

## **OBJECTIVE**

- Development of a harmonized pharmaceutical quality system applicable across the life cycle of the product i.e. From Manufacturing of Drug Mebendazole upto its shipment to Final Destination. Emphasizing an integrated approach to Quality Risk management and Regulatory science for Pharmaceutical Drug Mebendazole.
- To study different cases of formulation & API Industries to relate Quality Risks & its mitigation Methods.
- Better utilization of modern Scientific Knowledge based information exchanged between & within industry to the regulators throughout the product life cycle.
- Robust Product Quality Risk Management System, with appropriate knowledge management, assures Quality throughout product life cycle.

The ISPE Baseline® Guide: Risk-Based Manufacture of Pharmaceutical Products (Risk-MaPP) Second Edition provides a scientific risk-based approach, based on ICH Q9 Quality Risk Management, for managing the risk of cross-contamination within shared facilities. Risk management processes should be used to determine and document reasonable and acceptable risk, in order to maintain product quality and operator safety and to satisfy regulatory requirements. The ISPE Baseline Guide: Risk-Based Manufacture of Pharmaceutical Products (Risk-MaPP) Second Edition provides a process that allows manufacturers ... Abstract Does offshore production pose an added quality risk relative to domestic production? If so, what factors influence the quality risk? Progress addressing these deceptively simple questions has been hindered by the challenges associated with (1) difficulties in controlling for a wide range of factors that may potentially affect quality risk in offshore manufacturing and (2) the lack of available measures that are consistent across geographic regions.Â @inproceedings{Gray2011QualityRI, title={Quality risk in offshore manufacturing: Evidence from pharmaceutical Industry}, author={John V. Gray and Michael J. Leiblein and Aleda V. Roth}, year={2011} }.