Chapter IV
Computerized Systems Validation in the Pharmaceutical Industry

Kashif Hussain
University of Valenciennes, France

Shazia Yasin Mughal
University of Valenciennes, France

Sylvie Leleu-Merviel
University of Valenciennes, France

ABSTRACT

This chapter has reviewed the regulatory requirements definitions of FDA, AFSSAPS, EC and how computer systems can be validated with a relevant approach. By directing validation activities into a clear action plan, first, we need to analyze the specific organizational need according to the priorities and impacts to construct the required validation plan which can fulfill the requirements. The aim of the authors is to focus on a general approach to validation that can support several needs without addressing the technical aspects.

INTRODUCTION

The term validation appeared in the '60s, has become a topic of business concern today, and is considered to be one of the core issues in the pharmaceutical industries in terms of meeting regulatory requirements. In the recent past, an increase in the use of computerized-system validation (CSV) compelled quality and validation standards to be more precise to meet the industrial need. The utility of CSV has been an important catalyst in audits. Today, the phar-

maceutical industry makes use of CSV for several purposes (services, computers, equipment, process verification, change management [CM], etc.), exploring the ways how validation ensures the system in use is compliant and how to decrease failure rates, risks, long-term costs, and so forth. Currently, official inspections concentrate more and more on the validation of computerized systems due to good manufacturing practices (GMPs; Hoffmann, Kähny-Simonius, Plattner, Schmidi-Vckovski, & Kronseder, 1998).

Worldwide regulatory authorities have issued rules, regulations, and guidelines that are aimed to ensure true and real practices in the pharmaceutical organizations concerning public health. These requirements to maintain quality processes are the way to ensure that final consumers receive only safe and effective medical products. These authorities verify the required compliance before approving the license to the manufacturer. These requirements are available in several forms like GxP (good [clinical, laboratory, manufacturing] practice) or BPF (bonne pratique de fabrication). Each country has its own interpretation of quality and compliance requirements for the development of systems and procedures to achieve quality; however, basic rules and principles remain the same and are universally applicable. These regulatory requirements are established to define uniform standards that emphasize public health and safety as a first concern. In all cases, these regulations give an overview of the minimum requirements and dictate what must be done and by whom without specifying how it is to be done. It is the responsibility of management with respective validation teams for identifying schedules, priorities, and resources required for the preparation to meet these standards.

Computerized System

Several definitions are available to define a computerized system. We start with the principle described by the European Parliament in Annex-11 (Computerized System), relating to medicinal products for human use and investigational medicinal products for human use:

The introduction of computerised systems into systems of manufacturing, including storage, distribution and quality control does not alter the need to observe the relevant principles given elsewhere in the Guide. Where a computerised system replaces a manual operation, there should be no resultant decrease in product quality or quality assurance. Consideration should be given to the risk of losing aspects of the previous system which could result from reducing the involvement of operators. (EC, 2003)

The Food and Drug Administration (FDA, 1987) defines a computerized system as "computer hardware, software, and associated documents (e.g., user manual) that create, modify, maintain, archive, retrieve, or transmit in digital form information related to the conduct of a clinical trial."

A computerized system may include data input, electronic processing, and the output of information to be used either for reporting or automatic control. It may include automated manufacturing equipment, process-control systems, automated laboratory equipment, laboratory-data capture systems, clinical or manufacturing database systems, and so forth. Our study provides an overview of CSV acceptance criteria in the pharmaceutical industry. To carry out our study, we used the regulations applicable via the European Union parliament