DISSERTATION TRAINING

at

ANVKA Healthcare Pvt. Ltd.

A Report on

Role Of Standard Operating Procedures in Pharmaceutical Quality System and GMP Compliance: A Scoping Review

by

DR. PRIYA SINGH

PG/24/082

UNDER THE GUIDANCE OF - DR. VINAY TRIPATHI

PGDM (Hospital & Health Management)

2024-26



International Institute of Health Management Research
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New Delhi

Completion of dissertation certificate

The certificate is awarded to

Name: Dr Priya Singh

In recognition of having successfully completed her Internship in the department of

Department: Business Development (Pharma)

and has successfully completed her Project on

"Role of Standard Operating Procedures in Pharmaceutical Quality System and GMP Compliance: A Scoping Review"

Date: 10th May 2026

Organization: ANVKA Healthcare

She comes across as a committed, sincere & diligent person who has a strong drive & zeal for learning.

We wish him/her all the best for future endeavors.

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I wish her all success in all her future endeavors.

Dr. Punit Yadav
Academic and Student Affairs
IIHMR, New Delhi

Mentor
IIHMR, New Delhi

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Dissertation Examination Committee for evaluation of dissertation.

Name	Signature
Dr Sumesh Kumar.	
Dr Parveen Kumar.	

Certificate from Dissertation Advisory Committee

This is to certify that **Dr. Priya Singh**, a graduate student of the PGDM (Hospital & Health Management) has worked under our guidance and supervision. She is submitting this dissertation titled **"Role of Standard Operating Procedures in Pharmaceutical Quality System and GMP Compliance: A Scoping Review"** at **"ANVKA HEALTHCARE"** in partial fulfillment of the requirements for the award of the PGDM (Hospital & Health Management).

This dissertation has the requisite standard and to the best of our knowledge no part of it has been reproduced from any other dissertation, monograph, report or book.

Dr Vinay Tripathi,
Associate Professor,

IIHMR Delhi

Dr D Birdi

ANVKA Healthcare

INTERNATIONAL INSTITUTE OF HEALTH MANAGEMENT RESEARCH, NEW DELHI

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This is to certify that the dissertation titled **"Role of Standard Operating Procedures in Pharmaceutical Quality System and GMP Compliance: A Scoping Review**

and submitted by **Dr. Priya Singh.** Enrollment No. **PG/24 /082** under the supervision of **Dr. Vinay Tripathi** for award of PGDM (Hospital & Health Management) of the Institute carried out during the period from **March 2026** to **May 2026** embodies my original work and has not formed the basis for the award of any degree, diploma associate ship, fellowship, titles in this or any other Institute or other similar institution of higher learning.



Signature

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Name of the Student: Dr Priya Singh.

Name of the Organisation in Which Dissertation Has Been Completed: ANUKA Healthcare

Area of Dissertation: Business Development (Pharma)

Attendance: Full

Objectives achieved: • Gained practical exposure.
• Understood the Healthcare & Pharmaceutical industry.

Deliverables: Market Research & Competitor Analysis
Product Documentation.

Strengths: Analytical thinking, Quick Learner, effective communication.

Suggestions for Improvement: more practical exposure.
Regular feedback sessions.

Suggestions for Institute :
(course curriculum, industry interaction, placement, alumni)

- more industry interactions.
- practical training.
- Certificate programmes.

Dr. D. Bisht.

Signature of the Officer-in-Charge/ Organisation
Mentor (Dissertation)

Date: 28/7/26

Place: Gurugram.

IIHMR DELHI

INTERNATIONAL INSTITUTE OF HEALTH MANAGEMENT RESEARCH (IIHMR)

Plot No. 3, Sector 18A, Phase- II, Dwarka, New Delhi- 110075
Ph. +91-11-30418900, www.iihmrdelhi.edu.in

CERTIFICATE ON PLAGIARISM CHECK

Name of Student (in block letter)	~~Dr./~~Mr./Ms.: Puriya Singh.		
Enrollment/Roll No.	PG/24/08L	**Batch Year**	2024-26
Course Specialization (Choose one)	Hospital Management	Health Management	~~Healthcare~~ IT
Name of Guide/Supervisor	Dr./ Prof.: Dr Vinay Tripathi		
Title of the Dissertation/Summer Assignment	Role of Standard Operating Procedures in Pharmaceutical Quality System & GMP Compliance: A Scoping Review		
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Guide/Supervisor
Name: Dr Vinay Tripathi
Signature:

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Name: Dr Puriya Singh.
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ANVKA Healthcare Private Limited (founded in 2021) is a Gurugram-based healthcare network that operates an ecosystem of peripheral medical services. Its key brands include **Lintex** (medical textiles), **Care(TAB)** (in-home care), **IndiaMD** (medical travel), and **Curewith3D** (3D-printed orthopedicsolutions).

The company is led by directors Aashish Chaudhry and Pritam Bokadia. Operating out of Udyog Vihar Phase IV, their overarching goal is to make healthcare more accessible, holistic, and efficient beyond traditional hospital walls.

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ABSTRACT

Standard Operating Procedures (SOPs) are important aspects of pharmaceutical companies for ensuring compliance to Pharmaceutical Quality Systems (PQS) and Good Manufacturing Practice (GMP). SOP systems provide a set of standardized written procedures for ensuring the uniformity of operations, controlling documentation, ensuring traceability and quality, and meeting regulatory requirements. The concept of the importance of SOP and controlled documentation is supported by several international regulatory organizations, including WHO, FDA, EU GMP, ICH, EMA, PIC/S and the CDSCO.
The purpose of this study, "Role of Standard Operating Procedures in Pharmaceutical Quality Systems and GMP Compliance: A Scoping Review", was to investigate the importance of the SOP system in ensuring pharmaceutical quality management and GMP compliance using a PRISMA-ScR guided scoping review.

Secondary data for the scoping review were sourced from the following: WHO guidelines FDA guidance documents EU GMP requirements ICH quality frameworks EMA guidance PIC/ S recommendations CDSCO Schedule M Google Scholar PubMed and literature on pharmaceutical quality assurance.

The scoping review was guided by the framework of Arksey and O'Malley, as outlined by Levac et al. and based on the PRISMA-ScR guidelines.
The study found that SOP systems are essential for:
GMP compliance, documentation control, standardization of processes, validation processes, personnel training, inspection readiness and data integrity control.

CHAPTER 1: INTRODUCTION

1.1 Overview Of Pharmaceutical Industry

Pharmaceutical industry is a pillar of the healthcare industry as it plays the most important role in developing medicine. It plays a vital role in improving the well-being and quality of patients. The healthcare industry can prevent, treat and manage various diseases with safe and effective high-quality products.

Over the last few decades the pharmaceutical industry has grown and developed due to the growth in technology and science, also due to the increasing needs for healthcare and the prevalence of new diseases. This has contributed to the pharmaceutical industry becoming globalized pharma manufacturing and more complex operations, supply chains and products. To keep up with this, standards are being tightened up by regulatory authorities so that pharmaceutical products get produced to a consistent and acceptable standard.

The impact of quality failures in the pharmaceutical industry on patient safety is huge leading to product recalls and regulatory action. This leads to large financial fallout for companies and loss of trust. Therefore, quality management systems play a vital role for pharmaceutical companies to keep up with regulatory obligations and maintain trust.

1.2 GOOD MANUFACTURING PRACTICES (GMP)

Good manufacturing practices (GMP) are the internationally accepted quality standard for the manufacturing of pharmaceuticals, and help the regulatory authorities to ensure that the pharmaceuticals are validated as safe and as the quality to which they intend to be.

The WHO states that GMP is an element of quality assurance and that it controls and ensures that products are manufactured within an established quality standard.

The objectives of GMP are to:

Ensure the quality and safety of products, reduce the risk to the consumer, prevent product and process deviations, reduce the risk of contamination, ensure that records are permanent, and ensure continuity of operations.

GMP is a general term and contains other standards such as:

Employees, workspaces and tools, documentation of quality, quality assurance and quality control, validation, self-auditing, and complaints.
An important pillar of GMP is Quality Documentation.

1.3 Pharmaceutical Quality System(Pqs)

Pharmaceutical Quality Systems (PQS) are integrated management systems used by pharmaceutical organizations to consistently achieve quality objectives and meet regulatory expectations. ICH Q10 describes Pharmaceutical Quality Systems as organized quality systems designed to enable optimization and lifecycle management of pharmaceutical products. PQS comprise various quality features, including:
Standard Operating Procedure (SOP) systems, documentation controls, change control, Corrective and Preventive Action (CAPA) controls, validation controls, quality risk management, and training controls.
SOP systems support the Pharmaceutical Quality System by defining roles and responsibilities, enforcing standard operating procedures, monitoring traceability, and ensuring quality documentation.
An effective Pharmaceutical Quality System supports improvement in: Operational performance, inspection readiness, quality assurance, and patient safety.
Modern pharmaceutical organizations are expanding their Pharmaceutical Quality System with a focus on digital technologies, including:

Electronic Document Management System (EDMS),

Electronic Quality Management System (eQMS),

DigitalSOPsolutions

1.4 Standard Operating Procedures(Sop)

Standard operating procedures are procedures which have to be followed to perform a task in a particular way, as a result of external compliance requirements.
Standard operating procedures are developed for employees, and as such, ensure that regardless of who is working and what is happening at work, important tasks will be done in the same way.
SOP's for pharmaceutical companies can be found in the following areas:
Operation, equipment usage, cleaning, testing and quality control, sanitation, validation,

documentation, Documentation, warehousing, deviation management, change control, training, and documentation.

SOP's are performed for the following reasons:

The process is standardized, reduction in human error, external compliance requirements are met, tasks are performed better by employees, documents are improved, and quality assurance is improved.

SOP's are a process that ensures consistency within a process and during inspections.

1.5NeedforStudy

However, there have been some deficiencies reported by the regulators in the area of documentation systems, implementation of SOPs, and data integrity despite the presence of such stringent requirements for the pharmaceutical industries.Due to the complex nature of regulations and digital quality system within the pharmaceutical industry, it is vital to conduct a detailed study on the efficacy of SOPs within Pharmaceutical Quality System.

Also, with the advent of electronic SOP system and digital quality, there is a need for better comprehension of the following areas:

Document control, data integrity, audit readiness, and digital compliance systems.

As a result, this study is undertaken to evaluate the role of SOPs in Pharmaceutical Quality System and GMPs through scoping review methodology.

1.6 AIM & OBJECTIVE

Aim: To evaluate the role of Standard Operating Procedures in Pharmaceutical Quality System and GMP Compliance: A Scoping Review

Objective:

- To understand the importance of SOPs in pharmaceutical industries.
- To evaluate SOP contribution toward GMP compliance.
- To compare international regulatory expectations.
- To identify SOP implementation challenges.
- To evaluate SOPs in inspection readiness.

CHAPTER 2: LITERATURE REVIEW

2.1INRODUCTION

The pharmaceutical industry is one of the most highly regulated industries worldwide as pharmaceutical products have a direct impact on patient safety and public health. Pharmaceutical manufacturers have the responsibility to produce and control the medicines consistent with pre-defined quality specifications. Pharmaceutical companies have to use Good Manufacturing Practices (GMP), Pharmaceutical Quality Systems (PQS), validation Programmes, quality risk management systems, documentation systems and Standard Operating Procedures (SOPs).Standard Operating Procedures (SOPs) are written approved instructions for completing routine and critical activities in a standardized and controlled manner. They are a critical element in any pharmaceutical quality system and considered as a best practice by major international regulatory agencies such as World Health Organization (WHO), United States Food and Drug Administration (USFDA), European Medicines Agency (EMA), Pharmaceutical Inspection Co-operation Scheme (PIC/S), International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH), European Union Good Manufacturing Practice (EU GMP) and Central Drugs StandardControlOrganization(CDSCO)(1-8).

2.2 CONCEPT AND DEFINITION OF STANDARD OPERATING PROCEDURES

These three cancers are grouped together in Indian health policy. Since 2010 the National Standard operating procedures (SOPs) are the one authorized procedure written that provide step-by-step instructions to perform operations correctly and consistently. SOPs are described as: "Authorized written procedures (including procedures not necessarily product or material specific) that provide instructions for the performance of consistent and correct operations." (1)

SOPs are the operational control instruments that guarantee to: Standardization of pharmaceutical activities, continuity of operations, avoiding human errors, traceability of the documentation, regulatory compliance, training and competency of employees, and quality assurance. The typical contents of the SOP are: Objective, scope, responsibility, accountability, procedure, annexures, enclosures,

references, SOP distribution list, abbreviations, and SOP revision history. SOPusedindifferentDepartmentare:

Quality Assurance Department, Quality Control Department, Warehouse Department, Regulatory Affairs, Engineering Department, Information Technology Department, Human Resource Department, Art Work Department, Purchase/Commercial, Production Planning and Inventory Control, Sales Marketing Export, Sales Marketing Domestic, Sales Marketing Hospital, and Sales Business Development.

2.3 EVOLUTION OF SOP IN PHARMACEUTICAL INDUSTRY

The evolution of pharmaceutical quality systems is tightly associated with the evolution of the concept of GMP. The early days of pharmaceutical production were largely based on manual work and personal experience and were accompanied by limited documentation. However, due to ever increasing concerns about contamination, product quality and product variation, and ultimately patient safety, an increasing need for regulations and documentation controlled processes has emerged.In the former WHO GMP guidelines, the importance of written procedures was emphasised, together with documentation controls, validation systems, personnel training systems and readiness for inspections (1). The US FDA was involved in formative changes of the cGMP regulations that also discussed on expectations for written procedures, documentation accuracy, validation and an inspection-ready state of the production (3).

The PIC/S development was a major move towards international harmonization of GMP inspection systems and the creation of local inspection systems and quality systems (9). The newer ICH guidelines have expanded the use of SOPs in pharmaceutical industry and emphasised the importance of new quality systems, like the Pharmaceutical Quality Systems, Quality Risk Management, CAPA systems and quality by design concepts (6, 30).The modern pharmaceutical industries are adopting following systems:

Electronic Document Management Systems (EDMS), Electronic Quality Management Systems (eQMS), electronic batch records, electronic signatures, and automatic training systems.

Table 2.1 Evolution of SOPs in Pharmaceutical Industry

ERA/PERIOD	MAJOR DEVELOPMENT	IMPACT ON SYSTEM
Early Manufacturing Era	Manual Operations with limited documentation	Minimal Standardization
Introduction of GMP	Written Procedures Introduced	SOPs became Introduced
Expansion of USFDA cGMP	Increased Documentation Control	SOP Compliance Strenthened
WHO and PIC/S Harmonization	Global GMP Expectations Increased	SOPs Standardized Internationally
ICH Quality Guidelines	PQS and QRM Concepts Introduced	SOPs Integrated in to Quality System
Digital Quality Era	Electronic Documentation System Introduced	Electronic SOP System Implemented

2.4 SOPS AND PHARMACEUTICAL QUALITY SYSTEMS

A Pharmaceutical Quality System is a systematic plan to implement for ensuring that pharmaceutical products consistently meet specified quality standards during their complete lifecycle. ICH Q10 defines several key elements within a Pharmaceutical Quality System, such as process performance monitoring, CAPA systems, change management, management review, and continuous improvement (6).

SOPs serve as the operational base of Pharmaceutical Quality Systems by: Specifying operational responsibilities, internal and external standardization of procedures, supporting documentation systems, providing quality controls, and providing traceability and accountability. According to the WHO guidelines, quality assurance systems must be fully documented and monitored routinely (1).SOPs therefore transform quality policies and regulatory requirements into operational activities in order to implement them. Companies with well-developed SOP systems tend to achieve the following:
The findings indicated that SOP systems improve GMP compliance, reduce deviations, enhance inspection readiness, and establish robust documentation systems, thereby strengthening overall quality assurance and regulatory compliance.

2.5 Sops and Gmp Compliance

GMP (Good Manufacturing Practices) was introduced to enforce that pharmaceutical products are always manufactured and controlled under conditions that ensure product quality and suitability for use.
GMP systems include:
The review identified that effective SOP systems are supported by written procedures, controlled documentation, qualified personnel, validated processes, calibrated equipment, and comprehensive quality oversight systems, ensuring consistent GMP compliance and product quality.SOPs are an important element of GMP because they ensure that activities are carried out in accordance with established procedures. SOPs also ensure:
Decreased operational variability

- Control of contaminations
- Prevention of cross-contamination

- Control of mix-ups
- Accuracy of documentation
- Prevention of process deviations

2.6 Regulatory Perspectives On Sops

2.6.1 WHO Perspective

GMP is a vital component of the overall pharmaceutical quality assurance system, according to WHO. In this regard,
The WHO points out that it is necessary to:

- Written procedures
- Documentation systems
- Personnel training
- Validation systems
- Complaint handling
- Product recall systems
- Self-inspections (1)

Moreover, it is required that quality assurance is sensitive to capture and documented, and continuously monitored. SOPs are therefore vital in the implementation of the WHO GMP system.

2.6.2 Eu Gmp Perspective

EU GMP Chapter 4 lists documentation as an integral part of Pharmaceutical Quality Systems. Documentation can be paper-based or electronic and must achieve the following requirements:
The findings indicated that effective SOP systems emphasize clarity, accuracy, inspection readiness, revision control, and traceability to ensure consistent documentation, regulatory compliance, and operational efficiency.
EU GMP mandates SOPs for:
The review found that SOP systems standardize critical pharmaceutical operations, including testing, validation, cleaning, maintenance, complaint handling, and manufacturing, thereby ensuring process consistency, product quality, and regulatory compliance.

2.6.3 USFDA Perspective:

USFDA guidance focuses on SOP development, issuance, maintenance, accessibility and revision. SOPs are viewed as important internal operational document supporting consistency and compliance (3).

FDA inspections often review:

- Data integrity
- Documentation practices
- Training systems
- Laboratory controls
- SOP adequacy

2.6.4 ICH Perspective:

ICH Q7 Emphasizes:

The review found that SOP systems strengthen quality management by clearly defining quality unit responsibilities, supporting quality management systems, maintaining effective documentation systems, ensuring validated processes, facilitating internal audits, implementing change control procedures, and conducting product quality reviews.

SOPs provide this basis for GMP implementation in a homogeneous manner.

2.6.5 EMA Perspective:

EMA guidance points out:

The review found that modern SOP systems support risk-based inspections, electronic documentation systems, remote inspections, CAPA audits, and digital quality systems, thereby enhancing regulatory compliance, inspection readiness, and operational efficiency.

EMA guidance underlines the increasing importance of having an electronically controlled SOP system.

2.6.6 PIC/S Perspective:

PIC/S promotes Harmonized GMP Inspection system and Requires:

The review found that SOP systems establish standardized inspection procedures, quality manuals, training systems, self-assessment procedures, and audit systems, thereby promoting regulatory compliance, operational consistency, and continuous quality improvement.

SOPs therefore support both pharmaceutical operations and regulatory inspection consistency.

2.6.7 CDSCO Perspective:

CDSCO Schedule M provides GMP compliance criteria for manufacturing facilities in India, including:

The review found that SOP systems support standardized procedures and documentation, ensure the adequate capacity of premises and equipment, strengthen quality systems, facilitate process validation, and enhance inspection readiness, thereby promoting GMP compliance and operational excellence.

GDP guidelines from CDSCO emphasize SOP procedures for:

- Safety in distribution
- Safety in storage
- Safety in transport
- Controlled temperatures

Table:2.2 Comparative Regulatory Perspectives on SOP Systems in Pharmaceutical Industry

Regulatory Authority	Key Guideline / Regulation	Major SOP-Related Requirements	Primary Focus Area	Impact on Pharmaceutical Operations
World Health Organization	WHO GMP Guidelines	Written procedures, validation, documentation control, personnel training, self-inspections, complaint handling	GMP compliance and quality assurance	Ensures standardized manufacturing practices and global quality consistency

European Commission	EudraLex Volume 4 – EU GMP	Controlled documentation systems, revision control, traceability, record retention, electronic documentation	Documentati on integrity and traceability	Improves regulatory compliance, accountability, and document lifecycle management
USFDA	cGMP Regulations and FDA Guidance	SOP Preparation , approval, Implementation, Periodic Review, Data Integrity controls , Employee Training	SOP Governance and Data Inegrity	Minimizes Compliance risks , Inspections, Observations, and Operational Errors
International Council for Harmonisation	ICH Q7 and ICH Q10	Pharmaceutical Quality System (PQS), CAPA, Change Manage-ment, Risk Management Lifecycle	Integrated Quality System and Continuous Improvement	Enhance Process Consistency, Quality culture and Risk based Decision making
European Medicines Agency	EMA GMP/GDP Guidance	Electronic quality systems, distant assessments, audit preparedness, computerized documentation	Digital quality systems and inspections	Supports electronic SOP management and inspection readiness

		systems		
Pharmaceutical Inspection Cooperation Scheme	PIC/S GMP Inspection Standards	Inspection procedures, internal audits, self-assessment systems, harmonized GMP practices	Inspection harmonizatio n and audit systems	Facilitates global regulatory alignment and consistent inspection standards
Central Drugs Standard Control Organization	Schedule M and GDP Guidelines	SOP-controlled manufacturing, storage, distribution, validation, quality assurance, temperature monitoring	Schedule M and GDP compliance	Strengthens pharmaceutical manufacturing and distribution quality in India

Key findings:

- Standard Operating Procedures" are considered as major requirement of all sanctioning authorities for compliance with GMP
- The importance of documentations, training and validation is strongly stressed by WHO, USFDA, and CDSCO
- The emphasis of ICH and EMA is mainly in the area of quality cycle and digital quality systems
- Harmonization of the GMP inspection process is the main focus of PIC/S
- European GMP highlights the importance of documentations traceability.

2.7 Challenges in SOP Implementation:

Getting SOPs (Standard Operating Procedures) up and running smoothly isn't always easy, there are a bunch of:

Challenge	Impact
Poor SOP Structure	Employee Confusion
Inadequate Training	SOP Non-Compliance
Outdated SOPs	Use of Obsolete Procedures
Excessive Documentation	Reduced Usability
Weak CAPA System	Repeated Deviations

2.8 ResearchGap:

There has been a vast availability of information on GMP Systems and pharmaceutical quality management. However, very few studies have focused on examining the use of SOP systems as a standalone tool for quality management. To our best knowledge, no study has yet been conducted in order to explore what WHO, EU GMP, USFDA, ICH, EMA, PIC/S, and CDSCO think about it.

CHAPTER 3: METHODOLOGY

3.1 Research Design:

The present study followed a Qualitative Scoping Review Research Design.The scoping review method was used because the study sought to:

Map the existing literature, identify key concepts, compare regulatory requirements, assess evidence about SOP systems, and identify research gaps about pharmaceutical quality systems and GMPs.

Study methodology was guided by the scoping review design as presented in the works of: Arksey & O'Malley (2005) and expanded upon by: Levacetal.(2010)

Reporting on the study was done in accordance with PRISMA-ScR(Preferred Reporting Items for Systematic Reviews and Scoping Reviews) Guidelines to maintain:

Clarity, methodological rigour, systematic review of the literature, and structured presentation of results.

3.2 Research Framework:

The followed the five -stage scoping Review framework proposed by Arksey & O'Malley. These Stage include:

STAGE 1: Identification of Research Question

STAGE 2: Identification of relevant studies and Regulatory Documents

STAGE 3: Selection and Screening of Literature

STAGE 4: Data Extraction and Charting of Information

STAGE 5: Collation, summarization and reporting of findings

3.3 Research Question:

The present study was guided by the following Research question:

"What is the role of SOP in Pharmaceutical Quality System and GMP Compliance within Pharmaceutical industries?

3.4 Data Sources:

The major Data Sources include the Regulatory guide lines:

The review identified that SOP requirements are guided by major international and national regulatory frameworks, including the FDA Guidance for Industry, EU GMP Guidelines, ICH Quality Guidelines, EMA Guidance Documents, PIC/S Guidelines, CDSCO Schedule M Requirements, and WHO GMP Guidelines.

3.5 Inclusion Criteria:

Studied works regarding SOPs for pharmaceutical industries.

Literature on GMP and Pharmaceutical Quality Systems.

WHO guidelines, FDA regulations, EU GMP, ICH, EMA, PIC/S, and CDSCO guidelines.

3.6 Exclusion Criteria:

- Literature not linked to the pharmaceutical industry.
- Non-GMP relevant literature
- Irrelevant or non-academic literature
- Duplicate entries
- Full-text access restricted articles
- Articles in languages other than English
- Literature not associated with SOP systems or pharmaceuticals quality management

3.7 Study Selection Process:

The Literature selection process was performed according to PRISM-ScR Guidelines.

The study selection process included:

Identification of records, Removal of Duplicate studies, Title and abstract screening, Full text assessment and Final inclusion of Relevant studies and Regulatory Documents.

3.8 Data Extraction Process:

Data were then extracted and organized according to the following parameters from selected studies and regulations.

Extracted data included:

Author and year of publication, Country or regulatory body, Study focus, SOP-related topics, Quality system elements, Results related to GMP compliance, Documentation practices, Validation practices, and Key conclusions.

3.9 Data Analysis Plan:

Thematic Analysis

Comparative Regulatory Analysis

Evidence Mapping

CHAPTER 4: RESULTS

4.1 Prisma-Scr Literature Identification & Screening Analysis:

The present study followed the PRISMA-ScR framework for: Identification, screening, eligibility assessment, and final inclusion of literature. The Literature search identified studies and guidelines related to: SOP system, GMP compliance, pharmaceutical quality system, documentation system, regulatory expectation, validation system, data integrity, and quality assurance system.

Table 4.1 Study Selection Summary

Selection Stage	Number of Records
Records identified through data bases & uploaded References	**78**
Additional records identified through reference screening	**15**
Total records identified	**93**
Duplicate records removed	**14**
Records screened	**79**
Records Excluded	**39**
Final guidelines included	**26**

Interpretation Of PRISMA-ScR findings:

Systematic reduction of Literature through: Relevance Screening, Duplicate removal, Eligibility assessment and Full text Evaluation.

The final selected Literature finally consisted of:

WHO GMP Guidelines, FDA Guidance Documents, EU GMP Guidelines, ICH Quality Guidelines, EMA Guidance, PIC/S Inspection Documents, CDSCO Schedule M Guidelines, and the broader body of pharmaceutical quality assurance literature.

Table 4.2 Types of Literature Included in The Review

Types Of Literature	Numbers Included
Regulatory Guidelines	**12**
GMP Manuals	**02**
Pharmaceuticals QA References	**01**

Interpretation

The findings demonstrated that the majority of evidence related to SOP systems originates from International Regulatory framework.

This indicates that SOP implementation within Pharmaceutical industries is strongly driven by:

Regulatory expectations, GMP requirements, documentation systems, and inspection compliance standards.

4.2 Thematic Analysis of Sop System in Pharmaceutical Quality Management:

Thematic Analysis identified the following major themes:

The review is organized into eight key themes: SOPs and GMP compliance, SOPs and Pharmaceutical Quality Systems (PQS), SOPs and documentation systems, SOPs and validation processes, SOPs and personnel training, SOPs and data integrity, electronic SOP systems, and challenges in SOP implementation.

Table 4.3 Major Themes Identified in Reviewed Literature

Themes	Frequency Identified in Literature
Documentation System	**26**
GMP Compliance	**24**
Quality Assurance	**22**
Personnel Training	**20**
Inspection Readiness	**19**
Validation System	**18**

Data Integrity	**17**
CAPA System	**15**

Interpretation Of Thematic Findigs:

Documentation and GMP Compliance emerged as the most frequently emphasized theme across Review Literature and Regulatory Framework.

The analysis also showed that SOP system are closely integrated with:

The Pharmaceutical Quality System (PQS) encompasses key elements such as validation systems, Corrective and Preventive Action (CAPA) systems, and data integrity frameworks to ensure consistent product quality, regulatory compliance, and continuous improvement.

Table 4.4 Role of Sops in Gmp Compliance

GMP Area	Contributions of SOPs
Manufacturing Operations	Standardization of production process
Quality Control	Consistent sampling & testing
Validation Practices	Uniform validation procedure
Documentation System	Improved traceability
Personnel Training	Enhance employee competency
Audit & Inspections	Improved inspection readiness
CAPA System	Better deviation management
Recall System	Faster traceability & product recall

Interpretation:

The findings demonstrated that SOP system serve as operational framework for implementing GMP requirements.

SOP system improves consistency and reduce Variability in Pharmaceutical Operations.

TABLE 4.5 Contribution of Sops in Documentation System

Documentation Function	SOP Contribution
Record Management	Improved Traceability
Revision Control	Prevention of Obsolete SOP usage
Audit Trails	Improved Accountability
Documentation Consistency	Reduced Operational Variability
Data Integrity	Better Compliance & Traceability

Interpretation

The findings demonstrated that Documentation System Represent one of the strongest functional areas supported by SOP Implementation.

TABLE 4.6 Impact of Sop Training on Gmp Compliance

Training Outcome	Observed Impact
Better SOP Understanding	Improved Compliance
Reduce Human Error	Lower Deviations
Increase Employ Competency	Better Operational Consistency
Improved Documentation Practices	Better Audit Readiness

Interpretation

The findings demonstrated that SOP effectiveness depends significantly on personnel competency and Organizational Training Systems.

Sop and Pharmaceutical Quality System

ICH Q10 AND WHO GMP guidance emphasized that PQS should include:

The findings showed that SOP systems support the Pharmaceutical Quality System (PQS) by establishing a robust documentation system, facilitating change management,

strengthening Corrective and Preventive Action (CAPA) systems, supporting validation systems, integrating quality risk management, promoting continuous improvement, defining clear roles and responsibilities, standardizing operational activities, enhancing documentation and traceability, and improving accountability and regulatory compliance.

Interpretation:

The findings demonstrated that SOP systems are not merely documentation tools but operational Quality Management System that supports:

The findings indicated that SOP systems enhance process control, reduce operational and quality-related risks, ensure traceability throughout manufacturing and documentation processes, and facilitate effective implementation of Good Manufacturing Practices (GMP).

Sop and Data Integrity

Data integrity emerged as a Major theme in Modern Pharmaceutical Quality System.

The findings demonstrated that SOP systems support:

The findings showed that SOP systems support data integrity by ensuring controlled documentation, maintaining audit trails, implementing electronic signatures, establishing data review procedures, and strengthening traceability systems.

Interpretation

The findings demonstrated that the SOP system function as Important Data Governance Tools within Pharmaceutical Industries.

Table 4.8 Major Challenges associated with Sop Implementation

Challenge	Observed Impact
Poor SOP Structure	Employee Confusion
Inadequate Training	SOP Non-Compliance
Weak Revision Control	Use of Outdated Procedures
Excessive Documentation	Reduced Usability
Weak Quality Culture	Reduced SOP Effectiveness

Interpretation

Inadequate Training emerged as one of the most significant barriers affecting SOP effectiveness.

4.3 Comparative Regulatory Analysis

The comparative Review demonstrated strong Harmonization among International Regulatory Authority regarding SOP expectation.

TABLE 4.9 Comparative Regulatory Focus Areas

Regulatory Authority	Major SOP Focus
WHO	GMP & Quality Assurance
FDA	cGMP & Documentation Control
EU-GMP	Documentation & Traceability
ICH	PQS
EMA	Electronic System and Inspection
PIC/S	Inspection Harmonization
CDSCO	Schedule M& GDP Compliance

Interpretation

The findings demonstrated strong Global Harmonization regarding SOP Implementation & pharmaceutical Quality System.

CHAPTER 5: DISCUSSION

5.1 Sop System and Gmp Compliance:

The findings suggest that effective SOP systems underpin standardized pharmaceutical operations, reducing human error and operational variability. This standardization improves documentation accuracy, which in turn strengthens GMP compliance by ensuring activities are recorded and executed according to regulatory expectations. As compliance improves, regulatory deviations decrease, leading to better inspection readiness and stronger organizational preparedness for audits. Collectively, this progression demonstrates how effective SOP systems reinforce the Pharmaceutical Quality System (PQS), linking documentation practices, compliance outcomes, and overall quality performance. These findings support existing literature suggesting that SOP systems function not merely as administrative tools but as strategic drivers of regulatory compliance and continuous quality improvement in the pharmaceutical industry.

5.2 Sop System and Documentation Control

The findings indicate that controlled SOP documents form the basis of standardized record management, ensuring that documentation practices remain consistent across pharmaceutical operations. This standardization enhances traceability and accountability, as controlled documents allow organizations to clearly track who performed, reviewed, and approved specific activities. Improved traceability, supported by systematic revision control, contributes to more accurate and reliable documentation, since outdated or unauthorized versions are prevented from circulating within the system. As document accuracy and reliability improve, organizations experience greater regulatory transparency, allowing authorities to verify compliance with confidence during audits and inspections. This progression ultimately strengthens data integrity compliance, reinforcing the principle that reliable records are essential to demonstrating consistent quality and regulatory adherence. These findings align with existing literature emphasizing that controlled document systems are central not only to administrative efficiency but also to sustaining data integrity and regulatory trust within pharmaceutical quality systems.

5.3 Overall Study Findings

The findings suggest that a strong SOP system serves as a critical foundation for an effective Pharmaceutical Quality System (PQS), enabling organizations to maintain consistent and controlled operations. This effectiveness translates into improved GMP compliance, as well-structured SOPs guide personnel in performing activities in accordance with regulatory standards. Improved compliance is further supported by enhanced documentation control, which ensures that records are accurately maintained, updated, and readily available for review. This, in turn, strengthens validation and traceability processes, as controlled documentation provides a reliable basis for verifying that systems and processes consistently perform as intended. Stronger validation and traceability contribute to improved data integrity, ensuring that information generated throughout pharmaceutical operations remains accurate, complete, and trustworthy. Ultimately, this progression demonstrates that robust SOP systems, through their influence on compliance, documentation, and data integrity, play a vital role in enhancing patient safety and product quality. These findings reinforce existing literature suggesting that SOP systems are not isolated administrative tools but integral components that safeguard the overall quality and safety outcomes of pharmaceutical products

CHAPTER6:CONCLUSION

The present study concluded that SOP (Standard Operating Procedure) are the essential component of Pharmaceutical Quality System (PQS) and Good Manufacturing Practice (GMP) Compliance. SOP System plays major role in:Operational consistency, documentation control, process standardization, validation process, and inspection readiness within pharmaceutical industries.
The findings demonstrated that effective SOP Implementation improves: GMP compliance, traceability, data integrity, quality assurance, and patient safety.

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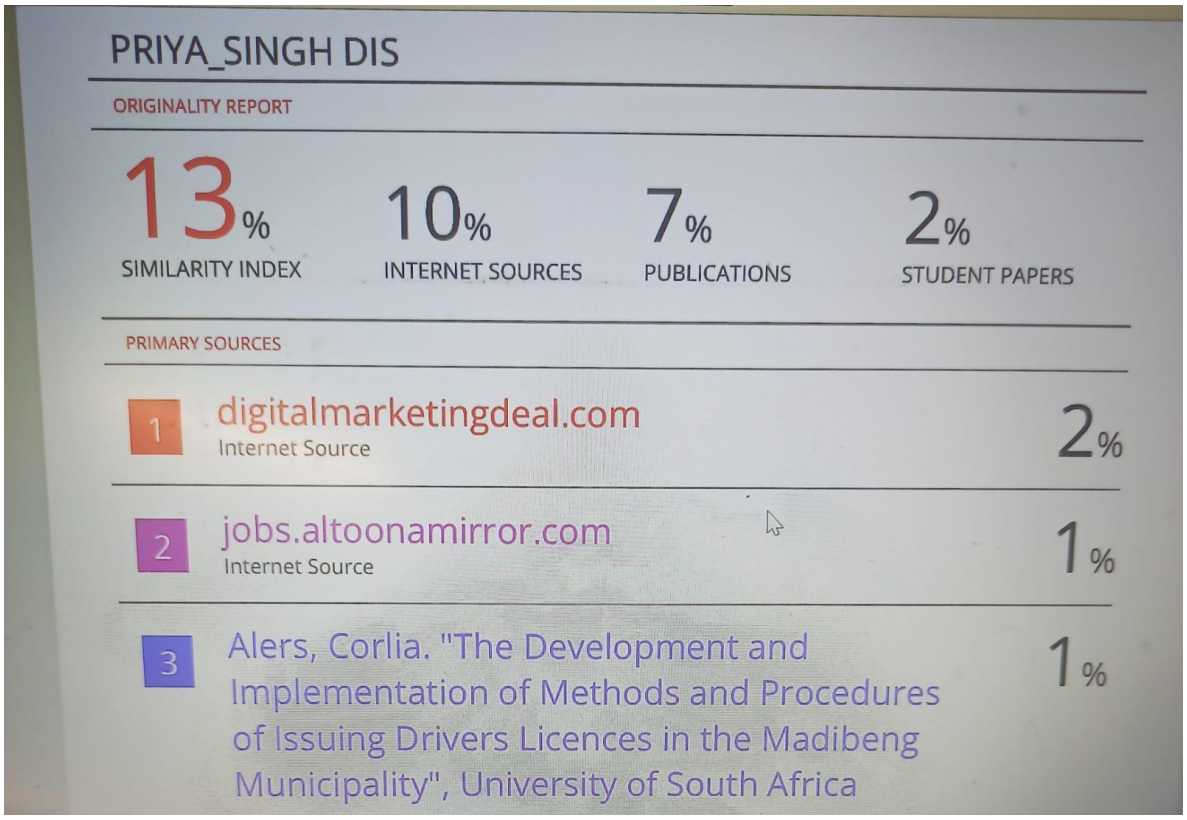
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