

Standard operating procedures (SOP) - Back Bone of Pharmaceutical Industries

By Sarvag Kumar Jain - 09/17/2008

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1. What is Sop

In the face of a challenging regulatory environment, some leading **Pharmaceutical** companies have found ways to improve quality and costs significantly. To drive this kind of beneficial change, companies must first create a culture where quality objectives are transparent, well understood, and undoubtedly these goals can be achieved by following certain sets of procedures called as **"Standard Operating Procedures"** (**SOP**). Procedures are essential for any plant's effectiveness and efficiency, and they are regulatory requirement in the Pharmaceutical Industry. A typical Pharmaceutical Industry has an average of 1200- 1300 SOPs. A Parenteral Drug Association (PDA) survey found that a typical pharmaceutical company must manage an average of 1250 CGMP-required SOPs and that the average maintenance burden is 15,000 h per firm.

A Standard Operating Procedure (**SOP**) is a set of written instructions that document a routine or repetitive activity which is followed by employees in an organization. The development and use of **SOPs** are an integral part of a successful quality system. It provides information to perform a job properly, and consistently in order to achieve pre-determined specification and quality end-result.

2. Need Of Sop

SOPs detail the regularly recurring work processes that are to be conducted or followed within an organization. They document the way activities are to be performed to facilitate consistent conformance to technical and quality system requirements and to support data quality. They may describe, for example, fundamental programmatic actions and technical actions such as analytical processes, and processes for maintaining, calibrating, and using equipment. Sops are intended to be specific to the organization or facility whose activities are described and assist that organization to maintain their quality control and quality assurance processes and ensure compliance with governmental regulations.

SOP must contain step by step instructions that employ must refer in daily work to complete various tasks more reliably and consistently. **SOP** makes clear about followings -

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RD Boyd



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