



# Mastering the Site Master File



**Blended  
Business  
Solutions**

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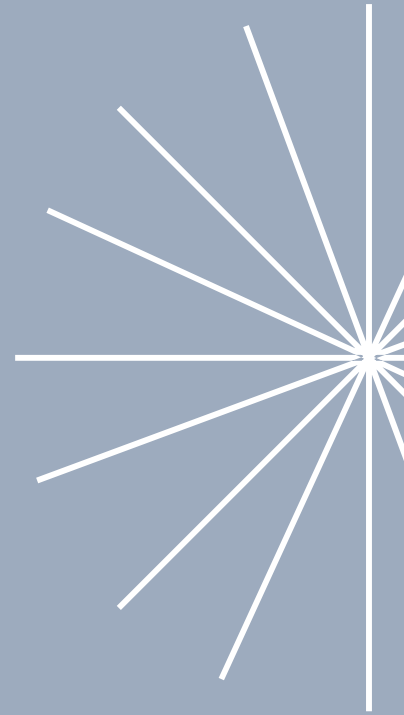
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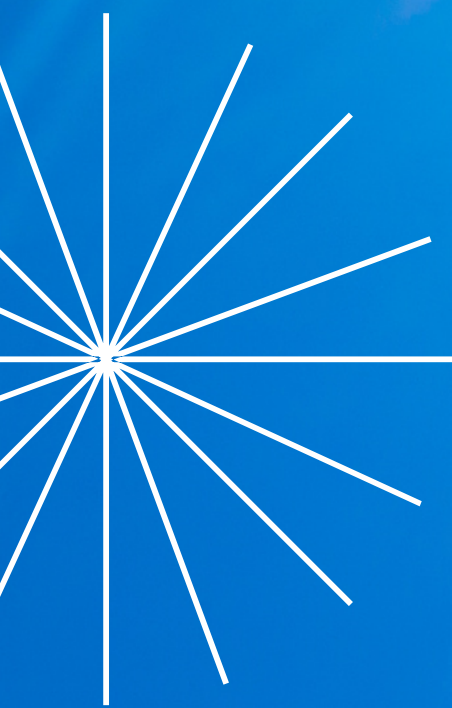
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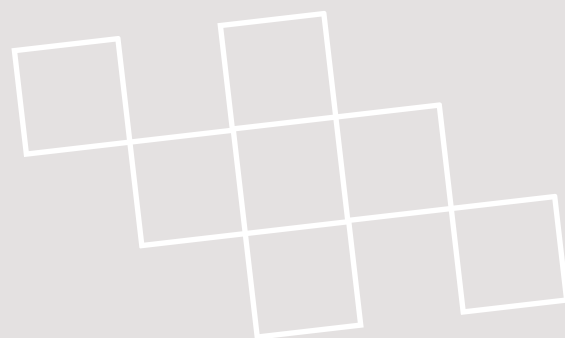
# NAVIGATE SMOOTHLY THROUGH SAHPRA LICENSING



Obtaining or renewing your SAHPRA license is crucial for operating successfully in South Africa's healthcare industry.

One critical document in this process is the Site Master File (SMF). It acts as a comprehensive roadmap, showcasing your facility's compliance with Good Manufacturing Practices (GMP) and quality standards.

But why is it necessary, and how can you navigate its development smoothly?



# WHY DO YOU NEED A SITE MASTER FILE?

- 01 Demonstrate Compliance:** Show SAHPRA inspectors your commitment to quality and adhere to regulatory requirements outlined in SAHPRA guidelines.
- 02 Expedite Licensing Process:** Provide essential information upfront, potentially streamlining your application or renewal process.
- 03 Reduce Audit Risk:** A well-organized SMF facilitates smoother audits by presenting key information readily available.
- 04 Ensure Business Continuity:** Maintain crucial documentation organized and accessible for internal reference and future audits.
- 05 Boost Confidence:** Showcase your professionalism and dedication to quality, potentially enhancing investor and stakeholder trust.



# CRAFTING YOUR SITE MASTER FILE: A COLLABORATIVE JOURNEY

## 01

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### SCOPE DEFINITION

Identify the specific site(s) and activities covered by the SMF based on your license application or renewal needs.

## 02

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### INFORMATION GATHERING

Compile relevant documents, SOPs, quality records, and facility details as stipulated in SAHPRA guidelines.

## 03

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### CONTENT CREATION

Organize information into clear sections addressing quality systems, production processes, personnel qualifications, and facility management.

## 04

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### QUALITY REVIEW

Ensure accuracy, completeness, and compliance with regulatory requirements through internal review and expert guidance.

## 05

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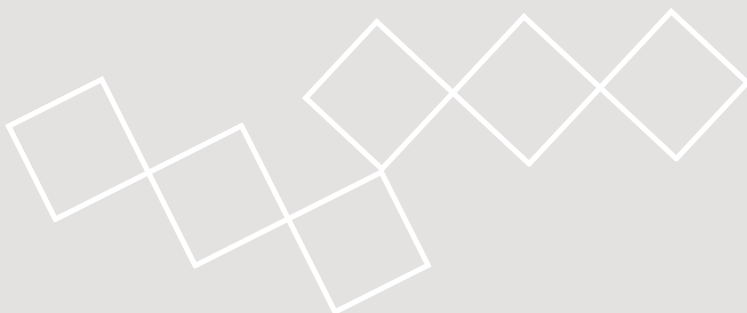
### VERSION CONTROL

Establish a system for updating and maintaining your SMF to reflect any changes or improvements.

# YOUR INPUTS



- Existing Documentation: Leverage existing quality manuals, procedures, records, and facility information.
- Personnel Expertise: Involve personnel from various departments familiar with production, quality control, and facility management.
- Internal Quality Audits: Utilize findings from recent audits to identify areas for improvement reflected in your SMF.



# THE OUTPUT

## Comprehensive Site Master File

A well-organized document meeting all SAHPRA requirements and showcasing your quality management system.

## Increased Confidence:

Peace of mind knowing your application or renewal is supported by robust documentation.

## Streamlined Audit Process

Facilitates smoother interactions with SAHPRA inspectors during potential audits.

## Sustainable Compliance

Establishes a foundation for ongoing compliance and continuous improvement within your facility.

# READY TO NAVIGATE WITH CONFIDENCE?


Developing a compliant and comprehensive Site Master File requires expertise and attention to detail. Partner with us to streamline the process, ensuring your file meets all SAHPRA requirements and contributes to a successful licensing outcome

## GET IN TOUCH

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