MANAGING THE RISKS POSED BY HAZARDOUS CHEMICALS IN A PHARMACEUTICAL COMPANY

1 General information

Country: Latvia.

Available language: Latvian.

The **sector covered** in this case study is manufacture of pharmaceutical products and pharmaceutical preparations.

Worker groups covered (vulnerable groups): all groups of workers; pregnant and breastfeeding workers.

The **purpose of this example of good practice** was to improve safety and to help prevent workers being exposed to hazardous substances in a pharmaceutical company, as well as to raise awareness.

The **target groups** are employers, workers, safety health and professionals, people responsible for safety and health, and workers' representatives.

2 Initiator/organisations involved

JSC Grindeks, Riga, Latvia.

3 Description of the case

3.1 Introduction/background

The story of Grindeks started in 1946 when its vitamin and hormones plant opened; the company developed into a vertically integrated pharmaceutical concern between 1946 and 1956. Grindeks is based in Riga, Latvia. Its main fields of activity are research, development, manufacturing and sales of original products, generic drugs and active pharmaceutical ingredients. The company specialises in the heart and cardiovascular medication, medication to treat the central nervous system and anti-cancer medication.

Figure 1: Grindeks' main building and production sites (photo by Grindeks).

The Grindeks Group consists of five subsidiary companies in Latvia, Estonia, Russia and Slovakia; representative offices have been opened in 12 countries. Grindeks' products are exported to 71 countries, with exports comprising 91 % of total turnover. Key markets include the EU countries, Russia and other Commonwealth of Independent States) countries, the USA, Canada, Japan and Vietnam.

Grindeks employs approximately 670 workers in production and quality control laboratories, of whom 67 % are women. In total, around 27 % of the workers are over 55 years old.

The company uses large amounts of chemicals in everyday production and there are more than 700 chemicals in use in its workplaces.

Hazard — physical state: liquids, aerosols, powder.

Hazard — health effect: carcinogens, mutagens, reprotoxic substances, toxic substances.

Exposure route: inhalation, dermal exposure.

Substance description (CAS/EC) (only if possible): fluorouracil, CAS number 51-21-8, EC number 200-085-6 (it is used in the warehouse, in the laboratory and in the department that manufactures active pharmaceutical ingredients).

The actions implemented were based on the results of risk assessments and feedback from workers, with the aim of ensuring occupational safety and health (OSH), in particular through the management of dangerous chemicals. Existing technical and organisational solutions were no longer sufficient to ensure the safety and health of workers, as a result of the volume of production and an increase in the range of hazardous substances used.

Several activities and interventions were implemented in four areas of the enterprise — in the warehouse; in the quality control laboratory; in the department that manufactures active pharmaceutical ingredients; and in the department that manufactures tablets/pills — on the basis of the OSH problems affecting each area. Some detailed examples of good practice implemented to improve working conditions in one of these areas, namely the quality control laboratory, are recounted here.

3.2 Aims

Grindeks aimed to minimise exposure to dangerous chemicals, as well as to heat and noise. To this end, a complex holistic approach was taken, involving several safety measures based on the results of risk assessments, observation and analyses of work procedures with regard to dangerous substances, as well as on feedback from workers.

3.3 What was done and how?

The quality control laboratory was involved in an intervention lasting several years that was intended to reduce exposures to dangerous chemicals and to improve OSH.

Workers were engaged in the entire preparatory process, as were consultants and OSH experts.

3.3.1 Identification of OSH problems

Several activities were conducted in order to identify all OSH problems, with a special focus on exposures to dangerous chemicals:

- A risk assessment was carried out for each process involving dangerous chemicals.
- A questionnaire was circulated and a group discussion conducted during the rollout.

Workers' representatives, working environment councils and heads of department were involved during the implementation stage.

3.3.2 Prevention measures

First step: almost all laboratory personnel require both laboratory and office support space, that is, they are engaged in analyses using laboratory equipment and paperwork (in a computer laboratory).

Based on workers' suggestions, all laboratory equipment and work has been relocated to a specially designed room in a strictly separated area in order to minimise exposure to noise, heat and some dangerous chemicals. As a result, there is better control of exposure risks, because the office area of the laboratory is now physically separated from the area where chemical analyses take place. Locating the office outside the laboratory environment creates a safer workspace where quiet work can be done; in addition, more paper and books can now be stored there. Workers were satisfied with the new working conditions in both the office area and the laboratory.

The new laboratory was equipped with local exhaust ventilation systems, and the walls were covered with carefully selected finishing materials with soundproof properties to decrease the noise level, ensure easy cleaning and maintain a high level of hygiene.

As a result of the measures implemented, most work can be carried out in conditions free from heat, noise and exposure to chemicals. Some work still needs to be done in a room where there are dangerous chemicals, of course; however, workers no longer spend all their working time in such a room.

Second step: for work on highly hazardous chemical substances, a separate room was set up, equipped with an effective ventilation system, specific work equipment, and finishing materials, to ensure compliance with cleaning procedures and special dressing arrangements.

Thanks to the measures taken, conditions have been created that enable the work to be done safely, protecting the staff carrying out the work and others.

3.3.3 Care for pregnant and breastfeeding workers

Generally, pregnant workers — after notification of the pregnancy — are no longer allowed to work in a role where they are exposed to dangerous chemicals and other hazards. Workers who have recently given birth or are breastfeeding are also moved to a job free from exposure to dangerous substances. In advance of the change, a comprehensive assessment of the working conditions in the new role is carried out by a safety manager and an occupational physician.

3.3.4 Managing safety knowledge regarding harmful substances

An extensive mix of individual and collective training for all workers was implemented using various learning techniques and methods. Additionally, special courses for those working with hazardous substances were organised in all departments.

Safety instructions and guidelines were developed to improve knowledge and skills among all workers, with a special focus on the management of dangerous chemicals (health effects, precautions, safety data sheets, collective protective equipment, personal protective equipment, etc.).

3.4 What was achieved?

The measures resulted in:

- improved technical safety measures/control of hazardous substances in the working environment;
- greater awareness on the part of workers of safety and health issues in the workplace;
- effective involvement and engagement of workers in safety and health activities;
- reduced hazards when handling hazardous substances in the laboratory, through making working processes safer;
- improved prevention of health problems related to chemicals.

3.5 Problems faced

Challenges were mainly related to existing requirements relating to certificates and procedures for inspection by government authorities in Latvia. Before the company can start the production of an active pharmaceutical ingredient or a certain tablet or pill, the production process has to be described in detail, with supervision and an audit carried out by the authorities; only when the manufacturing facility has been audited and found to demonstrate satisfactory compliance with the required Good Manufacturing Practice (GMP) standard can production begin.

The GMP certificate is a certificate relating to the manufacture of a therapeutic product, medicinal product, active pharmaceutical ingredient or cosmetic product, attesting that the manufacturer conforms with the relevant GMP standard (PIC/S, 2017). The assessment is made in accordance with the agreed European procedures for inspections and with that for the issuance of GMP certificates to pharmaceutical manufacturers in many European countries.

It was difficult and time-consuming to make changes to the system and the documents required when the interventions were being planned in Grindeks.

The lesson learned from this is that the requirements for an advanced level of safety and health need to be defined at the beginning of production, i.e. at the planning stage. Making changes later is expensive, time-consuming and difficult because of the existing requirements with regard to certification of production processes.

3.6 Success factors and challenges

Several success factors can be mentioned:

- The complex solution addressed highly relevant OSH problems in the establishments, namely exposure to dangerous chemicals, heat and noise.
- Workers' active involvement in the project allows a better assessment of their needs and expectations with regard to the safety management system. Consultancy, training and discussions with workers increased their awareness of risks and safety measures, and resulted in better compliance with safety requirements.
- A high level of job satisfaction on the part of workers in the laboratory was achieved.
- The commitment of the company's leadership to safety and health was demonstrated throughout the whole project.

3.7 Transferability

The approach used is applicable to any laboratory that deals with hazardous chemicals.

3.8 Costs and/or economic impacts

Data about costs and/or economic impacts has not yet been received.

3.9 Evaluation

This case study is a good example of chemical safety management because of a combination of several factors:

- recommendations and advice come from credible sources (OSH experts, etc.);
- essential — there were certain problems to be resolved in the quality control laboratory;
- effective — the solutions introduced were effective and it was possible to prove this using measurements or other indicators;
- target groups — the solutions were useful for a specific target group (pregnant and breastfeeding workers, workers handling chemicals);
- there was a positive impact on morale and on the image and reputation of the

establishment;
- there was a focus on preventing risk at sources;
- workers were involved;
- a better level of safety and health was achieved, as well as an increase in employers' and workers' awareness;
- the employer's commitment was demonstrated;
- the measures were easy to understand;
- the intervention is transferable to other enterprises and countries;
- potential applicability — the programme educates workers and employers and engages them; it also empowers everyone within the enterprise to deal with safety and health issues.

3.10 Further information

Contact

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About Grindeks: http://grindeks.eu

4 References and resources

PIC/S (The Pharmaceutical Inspection Co-operation Scheme), 2017, 'Guide to good manufacturing practice for medicinal products', PIC/S Secretariat. Available at: https://www.picscheme.org/en/publications?tri=all#selCategory_Documents%20for%20Industry (accessed 21 February 2018).