

Standard Operating Procedure

Title: Housekeeping Audit Procedure

QMS-035	Deviation Report System
MAN-055	Procedures for Line Clearance, Line Opening and Line Cleaning
QMS-080	Audits

EHS Statement

Non-compliances will be to addressed via the DR system, (see **SOP QMS-035**)

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1. Introduction

- 1.1. There are nominated process and support teams responsible for completing Housekeeping Audits.
- 1.2. The Housekeeping Auditor should follow the audit roster and the teams are to ensure that all production lines and shifts have been audited within the month.
- 1.3. The Housekeeping Auditor will ensure that a roster is sent to the QA Staffs assigned for the areas at the beginning of each roster period.
- 1.4. Any statement that no longer applies must be removed and replaced with an alternate statement by following the procedures set out in **SOP QMS-015** for updating documents.

2. Housekeeping Audit Procedure

- 2.1. **QA Staffs with the Process Manager conduct monthly housekeeping audits.** A QA representative will hence audit each of the production areas each month.
- 2.2. The schedule and location of these audits will be arranged monthly between the QA representative and Process Manager. QA housekeeping audits may be performed in lieu of, or in addition to, an audit by the Process line housekeeper.
- 2.3. The audit should last approximately half to one hour and will cover the following items:
 - Cleanliness of area including floors and walls
 - Tidiness of area (no rubbish left around)
 - Labelling/ Expiry date
 - Status labels
 - Calibrations
 - Safety.

Housekeeping Audit Check Sheet for Laboratory

(Ref. SOP QMS-105)

Area Audited					Comment
Audit Date					
GMP & GLP ITEMS	Comply ✓ Yes Or X No	Comply ✓ Yes Or X No	Comply ✓ Yes Or X No	Comply ✓ Yes Or X No	
Area waste bins are not overflowing.					
Waste bins are used for appropriate materials only.					
Benches are free of items that are not in use.					
Equipment surfaces are free of dust.					
Reagents and Standards are labelled and within stated expiry.					
All IPA bottles are labelled and within stated expiry.					
Storerooms and cupboards are clean and tidy.					
Equipment/trolleys not in use is switched off and stored in designated areas.					
pH meter buffer standards within expiry					
HPLC was bottles are kept full.					
Balances are clean and items removed after weighing. Calibration stickers current.					
Weekly calibrations completed as required.					

Housekeeping Audit Check Sheet for Production Services

(Ref. SOP QMS-105)

Form-430

Issue Date

Area Audited					Comments
Audit Date					
Week	Wk1	Wk2	Wk3	Wk4	
GMP ITEMS	Comply ✓ Yes Or X No	Comply ✓ Yes Or X No	Comply ✓ Yes Or X No	Comply ✓ Yes Or X No	
Area waste bins are not overflowing.					
Waste bins are used for appropriate materials only.					
Floor is clear of equipment not in use					
All equipment and tools not in use are stored in designated areas.					
Equipment stored on shelving is clean and tidy.					
All benches tidy when not in use.					
All containers clearly labelled.					
Computer terminals free of post-it notes					

ENVIRONMENTAL, HEALTH AND SAFETY					Comments
	Comply ✓ Yes Or X No	Comply ✓ Yes Or X No	Comply ✓ Yes Or X No	Comply ✓ Yes Or X No	
All fire/emergency exits are unimpeded.					
Safety clothing/equipment worn and used correctly for appropriate tasks.					

Housekeeping Audit Check Sheet for Electrical & Mechanical Workshop

(Ref. SOP QMS-105)

Hair is covered, sleeves covering arm, no jewellery other than small sleepers.					
Laptop computers locked in cupboard in the storage room.					
Communal tools stored in designated areas.					

ENVIRONMENT, HEALTH AND SAFETY	Comply ✓ Yes Or X No	Comply ✓ Yes Or X No	Comply ✓ Yes Or X No	Comply ✓ Yes Or X No	Comments
All fire/emergency exits are unimpeded.					
Safety clothing/equipment worn and used correctly for appropriate tasks.					
Fire extinguishers and hoses visible and accessible.					
All fire extinguishers in test (Tested 6 monthly).					
Floors are clear of equipment or spare parts not in use. Clear of waste and spills.					
Danger tags available for use.					

Housekeeping Audit Check Sheet for Warehouse

(Refer SOP QMS-105)

Area Audited					Comments
Audit Date					
Week	Wk1	Wk2	Wk3	Wk4	
Office	Comply ✓ Yes Or X No	Comply ✓ Yes Or X No	Comply ✓ Yes Or X No	Comply ✓ Yes Or X No	
Documentation appropriately stored					
Contact lists near phones are clearly displayed, current and easily accessible.					
All personal items are stored in lockers.					
SOPs	Comply ✓ Yes Or X No	Comply ✓ Yes Or X No	Comply ✓ Yes Or X No	Comply ✓ Yes Or X No	Comments
SOP Files are accessible and filed alphanumerically.					
Superseded versions have been returned to QA.					

ENVIRONMENTAL, HEALTH AND SAFETY ITEMS	Comply ✓ Yes Or X No	Comply ✓ Yes Or X No	Comply ✓ Yes Or X No	Comply ✓ Yes Or X No	Comments
All fire/emergency exits and stairs are clear.					
Safety signs are clearly visible					
Access paths are unimpeded					

Housekeeping Audit Check Sheet for Warehouse

(Refer SOP QMS-105)

Pallets of Goods to be Shrouded correctly stored and labelled					
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ENVIRONMENTAL, HEALTH AND SAFETY ITEMS	Comply ✓ Yes Or X No	Comply ✓ Yes Or X No	Comply ✓ Yes Or X No	Comply ✓ Yes Or X No	Comments
All fire/emergency exits and stairs are clear.					
Fire extinguishers / hoses visible and accessible.					
All fire extinguishers in test					
Safety signs are clearly visible					
Forklifts parked away from traffic flow with tines lowered and keys removed when not in use.					
Floors are clear of spills, chemical residue and excess materials.					
Access paths are unimpeded.					

Flammable Goods Store	Comply ✓ Yes Or X No	Comply ✓ Yes Or X No	Comply ✓ Yes Or X No	Comply ✓ Yes Or X No	Comments
Flammable store is locked when not in use. Keys are not left in door					

Housekeeping Audit Check Sheet for Warehouse

(Refer SOP QMS-105)

WASTE AREA	Comply ✓ Yes Or X No	Comply ✓ Yes Or X No	Comply ✓ Yes Or X No	Comply ✓ Yes Or X No	Comments
Ground area is free of waste.					
All waste is in the correct waste disposal area.					
Equipment is stored appropriately and not blocking access ways.					
Waste from laboratory is adequately labelled and segregated					

ENVIRONMENTAL, HEALTH AND SAFETY ITEMS	Comply ✓ Yes Or X No	Comply ✓ Yes Or X No	Comply ✓ Yes Or X No	Comply ✓ Yes Or X No	Comments
Forklifts parked away from traffic flow with tynes lowered and keys removed when not in use.					
All fire/emergency exits and stairs are clear.					
Fire extinguishers /hoses visible and accessible.					
All fire extinguishers in test					
Safety signs are clearly visible.					
Safety equipment worn and used for appropriate tasks (ear protection/safety glasses/gloves)					