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Process Validation and Revalidation in Medical Device Production

Yincheng Zhao^a, Kuangjie Sheng^b, Zheng Wang^a, Xilin Zhang^a, Hengyi Yang^a, Rui Miao^{a,*}

^a*School of Mechanical Engineering, Shanghai Jiao Tong University, Shanghai 200240, China*

^b*School of Mechanical Science and Engineering, Huazhong University of Science and Technology, Wuhan 430074, China*

Abstract

In this paper, the author according to ISO13485:2003, YY / T 0287-2003 quality management system for medical device regulatory requirements, and process validation guidance document GHTF-SG3-N99-10-2004, combined with the actual implementation process in the enterprise, detailed the process and applications of process validation. Then share some the statistical methods of data collection and analysis, describe how to do Design of Experiment experiments by Minitab software.

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1. Process Validation Introduction

The process validation is establishing by objective evidence that a process consistently produces a result or product meeting its predetermined requirements. Since in some cases, such as some defect of product can't be direct verified by process inspection, but it will become manifest only after the product has been used. These processes should be identified in advance or validation in order to ensure process capability and control all key parameters of process.

Thus the process validation is to establish a documentary evidence that specific procedure can produce product of meeting predefined specification and quality characteristic continuous with high confidence.

* Corresponding author. Tel.: +86-13671789106; fax: +86-21-64160192.

E-mail address: miaorui@sjtu.edu.cn

2. Implement of process validation

2.1. Process validation implementation step

Concrete steps of validation is as follows. First, the establishment of the validation team, clearly functions as a member. Determine process validation purposes. Clear the need of process. Master the principles of the process for determining the specific process parameters and desired output. Determine the evaluation and acceptance criteria, test methods, test tools, statistical analysis tools.

Then write process validation protocols, implement IQ, OQ, PQ. Finally, determine ongoing process controls, and process monitoring. When appropriate, get on revalidation. A flow chart shown in Fig. 1.

2.2. Process Validation Protocols (PVP)

Process validation protocols include a detailed scheme about how to implement Installation Qualification (IQ), Operational Qualification (OQ), Performance Qualification (PQ), and revalidation.

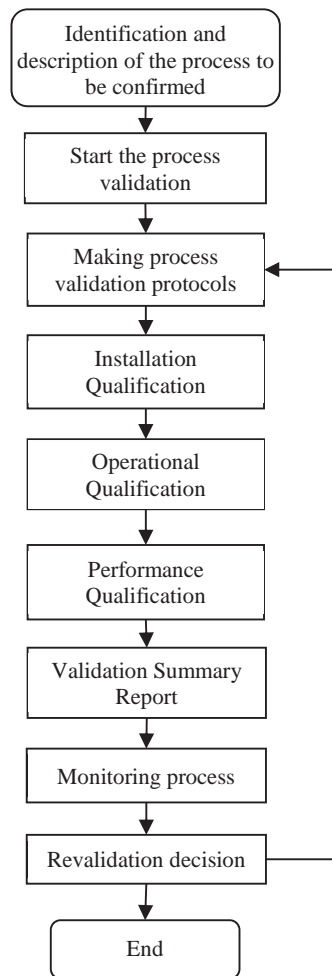


Fig.1 Process validation implementation step

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