

Risk management – a chance for the API industry

The introduction of risk management (ICH Q9a) provides a very useful approach for pharmaceutical industry. The successful application of this approach can significantly reduce the cost of company without compromising the compliance with the ICH Q7a. This article describes how to properly implement Q9 in the API production with the special consideration on the aspects of design, basic engineering, organization, qualification and validation, etc..

Key Words:

Risk management, ICH Q9, active pharmaceutical ingredient (API), ICH Q7a, GMP, cost-effective