FDA green lights Adcock Ingram's R&D facility

The Centre for Drug Evaluation and Research of the Food and Drug Administration (FDA) has accepted Adcock Ingram's Research and Development (R&D) facility, which is located in Aeroton, south of Johannesburg. Adcock Ingram's R&D facility is registered with the Medicines Control Council (MCC) as a current Good Manufacturing Practice facility.

One of the key outputs from the in-house R&D laboratory is the timeous development of critical medication, such as anti-retrovirals (ARVs). The R&D activities were the focus of the FDA inspection which took place in November 2011, and in August 2012 the FDA confirmed the acceptance classification of this facility. The R&D establishment is adequately equipp to conduct research for liquid, semi-solid and solid oral dosage forms.

The R&D site is fitted with large environmentally controlled walk-in stability chambers, necessary for accelerated and long-term stability studies for finished pharmaceutical products in accordance with International Conference on Harmonisation (ICH) guidelines.

The team of pharmacists and scientists at the site also develop and validate analytical methods for pharmaceutical product and in so doing support the formulation and process development for new product and product improvement projects. Activities that are central to the facility include pre-formulation and formulation of a variety of dosage forms, stability studie and the manufacturing of laboratory-scale batches.

To achieve scientific and technical objectives, while maintaining quality assurance and regulatory compliance, a comprehensive Quality Management System (QMS) has been implemented at the facility. This allows for a feedback mechanism on systems and processes, ensuring continuous improvement in the development and testing of pharmaceutic products.

FDA acceptance of Adcock Ingram's facility is evidence of the quality of product and the processes that go into the manufacturing of Adcock's products. FDA approval is a pre-requisite to accessing donor funding and being able to fulfil tenders in the rest of Africa.

The R&D facility's acceptance by the FDA also serves as a stepping stone to ensuring global best practices are in place across all production sites. Adcock Ingram expects to continue pharmaceutical medicinal development at this facility.