PRE-INSPECTION DOCUMENT REQUESTS TEMPLATE

Following the announcement of the collaborative hybrid inspection, the lead inspectorate and the participating RAs will agree on the information to be obtained from the facility prior to the inspection. The requests will be coordinated by the lead inspectorate.

The table below includes a standard list of pre-inspection documents that the facility may be requested to provide to the inspection team.

The list is non-exhaustive and may vary depending on the scope of the inspection and the type of submission. Documents can be provided in Word, Excel, or PDF. Documents should be provided in English and should be sortable and searchable, or alternatively, should be exportable to a spreadsheet.

#	Pre-Inspection Requests
1. General Information	
1.1	Information on any special safety requirement for visitors.
1.2	Copy of the current version of the Site Master File document, including all appendices listed in the current PIC/S PE 008-4 Explanatory Notes for Pharmaceutical Manufactures on the Preparation of a Site Master File.
1.3	Copy of the current version of the Validation Master Plan, including the Process, Cleaning and Computerized Systems Validation Plans.
1.4	Business hours, including manufacturing, laboratory and warehouse operating hours.
1.5	Brief description of the major changes that have occurred since the last inspection by the participating authorities with respect to facility/utilities, equipment & instrumentation, key personnel, suppliers, clients, products, activities.
1.6	List of current Standard Operating Procedures (*SOP Index*) including the code, title, version and effective date. Identify the SOPs applicable to manufacturing, testing, storage, shipping of *[Product in scope]*.
1.7	A copy of the SOP(s) describing the procedures for the following quality system: - *To be determined (ex. Deviation, CC, CAPAs, Rework/Reprocess, etc.)*
1.8	Production schedules for *[Product in scope]* for the planned inspection week(s).

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2. Quality Systems	
2.1	List of suppliers and contractors that support the manufacture of *[Product in scope]* (e.g., facilities support, testing laboratories, shipping firms, DS storage facilities, etc.), including the address and support function. For each supplier/contractor, specify if a Quality Agreement is in place.
2.2	List of all ***Change Controls*** applicable to *[Product in scope]* manufacturing process, equipment, utilities, and manufacturing areas since the initiation of the PPQ. Include the change description, status, criticality, dates of initiation, and dates of closure (where applicable). ** Please provide this information in an **Excel** spreadsheet format.*
2.3	List of all ***Deviations*** for all equipment, utilities, & facilities used for the manufacture of *[Product in scope]* since the initiation of the PPQ. Include the detailed summary, status, type (planned / unplanned), classification / criticality, date of occurrence, date of investigation initiation, associated CAPAs, and date of investigation closure (where applicable). ** Please provide this information in an **Excel** spreadsheet format.*
3. Production	
3.1	Manufacturing process flow diagrams showing critical control points and critical process parameters for *[Product in scope]*.

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3.2	List of all *[Product in scope]* lots manufactured or attempted (e.g., research, engineering, study, exhibit, PPQ, commercial scale), including batches that were rejected, re-worked, and re-processed, and initiated but terminated prior to completion and reference the associated investigation numbers. Include production dates, lot numbers & disposition, corresponding drug substance lots, as well as the use of the lots (e.g., comparability, stability, development, process validation, commercial, etc.). ** Please provide this information in an **Excel** spreadsheet format.*
3.3	A blank copy of the *[Product in scope]* label.
4. Facility and Equipment	
4.1	Layout of the areas used to manufacture *[Product in scope]***,** including a brief description of the activities conducted in each room/area/building**.** Include: - description of the activities conducted in each room/area/building, - room numbers, - air classifications, - pressure differentials, - personnel, materials, components, products and wastes flows.
4.2	List of major processing equipment used to manufacture *[Product in scope].* Specify: - the equipment ID number, - the equipment name, - the calibration / validation / qualification status, include the corresponding validation / qualification document numbers, - if the equipment is dedicated for the manufacture *[Product in scope]* or multi-product. If the equipment is multi-product, specify with which other products the equipment is shared.

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4.3	Procedure(s) for the ***Introduction of New Products*** in the areas used to manufacture *[Product in scope],* including shared facilities Risk Assessment and cell bank safety testing requirements.
4.4	***Environmental Monitoring*** summary reports (*trend reports*) for the past (2) years for all controlled GMP manufacturing areas used for the manufacture of *[Product in scope],* with a list of all excursions encountered during this time period. For each excursion, include the date of occurrence, date of investigation initiation, date of closure, and status.
4.5	Monitoring summary report (summary of chemical and microbial data) for the past two (2) years for ***Critical Utilities*** in the areas used to manufacture *[Product in scope],* with a list of all excursions encountered during this time period. For each excursion, include date of occurrence, date of investigation initiation, date of closure, and status.
5. Laboratory	
5.1	List of major laboratory equipment used for the testing *[Product in scope],* including a short description of the system's use. Specify: - equipment ID number, - equipment and related computerized system (if applicable), qualification / validation document number(s), - qualification/validation completion date(s).
5.2	In-process, release and stability specifications for *[Product in scope].*
5.3	List of ***OOS, OOT / OOE*** investigations related to *[Product in scope],* including all bioburden, endotoxin, stability and sterility failures (confirmed and unconfirmed). Include a brief description, criticality, type of analysis, impacted batch/lot number, status, dates of occurrence, initiation, and date of closure (where applicable). ** Please provide this information in an **Excel** spreadsheet format.*