Operational Qualification (OQ) Plan

Title of OQ
OQ Plan Injection Moulding Stopper Luer Lock 18 (SLL18)

Approvals
The signatures below show acceptance of and approval to proceed with this protocol.

	Print Name	Signature	Approval Date
Author			
Engineering			
Quality Management			

Disclaimer:
This document was written by the quality practitioners

- Simon Foeger (https://www.linkedin.com/in/simonfoeger) and
- Michael Schaefer (Medical Device Expert, www.quality-on-site.com)

aiming to provide easy-to-use solutions for process validation activities as per ISO 13485:2016 and 21CFR820.75. The authors did not intend to generate an over-the-top and/or bullet-proof process validation document; therefore, this document was written to a reasonable level of complexity and compliance. The example chosen, although intentionally simplified, seems to be representative for many injection molded components in medical device industries. The solutions presented within this document are not fully complete and will offer enough room for additional input for both technical and regulatory aspects. This document may be used as an element of QA/RA trainings. It is not a real quality document. The authors do not take any responsibilities for correctness and completeness.

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1. Introduction

1.1. Scope

This plan describes the work required to conduct the operational qualification (OQ) as per SOP Validation version 07 for the injection moulding process of the stopper luer lock SLL18.
The SSL18 is a new component used in several final finished medical devices and is shown in the picture below.

Picture 1: Stopper Luer Lock SSL18
Disclaimer: I took the picture of this device during my last stay in hospital. I hope the manufacturer, whoever it is, doesn't mind that I took it as an example. The device worked great.

The SLL18 is described in drawing DWG-SLL18 version 01. The stopper luer lock contains a male and a female luer lock in alignment to ISO 80369-7:2016. The SLL18 is commonly used to close infusion sets, connectors or syringes in hospital use and does therefore not contain any fluid lumen (for detailed intended uses see relevant technical documentations of the final finished medical devices). SLL18 is made from ABS (Acrylnitril-Butadien-Styrol) as specified in Mat-Spec-SSL18 version 03.

1.2. Process description

The process of injection moulding SSL18 contains the following different steps:

- Material supply: The ABS material is supplied in octabins from the supplier. The octabins are placed at the injection moulding machine directly.
- Drying: As recommended by the supplier of the ABS material, granulate is dried before injection moulding in a desiccant dehumidifying hopper dryer.
- Injection moulding:
  - Directly after drying, granulate will be moulded in a reciprocating screw injection moulding machine.
  - Currently, there is only one injection moulding tool available, containing 8 cavities.
  - Excess material and scrap will not be reused within the process but will be removed from the process chain.
- Packaging: The injection moulded SSL18 will drop from the conveyer belt of the injection moulding machine directly into PE bags in boxes. Packaging is done manually by the machine operators.

2. References

Documents	Version / Status
SOP Validation	07
Guidance Validation Sampling Plans	12
DWG-SLL18	01
ISO 80369-7	2016
ISO 16269-6	2014
Mat-Spec-SSL18	03
IQ Report Injection moulding machine AB1236	07
IQ Report Injection mould SSL18-AB1236	01
IQ Report Hopper Dryer HD9	04
Work Instruction IM SSL18	0.1 (draft for OQ)
Test Method Dimensional Measurements	03
Test Method Leakage Test	01
SOP Training and Education	14
CRQ Report AnS 123	Approved 2017-12-31
EPS Kurby 45	Approved 2017-12-31
MegaBlow 18	Approved 2017-12-24
PD report SSL18	03

3. Training

All employees involved in this OQ must be trained to their relevant tasks. Training records are to be kept as per SOP Training and Education version 14.

4. Materials

Article	Description	Lot# (if already known)
ABS-SSL18	ABS (Acrylnitril-Butadien-Styrol)	123-2018
PE-176	PE Bags	n/a, not traced

5. Equipment

Equipment	Qualified	Qualification Approval Date
Injection moulding machine AB1236	Yes	2017-11-23
Injection mould SSL18-AB1236	Yes	2018-08-30
Hopper Dryer HD9	Yes	2017-11-23
3D Test system	Yes	2016-03-31
Leakage tester	Yes	2018-02-28

6. Facilities and Utilities

This section must be completed prior to protocol approval.

Description	Reference	Qualification Approval date
Controlled Environment ISO 8	CRQ Report AnS 123	2017-12-31
Electrical Power Supply	EPS Kurby 45	2017-12-31
Compressed Air System	MegaBlow 18	2017-12-24

7. Events and failures

Any unplanned event or failure during sample preparation or test execution is to be documented in the relevant raw data sheets and listed within the log in Annex B.

8. Product Acceptance Criteria and Process Parameters

For this OQ, all critical process parameters are chosen to confirm that the injection moulding process at the worst-case limits of the process window will produce SSL18 within pre-determined acceptance criteria.

Predetermined product acceptance criteria are given in drawing DWG-SLL18 version 01. The drawing includes acceptance criteria that are subject to 100 % inspection including

- blue colour, and
- freedom from dirt or particles.

As these criteria will be fully inspected on all components to 100% in routine manufacturing, they are not included in OQ testing.

The remaining product acceptance criteria, which will not be subject to 100% measurement and/or inspection, are

- overall length L1 = 20mm ± 2mm
- outer diameter male OD1= 7.78mm ± 0.05mm
- outer diameter female OD2= 10mm ± 1mm
- no burrs
- no leakage: pressure decay test, no leak by more than 0,005 Pa*m³/s to an applied pressure of between 300kPa and 330kPa for 15-20s using air as medium (as per ISO 80369-7:2016, clause 6.1.2).

Disclaimer:
For the purpose of this training document, only a few acceptance criteria were chosen. The relevant acceptance criteria are given in ISO 80369-7:2016.

Prior to OQ, the critical process parameters were characterized based on material supplier's recommendation and in-depth process development (see PD report SSL18 version 03). An overview of the critical process parameter and rationales for their relevance with the pre-determined product acceptance criteria is given in the following table:

Critical Process Parameter	Worst case limits to achieve product acceptance criteria		
	Dimensions	Burrs	Leakage
Drying	Drying will be done to decrease pellet moisture rate. If the moisture rate would be too high due to low drying it will cause degradation.		
Injection Pressure	High injection pressure must be employed to fill the mould rapidly and before the plastics material sets in the feed system.		
	Too little pressure can cause sink marks and/or short shots and may affect dimensional stability.	Too much pressure can cause overfilling leading to burrs and/or sticking of parts to mould.	Too much pressure can cause overfilling leading to warpage (fold, bend, twist or bow) and/or sticking of parts to mould. Both defects could cause leakage.
Holding Pressure	Holding pressure is applied to compensate for resin shrinkage caused by cooling.		
	Too little holding pressure can cause sink marks and/or short shots and may affect dimensional stability.	Too much pressure can cause overfilling leading to burrs and/or sticking of parts to mould.	Too much pressure can cause overfilling leading to warpage (fold, bend, twist or bow) and/or sticking of parts to mould. Both defects could cause leakage.

Critical Process Parameter	**Worst case limits to achieve product acceptance criteria**		
	Dimensions	Burrs	Leakage
Temperatures	• Melt temperature is the actual temperature of the material as it exits the nozzle and enters the mould. • The barrel temperatures represent the tools used to arrive at the desired melt temperature. • Mould temperature needs to be in a sound relationship to the melt temperature.		
	Higher melt temperatures (generated by higher barrel temperatures) in combination with lower mould temperatures produce higher levels of moulded-in stress and consequently can cause sink marks. Lower melt temperatures (generated by higher barrel temperatures) can also produce higher levels of moulded-in stress and consequently can cause sink marks.	Higher melt temperatures (generated by higher barrel temperatures) in combination with lower mould temperatures can cause overfilling leading to burrs and/or sticking of parts to mould.	Higher melt temperatures (generated by higher barrel temperatures) in combination with lower mould temperatures can cause mould warpage (fold, bend, twist or bow). Warpage could cause leakage.
Injection time	Injection time (filling time + pressure keeping time)		
	Too little injection time can cause sink marks and/or short shots and may affect dimensional stability	Too much injection time can cause overfilling leading to burrs and/or sticking of parts to mould.	Too much injection time can cause overfilling leading to warpage (fold, bend, twist or bow) and/or sticking of parts to mould. Both defects could cause leakage.

9. Test plan

Based on the critical process parameter and rationales for their relevance with the pre-determined acceptance criteria in section 8 of this OQ protocol, the following test runs were determined for OQ:

Test run #, Title:

Test run OQ1, worst-case 1

Run conditions:

Within the test run OQ1, the process will be challenged at worst-case conditions:

- Drying: time 95%, temperature 91% (worst case low)
- Barrel temperatures (worst case low)
  - Rear: 97%
  - Middle: 98%
  - Front: 98%
  - Nozzle: 98%
- Melt temperature: 95% (worst case low)
- Mould temperature: 93% (worst case low)
- Injection pressure: 77% (worst case low)
- Hold pressure: 58% (worst case low)
- Injection time: low (worst case low)

Sampling Plan:

Sampling will be undertaken in accordance with Guidance Validation Sampling Plans version 12. All sampling will be done to 95 % confidence, 95 % probability as required for acceptance criteria with severity 4 or higher.
Variable measurement will be based on a sample size of 15. Samples will be taken at random from product that has passed all 100 % inspection steps. No failures are allowed (c=0). Statistical analysis of results will be done as per ISO 16269-6:2014 using the k-factor approach xbar +/- k*stdev. The k-factor k= 2.965 will be taken from table D.5 (2-sided k-factors, n=15).

Test Methods:

- L1, OD1, OD2 will be measured as per Test Method Dimensional Measurements version 03

Acceptance Criteria:

- overall length L1 = 20mm ± 2mm
- outer diameter male OD1= 7.78mm ± 0.05mm
- outer diameter female OD1= 10mm ± 1mm

Test equipment:

The test equipment to be used is fully described in the relevant test methods.

Planned documentation of results:

Measurement results are to be recorded in the attached forms. Manual entries are to be signed and dated.

Test run #, Title:

Test run OQ2, worst-case 2

Run conditions:

Within the test run OQ2, the process will be challenged at worst-case conditions:

- Drying: time 95%, temperature 91% (worst case low)
- Barrel temperatures (worst case high)
  - Rear: 103%
  - Middle: 102%
  - Front: 102%
  - Nozzle: 102%
- Melt temperature: 95% (worst case high)
- Mould temperature: 93% (worst case low)
- Injection pressure: 77% (worst case low)
- Hold pressure: 58% (worst case low)
- Injection time: low (worst case low)

Sampling Plan:

Sampling will be undertaken in accordance with Guidance Validation Sampling Plans version 12. All sampling will be done to 95 % confidence, 95 % probability as required for acceptance criteria with severity 4 or higher.
Variable measurement will be based on a sample size of 15. Samples will be taken at random from product that has passed all 100 % inspection steps. No failures are allowed (c=0).
Statistical analysis of results will be done as per ISO 16269-6:2014 using the k-factor approach xbar +/- k*stdev. The k-factor k= 2.965 will be taken from table D.5 (2-sided k-factors, n=15).

Test Methods:

- L1, OD1, OD2 will be measured as per Test Method Dimensional Measurements version 03
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Acceptance Criteria:

- overall length L1 = 20mm ± 2mm
- outer diameter male OD1= 7.78mm ± 0.05mm
- outer diameter female OD1= 10mm ± 1mm

Test equipment:

The test equipment to be used is fully described in the relevant test methods.

Planned documentation of results:

Measurement results are to be recorded in the attached forms. Manual entries are to be signed and dated.

Test run #, Title: **Test run OQ1, worst-case 3**

Run conditions:
Within the test run OQ1, the process will be challenged at worst-case low conditions:
• Drying: time 95%, temperature 91% (worst case low)
• Barrel temperatures (worst case high)
  ○ Rear: 103%
  ○ Middle: 102%
  ○ Front: 102%
  ○ Nozzle: 102%
• Melt temperature: 95% (worst case high)
• Mould temperature: 93% (worst case low)
• Injection pressure: 123% (worst case high)
• Hold pressure: 142% (worst case high)
• Injection time: high (worst case high)

Sampling Plan: Sampling will be undertaken in accordance with Guidance Validation Sampling Plans version 12. All sampling will be done to 95 % confidence, 95 % probability as required for acceptance criteria with severity 4 or higher. Attributive acceptance criteria require n=59 (as per ISO 16269-6:2014, table E.1) and no failures are allowed (c=0).
Test Methods: • Leakage will be measured as per Test Method Leakage Test version 01 • Absence of burrs will be conducted as per Work Instruction IM SSL18 (drafted version 01 for OQ)
Acceptance Criteria: • no leakage • no burrs
Test equipment: The test equipment to be used is fully described in the relevant test methods.
Planned documentation of results: Measurement results are to be recorded in the attached forms. Manual entries are to be signed and dated.

10. Annex A

Personnel executing this plan must read its content fully and sign the table below to confirm that they understand the requirements therein. Further copies of this sheet may be attached if more space is required.

Name	Department	Signature	Date

11. Annex B –Log of events and failures

Sheet may be copied as required (Sheet ____ of ____)

No.	Date	Protocol Section	Description	Initial/Date
Comments:				
Reviewed By:		**Date:**		