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## *The Experience and Expertise of KPA in Statistical Analysis and Quality Management for the Pharmaceutical Industry*

### **On Knowledge**

Knowledge is a key ingredient to competitive management processes. Evidence based knowledge builds on information derived, through analysis, from data. Kenett and Shmueli (2009) introduced the concept of Information Quality (InfoQ) as a measure of information gained from data and analysis. InfoQ builds on the quality of the analysis and the quality of the data. Deriving knowledge from high quality information requires experience and expertise in quality management, data evaluation and statistical analysis.

### **On KPA**

*KPA Ltd.*, is a management consulting firm with offices in Raanana and affiliates in Norway, Italy, the UK, Turkey and the US. The company employs, in Israel, 30 consultants with various background and expertise, including statisticians and industrial engineers. The company developed special expertise by working with global pharmaceutical companies. A partial list of clients, in this domain, includes: Perrigo Israel Pharmaceuticals, Perrigo Global, ChemAgis, Teva, Kamada, Theravita, BTG, Superdimension, Meditor, Polyheal, Savyon Diagnostics, Foamix, Interpharm (now Merck Serono). *KPA* is also collaborating with GSK, Novonordisk and Novartis on the development of statistical methodologies supporting the Quality by Design paradigm.

We have trained over 1000 engineers, quality experts and scientists in the application of statistical methods to their specific problems. Our experience shows that training, disconnected from specific tasks, is ineffective. We recommend assigning to trainees specific work related tasks, so that they can apply what they learn to their work.

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## Our Offering

Our customers have taught us how to provide hand's on statistical expertise by emphasizing problems and solutions over methodology. Specifically, we conduct most of our training in computer labs where trainees have access to statistical packages such as Minitab, JMP or Statgraphics. This approach allows us to focus on the interpretation of statistical analysis, without the need to spend time on theoretical and mathematical considerations. Based on this expertise and experience, we have expertise in designing tailored programs for organizations interested in implementing statistical methods for improved knowledge acquisition.

As a result of such programs, our customers have experienced dramatic gains in efficiency and effectiveness. In addition, such initiatives match perfectly current regulatory trends as reflected by ICH guidelines Q8, Q9, Q10 and Q11. We have the material and methodology for supporting such initiatives, and gained a reputation as a center of excellence in *Quality by Design* in Israel, the US and Europe.

## Our Founder

**Ron S. Kenett** Ph.D., CEO and Senior Partner of *KPA Ltd.* and Research Professor at the University of Torino, Italy. His Ph.D. is in Mathematics (1978) from the Weizmann Institute of Science, Rehovot with a thesis on “*Studies in Enzyme Kinetics*” that was supervised by Professor Sam Karlin from Stanford University. His B.Sc. is in Mathematics and Statistics (1974) from Imperial College of Science and Technology, with first class honors, London University, London, UK. Ron has over 25 years of work experience with the pharmaceutical industry including medical researchers and clinical pharmacologists in a variety of areas such as clinical trial design, validation of clinical trials through specialized simulations, bioequivalence analysis, stability studies and annual reports for the FDA and the Israeli Ministry of Health. He is a recognised expert in Quality by Design, Risk Management, Quality Management, Design of Experiments and Statistical Process Control. Ron was Professor of Management at the State University of New York where he was a GE Quality Management Fellow. He has published 4 books and over 160 scientific papers.

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## **Selected Biostatistics and Quality Management papers by Ron Kenett and colleagues**

1. "The Relationship Between HLA Antigens and Bermuda Grass Hayfever" (with C. Geller, R. Zamir, S. Karlin and M. Sela), *Immunogenetics*, 7, pp. 259-264, 1978.
2. "Genetic Markers: Benign and Normal Traits of the Ashkenazi Population in Israel" (with B. Bonne and S. Ashbel) in *Genetic Diseases in Ashkenazi Jews*, eds.: R. Goodman and A. Motulsky, Raven Press, New York, pp. 59-76, 1979.
3. "Analysis of Biochemical Genetic Data on Jewish Populations: I. Historical Background, Demographic Features and Genetic Markers" (with S. Karlin and B. Bonne), *American Journal of Human Genetics*, 31, pp. 324-340, 1979.
4. "Analysis of Biochemical Genetic Data on Jewish Populations: II. Results and Interpretations Heterogeneity Indices and Distance Measures with Respect to Standards" (with S. Karlin and B. Bonne), *American Journal of Human Genetics*, 31, pp. 341-365, 1979.
5. "Bioassay of Kinship in Populations of Middle Eastern Origin" (with N. Morton, S. Yee and R. Lew), *Current Anthropology*, 23, pp. 157-167, 1982.
6. Heritability of IgA levels in atopic families. C. Geller-Bernstein, R. Kenett, S. Tsur, L. Weissglas, A. Bejerano, M. Lahav and M. Sela, *Abstr. XII Cong. Eur. Acad. Allerg. Clin. Imm.*, Rome, Sept. 25-30, 1983, *Folia Allergologica et Immunologica Clinica*, 30, Suppl. 4, 105 (1983).
7. "Survey of Immunoglobulin Levels in Atopic Families" (with C. Geller, N. Keret, A. Bejerano, B. Reisman, S. Tsur and Michael Sela), *Asian Pacific Journal of Allergy and Immunology*, 2, pp. 181-185, 1984.
8. "Survey of Immunoglobulin E Levels in Atopic Families in Israel" (with C. Geller, L. Weisglass, N. Keret, R. Dun, A. Bejerano, M. Lahav and Michael Sela), *Israel Journal of Medical Science*, 20, pp. 1133-1137, 1984.
9. Low immunoglobulin A in atopic families. (with C. Geller-Bernstein, N. Keret, A. Bejerano, S. Tsur, L. Weissglass, M. Lahav and M. Sela), *Abst. 15 Meeting Israel Immunol. Soc.*, Tel Aviv, p. 70, 1984.
10. "Atopic Babies with Wheezy Bronchitis" (with C. Geller, L. Weisglass, S. Tsur, M. Lahav and S. Levin), *Allergy*, 42, pp. 85-91, 1987.

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11. "IgA, IgG, IgM, and IgE Levels in Normal, Healthy, Non-atopic Israeli Children" (with C. Geller, T. Barsky, S. Tsur, M. Lahav and S. Levin), *Annals of Allergy*, 61, pp. 296-299, 1988.
12. "Aerobiology as a Tool for Prevention of Hay Fever" (with C. Geller-Bernstein, N. Keynan, Shomer-Ilan and Y. Waisel), *Grana*, 30, pp. 76-78, 1991.
13. "Aerobiology in the prevention of Allergy" (with C. Geller-Bernstein and Y. Waisel), in *Clinical Applications of Aerobiology*, The UCB Institute of Allergy, Syed Tariq Editor, pp. 69-75, April 1996.
14. "Pollen Allergy in Israel" (with C. Geller-Bernstein, G. Hassoun, C. Lahoz, M. Iancovici-Kidon, Y. Waisel), *Pediatric Pulmonology*, Supplement 23:46-47, 2001.
15. "Low molecular weight heparin and warfarin in the treatment of patients with Antiphospholipid Syndrome during pregnancy" (with Rachel Pauzner, Mordechai Dulitzki, Pnina Langevitz, Avi Livneh, Amira Many), *Tromb. Haemost.*, 86, pp. 1379-84, 2001.
16. "Is it 'bad hygiene' to inhale pollen in early life?" (with C. Geller-Bernstein, C. Lahoz, B. Cordaba, G. Hassoun, M. Iancovici-Kidon, Y. Waisel), *Allergy*, 57, Suppl. 71, 2002.
17. "Does Skin Prick Test Correlate with Basophil-Associated Mite-Specific IgE in Atopic Children?" (with M. Iancovici-Kidon, C. Geller-Bernstein, G. Dwin, A. Licht and I. Pecht), *J. Invest Allergol Clin Immunol*, 13, pp. 73-75, 2003.
18. "Hepatic infarctions during pregnancy are associated with the antiphospholipid syndrome and in addition with complete or incomplete HELLP syndrome" (with R. Pauzner, M. Dulitzki, H. Carp, H. Mayan, Z. Farfel and A. Many), *Journal of Trombosis and Haemostasis*, 1, pp. 1758-1763, 2003.
19. "Allergies in immigrants" (with C. Geller), *European Journal of Allergy and Clin. Immunol*, 36, 8, pp. 313-316, 2004.
20. "Quality and productivity at ChemAgis; From using statistical tools to six sigma" (with E. Urkin and A. Kost), *Proc. of the 8th National Quality Conference*, Tel Aviv, November 2005.
21. "Scale Up Optimization Using Simulation Experiments" (with Moshe Ben Tollila Simona Malca, Roberto Novoa and Benny Yoskovitch) *2006 Process Development Symposium: Learn from the Past, Plan for the Future*, The American Institute of Chemical Engineers (AIChE), Palm Springs California, June 11-16, 2006.

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22. "Validating clinical trials protocols with simulations" (with T. Greenfield). European Network for Business and Industrial Statistics (ENBIS) *Seventh Annual Conference on Business and Industrial Statistics*, Dortmund, Germany, September 2007.
23. "Risk Management Approach and Six Sigma Implementation in the Pharmaceutical Industry" (with N. Kalman, E. Urkin, A. Ingher, H. Shenkman and E. Kuperman). *The 12th International Conference on Quality and Productivity Research*, July 2007.
24. "Acceptance Sampling Plan Optimization in the Pharmaceutical Industry" (with B. Magenheim, E. Kuperman, E. Urkin and N. Kalman). *Proc. of the 9th National Quality Conference*, Tel Aviv, November 2007.
25. "Quality by Design Applications in Biosimilar Technological Products" (with D. Kenett), *ACQUAL, Accreditation and Quality Assurance*, Springer Verlag, Vol. 13, No 12, pp. 681-690, 2008.
26. "Drug Development Strategy: The interface between QbD and statistical methods" (with Y. Stark). *Global Pharmaceutical Conference Practical Application of QbD in Accelerated Development: Laboratory, Quality and Regulatory Considerations*, Frankfurt, Germany, April, 2-4<sup>th</sup>, 2008.
27. "From Data to Information to Knowledge", *Six Sigma Forum Magazine*, pp. 32-33, November 2008.
28. "Quality by Design Applications to Analytical Methods in the Pharmaceutical Industry" (with D. Kenett), *Advanced Mathematical and Computational Tools in Metrology and Testing VIII*, Series on Advances in Mathematics for Applied Sciences, Vol. 78, World Scientific Publishing Company, pp. 183-194, 2009.
29. "Integrated Management - A challenge to the QA manager" (in Hebrew with E. Urkin), *Eihut*, 45, February 2009.
30. "Quality by Design Applications in the Pharmaceutical Industry", *Quality by Design: Linking Production and Development in High Tech Manufacturing*, *JMP-SAS Conference*, Manchester, U.K., June 18<sup>th</sup>, 2009.
31. "Quality, Risk and the Taleb Quadrants" (with C. Tapiero), <http://ssrn.com/abstract=1433490>, *Risk and Decision Analysis*, in press.
32. "On Information Quality" (with G. Shmueli), <http://ssrn.com/abstract=1464444>, submitted, 2009.