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Latest news and updates from the Faculty of Pharmacy



Faculty of Pharmacy UiTM

GMP COMPLIANCE IN MALAYSIA: MEETING GLOBAL STANDARDS FOR QUALITY AND SAFETY IN PHARMACEUTICAL, HEALTH SUPPLEMENT, TRADITIONAL AND COSMETIC INDUSTRIES

In the field of pharmaceutical production, Good Manufacturing Practices (GMP) play a critical role in ensuring the safety and quality of products. Defined by the World Health Organization (WHO, 2021), GMP is a component of quality assurance that guarantees products are consistently produced and controlled to the appropriate quality standards. The principle behind GMP is that quality is integrated into the production process rather than simply tested in the final product. This ensures that the product not only meets final specifications but is also manufactured using the same procedures and under the same conditions every time.

GMP guidelines apply to various aspects of production, including quality management, personnel, facilities, equipment, documentation, production, quality control, complaints, product recalls, and self-inspection. These guidelines emphasise the importance of properly designed premises, validated processes, trained personnel, effective storage and distribution, and an orderly system of working and documentation procedures.

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In Malaysia, GMP implementation began in 1985, following WHO guidelines. Since joining the Pharmaceutical Inspection Cooperation Scheme (PICS), Malaysia's GMP guidelines have been based on PICS guidelines. All traditional, cosmetic, pharmaceutical, and health supplement industries must possess a GMP-certified plant before they can manufacture their products. Certification is currently managed by the Ministry of Health's National Pharmaceutical Regulatory Agency (NPRA, 2021), which conducts audits on industries to improve GMP implementation standards.

GMP provides numerous benefits not only to the industry but also to consumers. It ensures that products are consistently produced and controlled in accordance with established quality and safety standards and reduces the risk of adulteration and contamination (Jiang et al., 2018). Additionally, GMP reduces operating costs associated with rework, customer rejects, and complaints, and increases efficiencies by reducing errors (Prajapati et al., 2020). Ultimately, GMP demonstrates an organisation's commitment to producing safe products that increase customer confidence (Ghodeswar et al., 2021).

Despite being in place for over 50 years in over 100 countries, adulteration still occurs. According to our preliminary research on selected Malaysian pharmaceutical, health supplement, traditional, and cosmetics industries, the majority of manufacturers follow GMP guidelines as required. However, some manufacturers, particularly in the traditional and cosmetics industries, lack certain GMP requirements, such as premise setting and documentation. This is often due to a lack of awareness of the importance of documentation in preventing cross-contamination and a shortage of qualified personnel to handle the required documentation (Jiang et al., 2018). This issue can be addressed through GMP training programs provided by the NPRA and educational institutions such as colleges and universities. These programs can include both short-term and ongoing GMP training for manufacturers. GMP training for employees improves their understanding of the guidelines and the importance of implementing them in their daily work, ultimately leading to improved efficiency, reduced errors and defects, and increased productivity (Prajapati et al., 2020).

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