Operational Qualification (OQ)

Title of OQ

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			

Table of contents

1. Description of Subject

Description:

2. Referenced Documents

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

3. Materials and adjuvants

The following materials and adjuvants will be used within this OQ. Materials and adjuvants 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 OQ.

Equipment / Fixture	Description	Qualification status

5. Manufacturing environment

This OQ will be manufactured within the following locations.

Location	Description	Qualification status

6. Product acceptance criteria and process parameters

Within this section the parameter influencing the manufacturing process and the relevant product acceptance criteria will be discussed. It will be discussed how the parameter will challenge achieving the relevant acceptance criteria.

Product acceptance criteria	Process parameter	Rationale / Reference
Discussion:		

7. Test plan

Based on the discussion of the parameter influencing the manufacturing process and the relevant product acceptance criteria, the following OQ runs will be conducted to best challenge the manufacturing process:

Test run #, Title, Objective:
Test or manufacturing run 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 OQ are to be recorded and discussed in the OQ report.

9. Training

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