

Professional Support for QbD Implementation in the Chemical and Pharmaceutical Industry

A process is well understood when all critical sources of variability are identified and explained, variability is managed by the process, and product quality attributes can be accurately and reliably predicted over the design space. Quality by Design (QbD) is a methodology emphasizing product and process understanding and process control based on sound science and quality risk management. The FDA and ICH have recently started promoting QbD in an attempt to limit rising development costs. It is also expected that QbD will help reduce regulatory barriers to innovation and creativity [2, 4, 5]. QbD is partially based on the application of multivariate statistical methods [1] and a statistical Design of Experiments strategy [3] to aid the development of both analytical methods and new drug formulations.

ISRU and **KPA** are working together to develop and deliver professional services for supporting pharmaceutical and chemical industries to implement QbD in an effective and efficient way.

KPA was founded in 1990 to improve the competitive position of its customers by promoting the implementation of advanced management methodologies. The company is currently involved in a wide range of projects in organizations from the industrial, service and public sectors. **KPA** is operating in Israel and 15 countries in Europe. A partial list of its customers includes Perrigo, Merck-Serono, Teva, Kamada, ChemAgis, Foamix, GeneGrafts, Carmel Olefins and Israel Chemicals.

ISRU is a well-established applied statistics consultancy unit set up in 1984 in Newcastle University. Early **ISRU** work focused on quality improvement projects in ICI using statistical methodologies such as design of experiments and SPC. Combining six sigma with lean and change management techniques, **ISRU** now offers a comprehensive process improvement package. Customers include process industries in the North East of England, service providers, manufacturing companies and utilities.

ISRU and **KPA** have worked together on a number of projects [6].

References:

1. Fuchs, C. and Kenett, R., **Multivariate Quality Control: Theory and Applications**, Marcel Dekker Inc., New York, 1998.
2. ICH, The International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use, Quality Guideline Q8 Pharmaceutical Development, 2006.
3. Kenett, R. and Zacks, S., **Modern Industrial Statistics: Design and Control of Quality and Reliability**, Duxbury Press, San Francisco, 1998, Spanish edition 2000, 2nd paperback edition 2002, Chinese edition 2004.
4. Kenett, R. and Stark, Y., "Drug Development Strategy: The interface between QbD and statistical methods" Global Pharmaceutical Conference Practical Application of QbD in Accelerated Development, Frankfurt, Germany, 2008.
5. Nasr, M., "Quality by Design (QbD) – A Modern System Approach to Pharmaceutical Development and Manufacturing – FDA Perspective", FDA Quality Initiatives Workshop, Maryland, USA, 2007.
6. Coleman, S. Y., T. Greenfield, Stewardson, D and Montgomery, D eds, **Statistical Practice in Business and Industry**, Wiley, 2008.

Services offered

Workshops

We can offer in house and open courses in several areas including:

1. **Introduction to Quality by Design** - a half day introduction for managers
2. **Principles of Designed Experiments** - a three days workshop on the fundamentals of statistically designed experiments
3. **Principles of Multivariate Data Analysis** - a three days workshop on methods for the analysis of multivariate data including Graphical Displays, Principle Components, Multivariate Control Charts, Multivariate Tolerance Limits and Capability Indices.
4. **Advanced Designed of Experiments Bayesian Methods** - Bayesian Networks, Simulation Experiments, Combining Physical and Simulation Experiments.
5. **Scale Up Processes** - Basics of Scale Up processes, designed scale ups on simulation platforms.
6. **Black Belt and Green Belt Training** – Six Sigma and lean methodology for a range of application areas including health care, manufacturing, process industries and finance.

The lead instructors:

Ron S. Kenett, Chairman and CEO of KPA Ltd. and Professor at the University of Torino, Torino, Italy. He has over 25 years of experience in restructuring and improving the competitive position of organizations by integrating statistical methods, process analysis, supporting technologies and modern human resource management systems. Specifically he is a recognized expert in Six Sigma, Risk Management and Quality by Design methodologies.

Shirley Coleman, Technical Director of the Industrial Statistics Research Unit (ISRU) in the School of Mathematics and Statistics, Newcastle University, UK. She has many years' experience of applying statistical thinking and analysis in a range of situations including process industries and health care. Her work has involved financial modeling and prediction in Hong Kong, Six Sigma training in Poland and the UK, developing SPC based safety measurement frameworks, rationalizing laboratory and materials testing.