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Leaderships role in implementing and maintaining pharmaceutical quality systems

Brian Hill

Brian Hill Consulting, USA

Having standards, policies and procedures in place within your organization will not, in themselves, guarantee that you will be in compliance with current Good Manufacturing Practice (cGMP). Nor will claiming that you have implemented or remediated a Quality management system.

To have an effective quality system that supports both your business and compliance needs it must contain at a minimum four key elements that assure that:

1. You can consistently and reliably produce and deliver high quality products throughout their life cycle
2. You establish and maintain a 'State of Control'
3. You establish and maintain a learning organization that demonstrates behaviors embracing quality beyond compliance
4. Your organization is capable of identifying, evaluating, escalating and mitigating risk effectively

Senior leadership within the pharmaceutical industry ultimately have a responsibility to ensure an effective quality system is in place to meet the companies quality and business objectives. They have a key role and responsibility in defining, communicating and importantly, living by the strategic vision of the quality system and expected desired outcomes.

In order to run an effective quality system management in various functional units/department must be aligned in order that they:

- Participate in the design, implementation, monitoring and maintenance of the Quality System.
- Ensure ongoing support of the Quality System
- Create a timely and effective communication and escalation process to raise quality issues to the appropriate levels of management
- Understand and define cross functional and individual roles, responsibilities, authority, accountability and interrelationships
- Conduct periodic management reviews of the performance, product quality and health of the Quality System.
- Are advocates of continual improvement and sustainability
- Commit appropriate resources

Leadership plays a critical role in ensuring that an effective quality system is in place and maintained. A Quality System trying to operate without the appropriate level of Leadership support will ultimately fail and failure can be very, very costly.

iambrianhill@icloud.com