

<b>Department</b>	<b>Environmental, Health and Safety</b>	<b>Document no</b>	<b>EHS-130</b>		
<b>Title</b>	<b>EHS Risk Assessment Methodology</b>				
Prepared by:		Date:		Supersedes:	
Checked by:		Date:		Date Issued:	
Approved by:		Date:		Review Date:	

## 1.0 AFFECTED PARTIES

All Environment, Health and Safety personnel

## 2.0 PURPOSE

This SOP details the steps and procedure involved in carrying out an [EHS Risk Assessment](#) in the GMP site.

## 3.0 SCOPE

In a GMP environment a risk-based approach has to be used to evaluate the hazards and controls used to mitigate them. Hence it is essential for Risk assessments to be performed to ensure that all hazards in a plant are identified and are controlled if the risk associated with them is unacceptable. To evaluate and control all risks, Risk Assessment Process has been developed and widely accepted by the industry.

## 4.0 RESPONSIBILITY \ BUSINESS RULES

It is the responsibility of all Colleagues to perform risk assessments whenever a risk based decision making is required. It is the responsibility of EHS team to advise and assist in the risk assessments and its associated controls if required. EHS will also file and keep all Risk Assessments in safe and secured manner.

The risk assessment process and the development of a risk control plan to eliminate or minimize those risks shall be undertaken and developed in consultation with the following personnel:

- [Environment Health & Safety](#) Committee Colleague;
- Area / Department Manager or delegate; i.e. supervisor or Team Leader;
- Colleagues directly responsible for the day-to-day use and/or operation and maintenance of the plant / equipment, substance, task being assessed.

All plant and equipment are required to be risk assessed and these risk assessments will be reviewed under the following conditions:

- When there is new plant / equipment to be installed;
- When there are changes / additions to plant, equipment;
- When new tasks or processes are to be performed;
- When the method or process of performing a task or process changes

<b>Department</b>	<b>Environmental, Health and Safety</b>	<b>Document no</b>	<b>EHS-130</b>
<b>Title</b>	<b>EHS Risk Assessment Methodology</b>		

- Hazard identification
- EHS Monthly Walk Around audits
- EHS Yearly Audits
- Introduction of new plant, equipment, substance and or process
- Modification of plant, equipment, substance and or process
- Manufacturer’s Directives or Recommendations.
- When new information becomes available that affects health and safety (i.e. Material Safety Data Sheet (MSDS))
- Assessments as required by legislation
- Reports from external persons / bodies
- Environmental / biological monitoring.

## 5.2 Risk Assessment

The risk assessment shall consider the following:

- The likelihood of the hazard causing harm (L)
- The severity of the consequences in the event of the hazardous event or situation occurring (C)
- The exposure of personnel to that hazard (E).

### 5.2.1 Likelihood (L)

5.2.1.1 Determine the numerical value for the likelihood of the identified hazard to cause harm. (See Table 1 - *Likelihood* below).

5.2.1.2 Record the determined value for consequences on the *EHS Risk Assessment Tool - form-435* and *EHS Risk Control & Assessment Form (Form 0436)*.

<b>Likelihood</b>	<b>Value</b>
May well be expected	10
Quite possible	6
Unusual but possible	3
Only remotely possible	2
Virtually impossible	1

**Table 1: Likelihood (L)**

### 5.2.2 Consequences (C)

5.2.2.1 Determine the numerical value for the most likely consequences if the identified hazard were to cause harm. (As per Table 2 - *Consequences* below).

5.2.2.2 Record the determined value for consequences on the *EHS Risk Assessment Tool* form (Form 0435) and *EHS Risk Control & Assessment Form (Form 0436)*.

### 5.2.3 Exposure (E)

<b>Department</b>	<b>Environmental, Health and Safety</b>	<b>Document no</b>	<b>EHS-130</b>
<b>Title</b>	<b>EHS Risk Assessment Methodology</b>		

In many cases, it will be necessary to use more than one control method from the Hierarchy of Controls. Back-up controls (such as PPE and administrative controls) should only be used as a last resort or as a support to other control measures.

<b>Control Hierarchy</b>	<b>Description</b>
Eliminate	Eliminate the substance, plant and / or risk
Substitute	Substitute the substance, plant and / or task from personnel or personnel from the task
isolate	Isolate the substance, plant and / or task from personnel or personnel from the task
Engineering	Redesign or modify substance, plant and / or task E.g. Provide guarding, ventilation, extraction
Administrative	Provide training, information, instruction, operator rotation, supervision on substance, plant and / or task
PPE	Provide suitable PPE as to reduce risk of exposure of personnel to that hazard. Note PPE does not reduce the likelihood or exposure, however it may reduce the consequences.

**Table 5: Hierarchy of controls**

#### 5.4 Monitor and Review

After risks associated with a hazard have been assessed and control measures introduced those controls must be monitored and reviewed to evaluate their effectiveness.

This is to ensure that no hazards were overlooked in the original assessment process, and that no new unforeseen hazards have been introduced as a result of the implemented controls.

Monitoring and review shall involve the systematic re-implementation of the original risk management program steps of:

- Hazard identification
- Risk assessment
- Risk control

This shall be done as soon as is practicable after the implementation of control measures.