Example of research paper on how mcqm connects all processes critical to fda iso ...

The FDA and the ISO agree that quality control has to be built into the product, testing alone cannot insure product quality. . This is the integral premise behind the Current Good Manufacturing Practice (CGMP) Regulations. In the same way as the FDA regulations work, the ISO 9000 services of standards further make quality an integral part of the manufacturing processes that it regulates. Manufacturing Control and Quality Management (MCQM) software helps insure compliance with these standards and streamline the entire manufacturing process.

MCQM software automates the compliance procedure and makes compliance more efficient. In a manufacturing compliance environment where a routine inspection can take, as short as one week or can last up to five weeks having the electronic data readily available for compliance review can make a great difference in many ways. Everyone knows that even a routine inspection disrupts and distracts everyone from the CEO to the janitor who sweeps the floor at the end of the day. Electronic record keeping provides the data necessary for the review to progress with the least possible interruption to the manufacturing flow.

Holistic Quality Management helps pinpoint flaws in the manufacturing process so that if a defective product is produced it is easier to determine and correct. Considering that a product review starts with R & D and progresses from there, involving many different people, teams and data sources the right software can keep everyone working together to get through the problem solving portion, on to product re-approval, and back into manufacturing.

An effective MCQM product includes analytics and reporting tools that allow them to see trends and quality issues so that they can work proactively, before problems develop; instead of responding reactively after the situation becomes a problem. This not only streamlines the whole product production process, it can also prevent lawsuits, and the losses associated with the distribution of a flawed product.

A flexible system also supports a business's change and growth. It just stands to reason, when the CEO can review reports that include market trends, sales figures and manufacturing processes choices can be made in advance, on how the company can act, proactively, to stay on the cutting edge, without sacrificing the quality controls that guarantee a superior product.

MCQM also makes training new staff and compliance with the CGMP regulations for ongoing training of experienced staff easier. One of the most common reasons a company gets a Form FDA-483 is because it failed to keep its staff trained. . Having a MCQM process in place helps pinpoint when mandatory training must be updated for compliance purposes.

MCQM can help with all other aspects of continuous validation as well. Compliance validation informational data is always available with just a few keystrokes. Turnaround time is minimized and far more painless that with a paper or hybrid paper-electronic data system. With an effective system in place the continuous validations compliance controls are built right into the system, so that when upgrades are installed the subsequent validation does

not take months to implement. The right system can also help control costs in other sectors, such as insurance as well. Having all these resources available validates the initial investment involved in implementing an electronic MCQM system along with the few ancillary expenses of keeping it up to date.

References

Master Control. (2010). Six Ways to Optimize Your Quality Management System and Ensure FDA and ISO Compliance. Master Control.

Master Control, Inc. (n. d.). ISO Compliance. Retrieved 4 2, 2012, from Master Control, Inc.: http://www. mastercontrol. com/resource/online_resources. html#od

Master Control, Inc. (n. d.). Master Control FDA Compliance Video. Retrieved 4 2, 2012, from Master Control, Inc: http://www. mastercontrol. com/three_min_demo. html

Master Control, Inc. . (n. d.). Master Control Resource Center. Retrieved 4 2, 2012, from Master Control, Inc. : http://www. mastercontrol. com/resource/online_resources. html#od

United State's Department of Health & Human Services. (n. d.). Inspections, Compliance, Enforcement, and Criminal Investigations. Retrieved 4 2, 2012, from United State's Department of Health & Human Services: http://www. fda. gov/ICECI/ComplianceManuals/default. htm

United States Environmental Protection Agency. (n. d.). Environmental-Management-System-ISO-14001-Frequently-Asked-Questions. Retrieved 4 2, 2012, from United States Environmental Protection Agency: http://water.

epa. gov/polwaste/wastewater/Environmental-Management-System-ISO-

14001-Frequently-Asked-Questions. cfm

Single Spaced - Hanging Indent