# OHTA1002 - OCCUPATIONAL HYGIENE IN THE PHARMACEUTICAL INDUSTRY

## Course Description

Photo courtesy of Maharshi Mehta


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# OHTA1002 - OCCUPATIONAL HYGIENE IN THE PHARMACEUTICAL INDUSTRY

The pharmaceutical industry is essential to everyday life. Pharmaceutical companies deliver life-changing medicines that prevent illness, treat health conditions that extend lives, and strengthen public health around the world. Indeed, the demand for pharmaceuticals is surging worldwide with aging populations, increase in chronic diseases, breakthroughs in new therapies, and expanded access to healthcare in some emerging economies.

## Where are pharmaceuticals produced?

Several countries dominate the pharmaceutical industry with each one producing specific compounds on the supply chain. For example, China and India lead the world in the production of raw drug ingredients and together account for most of the building blocks of modern medicine. India is also the world's largest generic drug exporter. The U.S. is a leader in brand-name drugs, but imports most of its generic drugs. Biologics such as insulin, monoclonal antibodies for cancer, and vaccines require specialized facilities. Thus, most are in the U.S., Canada, Western Europe, and the Asia-Pacific region (See more here).

## What are some of the occupational health and safety issues in pharmaceutical industries?

Like any industry, workers at pharmaceutical companies can be exposed to common workplace hazards such as noise, dust, ergonomic stressors, and solvent exposures resulting in toxic, corrosive, and irritant effects. In fact, U.S. NIOSH (National Institute for Occupational Safety and Health) issued a Health Hazard Evaluation report in 2023 on dust and noise at a pharmaceutical manufacturing site that prepared placebos. (HHE Report no. 2021-011103391). In this study, NIOSH noted high respirable dust levels for short periods of time particularly when hand-scooping powders during tablet pressing. NIOSH also noted that the highest noise exposures were found in the bottling room when workers used compressed air to clean equipment. In 2024, NIOSH issued a Health Hazard Evaluation report on ergonomic issues in radiopharmaceutical tasks noting that workstations and tools needed better ergonomic design to reduce work-related musculoskeletal disorders. (HHE Report No. 2020-0020-3406)

In addition, there are some unique hazards to workers in this industry. In the primary manufacture of the active pharmaceutical ingredients (API), workers can be exposed to respirable API dust that can lead to allergic reactions and biological effects based on the intended pharmacology of the drug being handled. Allergens found in excipients and in animal handling during Research and Development activities can also lead to respiratory problems. Secondary manufacture of pharmaceuticals including tasks such as compounding, blending, production of tablets and capsules, and maintenance activities can also lead to exposures. In addition, for biological manufacturing such as fermentation, there are hazards which must be controlled. This course will help attendees understand that these health hazards are found frequently across all companies engaged in developing and manufacturing pharmaceutical agents and how to prioritize actions that must be taken to identify, assess, and control exposure potential.

The biggest challenge to OHS professionals in this industry is that many of the compounds do not have established occupational exposure limits (OELs). This means hazard assessment is not straight forward, and a control banding approach is commonly applied. Similarly, hazard control in this industry can be quite complex using a mix of engineered containment, maintenance, personal protective equipment (PPE), respiratory protective equipment (RPE), along with control banding.

# How can the new OHTA Specialist Course help pharmaceutical companies?

Pharmaceutical companies require IH/OH experts with specialized training to address the industry's complex hazard recognition and control needs. The OHTA1002 Specialist course equips participants with knowledge they can use and share with OHS generalists and management to raise awareness of health hazards, risk management, control strategies, and to comply with legal requirements. OHTA has partnered with the Pharmaceutical Supply Chain Initiative (pscinitiative.org) and many experienced IH/OH professionals to prepare this training course. OHTA-approved trainers teaching this Specialist course are required to have at least 5 years of pharmaceutical industry experience, providing a strong foundation of practical, real-world knowledge.

# Students will learn...

The hazards of APIs and excipients

Processes and technologies in primary and secondary manufacturing

Hazard Assessment and Communication

Exposure Assessment: Qualitative and Quantitative sampling methods

Exposure control: Engineered containment; Maintenance; Verification testing; Use of RPE and PPE

Control Banding

Management of Occupational Hygiene

Safe Handling of Hazardous Drugs by End Users

# Course Design

Delivered as a 3-day on-line or classroom training program followed by on-line multiple choice (MCQ) exam. Translation of the manual and exam into other languages is possible depending on demand. The comprehensive student manual will be available for download only by OHTA trainers approved for this course and/or students registered for the course.

# Become a Trainer

Training providers for the OHTA1002 course may include pharmaceutical companies and organizations, national IH/OH associations, or IH/OH consultancies. Training providers must have a dedicated OHTA Training Director with an IH/OH certification recognized by the National Accreditation Recognition (NAR) Committee of the International Occupational Hygiene Association (IOHA) such as CIH, ROH, etc. Individual trainers working under the Training Director for the OHTA1002 course should also have an IOHA NAR certification and 5 years' experience in the pharmaceutical industry.

OHTA is now seeking qualified trainers for the new 1002 course. Approved trainers may provide the OHTA1002 course for in-house competency development or for external training events. Note that training providers set and keep their own fees set in local currency. The only fees paid to OHTA are £150 (approximately 200 USD) per student for the mandatory on-line exam.

OHTA invites PSCI organization members to become an approved OHTA training provider for the OHTA1002 course. So if you are a PSCI member, please email team@ohtatraining.org to receive the PSCI trainer application for this course.

If you are not a PSCI member, complete the application to become a training provider here. Note that only approved trainers for the OHTA1002 course will have access to the student manual, trainer's materials, and on-line exam.

# Testimonial

Have a look at what OHS professionals with extensive experience are saying about the OHTA 1002 course:

*“For the first time ever, OHTA and PSCI have collaborated to create one of the most comprehensive occupational hygiene training modules available to the pharmaceutical industry. In the OHTA 1002 Specialist course, certified occupational hygiene leaders from across the pharmaceutical sector share practical guidance on reducing occupational health risks and implementing pharmaceutical-specific exposure controls.*

*Their collective expertise is captured in a detailed course manual and reinforced through OHTA’s trainer materials. The course is designed to strengthen occupational hygiene competency across the pharmaceutical industry—an area where the demand for specialized knowledge continues to grow.!*

***Maharshi Mehta, CSP, CIH, FAIHA, Global Leader***
***International Safety Systems Inc.***