ZAMRA ASSESSORS TRAINED IN STERILE PRODUCTS ASSESSMENT

Sterile products such as injectable medicines, intravenous fluids, eye solutions, and certain surgical implants, are among the highest-risk medicines because they are delivered directly into the body.

This makes it critical that they remain completely free from microbial contamination at every stage, including manufacturing, transportation, storage, and administration.

To safeguard public health, the Zambia Medicines Regulatory Authority (ZAMRA), from 29th September to 10th October 2025, conducted an intensive ten-day training for its assessors to strengthen expertise in evaluating sterile products to ensure that only safe, effective, and high-quality medicines are approved for use in Zambia.

The training, which was facilitated by the Chief Registration Officer at the Food and Drugs Authority (FDA) Ghana, Mr. Nathaniel Nkrumah focused on;

1. New technologies in sterile manufacturing
2. Current Good Manufacturing Practice (GMP) requirements
3. Risk assessment in the evaluation process
4. Identification and mitigation of risks in sterile product manufacturing processes
5. Evaluation of prescriber information to support safe and appropriate medicine use
6. Lifecycle monitoring of product quality, safety, and efficacy
7. Dossier evaluation methodologies to enhance regulatory efficiency and reduce review timelines

Speaking during the closing session, ZAMRA Director-General, Mr. Makomani Siyanga expressed appreciation to the facilitator, Mr Nathaniel Nkrumah, for his expertise in delivering the training.

"The knowledge and skills imparted during this program are critical to strengthening regulatory performance," said Mr. Siyanga.

He added that such training programs and partnerships with other regulatory authorities will continue to promote regulatory harmonization, enhance dossier evaluation efficiency, and align with international best practices.

In his remarks, Mr. Nkrumah highlighted that many African regulatory authorities face similar challenges in the regulation of sterile formulations. He emphasized the need for stronger inter-agency collaboration and knowledge sharing, commending ZAMRA for its active participation in regional initiatives that promote excellence in dossier evaluation.

The training marks another milestone in ZAMRA's ongoing efforts to strengthen regulatory systems and safeguard both human and animal health.