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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **AUDIT INFORMATION** | | | | | | | | | | | | | | | |
| AUDIT DATE: | | | | | AUDIT SCOPE: | | | | | | | | | AUDITOR: | |
| **SUPPLIER INFORMATION** | | | | | | | | | | | | | | | |
| SUPPLIER NAME: | | | | | | | | | | | | | CEO: | | |
| ADDRESS: | | | | | | | | | | | | | PLANT MANAGER: | | |
| CITY: | | | | | | STATE: | | | | ZIP CODE: | | | QA/QC MANAGER: | | |
| CONTACT PERSON (NAME AND TITLE): | | | | | | | | | PHONE: | | | | MANUFACTURING MANAGER: | | |
| EMAIL: | | | | | | | | | | | | | PURCHASING MANAGER: | | |
| YEARS IN BUSINESS: | | | | OTHER PLANT LOCATION(S): | | | | | | | | | | | |
| # OF EMPLOYEES: | | # OF MFG EMPLOYEES: | | | | | | # OF QA EMPLOYEES: | | | # OF SHIFTS: | QA COVERAGE ON ALL SHIFTS? | | | QA REPORTS TO? |
| FDA REGISTRATION: | | | | | | | | DATE OF LAST FDA AUDIT: | | | | ISO CERTIFIED? IF YES, CERTIFICATE(S) # AND EXPIRATION DATE. | | | |
| **EVALUATION CRITERIA** | | | | | | | | | | | | | | | |
| Compliance **(C)** | | | | | | | Procedures, processes, and/or systems are well defined, documented, executed, and meet or exceed quality standards. | | | | | | | | |
| Minor nonconformity **(MI)** | | | | | | | Procedures, processes, and/or systems are partially defined, documented, and executed. They meet most of the standards with *minor* deficiencies. | | | | | | | | |
| Major nonconformity **(MA)** | | | | | | | Procedures, processes, and/or systems are inadequate or non-existent. There are *major* deficiencies. | | | | | | | | |
| Not applicable **(N/A)** | | | | | | | Evaluation point is not applicable to company or not evaluated during the audit. | | | | | | | | |
| **INSTRUCTIONS & TIPS FOR THE AUDITOR** | | | | | | | | | | | | | | | |
| **Instructions** | | | 1. Complete Audit and Supplier Information sections on Page 1. Make sure to understand the Evaluation Criteria on Page 1 before starting the audit. 2. Select the sections at Page 2 that will be covered during the audit. If it is a partial audit, justify in the designated section on Page 2. 3. Depending on the sections selected for the scope of the audit, go to the appropriate Audit Questions section starting at Page 4 of this document and conduct the audit accordingly. Blue text is instructional for the auditor. Delete to add your findings, observations, and notes. Make sure to document any finding/observation and provide (or reference to) evidence if possible. 4. After conducting the audit, summarize the results at Page 3 and sign the form at the bottom of the List of Nonconformities. | | | | | | | | | | | | |
| **Tips** | * When on the facility tour, make as many notes as possible regarding equipment, people, processes observed. Use notes taken on the tour to drive records requested. * Where possible and as time allows, look at three examples for each type of record requested. | | | | | | | | | | | | | | |

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| --- | --- | --- | --- |
| **SECTIONS INSPECTED DURING THE AUDIT** | | | |
| Select the audited subpart(s): | | | |
| **21 CFR Part 820** | | | |
|  | Subpart A – General Provisions | | |
|  | Subpart B – Quality System Requirements | | |
|  | Subpart C – Design Controls | | |
|  | Subpart D – Document Controls | | |
|  | Subpart E – Purchasing Controls | | |
|  | Subpart F – Identification and Traceability | | |
|  | Subpart G – Production and Process Controls | | |
|  | Subpart H – Acceptance Activities | | |
|  | Subpart I – Nonconforming Product | | |
|  | Subpart J – Corrective and Preventive Action | | |
|  | Subpart K – Labeling and Packaging Control | | |
|  | Subpart L – Handling, Storage, Distribution, and Installation | | |
|  | Subpart M – Records | | |
|  | Subpart N – Servicing | | |
|  | Subpart O – Statistical Techniques | | |
| IF AUDIT IS PARTIAL. PROVIDE JUSTIFICATION HERE: | | | |
| **AUDIT SUMMARY AND OUTCOME** | | | | |
| Decision: | | Supplier recommended for approval or continuation of use | | | |
| Reaudit recommended | Recommended date of reaudit: | | |
| Supplier demoted to conditionally approved status | Disqualified | | |
| Approved By (*Print Name and Title*): | | | Signature & Date: | | |

**Observation(s):**

* [Please provide a detailed description of the positive observation(s) identified during the audit. It is unlikely that any audit would conclude without any commendations.]

Report in the chart below any nonconformity (minor or major) found during the audit.

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **NC #** | **Minor or Major** | | **21 CFR 820 Subpart\*** | **Description of nonconformities (NC) found during the audit**  ***\*\*\*If corrective action is needed, attach to audit results\*\*\**** | | | | **Corrective action due** |
| **MI** | **MA** |
| NC1 |  |  | B | ***The organization has failed to comply to:***   * *Sec. 820.25 Personnel.*   *(b) Training. Each manufacturer shall establish procedures for identifying training needs and ensure that all personnel are trained to adequately perform their assigned responsibilities. Training shall be documented.*  ***Evidence:***   * *Ex. Some of the training records are missing. In particular, the form FORM0123-01.docx is not completed for employees X, Y, Z as required by procedure SOP 123.* | | | | 2015-10-31 |
| NC2 |  |  | … | ***The organization has failed to:***   * [cite standard directly]   ***Evidence:***  [Provide specific objective evidence of non-conformity. Include references to procedures, material numbers, records, equipment, etc. as appropriate.] | | | | … |
| NC3 |  |  | … | ***The organization has failed to:***   * [cite standard directly]   ***Evidence:***  [Provide specific objective evidence of non-conformity. Include references to procedures, material numbers, records, equipment, etc. as appropriate.] | | | | … |
| **Miscellaneous:** | | | | | | **\* 21 CFR 820:** | | |
| Subpart A – General Provisions  Subpart B – Quality System Requirements  Subpart C – Design Controls  Subpart D – Document Controls  Subpart E – Purchasing Controls  Subpart F – Identification and Traceability  Subpart G – Production and Process Controls  Subpart H – Acceptance Activities | Subpart I – Nonconforming Product  Subpart J – Corrective and Preventive Action  Subpart K – Labeling and Packaging Control  Subpart L – Handling, Storage, Distribution, and Installation  Subpart M – Records  Subpart N – Servicing  Subpart O – Statistical Techniques | |
| AUDITOR SIGNATURE: | | | | | DATE: |

| **21 CFR 820 Subpart A – General Provisions** | | **C** | **MI** | **MA** | **N/A** | **Finding/Observation – Evidence** |
| --- | --- | --- | --- | --- | --- | --- |
| §820.5 | Does the company operate in a state of control as defined by the GMP regulations? Is there any relevant certificates? If so, provide a copy where certification number and expiration date can be assessed. |  |  |  |  | *Ex.:* Yes, the Supplier has a relevant certification issued by Bureau Veritas:  GMP (US FDA, 2008)  Certification n°: AAAAA BBBBB-C-00000-B  Exp. date: 2019-09-29  This certificate was re-issued in 2019-MM-DD. The Supplier will provide a copy of the new certificates upon receipt. |
| Is there a detailed description of the Quality System in the Quality Manual? Is the scope of the Quality System established and described for the organizational units, production sites and products produced? Is the structure of the Quality System and Quality documents described? |  |  |  |  | Yes or no. Get familiar with the structure and read the description of the Quality System in the Quality Manual. |
| Does the Quality Manual contain a date of issue and revision number? |  |  |  |  | Note the last date of issue and the revision number of the Quality Manual |
| **Comments:** | | | | | | |

| **21 CFR 820 Subpart B – Quality System Requirements** | | **C** | **MI** | **MA** | **N/A** | **Finding/Observation – Evidence** |
| --- | --- | --- | --- | --- | --- | --- |
| §820.20 | Is the Quality Policy established and documented in a declaration by management? |  |  |  |  | Is the Quality Policy visible for the employees in the facility? |
| Is there an organizational chart? |  |  |  |  | Note here the name of the document containing the organizational chart. An organization chart by function should show interdepartmental relationships as well as relationships to top management of the company. |
| Is the suitability and effectiveness of the Quality System reviewed and documented by management at fixed intervals? |  |  |  |  | When was the last management review conducted? Note date and name of the report. |
| §820.22 | Are procedures and responsibilities established for planning and performing internal audits and for implementing the resulting measures? |  |  |  |  | Ask to see the procedure for internal audit. Note the name of the document here. Ask to see the internal audit schedule. When was the last internal audit? When is the next internal audit? |
| Are the appointed auditors independent of the areas to be audited? |  |  |  |  | Ask to see an example of audit report and verify that the appointed auditors did not audit an area to which they were responsible or involved. |
| In the event of nonconformities, are nonconformance reports written and corrective actions with deadline and responsibility established? |  |  |  |  | Ask for an example of nonconformity that has been revealed during an internal audit. Explain how this nonconformity was handled. |
| Are implementation and effectiveness of corrective actions recorded in subsequent internal audits? |  |  |  |  | Was the effectiveness of the corrective actions evaluated? |
| §820.25 | Are procedures and responsibilities established for training personnel? |  |  |  |  | Note the name of the procedure(s) established for training personnel. Note names of operators on the manufacturing floor and verify training records on observed activities. |
| Are records/proofs kept of qualifications, external training and Quality System training? |  |  |  |  | *Ex.: Employee training procedure SOP 123 specifies every employee should have completed form FORM0123-01.docx. Training records were pulled for employees X, Y, Z. This form was not completed for these employees.* |
| Is it ensured that all personnel working under special environmental conditions or performing special processes or functions are appropriately trained or supervised by a trained person? |  |  |  |  | Are there any special environmental conditions or special processes required for production? If yes, assess the training records of the employees in charge of these special conditions/processes. |
| **Comments:** | | | | | | |

| **21 CFR 820 Subpart C – Design Controls** | | **C** | **MI** | **MA** | **N/A** | **Finding/Observation – Evidence** |
| --- | --- | --- | --- | --- | --- | --- |
| §820.30 | Are procedures and responsibilities established for all phases of design? |  |  |  |  | Assess that the procedures exist and note the name of the documents. |
| Are the milestones tracked and executed on-time with formal reviews and management sign-off? Does each device have a DHF? |  |  |  |  | Yes or no. Provide explanations or documents. Note the name of the DHF you audited. |
| Are all design verification activities documented and maintained? |  |  |  |  | How was the verification conducted for your product(s)? Provide details or name of the documents containing the details. |
| Are design changes identified, recorded, inspected and approved by authorized personnel in the device history file (DHF)? |  |  |  |  | Ask for an example of design review. |
| Is there an independent evaluation (validation) of the production units under actual or simulated use conditions? |  |  |  |  | How was the validation conducted for your product(s)? Provide details or name of the documents containing the details. |
| Is a risk analysis performed for each product? |  |  |  |  | Yes or no. Provide explanations or documents. Note the name of the risk analysis applicable to your product(s). |
| Are there procedures to ensure that the final design is correctly transferred to production? |  |  |  |  | Ask for the procedures used to transfer a device to production. Note the name of the document(s). |
| **Comments:** | | | | | | |

| **21 CFR 820 Subpart D – Document Controls** | | **C** | **MI** | **MA** | **N/A** | **Finding/Observation – Evidence** |
| --- | --- | --- | --- | --- | --- | --- |
| §820.40 | Are guidelines, procedures and responsibilities established for the control of all quality related documents and data? |  |  |  |  | Note the name of the documents. |
| Is a master list of equivalent document control procedure implemented to control document validity? Do documents include the following information: revision status, author, date, identification? |  |  |  |  | Ask for the list and note the name of the document. Assess this based on the document already inspected previously. |
| Is it ensured that all relevant standards and legal documents are at hand, up to date and adequately distributed? |  |  |  |  | Which standards are used by the supplier? Is there a hard copy? Where is it stored? How does the supplier make sure revisions are current? |
| **Comments:** | | | | | | |

| **21 CFR 820 Subpart E – Purchasing Controls** | | **C** | **MI** | **MA** | **N/A** | **Finding/Observation – Evidence** |
| --- | --- | --- | --- | --- | --- | --- |
| §820.50 | Are procedures and responsibilities established for the selection and evaluation of suppliers? |  |  |  |  | Is there a procedure to qualify suppliers? Note the name of the procedure(s). Ask for the list of acceptable suppliers. Which supplier(s) is/are used for your product(s) |
| Are purchasing documents subject to an inspection regarding completeness and clarity and is there an approved procedure? |  |  |  |  | What are the controls in place for purchase from suppliers? |
| Is there an agreement with the supplier(s) to notify the company of any changes? |  |  |  |  | Yes or no. Provide explanations. |
| Are supplier files up-to-date and supplier performance reviewed on a regular basis? |  |  |  |  | Audit the supplier files to make sure they are complete, and that the suppliers’ performance is reviewed and documented. |
| **Comments:** | | | | | | |

| **21 CFR 820 Subpart F – Identification and Traceability** | | **C** | **MI** | **MA** | **N/A** | **Finding/Observation – Evidence** |
| --- | --- | --- | --- | --- | --- | --- |
| §820.60-65 | Are procedures and responsibilities established for product identification and traceability?  Is the degree of traceability defined, documented and maintained so that corrective actions are supported? |  |  |  |  | Note the name of the procedures.  Note the degree of traceability for your product(s). |
| Does this take all phases of product realization into account? |  |  |  |  | When is the identification code given to your product(s)? |
| Is it ensured that mix-ups cannot occur? |  |  |  |  | Ask for examples and explanations on how they avoid mix-ups during all phases of product realization. |
| **Comments:** | | | | | | |

| **21 CFR 820 Subpart G – Production and Process Controls** | | **C** | **MI** | **MA** | **N/A** | **Finding/Observation – Evidence** |
| --- | --- | --- | --- | --- | --- | --- |
| §820.70 | Are procedures and responsibilities established for controlled production? |  |  |  |  | What are the procedures used to manufacture your product(s)? Note the name of the procedures. |
| Do machines and tooling (dies, molds, etc.) have identification numbers? |  |  |  |  | Which machines/tooling are used to produce your product(s)? Do they have identification numbers? |
| Are production documents and the relevant work instructions available at the place of work and are they being used? |  |  |  |  | Where are located the production documents? |
| Is the qualification of process, equipment, personnel specified and are records of these qualifications maintained? |  |  |  |  | Ask for an example of process or equipment qualification. |
| Are requirements defined and maintained for health, hygiene or clothing of personnel if contact between such personnel and product can adversely affect product quality? |  |  |  |  | Yes or no. Provide evidence. |
| Where appropriate, are the environmental conditions controlled and/or monitored? |  |  |  |  | *Ex.: Yes, the products are stored in a temperature and humidity controlled environment. The temperature and humidity are recorded continuously and evaluated each week for acceptability.* |
| Are the requirements on the cleanliness of the product defined, documented and maintained? |  |  |  |  | *Ex.: Yes, the products are manufactured in a Class 100,000 (ISO 8) clean room.* |
| §820.72 | Is the equipment routinely calibrated, inspected, checked, and maintained? |  |  |  |  | Ask for an example of calibration, inspection or maintenance records for particular equipment. Ask for records for equipment observed in use on the manufacturing or inspection areas. Note the name of the document. |
| Is the validity of previous quality tests evaluated and recorded when a piece of test equipment is found to be faulty, out of calibration or there are adjustment changes? |  |  |  |  | Ask if this has happened in the past. Provide details. |
| §820.75 | Are there any special processes where the results cannot be fully verified on the product? Is there a validation for these processes? |  |  |  |  | Ask for the latest validation report of any special processes related to your product(s). Is it approved, dated and signed? Who performed the validation? |
| How does the Supplier ensure that the specified requirements for the validated processes continue to be met? |  |  |  |  | Is there any work instructions used? Are the parameters continually monitored? How can we retrieve the date that the special process was performed and the identity of the operator? |
| Is the process reviewed and evaluated when changes or process deviations occur? Is this documented? Is a process revalidation performed when appropriate? |  |  |  |  | Do you have an example of re-validation report? |
| **Comments:** | | | | | | |

| **21 CFR 820 Subpart H – Acceptance Activities** | | **C** | **MI** | **MA** | **N/A** | **Finding/Observation – Evidence** |
| --- | --- | --- | --- | --- | --- | --- |
| §820.80 | Are procedures and responsibilities established for the writing, approval and execution of inspection plans for incoming, in-process and final inspection? |  |  |  |  | Assess that the procedures are in place and note the name of the procedures. |
| Is the result of receiving inspection and testing recorded? |  |  |  |  | Ask for an example of receiving inspection and testing records concerning your product(s). |
| Can inspected products be distinguished from uninspected products? |  |  |  |  | How do they ensure that received products are not used before they are inspected, tested or approved |
| Is final inspection and testing documented and are the results recorded? |  |  |  |  | Ask for an example of inspection and testing records concerning your product(s). |
| §820.86 | Are procedures and responsibilities established for the identification of inspection and test status throughout all phases of production? |  |  |  |  | Assess that the procedures exist and note the name of the procedures. |
| Are nonconforming received products specially marked or stored separately? |  |  |  |  | Can the supplier provide an example of rejected products? Is there a quarantine area? |
| Is it ensured that only products which have successfully passed all production, inspection and test steps are released for delivery? |  |  |  |  | Are the inspection and test status retained and indicated by appropriate means from receiving to shipping/final storage? |
| **Comments:** | | | | | | |

| **21 CFR 820 Subpart I – Nonconforming Product** | | **C** | **MI** | **MA** | **N/A** | **Finding/Observation – Evidence** |
| --- | --- | --- | --- | --- | --- | --- |
| §820.90 | Are procedures and responsibilities established for the handling, recording and reporting of nonconforming products? |  |  |  |  | Assess that the procedures exist and note the name of the procedures. |
| Are there procedures for the identification and separate storage of nonconforming products? |  |  |  |  | Is there a quarantine area? |
| Are responsibilities established for the following decisions and are these documented: approval or customer release, re-work, re-grading or alternative use, rejection, return to Supplier? |  |  |  |  | Assess that the procedures exist and note the name of the procedures. |
| Are acceptable nonconformities and reworkings documented? Are additional inspections and tests recorded for repaired or reworked parts? |  |  |  |  | Ask for an example and note the name of the document. |
| How are nonconformities documented and processed? Are records handled appropriately? |  |  |  |  | Audit NCR records and assess how they are documented. |
| **Comments:** | | | | | | |

| **21 CFR 820 Subpart J – Corrective and Preventive Action** | | **C** | **MI** | **MA** | **N/A** | **Finding/Observation – Evidence** |
| --- | --- | --- | --- | --- | --- | --- |
| §820.100 | Are procedures and responsibilities established for the initiation, performance and surveillance of corrective and preventive actions? |  |  |  |  | Assess that the procedures exist and note the name of the procedures. |
| Do the procedures or corrective actions include: handling of customer complaints, reports on product nonconformities, classification of nonconformities, determination of actions, informing affected units, surveillance of effectiveness of actions, advisory notices and recalls? |  |  |  |  | Assess the content of the procedure. |
| Do the procedures for preventive action include the following: analysis of data/information, determination of appropriate preventive actions, surveillance of the effectiveness, submission of information for management review? |  |  |  |  | Assess the content of the procedure. |
| Is there a CAPA log in place to keep track of each CAPA and to make sure they are closed in a timely manner? Are CAPA records handled in accordance to the procedure? |  |  |  |  | Request the CAPA log and assess its content. Audit CAPA records from the list to determine if they were closed in a timely manner with an effectiveness verification. |
| **Comments:** | | | | | | |

| **21 CFR 820 Subpart K – Labeling and Packaging Control** | | **C** | **MI** | **MA** | **N/A** | **Finding/Observation – Evidence** |
| --- | --- | --- | --- | --- | --- | --- |
| §820.120-130 | Are there procedures established and maintained to control labeling activities? |  |  |  |  | Assess that the procedures exist and note the name of the procedures. |
| Are the labels printed and applied in such a manner to remain legible and affixed during the product lifecycle? |  |  |  |  | Describe the labelling of your product(s) and how it’s appropriate for their lifecycle. |
| Prior to storage or use, is labeling examined for accuracy including, where applicable, the correct unique device identifier (UDI) or universal product code (UPC), expiration date, control number, storage instructions, handling instructions, and any additional processing instructions? |  |  |  |  | Provide an example of records for labeling inspection. |
| Is the labeling used for each production unit, lot, or batch documented in the DHR? |  |  |  |  | Assess that the release of labeling, including the date and signature of the inspector, is documented |
| Are the device packaging and shipping containers designed and constructed to protect the device from alteration or damage during the customary conditions of processing, storage, handling, and distribution? |  |  |  |  | Provide a rationale or tests results. |
| **Comments:** | | | | | | |

| **21 CFR 820 Subpart L – Handling, Storage, Distribution, and Installation** | | **C** | **MI** | **MA** | **N/A** | **Finding/Observation – Evidence** |
| --- | --- | --- | --- | --- | --- | --- |
| §820.140-170 | Are procedures and responsibilities established for: handling and storage in receiving area, receiving storage, in-process storage, packaging, preservation, delivery of products? |  |  |  |  | Assess that the procedures exist and note the name of the procedures. |
| Are specially marked storage areas available for receiving, receiving storage, in-process storage, final storage, and storage of nonconforming products in order to prevent damage, deterioration or contamination of products? |  |  |  |  | Can be assessed by visiting the facility. |
| Are there procedures and controls in place to prevent cross contamination, damage or deterioration of products? |  |  |  |  | Provide examples (e.g. “First In-First Out” stock rotation). Are there procedures and records for the control of products with limited shelf life or requiring special storage conditions? e.g. away from heat, sources of ignition and incompatibles such as strong oxidizers, out of direct sunlight, etc. |
| Are there written preservation and packaging instructions? |  |  |  |  | Ask for the preservation and packaging instructions of your product(s). |
| Are special instructions pertaining to the use of products such as a user manual included? |  |  |  |  | Ask for the user manual of your product(s). |
| **Comments:** | | | | | | |

| **21 CFR 820 Subpart M – Records** | | **C** | **MI** | **MA** | **N/A** | **Finding/Observation – Evidence** |
| --- | --- | --- | --- | --- | --- | --- |
| §820.180-186 | Are the records maintained at the manufacturing establishment or other location that is reasonably accessible to responsible officials of the manufacturer and to employees of FDA designated to perform inspections? |  |  |  |  | Where are the records kept? Are the records readily available for review and copying by FDA employee(s)? |
| Are the records legible, stored to minimize deterioration and prevent loss, and backed up? |  |  |  |  | Is the storage of the records appropriate? |
| Are the records retained during the expected life of the device, but in no case less than 2 years from the date of release for commercial distribution by the manufacturer? |  |  |  |  | Specify for how many years the records are retained. |
| Does the Supplier prepare, approve and maintain device master records (DMR’s)? |  |  |  |  | Ask for a DMR example. |
| Does the Supplier maintain device history records (DHR’s) for each batch, lot, or unit? |  |  |  |  | Ask for a DHR example. Could be helpful to review DHR’s associated with a NCR or CAPA issue to see how nonconforming product was addressed in the DHR. Verify acceptance criteria and process parameters meet specification. |
| Are procedures and responsibilities established for identification, distribution, storage location, retention period, availability/release, writing, collection and maintenance of quality records? |  |  |  |  | Assess that the procedures exist and note the name of the procedures. |
| Are verified and authorized records kept for each batch of product that provides the required traceability to identify the quantity produced and released for distribution? |  |  |  |  | Ask for an example of records. |
| §820.198 | Are there procedures for receiving, reviewing, and evaluating complaints? |  |  |  |  | Assess that the procedures exist and note the name of the procedures. |
| Are the complaints processed and documented in a uniform and timely manner? |  |  |  |  | Ask for complaint log. Look for trends or issues that appear critical and see how investigations were handled. |
| How does the Supplier determine if an investigation is necessary? |  |  |  |  | Ask for explanations. Is there a record stating the reason and the person responsible for such a decision? |
| **Comments:** | | | | | | |

| **21 CFR 820 Subpart N – Servicing** | | **C** | **MI** | **MA** | **N/A** | **Finding/Observation – Evidence** |
| --- | --- | --- | --- | --- | --- | --- |
| §820.200 | Are procedures and responsibilities established for informing customers regarding the use of products, equipment and information supplied to Customer Care representatives, feedback from the market, handling of customer complaints, spare parts? |  |  |  |  | May not be applicable, i.e. outside of the scope of services provided by the supplier. If so, select “N/A”. |
| Are there suitable documents for informing customers about installation instructions, product information, user manuals, maintenance instructions or spare parts list? |  |  |  |  | May not be applicable, i.e. outside of the scope of services provided by the supplier. If so, select “N/A”. |
| Are Customer Care representatives equipped with suitable resources and documents such as tools, inspection, measurement and test equipment, product information, instructions/manuals? |  |  |  |  | May not be applicable, i.e. outside of the scope of services provided by the supplier. If so, select “N/A”. |
| Are Customer Care representatives suitably trained? |  |  |  |  | May not be applicable, i.e. outside of the scope of services provided by the supplier. If so, select “N/A”. |
| Are customer complaints submitted to the relevant units for further handling? |  |  |  |  | May not be applicable, i.e. outside of the scope of services provided by the supplier. If so, select “N/A”. |
| **Comments:** | | | | | | |

| **21 CFR 820 Subpart O – Statistical Techniques** | | **C** | **MI** | **MA** | **N/A** | **Finding/Observation – Evidence** |
| --- | --- | --- | --- | --- | --- | --- |
| §820.250 | Are statistical procedures applied to receiving inspection and testing, in process inspection and testing, final inspection and testing and Suppliers? |  |  |  |  | Note the name of the procedures containing the statistical techniques and when these procedures are applicable. |
| Are the applied sampling methods based on relevant standards? And are they suitable? |  |  |  |  | Yes or no. If yes, provide the name of the standard used by the supplier (e.g. ISO 2859). |
| Is there a regular review of the sampling methods with respect to reports of nonconforming products, quality audit reports, customer feedback and other appropriate information? |  |  |  |  | When was the last revision of the procedure(s)? Have a look at the review history and ask for explanations if review description is not clear/incomplete/missing. |
| **Comments:** | | | | | | |