

Course Specification

Course title	Occupational Hygiene in the Pharmaceutical Industry
Code	
Level	Advanced
Pre-requisites	ICertOH or equivalent
Course material	Available from OHlearning.com
Coordinating editors	Nancy McClellan, Steve Bailey, Adrian Hirst, Maharshi Mehta
Approval date	
Review date	

Aims

This course aims to:

- Give a specialist insight into the practice of occupational hygiene in the Pharmaceutical Industry;
- Provide an overview of the industry its hazards and processes;
- Describe the industry specific techniques which are used to assess and control exposures;
- Equip hygienists with the knowledge and skills to practice occupational hygiene at professional level in the pharmaceutical industry.

Learning outcomes

On successful completion of this module the student should have an understanding of the following in the context of the Pharmaceutical Industry:

- The structure of the Industry
- The hazards associated with the Active Pharmaceutical Ingredients
- Processes used in the Industry
- Techniques used for exposure assessment
- Exposure control technologies
- The management of Occupational Hygiene

Course Format

The course is normally run as a taught course over 5 days (minimum of 40 hours including overnight questions and guided reading).

There will be a formative assessment process.

Target audience

- Professional occupational hygienists who desire a comprehensive learning experience in the Pharmaceutical industry.
- Pharmaceutical industry personnel with basic hygiene training who want to progress to more senior hygiene

Content:

Topic	Title	Time
1	Understanding the Pharmaceutical industry	10%
2	Pharmaceutical Products and their Hazards	5%
3	Processes and Technologies	20%
4	Hazard Assessment and Communication	10%
5	Exposure Assessment	10%
6	Control of Exposure	20%
7	Control Banding	10%
8	Management of Occupational Hygiene	10%
9	End User Safe Handling of Hazardous Drugs	5%

Detailed Course Content

1 UNDERSTANDING THE PHARMACEUTICAL INDUSTRY

1.1 Development of the industry

- 1.1.1 Origins
- 1.1.2 The Story of Aspirin
- 1.1.3 The Development of Antibiotics
- 1.1.4 Rational Drug Design
- 1.1.5 The Growth of Regulation
- 1.1.6 Regulatory Regimes

1.2 Areas of the Business

- 1.2.1 Drug Discovery
- 1.2.2 Drug Development
- 1.2.3 Manufacturing

1.3 Commercial Pressures

- 1.3.1 The Blockbuster Model
- 1.3.2 The Generics Industry
- 1.3.3 Intellectual Property
- 1.3.4 Litigation and Liabilities
- 1.3.5 Commercial Responses

1.4 Present and Future Trends

- 1.4.1 Genetics and Personalised Medicines
- 1.4.2 Gene therapy
- 1.4.3 Epigenetics
- 1.4.4 Monoclonal Antibodies

1.5 Related industries

- 1.5.1 Biotechnology and Biopharmaceuticals
- 1.5.2 Vaccines
- 1.5.3 Medical devices
- 1.5.4 Other Related Industries

Annex 1 Some Major Companies in the Pharmaceutical Industry

2 PHARMACEUTICAL PRODUCTS AND THEIR HAZARDS

- 2.1 APIs and their Significance for Exposure
- 2.2 Excipients
- 2.3 Hazards of API Major Categories
 - 2.3.1 Central Nervous System
 - 2.3.2 Renal and Cardiovascular System
 - 2.3.3 Gastrointestinal System
 - 2.3.4 Anti-Infectives and Target Organs
 - 2.3.5 Immune System
 - 2.3.6 Chemotherapy Agents
 - 2.3.7 Endocrine System
- 2.4 Hazards of Associated Materials
 - 2.4.1 Animal Allergens
 - 2.4.2 Latex Allergies
- 2.5 Precautionary Approach and Assumptions

3. PROCESSES AND TECHNOLOGIES

- 3.1 Introduction
- 3.2 Active Pharmaceutical Ingredient (API) manufacture (Primary Manufacture)
 - 3.2.1 Biological Processes
 - 3.2.2. Organic chemical synthesis
 - 3.2.3. Extraction from a Biological source
- 3.3 Formulated product (FP) manufacture (Secondary Manufacture).
 - 3.3.1. Compounding
 - 3.3.2. Granulation
 - 3.3.3. Drying
 - 3.3.4. Milling
 - 3.3.5. Blending
 - 3.3.6. Tableting
 - 3.3.7. Tablet Coating
 - 3.3.8. Capsules
 - 3.3.9. Non-Oral Formulations
 - 3.3.10. Packaging
 - 3.3.11. Cleaning and maintenance activities
- 3.4 Sterile production
 - 3.4.1 Clean Rooms
 - 3.4.2. Sterilisation Hazards
 - 3.4.3. Production Hazards

3.5 Research and Development

References

4 HAZARD ASSESSMENT AND COMMUNICATION

4.1 Hazard Assessment and the Product Development Process

4.2 Occupational toxicology testing

4.3 Determination of an Occupational Exposure Limit (OEL)

4.3.1 Identification of a Lead Effect

4.3.2 Estimated Human NOEL

4.3.3 Allowable Daily Exposure

4.3.4 NOEL Calculation

4.3.5 Calculation of OELs

4.4 Acceptable Surface Limits

4.5 Hazard Banding

4.5.1 Definition of an Occupational Hazard Category

4.5.2 Assigning Substances to OHCs

4.7 Hazard Communication

Appendix 1: Example Criteria for Allocation of Substances to OHCs

Glossary of Terms

5 EXPOSURE ASSESSMENT

5.1 Introduction

5.2 Air Sampling

5.2.1 Selection of Sampling Equipment

5.2.2 Sampling Methodology

5.2.3 Practical Considerations

5.2.4 Data Interpretation

5.3 Exposure Prediction

5.3.1 Qualitative Expert Judgment

5.3.2 Exposure Modelling

5.4 Method development and validation

5.5 Direct Reading Instruments

- 5.6 Skin Exposure
- 5.7 Wipe Sampling
 - 5.7.1 Applications of Wipe Sampling
 - 5.7.2 Standards for Surface Contamination
- 5.8 Biological Monitoring
- 5.9 Qualitative Exposure Assessments and Surrogate Sampling

References

6 CONTROL OF EXPOSURE

- 6.1 Exposure Control Principles and Containment in the Pharmaceutical Industry
 - 6.1.1 The Case for Containment
 - 6.1.2 Process Activities Giving Rise to Concern
 - 6.1.3 Developing a Scheme of Containment
- 6.2 Engineered Containment
 - 6.2.1 Performance of Engineered Containment
 - 6.2.1 Layers of Protection
 - 6.2.2 Facility Specification
 - 6.2.3 Equipment Specification
 - 6.2.4 Barrier Walls and Surfaces
 - 6.2.5 Pressure Zoning
 - 6.2.6 Airlocks
 - 6.2.7 Drainage Systems
- 6.3 Maintenance Concerns
- 6.4 Cleaning and Disinfection
- 6.5 Verification testing – FAT, SAT and SMEPAC
- 6.6 Use of RPE and PPE
- 6.7 Control in Healthcare Settings

Annex 1: Types of Engineered Containment Systems

7 CONTROL BANDING

- 7.1 Background and the Industry Structure
- 7.2 Developing a Containment Strategy
- 7.3 Pharma Process Activities with the Greatest Exposure Potential
- 7.4 Industry Control Banding Models

8 MANAGEMENT OF OCCUPATIONAL HYGIENE

- 8.1 Business Case for Occupational Hygiene
- 8.2 Organisational Structure
- 8.3 Occupational Hygiene Programmes
 - 8.3.1 Hazard Assessment
 - 8.3.2 Hazard Communication
 - 8.3.3 Exposure Assessment and Monitoring
 - 8.3.4 Health Surveillance
 - 8.3.5 Control Measures
 - 8.3.6 Training of Employees
- 8.4 Business Processes
 - 8.4.1 Operational Excellence
 - 8.4.2 Governance
 - 8.4.3 Capital Investment
 - 8.4.4 Due Diligence
 - 8.4.5 New product introduction
 - 8.4.6 Technology Transfers
 - 8.4.7 Awards Programmes
- 8.5 Corporate Responsibility
 - 8.5.1 The Importance of CR to Pharmaceuticals Industry
 - 8.5.2 Occupational Hygiene as a Corporate Responsibility Issue
 - 8.5.3 Corporate Responsibility Reporting
- 8.6 Sustainability
 - 8.6.1 Environmental Issues for the Pharmaceutical Industry
 - 8.6.2 Occupational Hygiene and Sustainability

9 END USER SAFE HANDLING OF HAZARDOUS DRUGS

- 9.1 Background
- 9.2 Hazardous Drug Handling in Healthcare
- 9.3 Exposure Assessment in the Healthcare Setting
- 9.4 Medical Surveillance of Healthcare Workers
- 9.5 Exposure Controls for Hazardous Drug Handlers

Learning and teaching activities

Learning time [hours]		
Scheduled contact hours: <i>[Note: these timings are estimates only and are subject to change per piloting feedback]</i>	Lectures	30
	Seminars [including homework feedback]	5
	Practical sessions and demonstrations	5
	Tutorials	0
	Examinations [including preparation]	0
	Other scheduled time	0
Guided independent study <i>[Note: include in guided independent study preparation for scheduled sessions, follow up work, wider reading or practice, revision]</i>	Independent coursework	0
	Independent laboratory work	0
	Other non-scheduled time	0
Total Hours		40

Assessment details

Methods of assessment	Based upon the Course Manual
Grading mode	Formative
Weighting (%)	100%
Pass mark	60%
Outline details	TBD

Indicative course materials and reading

ISBN number	Author	Date	Title	Publisher
	OHTA	2020	Occupational Hygiene in the Pharmaceutical Industry. Course Manual. Download for free from www.ohlearning.com	OHTA