

Standard Operating Procedure

Title: GMP Training

1.1. GMP Maintenance Education Points System

1.1.1. All staff within the Manufacturing Division are required to earn designated GMP points annually or on a pro rata basis, as determined by the GMP Training Officer. The GMP training calendar operates from January to December and employees are not allowed to carry over points from one year to the next. The level of points that various job roles and departments need to acquire is depicted in the table below. This is only a minimum requirement and may be exceeded in any particular year.

1.1.2. GMP Points can be earned through attendance at internal and external GMP Training courses, meetings, etc. GMP Points have been allocated based on the GMP content and duration of the courses and are not limited to the courses listed below. However, suggested courses will require GMP assessment and approval by the GMP Training Officer for the appropriate points allocation.

GMP Maintenance Education Points System

Position	Annual Point score required
Senior Manufacturing Management	100
Quality Managers	100
Quality Assurance Department	100
Production Managers/Engineering Managers	100
Process Area Managers	100
Validation Department	50
Process Engineers/Electrical Technicians	50
Project Engineers/Electrical Engineers	50
Process/Dispensary Operators	30
Technical Service Department	20
EHS Department	20
Laboratory analysts	20
Warehouse	20
Contract cleaners – factory areas	20

This is considered the minimum requirement and may be exceeded in any particular year.

Points for GMP Education are generally allocated as follows:

Education	Points allocation
External/Internal Provider GMP training 1 day and more	50/day
External/Internal Provider GMP training 1/2 day	25
Similar industry related organisation educational meeting ½ day or more	10
Similar industry related organisation educational meeting ~2 hours	5
GMP presentation	5 - 10
QA presentation ~ 1 – 2 hours (eg. investigations, change control, batch documentation, GMP targeted presentations based on Deviation Trends)	10 - 20

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- Designing assessments and documentation, i.e. ensuring the content and level of assessment is linked to the training conducted; ensuring the assessment questions are appropriately worded.
- The method of assessment is appropriate.

2.4. Conducting and recording of assessment

It is the responsibility of the assessor to correctly record the assessment of an employee and return the record to the employees training file located with the relevant Line Manager.

2.5. Management Reporting

2.5.1. The GMP Training Officer is responsible for the following:

- Assess compliance of internal training programs to organisational requirements.
- Provide reports on current GMP compliance status for training.
- Maintain training records for QA.
- Compile performance KPIs (Key Performance Indicator) as required.
- Facilitate annual review of QA training requirements.

2.6. Training Coordination and Promotion

It is the responsibility of the management to coordinate the booking of GMP training in consultation with the Area Manager, and the GMP Training Officer if they are facilitating the program. This includes booking of sessions, notifying employees and their Managers of time, date, location and costs where relevant.

The GMP Training Officer will be responsible for the promotion and awareness of the courses to the business.

2.7. Recording and Archiving Training Assessment

2.7.1. It is the responsibility of the training officer and the line manager that, the individual employee's file is up to date. These files are stored in the Training Officer's office.

2.7.2. Recording of Course attendance and Assessment:

It is the responsibility of the GMP Training Officer to record all courses booked for GMP training.

Details must include:

- Title of course and course code
- Date/s of course
- Trainer's name
- Name of employees who attended
- Assessment results where appropriate (A copy of the original assessment document including the assessor's signature should be filed in the employee's individual training file.

2.7.3. It is the responsibility of line management to advise the Training Officer, if an employee has attended a GMP training course not centrally coordinated. GMP Training Officer will then record this information in the in the employee's individual training file.