PHARMA REGULATORY CONSULTING SERVICES

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INTRODUCTION

- Pharma Regulatory Consulting and AmanziBee, based in Cape Town, have a cumulative pharmaceutical Regulatory, GMP, GWP and manufacturing experience of + 60 years.
- We can assist newly established and existing Pharma companies (Complementary and Orthodox medicine) with setting-up regulatory and quality systems as per the SAHPRA regulator's requirements in compliance with current legislation.
- Further, freeing up hands prior to employment of staff and / or assisting existing staff prior to employment of additional staff.
- Not exclusive, see further services listed as below.

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PRODUCT REGISTRATION & REGULATORY SERVICES	
CTD compilation	Compile registration documents as per regulatory standards for Allopathic medicines, Complementary medicines and Medical Devices, for CTD submission and licensing.
CTD Life Cycle Management	Manage the dossiers on behalf of the applicant during the pre-registration phase, and subsequent post registration updates, amendments, ongoing stability studies, newly acquired supportive data throughout the product's lifecycle.
Pharmacovigilance	Monitor the product in the market with regard to adverse events, side effects reported, current literature review and market tendencies.
Product recall	Perform product recall based on the outcome of quality and safety investigations.
Due diligence of existing dossiers and new product documentation	Assess dossier information in terms of compliance with legislative requirements, identifying gaps necessitating updating, and / or purchasing of dossiers that would require successful transfer of applicancy.
Label, PI & PIL development	• Draft labels, Package Inserts(PI) and Patient Information Leaflets (PIIL) in accordance with regulatory requirements. • Includes research on active ingredient health claims & dosage requirements.
Website product information assessment and advise	• Align website with PI & PIL information where relevant. • Ensure compliance with Marketing Code.

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SAHPRA & SAPC APPLICANT SERVICES	
QMS (Quality Management System)	For the purpose of licensing with the South African Pharmacy Council (SACP) and SAHPRA, design and prepare a custom made quality system based on site activities i.e. Applicant SOP's, Director's letters to SAHPRA and SAPC.
Final Product Release	Review batch documentation, analytical data and finished packed product prior to release to the market.
Auditing	• Audit 3rd party manufacturers, packers and laboratories. • Assist with preparation for regulatory audits by SAHPRA.
Annual Product Review	Review each marketed product by assessing / analysing the manufacturing & packaging documents, test results, production yields, out of specification results, complaints and any untoward trends.
Liaison / intermediary Person with 3rd party Production & Quality lab, Distributor, Clinical trial site	Coordinate / liaise with 3rd party contractors as required regarding: • Production including manufacturing and packaging operations, • testing, • changes / amendments (formula, process, packaging, PI, etc) • stability, studies, • bio-studies.
Stability Study management	Set-up and ensure timely execution of stability studies by the 3rd party laboratory.
Product Complaints related Quality & Safety matters.	• Investigate complaints. • Address quality / safety matters between the contracting parties.
API suitability assessment i.r.o DMF compilation	Assess the suitability of the active pharmaceutical ingredient (API) re: • Supportive information availability. • Compatibility of an alternative active ingredient supplier or alternative inactive ingredient in a product.

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OTHER SERVICES	
Project Management	Serve as inter departmental co-ordinator on projects.
Product development, scale-up & failure Investigations (new & generic & existing)	• Perform due diligence i.r.o regulatory requirements i.e. scheduling, claims, safety & efficacy, generic feasibility. • Advise on batch scale up i.r.o regulatory requirements. • Investigate feasibility of new & generic product addition / extensions from a regulatory point of view.
Deputy Responsible Pharmacist (RP)	Deputise as Responsible Pharmacist during the absence of the appointed Responsible Pharmacist.
Printed packaging Components (PI, PIL & Labels & Marketing Material)	Proof read printed PI and PIL and labels versus approved text and ensure correct layout by the approved / qualified printer.
Training	Provide basic training on new and existing guidelines as issued by SAHPRA and assist with implementation thereof, including Good Manufacturing Practises, Good Wholesale and Distribution practises and Good pharmacy practise.

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CONTACT DETAILS

LINDA STEENKAMP	TERIA VILJOEN
Email: linda@amanzibee.co.za	Email: teriav494@gmail.com
Cell: 083 273 8111	Cell: 082 324 6591