
	<b>POLIGAS Ltd.</b> <b>Standard Operating Procedure</b>	Reference No: <b>SOPGE/05/06/02</b> <b>Supersedes</b> <b>SOPGE/05/06/01</b>
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<div style="display: flex; justify-content: space-between;"> <span>Valid from: __/ __/ ____</span> <span>Due for Revision: Within 2 years</span> </div> <p><b>Distribution Points:</b></p>					

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## 1. SCOPE

This standard operational procedure applies to all the recruitment and training of staff at Poligas Ltd.

## 2. OBJECTIVE

Training is a key component of the Quality System. This SOP ensures that all personnel receive proper training in relation to Good Manufacturing Practice, current pharmaceutical legislations and regulations, operating procedures and safety issues.

- All employees' training and re-training needs are reviewed and that training needs are adequately identified, planned and provided for.
- All employees are adequately educated, trained or experienced for their job.
- Training records are maintained for all employees.

## 3. DEFINITIONS

N/A


## 4. RESPONSIBILITY

The responsibility for implementing this procedure lies with the Quality Assurance Manager, the Production Manager, and with the Chief Executive Officer for the training needs of all Poligas employees .

## 5. STATEMENT OF SOP

### 5.1 Recruitment and induction

The Chief Executive Officer following a recommendation from the respective manager decides whether to employ a person with the Company.

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This decision will normally follow a formal interview during which the interviewee will have been found to satisfy the expectations of the manager concerned.

For each new employee joining the Company, a short induction meeting is conducted during which issues listed in the Induction Meeting Record SOPGE/05/06/02/A-01 will be discussed.

## 5.2 Formal Qualifications and License Verification

Where formal qualifications, apprenticeships, or licenses are claimed, a photocopy of the certificate is kept in the Training Records File of the employee concerned.

## 5.3 Temporary Duties

Occasionally, Poligas Ltd. may employ temporary or part-time staff at various levels.

Where these temporary duties do not affect the quality of the product or service supplied by the company, no training file will be created, or appraisals carried out.

All staff, including temporary or part-time staff must complete the induction programme.

## 5.4 Training


All personnel employed at Poligas Ltd. shall receive training immediately upon commencing work and thereafter on a yearly basis *as per* SOPGE/05/06/02.

### 5.4.1 Internal training

Any internal training will be reviewed and authorized by the Chief Executive Officer on the Training Record Form SOPGE/05/06/02/A-02

Training shall be carried out by adequate personnel.

Training shall consist of a general overview of the:

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- principles of Good Manufacturing Practice and the importance of maintenance of the quality of pharmaceutical products
- Medicines Act and relevant Legal Notices
- Standard Operating Procedures (SOPs) relevant to their individual roles and responsibilities (Refer to the SOP Training Record Sheet SOPGE/05/06/02/A-03).

Individual responsibilities should be clearly defined and understood by the individuals concerned.

Whenever possible, company training needs shall be identified and addressed in advance of any perceived need.

All training sessions are recorded and documented *as per* SOPGE/05/06/02/A-04 Training Attendance Sheet

All the employees are assessed on Good Manufacturing Practice and a pass mark of 100% should be achieved. In case that this pass mark is not achieved, the employee is re-trained until a pass mark is obtained. Revision training courses are held every year.

#### **5.4.2 External training**


External training will be reviewed and authorized by the Chief Executive Officer on the Training Record Form.

Training may be carried out by:

- Specialist Training Companies
- A local University or College
- On site by a consultant or appropriate member of Poligas Ltd. staff, which may include on-the-job training.

#### **5.5 Documentation**

The recording of training opportunities and completed training shall be the responsibility of the Quality Assurance Manager (See Training Record Form – SOPGE/05/06/02/A-02.

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Poligas Ltd. shall strive to demonstrate that all training undertaken is effective in producing personnel who are fully competent in their assigned tasks.

The Qualified Person is duty bound to keep updated regarding changes in legislation and to then inform all the staff at Poligas Ltd. of these changes. These communications will be supported through written documentation.

## 6.0 REASON FOR REVISION

To change the review date from three years to two years from the date the SOP comes into affect

To reflect personnel changes in the company's infrastructure

To make necessary improvements in related appendices

## 7.0 APPENDICES

SOPGE/05/06/02/A-01: Induction Meeting Record

SOPGE/05/06/02/A-02: Training Record Form

SOPGE/05/06/02/A-03: SOP Training Record Sheet

SOPGE/05/06/02/A-04: Training Attendance Sheet

## 8 TRAINING LOG

### 8.1 Training Needs

CEO

Qualified Person

Quality Assurance Manager

Quality Control Manager

Production Manager

Production Engineer