DOCUMENT REQUESTS TEMPLATE – Inspection Day 1

The table below includes a standard list of documents that may be requested to be available on-site and remotely, on the first day of the inspection. The documentation requests will be coordinated by the lead inspectorate.

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.

#	Documentation Requests
1. General Information	
1.1	Documentation supporting the Data Governance system.
1.2	The most up-to-date production schedules (if applicable) for the inspection week(s). Specify the anticipated start/end times for operations related to *[Product in scope]*, including setup, filling, visual inspection, sterility testing, cleaning and disinfection of the grade A areas.
2. Quality Systems	
2.1	Copies of the current Quality Agreement with the suppliers and contractors supporting the manufacture, testing and handling of *[Product in scope]*, and related drug substances.
2.2	A copy of the Standard Operating Procedures (SOP) related to the following process/system: - *Deviation Management,* - *Change Controls,* - *Corrective and Preventive Actions (CAPA),* - *Training management program,* - *To be determined…*
3. Production	
3.1	Current Master Manufacturing and Packaging Batch Records for *[Product in scope]*, including version history, i.e. changes between versions of the master batch records.
3.2	Manufacturing process validation protocol (PPQ) and all process validation activities study reports for *[Product in scope]*.

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3.3	Records of release testing, in-process testing, and stability testing results for all lots of *[Product in scope]* manufactured.
3.4	Microbial quality (bioburden and endotoxin) **in-process** results for all lots of *[Product in scope]* manufactured.
3.5	A copy of the Standard Operating Procedures (SOP) related to the following process/system: - *To be determined…*
4. Facility and Equipment	
4.1	Large copies (high resolution) of the P&ID and layout diagrams for the purified water (PW), water for injection (WFI) and pure steam (PS) systems.
4.2	Large copies (high resolution) of the premises layout indicating: - the area classification and differential pressures, - the personnel and material flows.
4.3	A copy of the Standard Operating Procedures (SOP) related to the following process/system: - *Change-over and Line clearance for multi-product manufacturing operations,* - *Cleaning and sanitation for the facility and equipment used for the manufacturing of [Product in scope],* - *Qualification of critical utilities,* - *To be determined…*
4.4	Validation and efficacy studies for **cleaning methods and cleaning/disinfecting agents** used in *[Product in scope]* manufacturing areas.
4.5	Qualification (IQ/OQ/PQ) summary reports for **classified areas** (including rooms and hoods) related to the manufacturing of *[Product in scope]**.***
4.6	Qualification (IQ/OQ/PQ) studies summary reports for **critical utilities**, including *HVAC*, *water systems*, *clean steam*, and *process gases*, in the areas used to manufacture *[Product in scope]*.

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5. Materials	
5.1	Copy of the Supplier Qualification Program
5.2	A copy of the Standard Operating Procedures (SOP) related to the following process/system: - *Raw Materials supplier qualification,* - *Material management, including receipt, storage, distribution and disposition,* - *Storage of the bulk drug substance prior to shipment, including any procedures used to mitigate the risk of cross-contamination and/or mix-up of [Product in scope].* - *[Product in scope] Cell bank handling, including cell bank maintenance, handling, transfer, storage and monitoring,* - *To be determined…*
6. Laboratory	
6.1	A copy of the Standard Operating Procedures (SOP) related to the following process/system: - *OOS/OOT/OOE handling,* - *Batch review and release,* - *In-process, release and stability testing,* - *To be determined…*