The American Journal of Medical Sciences and Pharmaceutical Research
ISSN 2689-1026 | Open Access

TYPE Original Research
PAGE NO. 80-84
DOI 10.37547/tajmspr/Volume07Issue05-14

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Occupational health and safety (OHS) assurance in pharmaceutical manufacturing

OPEN ACCESS

SUBMITED 31 March 2025
ACCEPTED 29 April 2025
PUBLISHED 31 May 2025
VOLUME Vol.07 Issue05 2025

CITATION

Feruza. Sh. Tashpulatova. (2025). Occupational health and safety (OHS) assurance in pharmaceutical manufacturing. The American Journal of Medical Sciences and Pharmaceutical Research, 7(05), 80–84. https://doi.org/10.37547/tajmspr/Volume07Issue05-14

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Abstract: The specific features of occupational health and safety (OHS) assurance in pharmaceutical manufacturing have been analysed. The regulatory framework and the main risks associated with physical, chemical and ergonomic factors are examined. A systemic set of organisational, technical, sanitary and hygienic measures and socio-economic methods adapted to the particularities of pharmaceutical production is presented. Four practical case studies (evacuation SOP, microbiological air-contamination monitoring, solvent-evaporation prevention, ergonomics on packaging lines) are provided, together with an analysis of outcomes and quantitative indicators.

Keywords: Occupational safety, pharmaceutical manufacturing, GMP, microclimate, SOP, ergonomics.

Introduction: According to World Health Organization (WHO) data, approximately two million fatalities per year are attributed to work-related causes. In addition, about 160 million individuals worldwide suffer from occupational diseases, and in every third case the illness results in a loss of work capacity for four or more working days. The global number of occupational accidents, both fatal and non-fatal, is estimated at roughly 270 million per year [1].

The Constitution of the Republic of Uzbekistan, as the country's fundamental legal document, safeguards human rights, respects individual values and protects health. It enshrines provisions for the legal protection of life, liberty and personal security, and guarantees the

right to a decent life. Article 42 of the Constitution states: "Everyone has the right to decent work, free choice of profession and type of activity, and to protection, in accordance with the law, under working conditions that meet safety and hygiene requirements" [2]. This provision confirms that ensuring worker safety and health is an integral element of state policy.

Data from the press service of the Ministry of Employment and Poverty Reduction of the Republic of Uzbekistan indicate that during the first six months of 2024, 387 occupational accidents occurred in the production sector, injuring 416 workers. Of these, 303 persons sustained various degrees of physical trauma, 12 persons suffered minor injuries and, regrettably, 101 cases were fatal. The number of patients with occupational diseases registered in the Republic of Uzbekistan totalled 4 716 in 2019 and 4 759 in 2020; of the 43 newly identified cases in 2020, 40 were industry-related [2].

Pharmaceutical manufacturing is characterised by stringent requirements for cleanliness and environmental control. Adverse physical, chemical (solvent vapours, active-ingredient aerosols) and ergonomic (monotonous static work) conditions can lead to product-quality degradation, occupational disease and incidents [6].

The aim of the study is to develop and provide a systematic justification for a set of measures that ensure occupational health and safety (OHS) assurance for personnel at pharmaceutical enterprises.

METHODS

An interdisciplinary methodology comprising regulatory analysis, comparative assessment tools and practical observations with calculation of workplace-environment parameters has been applied. The approach was based on the principles of systemicity, evidence-based assessment and reproducibility.

Regulatory framework analysed: Constitution of the Republic of Uzbekistan (Article 42); Sanitary Rules SanQvaN 0071-24 [4] approved by the Committee for Sanitary and Epidemiological Welfare; GMP (Good Manufacturing Practice) standards; and legislative and subordinate acts on occupational safety.

Assessment tools: identification of hazardous and harmful workplace factors (GOST 12.0.003–74); quantitative occupational-risk assessment (probability vs. severity); comparison of measured values with permissible exposure limits (PELs) for harmful substances, noise and vibration defined in SanPiN and GOST.

Calculation of workplace-environment parameters:

- air-exchange rates in aseptic rooms (L = n × V);
- illumination levels and microclimate parameters (temperature, humidity, air velocity);
- risk coefficient (R = P × S), where P is probability and S is severity of consequences;
- normative analysis of personnel-evacuation time in emergency situations;
- analysis of practical case studies based on plant documentation.

RESULTS AND DISCUSSION

Air-exchange calculation for aseptic rooms

Aseptic areas require tightly controlled air-cleanliness parameters to prevent microbiological and mechanical contamination of products. One of the key indicators is the air-exchange rate—the number of complete air changes per hour—calculated in accordance with GMP requirements, SanQvaN 0071-24 and other sanitary standards:

L=n×V,L = n \times V,

where L is the required airflow per hour (m³/h); n is the air-exchange rate (class B aseptic zones: 20–40 h^{-1}); and V is the room volume (m³), calculated as length × width × height.

Example: for an aseptic room measuring 5 m × 4 m × 4 m,

V=5×4×4=80 m3; L=30×80=2400 m3/h.

Accordingly, the HVAC system equipped with HEPA filters must supply and circulate at least 2400 m³ of air per hour, thereby maintaining a stable air-cleanliness level corresponding to class B (≤ 100 CFU/m³ and ≤ 10 particles ≥ 5 µm per m³).

Calculation of the required air-exchange rate for aseptic rooms

Room designation	Dimensions (L × W × H), m	Room volume *V*, m³	Air-exchange rate *n*, h^{-1}	Required air flow *L* = *n* × *V*, m³ h^{-1}
Aseptic unit (main area)	5 × 4 × 4	80	30	2 400
Solution-preparation room	6 × 5 × 3.5	105	25	2 625

Ampoule-filling section	7 × 4 × 3	84	35	2 940
Packaging zone (clean area)	6 × 6 × 4	144	20	2 880

Microclimate monitoring is vital both for preserving product quality and for ensuring personnel comfort and safety. In accordance with SanQvaN 0071-24, GOST 12.1.005-88 [5] and QMQ 2.04.05-97 (referenced in SanQvaN) [4], optimal and permissible microclimatic parameters for production areas are defined, including air temperature, relative air humidity and air velocity.

Tab-2

Normative microclimate and illumination parameters for clean areas

Parameter	Normative value	Source of standard
Air temperature	18–22 °C	SanQvaN 0071-24, Appendix 3
Relative air humidity	40–60 %	QMQ 2.04.05-97 (referenced in SanQvaN 0071-24)
Air-flow velocity	Not more than 0.3 m s^{-1}	GOST 12.1.005-88
Illuminance	≥ 300 lx (general); ≥ 500 lx (visual-inspection areas)	SanQvaN 0071-24, Appendix 4

Calculation of the occupational risk coefficient

To obtain a quantitative assessment of occupational risk levels in a pharmaceutical facility, a universal method based on determining the probability of a hazardous event and the severity of its consequences has been applied. The risk is calculated using the following equation:

R=P×S, R = P \times S,

where

- R is the risk coefficient;
- P is the probability of the hazardous event (scored from 0 to 1);
- S is the severity of consequences (scores: 1 = minor infringement; 5 = critical outcome).

Risk appraisal. The risk of poisoning by vapours of a volatile solvent in the absence of local exhaust ventilation has been evaluated:

- P=0.2P = 0.2 — low probability of occurrence;
- S=4S = 4 — medium-severity consequences (temporary health impairment possible).

Hence:

R=0.2×4=0.8.R = 0.2 \times 4 = 0.8.

A value of R=0.8R = 0.8 lies within the moderate-risk zone. Should the indicator exceed 1, a high level of risk would be indicated, requiring mandatory corrective and protective measures, such as: installation of a fume hood; provision of respirators (A2P3); regular monitoring of vapour concentrations with gas analysers; and revision of standard operating procedures (SOP).

Note. The permissible risk level may be established by internal company regulations; for example, R>1.0R > 1.0 is regarded as critical, 0.5<R≤1.00.5 < R \leq 1.0 as moderate, and R≤0.5R \leq 0.5 as acceptable.

Tab-3
Gradation of occupational risk levels.

Risk level	Risk-coefficient value (R)	Description and interpretation	Required actions
Low	R ≤ 0.5	Acceptable risk; consequences are minor and probability is low.	Monitoring and adherence to standard procedures.

Moderate	$0.5 < R \leq 1.0$	Probability or consequences warrant attention; deviations are possible.	Precautionary measures and enhanced control are necessary.
High	$1.0 < R \leq 2.0$	Risk may entail serious consequences.	Immediate corrective actions and SOP revision.
Critical	$R > 2.0$	Unacceptable risk; threat to life or health.	Process must be stopped immediately, the hazard eliminated and protective measures implemented.

Normative analysis of personnel evacuation

The duration of personnel evacuation was assessed with consideration of corridor width, distance to exits, number of employees per shift and average walking speed (1.2 m s^{-1}). The evacuation time was calculated by the following expression:

T=Lv,T = \frac{L}{v},

where L is the distance to the exit (m) and v is the walking speed (m s^{-1}).

For an average distance of L = 25 m and v = 1.2 m s^{-1},

T=251.2≈21 seconds.T = \frac{25}{1.2} \approx 21\ \text{seconds}.

During a practical drill conducted at a site employing 48 staff members, the mean time for complete evacuation was 3.5 minutes, complying with the regulatory limit (≤ 4 min).

CONCLUSIONS

The calculations performed have confirmed that maintaining environmental parameters within regulatory limits requires continuous monitoring, technical upgrades and participation by trained personnel. A systemic approach not only minimises risks but also fosters a safety culture within the enterprise. The following protective measures may be applied to ensure occupational health and safety (OHS) assurance in pharmaceutical manufacturing; each is aimed at mitigating health risks to employees and safeguarding production processes.

Organisational measures

- Personnel training: Regular instruction in safety standards, including OHS and sanitary regulations, with particular emphasis on handling hazardous chemicals and responding to emergency situations.
- Development and implementation of standard operating procedures (SOP): Every facility shall maintain SOPs, especially for aseptic operations, microbiological contamination control and personnel evacuation.
- Evacuation planning and drills: Routine practical exercises verifying that evacuation times meet the normative requirement (e.g. ≤ 4 minutes).

Technical measures

- Ventilation and air purification: Installation of HVAC systems equipped with HEPA filters that deliver the required air-exchange rate (e.g. 30 air changes per hour in aseptic zones) to prevent airborne contamination.
- Illumination: Provision of adequate lighting levels (≥ 300 lx in production areas and ≥ 500 lx at visual inspection stations).
- Microclimate control: Maintenance of optimal microclimate parameters—temperature 18–22 °C, relative humidity 40–60 %, air velocity ≤ 0.3 m s^{-1}.
- Automation and environmental monitoring: Utilisation of automated systems to monitor temperature, humidity and airborne contaminant concentrations.

Sanitary and hygienic measures

- Regular disinfection: Scheduled disinfection of premises, equipment and work surfaces in accordance with sanitary regulations, with particular attention to surfaces in contact with medicinal products and packaging.
- Personal hygiene equipment: Provision of protective clothing (gowns, overshoes, gloves) and hand-sanitising facilities (disinfectants, washbasins).
- Sterilisation and disinfection control: Use of sterilisers and autoclaves for processing reusable medical instruments and packaging.

Ergonomic measures

- Workstations: Design of ergonomic workplaces to reduce monotony and static postures; for example, optimisation of packaging-line layouts to enhance worker comfort and decrease fatigue.
- Scheduled breaks: Implementation of regular rest periods, especially for personnel undertaking physically demanding tasks or working in static positions.

Preventive measures for minimising occupational diseases

- Use of protective equipment: Routine

replacement of ventilation filters; use of respirators and other protective devices when handling hazardous chemicals such as solvents and aerosols.

- Occupational-disease prevention: Establishment of health-monitoring programmes, periodic medical examinations and workplace conditions that prevent work-related illnesses.

These protective measures are mandatory for ensuring OHS in pharmaceutical facilities and shall comply with national standards and regulations.

Ensuring occupational health and safety (OHS) assurance in pharmaceutical manufacturing is a multifaceted task that encompasses strict adherence to sanitary norms and the adoption of contemporary risk-minimisation methods. Implementation of a comprehensive approach grounded in international standards and national sanitary requirements will secure high product quality and safety at every stage of the manufacturing process.

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