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Four Pillars of a Medical Device Process Validation System

By Yeong-Lin Chen Oct 24, 2018 1:36 pm PDT

Abstract

This article presents four critical elements in medical device process validation systems: process validation regulations & guidances, process validation SOPs, process validation work instructions, and process validation templates.

Introduction

This article explains how medical device process validation systems can comply with current regulatory requirements and medical devices that are fit for intended use by building upon an efficient and effective process validation system approach. Medical device regulatory requirements for process validation are generally described in principle in respective regulations, and the corresponding process validation guidance sometimes could be confusing because medical device manufacturing technology is quite different from pharmaceutical manufacturing technology. In addition, medical device products vary greatly . Therefore, in order to establish an efficient and effective process validation system, we should clearly understand the essence of both process validation regulatory requirements and process validation guidances. This knowledge, in combination with the knowledge of medical device processes, fundamental science & technologies, general statistics and current good manufacturing practices (cGMP), medical device companies will be able to develop their own, specialized and suitable process validation system's SOPs, work instructions, and templates.

Four Pillars of Medical Device Process Validation System

Process validation for the medical device industry is a broad and deep technique. Toa chieve compliance in medical device process validation systems in an efficient manner is essential. Process validation regulations are generally written in conceptual terms that do not go into details as to how validation is executed. Therefore, there is a need to develop execution details about the regulations for the industry use either by medical device regulatory agencies (e.g. FDA) or representatives from regulatory agencies and regulated industry (e.g. Global Harmonization Task Force GHTF, International Society for Pharmaceutical Engineering ISPE) [not for devices]. Compared to compulsory regulations, guidances are non-binding to regulatory authorities and the industry. However, guidances help and advise with how to proceed process validation in a pragmatic and detailed approach. Similarly, regulated company's process validation SOPs developed and based on the process validation regulations and guidance, as well as characteristics of the medical device products are considered compulsory according to cGMP. However, work instructions & templates, also called process validation execution instructions, can be considered as flexible and non-binding documents. They are developed based on process validation SOPs, regulations and guidance, as well as characteristics of the medical device products. In summary, medical device process validation systems comprises 4 pillars as figure 1 below.

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