Performance Qualification

Title of PQ:

Approvals

This plan was reviewed and accepted according to the appropriate procedures. The signatures below indicate acceptance of and approval to proceed with this plan.

	Print Name	**Signature**	**Approval Date**
Author			

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1. Description of Subject

Subject Description:

2. Referenced Documents

Documents	Rev# / Status
SOP Validation	
WI sampling plan	
VMP	
IQ report	
OQ report	
PFMEA	
Manufacturing flow chart	
Manufacturing instruction	
Test instruction	

3. Materials and adjuvants

The following materials and adjuvants will be used within this PQ. Materials and adjuvants are representative to routine manufacturing, fulfil specifications and are fully traceable.

Article / Part	Description	Lot# (if already known)

4. Equipment and fixtures

The following equipment and fixtures will be used within this PQ. Equipment and fixtures are representative to routine manufacturing.

Equipment / Fixture	Description	Qualification status

5. Manufacturing environment

This PQ will be manufactured within the following locations.

Location	Description	Qualification status

6. Routine manufacturing conditions

PQ will be manufactured as per the expected routine manufacturing conditions. This will ensure that the expected variability in manufacturing will be covered. The following table lists sources of variability to be considered within this PQ:

Parameter influencing the process	Routine conditions and expected variability	Relevance for this PQ
Discussion:		

7. PQ runs and test plan

Based on the discussion of the routine manufacturing conditions, the following PQ runs will be conducted to cover the expected variability in the manufacturing process:

Test#, Title, Objective:
Test conditions and Sampling Plan:
Test Method:
Acceptance Criteria:
Test equipment used and post-calibration:
Planned evaluation of results:

8. Events and failures

Any events and failures occurring during this PQ are to be recorded and discussed in the PQ report.

9. Training

All employees involved in this PQ must be trained to their work. Training records must be kept on file.