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Pharmaceutical regulations and PPE (Personal Protective Equipment)

Various regulations, standards and codes of practice govern the development, manufacturer, licensing and the bringing-to-market of pharmaceutical products. Globalisation of R&D, manufacturing, packaging, distribution and sales also often requires compliance with both European and US regulations. Mutual recognition agreement (MRU) between the European Union (EU) and the third-party country authorities, such as the US Food and Drug Administration (FDA), have been established to ease market access and encourage greater international harmonisation of compliance standards.

One important regulation concerning the manufacturer of active substances for medicinal use, is 'Good Manufacturing Practice' (GMP)[1].

Any manufacturer of medicines intended for the EU market, no matter where in the world it is located, must comply with GMP.

GMP requires that medicines:

- are of consistent high quality
- are appropriate for their intended use
- meet the requirements of the marketing authorisation or clinical trial authorisation

The GMP principles sets out strict criteria to ensure that medicines, and especially active substances, are quality controlled. Quality control steps cover quality management, personnel, premises and equipment, documentation, material management, production, in-process quality controls, packaging, labelling, laboratory controls, returns, complaints and recalls, contracting out and repackaging. Certain R&D and manufacturing processes require strict control of contamination and cross-contamination between personnel and product, e.g. prevention of contamination of the environment by their clothing or their actions, and production facilities and product e.g. where one production line may be used for different products.

In many operations throughout the research, development, manufacture and packaging phases of pharmaceutical production, personnel may be exposure to hazards substances and therefore controls need to be put into place to prevent or adequate control this exposure. The principles of hierarchy of control should be followed in the following order: elimination, substitution, engineering and administrative controls and finally the use of personal protective equipment (PPE). In the development and manufacturer of active pharmaceutical ingredients (API) as well as other processes, such as packaging, effective control of exposure can only be managed with the additional use of PPE.

GMP also requires that equipment and plant used in the manufacture of active substances is cleaned and where appropriate sanitised. Some cleaning compounds and disinfectants may be classified as toxic or corrosive and therefore can pose a health risk to the operative.

Having established the need that RPE is still required to reduce exposure down to safe levels, the next step is to select PPE that provide adequate levels of protection and that are suitable for the wearer, the task and the environment where the task is being conducted. GMP including clean room and sterile requirements can make the task of PPE selection for the task and the environment particularly challenging. In addition, where exposure to highly potent API is a risk then respiratory protective equipment (RPE) offering high levels of protection may be required.

Reference

1. Commission Delegated Regulation (Eu) No 1252/2014 supplementing Directive 2001/83/EC of the European Parliament and of the Council with regard to principles and guidelines of good manufacturing practice for active substances for medicinal products for human use.

Personal Safety Division

3M United Kingdom PLC
3M Centre
Cain Road, Bracknell
Berkshire RG12 8HT
t: 0870 60 800 60
www.3M.co.uk/Safety

3M Ireland Limited
The Iveagh Building
Carrickmines Park
Carrickmines
Dublin 18