Chapter 8

Project Management in Risk Analysis for Validation of Computer Systems in the Warehouse System

Jorge Lima de Magalhães
https://orcid.org/0000-0003-2219-5446
Instituto de Tecnologia em Fármacos
Farmanguinhos, Brazil

Juliana Satie Oliveira Igarashi
Daudt Oliveira Pharmaceutical Laboratory, Brazil

Zulmira Hartz
Institute of Hygiene and Tropical Medicine (IHMT). GHTM, NOVA University of Lisbon, Portugal

Adelaide Maria de Souza Antunes
National Institute for Industrial Property & Chemical School, University of Rio de Janeiro, Brazil

Elizabeth Valverde Macedo
https://orcid.org/0000-0002-4815-6878
Federal Fluminense University (UFF), Brazil

ABSTRACT

The informational and digital era of Big Data presents a non-trivial and unprecedented way in history for data and information management in organizations. Thus, to manage, protect, and ensure the validation of this data, it is imperative to develop new technologies for project management and their respective implementation in organizations. This chapter shows a case study in a pharmaceutical industry with the proposition of a methodology for validation of emerging technologies in the computerized systems. Data validation and security for project management in the organization is increasingly in demand. So, this implies that time and human resources in organizations are not infinite. It is necessary to prioritize the activities and resources dedicated to maintaining the validated state of the system. Authors propose a risk analysis to help companies with validation. They also present a proposed methodology for risk analysis from the point of view of the validation of computerized systems in a Warehouse Management module in a validated SAP ERP.

DOI: 10.4018/978-1-5225-9993-7.ch008
BACKGROUND

In the late 19th and early 20th centuries, the first pharmaceutical industries emerged in the world. In Brazil, the development of this segment was linked to sanitary practices to prevent and combat contagious diseases. During the first part military government was not yet talked about globalization in the world and in Brazil the pharmaceutical industry grew with the Technological Development Company (CODETEC - Brazilian term). Thus, there were developments and productions for drug companies. In this way, the Government bought the drugs until the middle of the 80’s. With the increase of inflation and with the beginning of the Fernando Collor government in 1990, the Brazilian economy opened. In this sense, the era of globalization began for any sector in Brazil. Since then, the internal dependence of drugs has started gradually in Brazil. With this scenario, the reduction of investments lasted from 1990 to 2000. In contrast, between 1980 and 2000, the lack of credibility of national products vis-à-vis the international ones, the patent law that enhanced the monopoly on products, as well as the increase of inspection with the creation of ANVISA in 1999 (Antunes; Mercado, 2000; Basil Achilladelis, 2001b; Chaves Et Al., 2007b; Jacobzone, 2000b; Magalhães; Quoniam; Boechat, 2013b).

The industries active in the pharmaceutical market are extremely regulated and are subject to national inspections periodically and internationally if they carry out exports of their products. In Brazil, the pharmaceutical industries are increasingly regulated by the National Health Surveillance Agency (ANVISA – Brazilian term) through various types of legal instruments such as the Resolutions of the Board of Directors (RDC – Brazilian term), Specific Resolutions (RE – Brazilian term), Normative Instructions (IN – Brazilian term) and Joint Ordinances with other actors of the federal government. In order to establish the minimum requirements to be followed for compliance with Good Manufacturing Practices (GMP) for Medicinal Products for human use, the Agency published RDC No. 17 on April 16, 2010, still in force, which included new requirements, among them the validation of computer systems (VCS) (ANVISA, 2019).

ANVISA released the Validation Guide for Computerized Systems (GVCS), still in force, which guides a set of criteria to perform the critical VCS that participates in the process of producing medicines for human use. A Computerized System is considered critical if it offers risk to the patient, product quality and data integrity. In this context of criticality, the computer system of the type Enterprise Resource Planning (ERP) is widely used in the industries (ANVISA, 2019; RICHMOND, L.; STEVENSON, J.; TURTON, A., 2003).

The ERP proposes to solve difficulties of integration, integrity and availability of information in a single Computerized System and to keep safe all the functionalities that support the activities of the various business processes of the companies (PINHEIRO, M. G.; DONAIRES, O. S.; FIGUEIREDO, L. R., 2011).

The German company SAP is one of the largest suppliers of ERP solutions on the market. Through ERP it is possible to place all the information in a single source of data, thus being able to carry out detailed searches of complete and updated data, attending to the needs of the clients more quickly.

The system is flexible and adjustable to meet the needs of the organization, directly assisting in decision making (VECCHIA, 2011). The modules of an ERP SAP system are related to the existing areas within the organization. Each module aggregates a set of different transactions2 and shares data with other modules (ERP SAP, 2019). In this sense, any relevant change in Good Practices, i.e., BPx 3