Centre for cGMP

Manipal College of Pharmaceutical Sciences

In Association with IDMA and Pharmexcil

MANIPAL ACADEMY of HIGHER EDUCATION
(Institution of Eminence Deemed to be University)

Our Inspiration

Founder : **Dr. T M A Pai,** Padmashree awardee

Centre for cGMP presents to you "cGMP AWARENESS SERIES" (2024/01)

THINK cGMP – cGMP is LIFE

Commitment | Adherence | Creating Quality Culture

3 GOOD HEALTH AND WELL-BEING

SOP

4 QUALITY EDUCATION

Topic : Understanding a Standard Operating Procedure, "SOP"

KNOW SOPs

SOPs are an integral part of the Documentation for Pharmaceutical Quality System.

Adherence to **SOPs** ensures consistency in the pharmaceutical manufacturing operations throughout the product life cycle.

SOPs are written, uniquely numbered, version-controlled and authorised instructions that are strictly controlled and are made available only to authorised users.

Every activity conducted (or) performed in pharmaceutical manufacturing shall be in accordance with written down procedures only i.e. **'SOP'**.

Any departure from the **SOPs** amounts to deviation that must be investigated. Deviations that are not investigated and corrected effectively to prevent occurrence of similar discrepancy can lead to a regulatory action.

SOPs are key source documents for GMP training of all employees that have a direct and indirect influence on the quality of products manufactured.

WRITING A GOOD SOP

Each company needs to have a **SOP** on **SOP** which defines the design and control of documentation system.

Format of SOP

SOPs shall be written in a specifically designed template with a header and a footer to contain predefined information that will appear on each page consistently.

The header shall contain

Title

SOP Number

Effective & Review Date

Page Number

The footer invariably contains a provision for signing by the relevant signatories.

The details such as font type, font style, font size, line spacing etc shall be defined in **SOP** on **SOP**.

MAJOR CONTENTS OF SOP?	DESCRIPTION
Objective	The purpose of the **SOP** shall be explained clearly and briefly here.
Scope	The applicability of the **SOP** to a relevant area, personnel or equipment shall be described.
Responsibility	The designations of the person / persons directly responsible for the operation mentioned in the Objective of the **SOP**.
Accountability	The designation of the person / persons directly responsible for ensuring the compliance of the **SOP**.
Definitions	The technical / legal terms used in the **SOP** shall be defined to clearly state the meaning of the term as used in the **SOP**.
Procedure	The procedure shall be written in simple sentences and shall provide step-by-step instructions. Use of pictures / visuals to explain the instructions shall be encouraged. Where necessary a Flow Chart that describes the key instructions in a sequence shall be provided.
Enclosures	If the **SOP** has an instruction to record any data of the implementation, a suitable Form (Template) shall be designed and attached to the **SOP** as an Enclosure.

AN EXAMPLE OF SOP NUMBERING SYSTEM: PC: QC: SOP: 001/A

PC stands for **P**harma **C**ompany (first two alphabets of company name)

QC stands for department code i.e QC for Quality Control

SOP stands for Standard Operating Procedure

001 stands for SOP number

A stands for revision number, A for first version; likewise, B for second version, etc

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