

8th International Conference and Exhibition on
Pharmaceutical Regulatory Affairs and IPR
&
8th International Conference and Exhibition on
Pharma Audit, GMP, GCP & Quality Control
June 08-09, 2018 | Philadelphia, USA

A hurdle too high? The challenges of managing regulatory and quality systems for cGMP within small businesses

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Within today's regulated companies there are many internal and external challenges to deal with for the regulatory and quality professional in relation to cGMP. The external challenges can originate through multiple avenues such as customer expectations, regulatory agency reviews and supplier issues. Consequently, these external challenges can be inflated if the internal challenges are not met through robust systems that are established and actively being executed for the company. Managing the regulatory and quality systems for cGMP within smaller organizations requires effective leadership and systems due to the inherent resource limitations within small businesses. The regulatory and quality leadership within the regulated environment needs to ensure the optimization of the core systems to convert these systems into transforming tools and thus adapting to and clearing the ever-changing business hurdle. These core systems or tools are related to change management, training, corrective actions, design and development controls, critical communication at all levels of the organization along with the support and acceptance of the top level management and/or owner. The definition of a small business does not have to be impeded by limitations as related to the challenges described but rather can be one of successful embracement of the core systems and tools through excellent leadership. This formula can eradicate the assumptions and connotations associated with a small business as related to regulatory and quality and holding to cGMP standards.

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