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DHF, DMR and DHR – the Three Ds of Medical Devices

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Abstract

It is fairly well known that the three Ds – DHF, DMR and DHR are fundamental requirements for Medical Devices companies to Design, Define Manufacturing, and actual Manufacture Medical Devices. Lot of fairly established (for a long time) Medical Devices Companies have some decant to sort of decent ways of how they manage their three Ds. Yet if we look at the Warning Letters received by Medical Devices companies over the past few years, it majority of them are due to inadequate Design Controls, CAPAs and Complaints Handling, and other minor process and records centric observations.

It is very important to understand the connection between the three Ds as well as their importance. Device History File (DHF) – is the collection of lot of records that will define the frozen design that includes the Design, Risk Assessment and a plan for making the device which could include Manufacturing processes. Device Master Record (DMR) is the collections of elements that make up the recipe to make a device. These include the frozen design specifications, process documents, tools and tooling specifications, inspections procedures, Labeling and Packaging etc., Device History Record (DHR) is the record of how a Device is Manufactured including the lot #s and such, which is very important for Complaints Investigations for mostly non-returned products but also for returned products sometimes.

An effective way to manage the three Ds is very central to Regulatory Compliance as well as Productivity gains. A very well thought out strategy should be executed for business success.

Biography

Rama Pidaparti is a Ph.D candidate from ASU and attended a Life Sciences and HealthCare courses from BEP Program at Sloan Business School, MIT. Has over 20 years of industry experience and is currently Principal Consultant, Medical Devices vertical, Wipro Technologies. Has worked at many large Global Medical Devices and Bio-Tech drug companies as a consultant, GEHC, J&J, Genzyme, Genentec, Zimmer, Medtronic, to name a few. Helping the clients with Processes and Validated implementations of Computerized Systems for R&D, Quality and Regulatory areas. He is an invited speaker on Quality and Compliance topics at similar events in the past 10 years.