A One Day Research Conference on

Quality by Design in Pre-Clinical and Clinical Research

Sunday, 13th of December, 2015

Tel Aviv University, Faculty of Medicine

Dolfi Auditorium http://www2.tau.ac.il/map/print-map1-eng.html

Participation is free but advanced registration is required.

To register, click **here** or send an email with name and affiliation to info@kpa-group.com with ***Dec 13th QbD Conference*** as subject.

Quality by Design (QbD) is a comprehensive approach to drug development and filing that combines methods of experimental design, risk management and multivariate analysis. The objective is to reach evidence based decisions that ensure quality of product, process and research, by design. The approach, in various versions, has been implemented in a range of areas including basic research, pre-clinical, clinical research, CMC and biosurveillance.

An example is the work combining experimental design methods in animal behavior studies (Richter et al, Environmental standardization: cure or cause of poor reproducibility in animal experiments?, *Nature methods*, 6(4), April 2009). Other examples include Bloch et al, A multifactorial analysis of complex pharmaceutical platforms: an application of design of experiments to targetable polyacrylamide and ultrasound contrast agents, *Polym. Adv. Technol.* (2015), and Liron et al., Ce3/4+ cation-functionalized maghemite nanoparticles towards siRNA-mediated gene silencing, *Journal of Materials Chemistry B* (2014). For an introduction to Quality by Design see: http://blogs.sas.com/content/jmp/tag/qbd.

The objective of the conference is to discuss various aspects of Quality by Design in pre-clinical and clinical studies with experts and practitioners.

Partial list of topics of interest:

1. Design of animal behavior trials
2. Risk management in clinical development
3. Preformulation of drug products
4. Reproducibility of pre-clinical and clinical research
5. QbD in toxicity studies
6. Ethical considerations and QbD aspects

Sponsors

- The Faculty of Medicine, Tel Aviv University, Israel
- The School of Pharmacy Institute for Drug Research, the Hebrew University of Jerusalem, Israel
- The KPA Group, Israel
- The Israel Statistical Association
- Teva Pharmaceutical Industries, Israel

Organizing and Scientific Committee

- Prof. Ron Kenett, School of Pharmacy, The Hebrew University of Jerusalem, The University of Turin, Italy and KPA Ltd., Israel, ron@kpa-group.com
- Prof. David Steinberg, Department of Statistics and OR, Tel Aviv University, dms@post.tau.ac.il
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- Dr Yafit Stark, Teva Pharmaceutical Industries, yafit.stark@teva.co.il
- Dr. Mira Markus-Kalish, Tel Aviv University, miram@post.tau.ac.il
- Prof. Uri Goldbourt, Tel Aviv University Faculty of Medicine and the Israel Statistical Association, goldbu1@post.tau.ac.il

Preliminary Program

8:30	**Registration**
9:00	**Opening***:* Prof. Ehud Grossman, Dean of Medicine**,** Tel Aviv University Faculty of Medicine and Sheba Medical Center
9:10	Drug Development in the 20th Century, Dr. Yafit Stark, Teva
9:30	QbD in Design, Analysis and Generalization of Statistically Designed Experiments, Prof. Ron Kenett, KPA and HUJI
9:50	A QbD example from targetable polyacrylamide and ultrasound contrast agents, Prof. Avri Rubinstein, HUJI
10:10	Issues in Experimental Design of Pre-Clinical Studies, Prof. David Steinberg, TAU
10:30	**Coffee Break**
11:00	Improving the quality of decision analysis in early stage drug development, by design, Dr. Itay Perlstein, Clinical PK Services
11:20	Pharmacovigilance, Dr. Ilan Matok, HUJI
11:40	QbD Panel: Dr. Itay Perlestein, Dr. Yafit Stark, Dr. Rony Kalman
12:30	**Lunch on Campus**
13:30	Practicalities in Animal Behavior Studies, Itschak Lamensdorf, Pharmaseed
14:30	Toxicological qualification of impurities and excipients, Dr. Doron Shinhar, Teva
15:00	**Coffee Break**
15:15	Special Invited Talk: Ethical consideration in animal experiments Professor Ehud Ziv, Diabetes Unit Hadassah University Hospital, former chairman of the Israeli Council for Animal Experimentation
16:00	Q&A Session
17:00	**Closure**