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"Speaking Out"

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Francis Lamm

Francis has worked extensively in the medical products industry and has a great working knowledge of the FDA's CGMP. He also specializes in the implementation and internal auditing of the various Quality Management System standards including, ISO 13485, AS9100, and ISO 9001.

QUALITY MANAGEMENT SYSTEMS

How Healthy Is Your Quality Management System

By Francis Lamm

One of the main services KAVON provides to clients is in assisting their organizations in developing and implementing Quality Management Systems (QMS) leading to ISO registration. After registration, companies are typically audited every six to twelve months by their registrar to insure compliance to the requirements of the standards. In addition to the required internal QA audits, periodic QMS audits may also be conducted by governmental agencies (Military, DOD, FDA, etc.) and customer auditors.

Many small to medium companies have limited resources and depend upon senior managers to multi-task and administer the QMS. In some cases, they may contact KAVON to provide post-registration services and additional training in various aspects of the QMS, including conducting internal and supplier audits. This often occurs when there is employee turnover, management restructures, or there are insufficient trained personnel readily available to take on these duties.

After initial registration, ISO implementation teams are usually dissolved and the individuals go back to their primary job functions. The main burden of the QMS then falls on the designated management representative and/or the quality function to enforce and police. In the beginning, most employees are somewhat enthusiastic and follow the "new" policies, procedures and record-keeping requirements and take the same ownership as when they were directly involved in the development phases.

Historically, after a period of time, there is an inherent tendency at various levels of any organization to let down and begin to take short cuts or by-pass required QMS processes. This is human nature to an extent and must be controlled to prevent falling back to the old ways where the main thrust of manufacturing operations is 'to get things done faster' and 'rush products out the door to meet schedules and billing.' In other instances, some employees look at the QMS as a nuisance to be tolerated. They take shortcuts whenever convenient and blow off participating in meaningful corrective actions when caught. The attitude is they're not going follow the rules unless they get caught and QA squawks to top management.

The general health of a company's QMS is usually determined by the number and type of deficiencies found during the required annual internal audits (if done correctly) and the dreaded registrar, FDA, and customer auditors. Other indicators are:

- the numbers of formal and informal corrective actions initiated and completed in a timely manner
- working familiarity with all QMS documentation, and documented periodic reviews and updates in their areas of functional responsibility
- meaningful management reviews of the QMS
- overall customer satisfaction through feedback and surveys
- selection and control of qualified suppliers
- top management's commitment and enforcement of the QMS
- effective internal communications and documented meetings, training, etc.

Top management has the overall responsibility to balance all disciplines and resources to run the business and provide conforming products and services to meet customer requirements. In this regard, they are also usually fully aware of where the company stands regarding compliance to the ISO Standard and the QMS. They must enforce the Quality Policies and SOPs, and delegate the authority required to the Quality function to maintain and continuously improve the QMS. In this regard, the general management staff and employees can be a help or a hindrance. Quality Management Systems are not self-sustaining without everyone's effort and full cooperation.

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*KAVON International, Inc. is a business consultancy that helps clients create **Value** in order to attain and sustain a **Competitive Advantage** in the markets they serve. If your company is seeking registration or compliance to any of the Quality Management System standards such as ISO 9001, ISO/TS 16949, AS9100, ISO 17025, ISO 14001, or ISO 13485, or wants to establish a continual improvement program using Lean Six Sigma methodologies, give us a call and let one of our Trusted Advisors help you with implementation and training.*

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