

Hygienic and safe manufacture of pharmaceuticals

The number of phases involved and the different substances being handled in the manufacturing process of medicinal products can be complex making hygiene and safety imperative to avoid contamination, exposure or direct contact.



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The process involves active ingredients handling to tabletting, right through to the finished packaged product.

"South Africa is a major manufacturing and export hub for the pharmaceutical industry and is subject to not only local legislative oversight but also to those of the countries the medicines or medical equipment is being exported to," says Emma Corder, managing director of cleaning products manufacturer, Industroclean.

In South Africa, the manufacturing of pharmaceuticals is guided by Good Manufacturing Practices (GMP) and overseen by the National Department of Health (NDoH).

GMP guidelines

The World Health Organisation (WHO) has established GMP guidelines in detail from which many countries, including South Africa, have formulated their own GMP

.Two of the main rules of GMP in the production of pharmaceuticals which pertain to cleanliness and hygiene states:

- Facilities must be cleaned, and high standards of hygiene and quality must be maintained from procurement to product.
- Cross-contamination must be prevented by temperature and humidity-controlled environments and by restricting entry to authorised staff with proper work gear.

“What is important to understand is that medicines produced in South Africa and exported to the US, for example, are also under scrutiny of the US’s Food and Drug Administration (FDA),” says Corder.

“The pharmaceutical company has to provide documents that the cleaning of the equipment and the room where it is manufactured has been through a process of validation,” she adds.

Non-specialist suppliers

Demand for sanitisers and hygiene products in response to the coronavirus has seen a number of non-specialist manufacturers and suppliers enter the market.

“With the level of scrutiny, hygiene and safety in this sector, close collaboration between cleaning solutions providers and pharmaceutical companies is crucial,” Corder continues.

\$5bn market

The global cleanroom technology market size is expected to reach \$5bn by 2028 and is expected to expand at a rate of 5.4% over the forecast period.

Key factors driving market growth is growing compliance with stringent regulatory standards for new product approvals and increased awareness about contamination-free products.

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