

WHAT IS REGULATORY?

Regulatory affairs is a profession developed from the desire of governments to protect public health.

They do this by controlling the safety and efficacy of products in areas including pharmaceuticals, veterinary medicines, medical devices, pesticides, agrochemicals, cosmetics and complementary medicines, and by the companies responsible for the discovery, testing, manufacture and marketing of these products wanting to ensure that they supply products that are safe and make a worthwhile contribution to public health and welfare.





Key Tasks

1. Collation of required documentation to prepare the dossier submissions
2. Due Diligence of dossiers if requested
3. Provide Gap Analysis report on performed Due Diligence if requested
4. Preparation collated documentation into eCTD submission format
5. General advice on variations and regulatory procedures

