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

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.
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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Global Pharmaceutical and Life Sciences Industry Group

The Global Pharmaceutical and Life Sciences Industry Group at PwC is dedicated to delivering effective solutions to the complex business challenges facing pharmaceutical and life sciences companies. A global leader in serving the pharmaceutical and life sciences industry, PwC has extensive experience working with companies on industry-specific strategic, operational, and financial issues. Our expertise includes assurance, tax and advisory services, as well as specialised capabilities in regulatory compliance, risk management, performance improvement and transaction support. In helping our clients, we draw on the full knowledge and skills of PwC's professionals. More than 161,000 people in 154 countries connect their thinking, experience and solutions to build public trust and enhance value for clients and their stakeholders.