



## **Multi-Tiered Approach to Drug Quality Assurance**

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Any regulatory agency is confronted with a myriad of problems to address in attempting to control the drug quality in their markets. To address every possible drug regulatory aspect—from the determination of safety and efficacy through quality production to patient use—would require more resources than any society would be willing to fund. It therefore is necessary to estimate product quality risks and allocate resources to obtain maximum public health protection within those limitations. Product registration is the first entry into the regulatory process, and product safety, efficacy, and quality are the critical attributes to address. These are complex issues, many of which have been addressed through marketing authorizations in the ICH market regions and by the WHO prequalification process. The quality assessment issues range from Good Manufacturing Practice (GMP) inspections, import-point labeling and document inspections, product testing, and dispensing-level compliance with standards.

This presentation will discuss using risk assessment in these various processes as a means to allocate always scarce resources.