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, send email with name and affiliation, and ***Dec 13th QbD Conference*** as subject, to info@kpa-group.com

Quality by Design (QbD) is a comprehensive approach to drug development 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 and clinical research. An example is the work of Hanno Wurbell et al combining experimental design methods in animal behavior studies (Richter, Garner and Wurbel, 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/2015/05/07/the-qbd-column-overview-of-quality-by-design.

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. Reformulation 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 (approval of some members still pending)

- 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. 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	Improving the quality of decision analysis in early stage drug development, by design, Dr. Itay Perlstein, Clin PK Services
9:50	QbD elements in Pre-Clinical and Clinical Research, Prof. Ron Kenett, KPA and HUJI
10:10	Issues in Experimental Design of Pre-Clinical Studies, Prof. David Steinberg, TAU
10:30	**Coffee Break**
11:00	QbD in Drug Delivery Research, Prof. Avri Rubinstein, HUJI
11:30	QbD in Personalized Medicine, Dr. Koby Atsmon, TASC
12:00	QbD Panel, Dr. Etty Klinger, Dr. Yafit Stark, Dr. Rony Kalman
12:30	**Lunch on Campus**
13:30	Practicalities in Animal Behavior Studies, Itschak Lamensdorf, Pharmaseed
14:30	QbD aspects in toxicity studies, Dr. Doron Shinhar, Teva
15:00	Special Invited Talk – Ethical considerations in animal experiments Professor Avi Israeli, Past Director General of Ministry of Health and Head of the National Institutional of Animal Care and Use Committee (IACUC)
16:00	Q&A Session
17:00	**Closure**