REFERENCES

1. ICH HARMONISED TRIPARTITE GUIDELINE QUALITY RISK MANAGEMENT, Q9 Current step 4 version dated 9 November 2005.
2. European Medicines Agency, Quality Risk Management (ICH Q9), 31 January 2011, EMA/INS/GMP/79766/2011
15. FDA Guidance “Inspections of Quality Systems” (Medical Devices), ORA Inspectional References.
19. USP Chapter <467> Residual Solvents.
28. C. Agut (2011), Transfer of analytical procedures: A panel of strategies selected for risk management, with emphasis on an integrated equivalence-based comparative testing approach, Journal of Pharmaceutical and Biomedical Analysis 56, 293–303
29. E. Smith (1996), Variability in toxic response - relevance to chemical safety and risk assessment at the global level, Environmental Toxicology and Pharmacology 2, 85-88
30. D. Blakey (2008), Regulatory aspects of genotoxicity testing: from hazard identification to risk assessment, Mutation Research/Genetic Toxicology and Environmental Mutagenesis 657, 84–90
35. Sven O. H. (2006), Evaluating the risk decision process, Toxicology 218, 100–111
36. Ioannis S A (2009), Application of Failure Mode and Effect Analysis (FMEA) and Cause and Effect Analysis in Conjunction with ISO 22000 to a Snails (Helix aspersa) Processing Plant; A Case Study, Food Science and Nutrition, 49 (7), 2009, 607-625
38. Giovanna B (2010), Clinical risk analysis with failure mode and effect analysis (FMEA) model in a dialysis unit, JNEPHROL, 23 (01), 111-118