

TWINZ REGULATORY AFFAIRS PHARMACIST CONSULTANTS



Pharmaceutical Regulatory Affairs

WHAT YOU NEED TO KNOW

ROLE OF REGULATORY AFFAIRS

The role of regulatory affairs in the pharmaceutical industry in South Africa is to ensure that pharmaceutical products comply with the necessary regulatory requirements before they can be marketed and sold to the public. This involves working closely with various regulatory authorities, including SAHPRA, to ensure that all necessary documentation is provided and that all requirements are met.

One of the key responsibilities of regulatory affairs is to ensure that pharmaceutical products are manufactured in compliance with current Good Manufacturing Practice (cGMP) guidelines. This involves ensuring that manufacturing facilities are inspected and that all necessary documentation, such as batch records and stability data, is provided. Regulatory affairs is also responsible for ensuring that pharmaceutical products meet the necessary safety and efficacy standards.



RECRUITMENT IN REGULATORY AFFAIRS



As a discipline, regulatory affairs covers a broad range of specific skills and occupations. Under the best of circumstances, it is composed of a group of people who act as a liaison between the potentially conflicting worlds of government, industry, and consumers to help make sure that marketed products are safe and effective when used as advertised.

The ability to analyze complex data, identify potential issues, and devise effective solutions is invaluable. Regulatory professionals often encounter diverse and intricate problems, ranging from safety concerns to documentation discrepancies.

Positions within regulatory affairs offer excellent job security.

The reason is simply supply and demand: not enough people today have experience in regulatory affairs. To be successful in this position, it helps to be very detail and process-oriented, and to possess excellent writing, communication, and interpersonal-skills. Regulatory affairs is a constantly evolving profession that requires continuous skill-updates. Graduates and experienced professionals alike should consider undertaking ongoing training.

Hence Twinz Regulatory Affairs Pharmacist Consultants together with it's sister company Zimbili Pharma, a Market Authorisation Holder (MAH), have been instrumental in servicing pharmaceutical companies with new regulatory submissions and amendments across the African continent with positive outcomes and assisted some of the world leading companies by providing Regulatory based training to their staff enabling South African Regulatory Affairs on a whole to reach international standard.

