samples?  | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Results of testing? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Date sample taken? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Are there formal written procedures for all performed tests? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Do you test every batch of Product according to full specification? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Are control samples routinely run with assays? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Are analytical calculations checked by a second person? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Do you perform trend analysis on analytical results? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Are the results of reference standard testing maintained on file? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Is there a procedure for documenting and investigating out-of-specification results? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Do you use any contract laboratories? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Have you qualified/evaluated these contract laboratories? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | What types of testing is contracted out? |       |
|  | Are quality standards or written control procedures available for: |  |  |  |
|  | Starting materials? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | In-process control? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Physical identification at all stages (e.g. labelling of semi-finished products)? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Finished products? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Microbiological control? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Are records kept of all control results? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | If yes, for how long do you keep those records? |       | Years |
|  | Is your critical analytical laboratory equipment fully qualified? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Is an equipment use log in place? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Is there a maintenance plan/procedure for laboratory equipment? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | If yes: |  |  |  |
|  | Do you have a calibration scheme? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Do you have calibration instructions? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Do you keep all records of calibration performances? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Does any laboratory equipment have software control? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | If yes:Is the software validated? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Are modifications of software (or its use) implemented by laboratory personnel? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Is there a procedure concerning the change of software and its copying? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Is the security of software controlled? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Are samples of final product taken by appropriately trained personnel? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Do you sample incoming materials, and Product according to an approved sampling plan? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Which sampling plan do you use: |
|  | For starting materials? |       |
|  | For intermediates? |       |
|  | For finished products? |       |
|  | Do you analyze each sample? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Do you keep retain samples of each lot? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | For how long do you keep retain samples? |       | Years |
|  | Is there a procedure in place to establish and manage reference standards? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Are all standards traceable to their preparation and the reagents used? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Are there procedures to define the storage of stability samples (including timelines for completion of tests for the specific time points, control of the quantity for the samples and withdrawal of samples from the stability chamber)? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Do you have a program for ongoing stability study? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Do you have a procedure for management of retain samples (raw materials, packaging materials and bulk/ finished product)? | Yes [ ]  | No [ ]  | N/A [ ]  |

| Quality Assurance |
| --- |
|  | 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 [ ]  |
|  | 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? |       |
|  | Do you have any written procedure to handle customer complaints? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Are procedures in place that control reworks/deviations to material, manufacturing processes, test methods, and/or product specifications? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Is there an independent Quality Assurance (QA) department within the company? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Is there a recall procedure in place? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Does the recall procedure include mock recall? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Is there an internal audit program implemented? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Do you establish and periodically measure quality indicators | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Is your company willing to sign a specification and quality assurance agreement according to Customer expectations and templates? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Who is responsible for evaluation and approval: |  |
|  | of specifications of end products? |       |
|  | of critical manufacturing process parameters? |       |
|  | Do you have procedures covering the release or rejection of material? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Who is responsible for release and reject of your end product? |       |
|  | On which quality data do you base the release of the product? |       |
|  | Are batch records reviewed / approved before the batch is dispatched? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Are deviations and non-conformances investigated, documented and filed? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Do you communicate doubts regarding the quality of the product to the customers? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Even when the product is still within specification? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Would you notify your Customer of any significant deviations that occur during manufacturing? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Do you introduce changes according to a written procedure? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Do you inform your customers about changes?  | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | If yes, how do you inform them? |       |
|  | Do you wait for approval of customers on major changes? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Would you notify your Customer in writing prior to implementing significant changes in analytical test methods, specifications, or manufacturing procedures/processes, and use of raw material source from animal, human, or vegetable origin? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Would you notify your Customer in writing prior to implementing major changes in plant, site of production, or contract manufacturing?  | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Describe how senior management is informed of quality-related issues: |       |
|  | Batch Certification |
|  | Do you supply the Certificate of Compliance (CoA) with cGMP for each batch? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | If ‘YES’, will the Certificate of Analysis include actual analytical results? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Is your CoA compliant with “Internationally harmonized requirements for batch Certification” when applicable? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Is the CoA approved by a quality representative? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Will you supply a Certificate of Sterilization with each batch? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Distribution / Transportation |
|  | Do you follow principles of Good distributionpractice, with well-defined and traceabledistribution channels? |       |  |  |
|  | Is there a process in place that would ensure that defects identified after distribution are notified to the Customer? |       |  |  |
|  | Subcontractors and Suppliers Qualification |
|  | Is there a procedure for approval and qualification of subcontractors (manufacturing steps, QC tests, etc.), suppliers (Raw Materials, API, excipients, packaging materials, etc.) and service providers (warehouse, shipment, and transportation, etc.)? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Is there a procedure for monitoring the approved subcontractors, suppliers, and service providers on a list? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Do you establish Quality Agreements with all your subcontractors and suppliers? Please comment. | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Do you perform on-site audits of suppliers as part of your approval / qualification package? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Did the contract testing laboratories and external manufacturers implement quality system according to international standards? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Data integrity |
|  | Do you have a defined Data Integrity Program? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Is there frequency-based Training (specific aspects of data integrity requirements as part of each responsible role)? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Have you any Quality Culture Programs in place linking the roles, responsibilities, and actions of employees to patient safety, quality, compliance, and the reputation of the company? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Is there a Continuous Improvement program? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Have there been any regulatory observations (verbal or written) against data integrity in your company previously? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Is there a secondary review of paper and/or electronic records, including all relevant audit trail characteristics (electronic or manually captured) as part of the batch release process, and are the personnel performing the review independently? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Are the procedures for associates to adhere to Data Integrity principles included in SOP’s? | 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? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | 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 [ ]  |

| Packaging, Labelling and Shipping |
| --- |
|  | If containers are reused, are they cleaned via validated cleaning procedures and inspected before use? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Are container labels reconciled and the number of labels printed, used and destroyed recorded? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Is each bag/container labelled with the lot/batch no.? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Will each bag/container on a pallet have the lot/batch no. and/or description clearly visible on it? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Do you keep records of all shipments to customers, including batch number and quantity? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Do you use your own transport for shipping to customers or do you use a contractor? | Own[ ]  | Contractor [ ]  | N/A[ ]  |
|  | If you use a contractor, Do you have an agreed contract between parties that specifies the required shipping conditions for materials? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | If yes, have they been evaluated? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Is the shipping temperature controlled? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Have stability studies for temperature-controlled shipments been performed? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Are written instructions available for |
|  | Packaging components? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Packaging operation? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Labels and labelling? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Does the labelling procedure emphasize special precautions to prevent unintentional mix-up or substitutions? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Do you maintain lot separation during packaging? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Are you prepared to meet the packaging and labelling requirements of your customers? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Does your labelling indicate: | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Name and quality? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | The site of manufacturing? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | The lot number? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Our order number? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Our code number? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Do you use re-usable containers? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | If yes: Do you have procedures to take special precautions to avoid cross-contamination in this case? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Do you have your own transportation system? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | If yes: |  |  |  |
|  | Do you have a SQAS assessment report? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Valid date of the SQAS report :  |      --      --       |
|  | Do you have a Quality-/Safety selection system for contracting carriers | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Do you have a regular carrier for your goods? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | If yes:  |  |  |  |
|  | What is the name of this company? |       |  |  |
|  | Who is the carrier's agent? |       |  |  |
|  | Do you contact your customer in case of delay? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Does your transport system make use of a tracking report? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Does your carrier have a Quality Manual? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | To which norm is this quality system related? |       |
|  | Does your carrier provide documented evidence of proper storage conditions during transportation? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | In the case of liquid products | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Do you use dedicated tankers? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Do you require cleaning of road tankers after every use? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Are cleaning certificates kept by the driver? | Yes [ ]  | No [ ]  | N/A [ ]  |
|  | Are cleaning certificates available for inspection by us? | Yes [ ]  | No [ ]  | N/A [ ]  |

| Safety, Health and Environment (SHE) |
| --- |
|  | Do you have an operational management system(s) for Safety, Health and Environment (SHE)? | Yes [ ]  | No [ ]  |
|  | If so, are these systems |
|  | a. based on an international standard (ISO 9001/14001/18001)? | Yes [ ]  | No [ ]  |
|  | b. certified by a accredited third party auditing body? | Yes [ ]  | No [ ]  |
|  | Do you have a dedicated organisation for safety, health and environment? | Yes [ ]  | No [ ]  |
|  | How many people are employed in this organisation? |       |
|  | Have you identified all relevant SHE aspects of your activities and all relevant legal requirements you have to comply with? | Yes [ ]  | No [ ]  |
|  | Do you have a structured SHE program, which is regularly monitored and updated? | Yes [ ]  | No [ ]  |
|  | Does your site comply with all licenses under relevant laws (Nuisance Act, Environmental Protection Act, Integrated Pollution Prevention, Hazardous Waste, etc.)? | Yes [ ]  | No [ ]  |
|  | Are the following subjects regulated by law and/or specific standards: |  |
|  | * emissions to air
 | Yes [ ]  | No [ ]  |
|  | * discharge of wastewater
 | Yes [ ]  | No [ ]  |
|  | * disposal of hazardous waste
 | Yes [ ]  | No [ ]  |
|  | * protection against/remediation of soil pollution
 | Yes [ ]  | No [ ]  |
|  | * risk control and reduction
 | Yes [ ]  | No [ ]  |
|  | * nuisance by noise/odor
 | Yes [ ]  | No [ ]  |
|  | * occupational safety
 | Yes [ ]  | No [ ]  |
|  | Does your site operate its own wastewater treatment installation? | Yes [ ]  | No [ ]  |
|  | Is your site controlled by regular inspections of authorities in the field of safety, health and environment? | Yes [ ]  | No [ ]  |
|  | Please specify |       |
|  | Is your personnel instructed on the handling of any kind of hazardous materials that you use and on how to act in case of unwanted events? | Yes [ ]  | No [ ]  |
|  | Do you have an adequate emergency response plan and organisation? | Yes [ ]  | No [ ]  |
|  | Do you run SHE (compliance/performance) audits? | Yes [ ]  | No [ ]  |
|  | Do you have a certified person: “Safety-advisor transport dangerous materials (road/rail)”? | Yes [ ]  | No [ ]  |
|  | Please enclose a copy of the certificate | Ref:       |
|  | Does the Safety-advisor make annually reports to the highest management about the transport activities of the company with respect to dangerous materials? | Yes [ ]  | No [ ]  |

**Thank you for taking the time to fill out this questionnaire.**

**Please also provide copies of the documents listed below. If, for some reason, you were unable to do so, please indicate this in ”Comments” column.**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Related Questionnaire section | Document title | Document Code | YES (Provided) | NO (Not Provided) | Comments |
| To be filled out during Questionnaire preparation |  |  |  |  |  |
| To be filled out during Questionnaire preparation |  |  |  |  |  |
| To be filled out during Questionnaire preparation |  |  |  |  |  |

|  |  |
| --- | --- |
| This Supplier self-assessment form was prepared and filled by: | Name: Klicken Sie hier, um Text einzugeben. Function: Klicken Sie hier, um Text einzugeben.Date/Signature:  |

**Section for evaluation by Company CDE**

|  |
| --- |
| **For internal evaluation only** |
| **Question Number** | **Acceptable** | **Not Acceptable** | **Comments** |
|  | [ ]  | [ ]  |  |
|  | [ ]  | [ ]  |  |

|  |
| --- |
| **Decision and comments (Company CDE):**Klicken oder tippen Sie hier, um Text einzugeben. |
| **Candidate is suitable for further evaluation** | Yes [ ]  | No [ ]  |

|  |  |
| --- | --- |
| This evaluation was done by: | Name: Klicken Sie hier, um Text einzugeben. Function: Klicken Sie hier, um Text einzugeben.Date/Signature:  |