# Chapter XXXII
# A Practical Approach to Computerized System Validation

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## ABSTRACT

*This chapter provides a practical approach to computerized system validation (CSV) for the pharmaceutical organizations for the users dealing with the validation. Validation package including plan, responsibilities, and documentation needed and created during the validation are also discussed. Any computer system can be validated utilizing the techniques described here. These activities address the organization commitment to implement the underlying system in order to improve, ensure and maintain the quality standards. The CSV is described as a reference and an orientation guide to understand the related quality processes. The activities presented here should be useful for initiating and conducting the principal tasks of validation. This chapter reflects a quick guide and addresses one of the "non-technical" aspects of CSV methodology. A clear approach is presented that defines the CSV activities and provides an efficient means of validation to new and existing systems, applications, and environments within the organization.*

## INTRODUCTION

CSV, short for computerized system validation, represents a major step forward for companies seeking to acquire regulatory requirements and to establish documentation proof of every activity to acquire validation. But to take full advantage of its potential cost and timesavings, many pharmaceutical organizations need to do more than simply use a traditional validation method. In recent years the introduction of computer systems for data handling in the pharmaceutical industry has increased (Friedli et al. 1998). Over the last three decades, the pharmaceutical industry has increasingly used computerized system to support the product development, less time in registration of patent, product development, manufacturing, and production, etc. The failure to validate a computerized system can have a significant financial and business implications from regulatory authorities including cancellation, delay in the issue of a license, delay in submission to regulatory authorities, negative publicity, removal of distribution of a product or recall of a product, shutdown of the manufacturing plant, etc (McDowall, 1995; Wingate, 2003).

Validation is vital and in fact, if pharmaceutical organizations aren't careful, they may run into several roadblocks that could derail the implementation and ultimately cost them more money over the validation of computerized system. Official inspections concentrate more and more on validation of computerized systems due to Good Manufacturing Practices (GMP) (Hoffmann et al., 1998).

World wide regulatory authorities (Food and Drug Administration - FDA, EC - European Council, AFSSAPS - French Agency of Health Safety of Health Products, Health Canada, and others) assure that all products are safe and effective and that's why impose certain conditions on the pharmaceutical organizations to ensure and maintain the critical quality processes. These authorities make it sure that all critical processes are validated and meet the required compliance before approving the license to the manufacturer. These requirements are provided in various forms like GxPs: Good (Clinical, Laboratory, Manufacturing) practices, BPF (Bonnes Pratiques de Fabrication), etc. All regulatory authorities consider the public health safety as the first priority and focus on pharmaceutical organizations to achieve all necessary measures to meet this challenging responsibility.

Companies have long relied on investments in validation activities (people, processes and technology) to provide more effective service. Invariably, such initiatives are often focused on the service variables within a company's control. Recent demands, however, have compelled organizations to look for the ways to enhance their validation process with capabilities similar to extreme requirements in performance and scalability.

A number of papers are available on the topics of validation, computerized system and system life cycle approach. However, few have combined and blended these topics into a practical set of principles for CSV. This is the ambitious task of our chapter. It provides a logical approach and comprehensive treatment of validation and also explains how the roles and responsibilities involved can improve the validation. For the validation specialist, the objective is to improve the utility and conformance of the system in validation. Such validation must always be designed from the point of view of the manager, user and compliance requirements. In order to achieve this, it is necessary that the validation activities are understood in the aforementioned context. This chapter investigates the role of validation activities to accelerate the development of business-specific validation.