

**GOOD
DOCUMENTATION
REGULATORY
CONSULTANTS (PTY) LTD**

A subsidiary of Qhayisa 2014 Trading and Projects (Pty)Ltd

COMPANY PROFILE

1. INTRODUCTION



Good Documentation Regulatory Consultants (PTY) LTD (is a subsidiary of Qhayisa 2014 Trading and Projects (Pty) Ltd was established in 2013 to provide expert regulatory advisory services and regulatory support services to the pharmaceutical industry.

2. COMPANY CONTACT INFORMATION

CONTACT	Mr. Siphamandla (Sipha) Thwala
DESIGNATION	Director
PHYSICAL ADDRESS	38 Tulbagh gardens, Cnr. Tulbagh and Mulders Rds, Glen Marais, Kempton park, 1619
TELEPHONE NUMBER	0714730026
FAX NUMBER	086 558 4886
E-MAIL ADDRESS	Siphamandla.thwala@gmail.com

3. COMPANY DETAILS

REGISTERED TRADE NAME	Good Documentation Consultants (Pty) Ltd
REGISTRATION NUMBER	2015/338854/07
INCOME TAX NUMBER	9852046169
HOLDING COMPANY	Qhayisa 2014 Trading and Projects (Pty)Ltd.
DIRECTOR	Siphamandla Thwala

4. COMPANY BACKGROUND

We enjoy a clear understanding of the regulatory environment in South Africa, its history, trends, current requirements and policies. We are associate members of many of the industry associations and in our professional capacities affiliated to the professional associations. These associations, together with networks we have nurtured, provide us with current information related to the health products industry.

Our aim is to provide exemplary quality regulatory support, thereby reducing unnecessary delays in the registration process.

We use the most up to date solutions to enable us to compile and publish eCTDs and paper CTDs. We are able to life-cycle manage documentation, thus maintaining registration documents in a fully validated electronic document management system.

We aim to empower our customers with the knowledge and understanding of the regulatory environment and processes. This is vital to our clients to understand the regulatory environment related to the industry and enables them to make informed decisions regarding their products.

Our services range from regulatory assistance with orthodox medicines to complementary medicines, from veterinary medicines to licensing of facilities.

We can answer all your questions and fulfil all your regulatory requirements!

5. LEADERSHIP

Good Documentation Regulatory Consultants (PTY) LTD (is a subsidiary of Qhayisa 2014 Trading and Projects (Pty) Ltd) is 100% Black Owned. The entity was founded in 2013 and is led by Siphamandla (Sipha) Thwala.



Siphamandla (Sipha) Thwala holds a Bachelor of Pharmacy degree from University of KwaZulu Natal (Westville branch) and also other related qualifications which are related to drug regulatory affairs and is registered with the South African Pharmacy Council. He worked for 10 years in the pharmacy environments including government and private hospitals, production and manufacturing and drug regulatory affairs.

6. OUR MISSION

To provide regulatory services in regulatory affairs that will meet the client's specific needs.

7. OUR VISION

- To be one of the leading companies providing regulatory services locally and internationally.
- To transfer skills to the youth who want to pursue a career in regulatory affairs.
- To deliver back to our communities by creating employment and conducting educational projects in healthcare.

8. OUR VALUES

- Ethical and professional in conducting the business.
- Integrity and honesty.
- Deliver services that meet the needs of the customer.
- Competency and reliability.
- Pro-active, responsive and decisive.
- Accountability and good governance.
- Easy to do business with.
- Continuous improvement.

9. OUR SERVICES SPAN THE FOLLOWING REGULATORY SEGMENTS:

- Compilation of new product registrations (New Chemical Entities, generics, complimentary medicines and additions to the line).
- Compilation of variations (safety and CMC) of registrations dossiers.
- Conducting due diligence on registration dossiers.
- Assessing registration dossiers for business development activities.
- Printing of the submissions and amendments and responses as required by MCC.
- Liaising with Health Authorities and Local Technical Representatives.
- Assisting with licensing requirements and GMP inspections.

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