

Standard Operating Procedure

Title: GMP Training

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| Department | Quality Management | Document no | QMS-095 |
| Prepared by: | | Date: | Supersedes: |
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Document Owner

Quality Assurance Manager

Affected Parties

All manufacturing colleagues

Purpose

The purpose of this document is to outline the delivery of GMP training.

Scope

The scope of this document covers all permanent, contract and casual staff, whose role has a direct and indirect impact on GMP.

Definition

| | |
|-----------------|---|
| Permanent staff | A person who has signed a letter of offer with regards to permanent employment. This person may either work full time or part time. |
| Casual Staff | A person who has signed a letter of offer with regards to employment where hours of work are not regular and may vary based on business requirements to meet a short-term need. |
| Contract Staff | A person who provides a service or performs a task on behalf of Sydco but is not employed by Sydco. |

Related Documents

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| QMS-100 | How to Write Training Materials |
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EHS Statement

Not applicable – there is no EHS impact.

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1. Procedure

All manufacturing employees are required to attend a formal GMP Induction training program at the commencement of employment as an introduction to the principles of Good Manufacturing Practices.

To ensure a continued knowledge of current GMP requirements, Manufacturing staff is required to undertake GMP education on an ongoing basis. The GMP Maintenance Education Points System is a means of ensuring this.

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2. Responsibilities for GMP

2.1. Identifying needs for GMP training

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

- Development and review of GMP training requirements and strategy across the Manufacturing Division and GMP impacting areas.
- Ensuring policies and plans are documented.
- Maintaining compliance with in-house and regulatory requirements.
- Allocation of points for GMP Maintenance Education courses, meetings and presentations.
- Reviewing and tracking GMP breaches and incidents to assess trends and organisational opportunities for training.
- Evaluating training programs and materials.

2.1.2. The Management Responsibilities

- Assisting the GMP Training Officer in the development and review of GMP training requirements and strategy across the Manufacturing Division and GMP impacting areas.
- Evaluating training programs and materials.

2.2. Training Design and Delivery

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

- The design of GMP training workshops for staffs.
- Facilitating GMP awareness and training for staffs (including non Manufacturing Division staff whose activities have GMP impact).
- Assessing participants against set criteria.
- Overseeing the design and delivery of programs provided by external organisations and ensuring skills of trainers are appropriate.

2.2.2. The Management is responsible for the following:

- Assisting the GMP Training Officer in the design of GMP training workshops for relevant staff.
- Assessing participants against set criteria.

2.3. Training Assessment Design

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

- Ensure technical terminology is correct.
- The level of GMP performance expected from the assessments is appropriate.
- Working with the management to design appropriate assessments and documentation.

2.3.2. Management is responsible for the following:

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- 2.7.4. It is the responsibility of the Training Officer to record GMP Training Points earned by employees within the Manufacturing division throughout the year.
 - 2.7.5. Training records for Manufacturing employees should be kept for 15 years after an employee has been terminated.
 - 2.7.6. If an employee transfers to another department and the Line Manager has kept their training file, this should be transferred to the new Line Manager.

3. Summary of Changes

| Version # | Revision History |
|-----------|------------------|
| QMS-095 | New |