

Sample-Management Compliance Services

DMA requires enhanced documentation of drug sample management policies and procedures, as well as compliance with more complex and stringent standards. In light of the increased regulatory requirements, pharmaceutical companies must review the policies and processes regarding their sample-management operations to ensure the appropriate controls are in place.

Implications for non-compliance with PDMA requirements include legal sanctions by government agencies, internal financial losses and loss of reputation in the industry and consumer communities.

How can pharmaceutical companies effectively comply with sample-management rules under PDMA?

The Prescription Drug Marketing Act (PDMA) requirements are in full effect, and pharmaceutical manufacturers must ensure they have policies and procedures in place to manage compliance requirements. The PDMA contains stringent regulations to ensure the proper use and distribution of pharmaceutical samples, and to combat drug diversion. PDMA provisions require pharmaceutical companies to implement controls to track all samples, from the time they leave the manufacturing facility to the time they are placed in the physician's hands.

Potential business risks?

While it is critically important to control the use and distribution of sample drugs, the monitoring and oversight process can be difficult in practice. When drug diversion does occur, the event often receives sensational publicity and results in damaged reputation and significant penalties to companies and their sales representatives. Considerable risks are associated with PDMA non-compliance, including:

Legal sanctions instituted by government agencies on manufacturers, distributors and representatives

Internal financial losses associated with mismanaged operations and non-compliance

Loss of reputation in industry and consumer communities

The PDMA regulation affects many facets of the sales and marketing function, including:

Labelling of samples

Process for requests and receipts for samples

Content of requests and receipts

Internal controls for receipt non-compliance

Inventory and reconciliation processes

Investigation of falsified records and drug diversion

Distribution of samples to charitable institutions

Threshold established for significant loss

Control processes for wholesale distribution

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Benefits You Can Realise

PwC has proven methodologies that will enable your company to comply with these new regulatory requirements. We will perform an initial assessment to gain an understanding of your existing sample-management control processes and determine areas that require modified controls. We work with you to develop new processes around a variety of functions, including:

Sample-management compliance and operating policies, procedures and training programmes

Overall risk mitigation and investigation processes and systems

Sample-inventory testing and reconciliation outsourcing

Electronic systems compliance, design and integration

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