Department	Environmental, Health and Safety		Document no	EHS-120
Title	Industrial Hygiene Sampling			
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 is to provide guidance on a uniform methodology for workplace sampling of personal exposures and engineering performance validation.

3.0 SCOPE
This SOP is applicable to all GMP manufacturing operations.

4.0 RESPONSIBILITY \ BUSINESS RULES
4.1 Need for Sampling Strategy

A sampling strategy should be developed prior to performing sampling. The objective and duration of the survey should be defined in conjunction with line management before sampling commences.

5.0 PROCEDURE
5.1 General Guidance
5. 1. lReview qualitative assessments, existing industrial hygiene data and production documentation to help determine:

5.1.1.1 What will be sampled – identify the key contaminants that should be sampled. These may be active pharmaceutical ingredients, excipients or industrial chemicals. If you are handling chemicals subject to specific regulatory exposure limits then exposures need to be assessed in line with regulatory requirements.

5.1.1.2 Who will be sampled – collect samples on colleagues who are performing tasks. If more than one colleague is involved, sample at least two colleagues.

5.1.1.3 Where to sample – determine if general area samples will be collected in conjunction with personal samples. Obtain one sample near to the source (within 1m) and one sample outside the area. Take additional samples to evaluate performance of specific controls.

5.1.1.4 When to plan sampling – sampling should be planned to represent normal operating conditions during the highest dosage production for a given product. This will represent the worst case scenario. Use the qualitative assessment to identify steps of the production process or operation. Isolating steps will assist in determining where exposures