

## **FDA's risk-based approach – old concept or new philosophy?**

The main focus of this article is the influence of risk management approach on the pharmaceutical industry. FDA can simplify its inspection by identifying the efficiency of risk management system of companies, instead of extensively testing every individual validation. On the other hand, with the successfully implementation of risk assessment according to the international ICH Q9, industry can avoid a lot of unnecessary validation work and thus save their own resources and costs. Therefore, a risk-based approach is beneficial for both inspectorate and for industry.

Key Words:

Risk management, risk assessment, ICH Q9, pharmaceutical industry, FDA, inspection, cost-effective