KOD Information Day Talk on Quality Risk Management, September 27th, 2012

References & Bibliography

- 1. Kahneman, D., Tversky, A., "Subjective Probability: A Judgement of Representativeness", Cognitive Psychology, 3:430-354, (1972)
- 2. Kahneman, D., Tversky, A., "On the Psychology of Prediction", Psychological Review, 80, No 4, 237 251 (1973)
- 3. Litai, D. A Risk comparison methodology for the assessment of acceptable risk, PhD Thesis, Massachusetts Institute of Technology, Cambridge, Mass., 1980.
- 4. Starr, C., Social benefit vs. technological risk, Science, 165:1232-38
- 5. Keller, A. Z., Perception and Quantification of Risk, ISPRA courses, Reliability and Data, JRC ISPRA, 21020, Italy, 1984
- 6. Morgan, M. G., Morris, S. C., Henrion, M., Amaral, D. A. L., Rish, W. R., "Technical Uncertainty in Quantitative Policy Analysis: A Sulphur Air Pollution Example", Risk Analysis, September 4, 1984, 201-216
- 7. Tidswell, Edward C., McGarvey, B, Quantitative Risk Modelling in Aseptic Manufacture, PDA Journal of Pharmaceutical Science and Technology, Vol. 60, No. 5, Sept. Oct. 2006, pp 267-283
- 8. Nauta, M. J., Separation of uncertainty and variability in quantitative microbial risk assessment models, International Journal of Food Microbiology, 2000, 57, pp 8-18
- 9. Morgan, M. G., Risk Analysis and Management, Scientific American, July 1993, pp32-41
- 10. Morgan, M. G., Henrion, M., "Uncertainty A Guide to Dealing with Uncertainty in Quantitative Risk and Policy Analysis", Cambridge University Press, 1990
- 11. Fischhoff, B., Slovic, P., Lichtenstein, S., Fault trees: sensitivity of estimated failure probabilities to problem representation, J. Exp. Psychol. Human Perception Perf. 4:330-44, 1978
- 12. Lichtenstein, S., Fischhoff, B., Phillips, L. D., "Calibration of Probabilities: The State of the Art to 1980", in Kahneman, Slovic and Tversky, eds., "Judgement under Uncertainty: Heuristics and Biases", Cambridge University Press, New York, 1982
- 13. Slovic, P., Peters, E., "Risk Perception and Affect," Current Directions in Psychological Science, Vol. 15 (2006), pp. 322–325
- 14. Mullen. T. M., Understanding and Supporting the Process of Probabilistic Estimation", PhD Dissertation, Carnegie Mellon University, Pittsburgh, 1986
- 15. Goldberg, L. R. "The effectiveness of clinicians' judgements: the diagnosis of organic brain damage from the Bender-Gestalt test", Journal of Consulting Psychologists, 23:23-33, 1959
- 16. Wallsten, T. S., et al., Measuring the Vague Meaning of Probability Terms, Journal of Experimental Psychology: General, 115: 348-365, 1986
- 17. O'Donnell, K., Strategies for Addressing the Problems of Subjectivity and Uncertainty in Quality Risk Management Exercises: Part I The Role of Human Heuristics, Journal of Validation Technology, Vol. 16, No. 3, Summer 2010
- 18. O'Donnell, K., Strategies for Addressing the Problems of Subjectivity and Uncertainty in Quality Risk Management Exercises: Part II Risk Communication and Perception, Journal of Validation Technology, Vol. 16, No. 4, Autumn 2010
- 19. Samaras, G.M., An approach to human factors validation, Journal of Validation Technology, May 2006
- 20. Pyy, P., Human reliability analysis methods for probabilistic safety assessment, Espoo 2000, Technology Research Centre of Finland, VTT Publications, December 2000, available at www.vtt.fi/inf/pdf/publications/2000/P422.pdf
- 21. Brier, G. W., "Verification of forecasts expressed in terms of probability", Monthly Weather Review, 78:1-3, 1950
- 22. Mosvick, R., Nelson, R. We've Got To Start Meeting Like This: A Guide To Successful Business Meeting Management. Glenview, Ill., 1987

- 23. Kaplan, S., Garrick, B. J., "On the Quantitative Definition of Risk", Risk Analysis, Vol. 1, No. 1, 1981, pp 11-27
- 24. O'Donnell, K., Zwitkovits, M., Greene, A., Calnan, N., Quality Risk Management Putting GMP Controls First, PDA J. of Pharm. Science & Technology, May/June, 2012
- 25. Climate change 2007: Synthesis Report, Contribution of Working Groups I, II and III to the Fourth Assessment Report of the Intergovernmental Panel on Climate Change, Core Writing Team, Pachauri, R.K. and Reisinger, A. (Eds.), IPCC, Geneva, Switzerland. pp 104
- 26. <u>Budescu, D.V.</u>, <u>Broomell S.</u>, <u>Por, H.H.</u>, Improving communication of uncertainty in the reports of the intergovernmental panel on climate change, <u>Psychol Sci.</u> 2009 Mar, 20(3):299-308. Epub, 2009 Jan 30
- 27. Faust, D. Declarations versus investigations: The case for the special reasoning abilities and capabilities of the expert witness in psychology/psychiatry, Journal of Psychiatry & Law, 13(1–2), pp 33–59, 1985
- 28. Hoch, S. J., Availability and Interference in Predictive Judgement, Journal of Experimental Psychology: Learning, Memory and Cognition, 10, No. 4, 1984
- 29. Ronteltap, A., van Trijp, J.C.M., Renes, R.J., Frewe, L.J., "Consumer acceptance of technology-based food innovations," Appetite, Vol. 49, pp. 1–17, 2007
- 30. Raz, T., Hillson, D., A Comparative Review of Risk Management Standards, Risk Management: An International Journal, 2005, 7(4), 53-66
- 31. Savadori, L., Savio, S., Nicotra, E., Rumiati, R., Finucane, M., & Slovic, P. (2004). Expert and public perception of risk from biotechnology, Risk Analysis, 24(5), pp. 1289–1299
- 32. Costa-Font, J., Rudisill, C., Mossialos, E., "Attitudes as an Expression of Knowledge and 'Political Anchoring", Risk Analysis, Vol. 28, No. 5 (2008), pp.1273-1287
- 33. Kunreuther, H., Novemsky, N., Kahneman, K., "Making Low Probabilities Useful," Journal of Risk and Uncertainty, Vol. 23, No. 2 (2001), pp. 103–120
- 34. Satterfield, T., et al., "Anticipating the perceived risk of nanotechnologies", Nature Nanotechnology, Vol. 4 (2009), pp. 752-758
- 35. MacDonald, J.A., Small, M.J., Morgan, M.J., "Explosion Probability of Unexploded Ordnance", Risk Analysis, Vol. 28, No. 4 (2008), pp. 825-841
- 36. Willis, H.H., DeKay, M.L., Morgan, M.G., Florig, H.K, Fischbeck, P.S., "Ecological Risk Ranking" Risk Analysis, Vol. 24, No. 2 (2004), pp. 363-378
- 37. Fischhoff, B., Bostrom, A., Quadrel, M., "Risk Perception and Communication," Annual Review of Public Health, Vol. 14 (1993), pp.183–203
- 38. Nivolianitou, Z., Risk Analysis and Risk Management: A European Insight, Law, Probability and Risk, 2002, 1(2): 161-174
- 39. Darby, M. R. and Karni, E., "Free Competition and the Optimal Amount of Fraud," Journal of Law and Economics, 16 (April), 67-88, (1973)
- 40. Ford, G.T., Smith, D.B., Swasy, J.L., (1988), "An Empirical Test of the Search, Experience and Credence Attributes Framework", Advances in Consumer Research, Volume 15, (eds. Houston, M.J. & Provo, UT, Association for Consumer Research, Pages: 239-244.)
- 41. Rasmussen, N. C., "The Application of Probabilistic Risk Assessment Techniques to Energy Technologies", Ann. Rev. Energy, 1981, 6:123-38
- 42. Garfield, E., 'Risk Analysis, Part 1, How we Rate the Risks of New Technology', Essays of an Information Scientist, Vol. 5, p643-651, August 16, 1982, available at www.garfield.library.upenn.edu
- 43. Morgan, M. G., Henrion, M., "Uncertainty A Guide to Dealing with Uncertainty in Quantitative Risk and Policy Analysis", Cambridge University Press, 1990
- 44. Vesper, J. L., Risk Assessment and Risk Management in the Pharmaceutical Industry, Davis Healthcare International Publishing, 2006
- 45. O'Donnell, K., Greene, A., Failure Modes Simple Strategies for improving qualitative Quality Risk Management exercises during Qualification, Validation and

- Change Control Activities, Journal of Validation Technology, Vol. 13, No. 2, February 2007.
- 46. Stamatis, D. H., Failure Mode and Effect Analysis: FMEA from Theory to Execution, 2nd edition, ASQ Quality Press, 2003
- 47. Hubbard, D.W., The Failure of Risk Management: Why It's Broken and How to Fix It, John Wiley & Sons, 2009
- 48. ICH Q9, Quality Risk Management, International Conference on Harmonisation, Brussels, November 2009
- 49. Pharmaceutical cGMPs for the 21st Century A Risk-Based Approach, Final Report September 2004, Department of Health and Human Services, U.S. Food and Drug Administration, available at http://www.fda.gov/cder/gmp/gmp2004/GMP finalreport2004.htm
- 50. International Standard ISO 31000, Risk management Principles and Guidelines, First Edition 2009-11-15, (ISO Reference number ISO 31000:2009(E)). Published in Ireland by the National Standards Authority of Ireland (NSAI) on October 15th, 2009
- 51. ISO 14971:2007, 'Medical Devices Application of Risk Management to Medical Devices', International Electronic Commission, Geneva, Switzerland, March 2007
- 52. O'Léime, C., O'Donnell, K., Greene, A., Moving towards Risk-informed Decision-making a possible path for the EU GMP Environment?", poster presented at the ISPE's Risk-based Qualification & Validation Seminar, Cork, Ireland, October 21st, 2010
- 53. O'Donnell, K., Greene, A., A Risk Management solution designed to facilitate risk-based Qualification, Validation & Change Control activities within GMP and Pharmaceutical Regulatory Compliance Environments in the EU, Part I & II, Journal of GXP Compliance, Vol. 10, No. 4, July 2006
- 54. Conrow, E. H., Effective Risk Management: Some Keys to Success, 2nd Edition, 2003, General Publication Series, <u>American Institute of Aeronautics and Astronautics</u>
- Kmenta, S., Ishii, K., Scenario-Based Failure Modes and Effects Analysis Using Expected Cost, Journal of Mechanical Design, November 2004, Volume 126, Issue 6, pp. 1027-1035
- 56. Rhee, J., Ishii, K., Using cost based FMEA to enhance reliability and serviceability, Advanced Engineering Informatics, Volume 17, Issues 3-4, July-October 2003, pp 179-188