

Standard Operating Procedure

Title: Procedures for Line Clearance, Line Opening and Line Cleaning

	documentation relating to the operation. This step is carried out at the completion of a batch production. This is the last step in the process.
Operation	This refers to a batch, BPN or re-work activity.
Authorised Persons	Someone who is trained and assessed to perform the Line Clearance, Line Opening and Line Cleaning procedures . Records of successful completion of training and line specific assessments must be kept in the individual's training file. The first Assessments for any new Line will be completed by Production Manager, or delegate.

Related Documents

VD-010	Line Clearance In Progress
Form-160	Example- Line Clearance, Opening and Cleaning form for Tablet Packing
Form-120	Printed Material Sample Sheet
QMS-015	Quality Documentation Management and Change Control
QMS-035	Deviation Report System
MAN-045	Checking of Components Prior to Use

EHS Statement

Appropriate protective equipment must be worn when cleaning with 70% IPA.

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1. General

- 1.1. A Line Clearance, Line Opening and Line Cleaning is required with a change of batch production.
- 1.2. A Line Clearance is done BEFORE a batch starts. This is followed by a Line Opening. Line Cleaning is carried out after the batch is completed - it is the last step in the process.
- 1.3. Line Clearance, Line Opening and Line Cleaning checklists are on one Form.
- 1.4. Each Process will have a specific checklist / form for each line or area. The layout and sequence of these forms will be the same.
- 1.5. If for any reason this procedure cannot be followed a **DR** is to be raised (see [SOP QMS-035](#)) and Management approval is to be sought prior to continuation of the line.

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- 2.8. If there are any non-compliances found during the Line Clearance check then these MUST be completed:
- Record in the Non-Compliance Table on the checklist
 - Record in the Non-Compliance Logbook; and
 - Report to and give non-compliance to the area Manager; and
 - Communicate to the Team.

NOTE:

A Non-Compliance found, other than from the BPN just completed, must be recorded as above and a DR must be raised immediately as per SOP QMS-035 and the Area/Production Manager notified immediately.

- 2.8 If a foreign product/material is found during a production run then these MUST be completed:
- Stop the line immediately,
 - Record in the Non-Compliance Logbook;
 - Report to and give to the area Manager immediately.
 - Raise a **Deviation**
 - Communicate to the Team.

3. Line Opening

- 3.1. A Line Opening is carried out after a Line Clearance has been completed and signed to ensure that all related components, machine settings, BPN, Expiry Date, Date of Manufacture (if required) and information boards are all correct and complete before Production starts.
- 3.2. Layout of Line Opening checklist must be used in conjunction with Batch Documents (MI sheet Phases). It will ensure that the components are correct. A sample of each component is to be taken and attached to appropriate sample sheet (**Form-120**). Each sample is to be entered in relevant section of MI Sheet and, upon confirmation of correct details, the sample is ticked, signed and dated by each person carrying out Line Opening. Each and every Laboratory Batch No. must be sampled and checked in the same manner.
- 3.3. The Line Opening form must be completed and signed by two Authorised Persons as the process is carried out. The Line Opening checklist and other batch documentation must be completed before production starts. All components must be checked according to **SOP MAN-045**. All **printed materials** must be sampled.
- 3.4. **NOTE:**
If an additional issue of components is brought into the area during a process run, the components MUST be checked correct against the batch documentation and entered into the MI sheet. A sample must be taken of all printed materials, signed, and attached to Sample sheet (**Form-120**).
- 3.5. Product must be checked for correct details (Batch, Expiry, embossing and product details) during a Line Opening.

4. Line Cleaning

- 4.1. The Line Cleaning form must be signed by an **Authorised Person**. More than one Team member may clean and clear the line, but it is the responsibility of the Operator trained and assessed in Line Cleaning to ensure that the tasks have been performed and the Line