4th Jerusalem Conference on Quality and Pharma Sciences

A unique podium for highlighting applications of quality by design (QbD) to the Pharma Sciences

May 20-22nd, 2014

Belgium House (www.bb.huji.ac.il), The Edmond Safra Campus
The Hebrew University of Jerusalem

Conference direct e-mail: pharmacy@ekmd.huji.ac.il

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PROGRAM

Day 1: May 20th, 2014

8:30 **Registration**

9:00 **Opening**: *Prof. Simon Benita*, *Head School of Pharmacy Institute for Drug Research*

9:10 ***Keynote:*** Attaining and Sustaining Pharmaceutical Product Quality - A Quality Culture Approach
Louis W. Yu, Ph.D. Executive V.P. Quality Control, Perrigo

1. A Pharmaceutical Quality

Chairperson:

9:50 (2) **A2** The Role of Organization Learning to prevent Pharmaceutical Quality Drift from Quality Suitability
Claudio Pincus, President of the Quantic Group, USA

10:20 (3) **A3** Pharmaceutical Quality and Clinical Research Quality: The interaction
Dr. Yafit Stark, Teva, Israel

10:40 **Coffee Break**

2. B Analytical Methods

Chairperson:

11:00 (1) **B1** Analytical Method Development - A Life Cycle Quality by Design
Rosario Lo Brutto, Director, Analytical R & D Teva, USA

11:30 (2) **B2** Uncertainties in Analytical Methods
Professor Dany Gibson, Hebrew University, School of Pharmacy, Jerusalem, Israel

12:00 (3) **B3** Statistical Models for GR&R (Gauge Repeatability and Reproducibility) Studies
Professor David Steinberg, Tel Aviv University, Israel

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12:30 **Lunch**

3. C DOE in Pharmaceutical Research

Chairperson:

14:00 (1) **C1** A Design of Experiments (DoE) Approach to Optimized Fabrication of Magnetic Maghemite Nanoparticles for Imaging and Gene Silencing
Professor M. Lellouche, Bar Ilan University, Israel

14:30 (2) **C2** TBD
Speaker from Sol-Gel

15:00 (3) **C3** QbD in Liposome Development
Professor Yechezkel (Chezy) Barenholz, Hebrew University, Medical School, Jerusalem, Israel

15:30 **Day 1 closure**

18:00 **Conference Dinner**

Day 2: May 21st, 2014

8:30 **Registration**

9:00 ***Keynote:*** Rapid Screening Methods for FDA Pharmaceutical Surveillance
Dr. Lucinda (Cindy) Buhse, Director, FDA Division of Pharmaceutical Analysis, FDA St. Louis, USA

4. D Regulatory Updates

Chairperson:

9:40 (1) **D1** FDA - Update on Office of Pharmaceutical Quality
Keith Webber - Head of Regulatory Review, Perrigo

10:10 (2) **D2** Using Dashboards to Integrate and Communicate Process Understanding
Martin Owen, GlaxoSmithKline, UK

10:40 (3) **D3** International Quality Operations: Approaches to Quality Metrics and Continuous Improvement
Stacy Berkshire, Perrigo

11:10 **Coffee Break with light meal**

5. E QbD in Pharmaceutical Development

Chairperson:

12:00 (1) **E1** Applications of non-standard DOE in QbD
Inna Ben-Anat,Teva

12:30 (2) **E2** QbD development of topical products
Michal Arnon, Perrigo

13:00 (3) **E3** QbD in formulations of generics
Dr. Tzviel Sheshkin and Hadassah Zuckerman, Taro

6. F Quality Challenges in 2020 Drug Products

13:30 Panel – Moderator: Prof Philip Lazarovici
Dr. Yafit Stark, Teva
Prof. Louis Yu, Perrigo
Prof. Mel Weinswig, UW, USA
Prof. Ron Kenett, KPA, Hebrew Univ. and Univ of Turin
Rosario Lo Brutto, Analytical R & D Teva,
Dr. Lucinda Buhse, FDA Central Laboratories, USA
Claudio Pincus, Quantic Group, USA

14:30 **Day 2 closure**

Day 3: May 22nd, 2014

A Special Introductory Workshop on:

Statistical Tools Supporting the New Process Validation Guidelines

Presenters: ***Prof Ron Kenett and Prof David Steinberg***

The FDA new Process Validation Guidelines cover 3 stages in the lifecycle of the product. The first phase is the design of the product and production process, the second phase is qualification of the process and the third phase is ongoing monitoring of the process. The January 2011 guidelines on process validation offer new possibilities and challenges and require the application of various statistical methods. The new approach is scientific based and builds on all quality by design guidelines. The guideline is driving industry to move from an inspection focus, where things are inspected and the output of an inspection is pass/fail, to a deeper understanding and a more in-depth analysis of what is going on. The three stages and the corresponding main statistical tools supporting them are listed below.

Stage 1: **Process Design**; Development through submission **– Statistical Design of Experiments (DOE).**

Stage 2: **Process Qualification**; Submission through launch - **Acceptance Sampling Plans**

Stage 3: **Continued Process Verification**; During the commercial manufacturing of the product – **Statistical Process Control (SPC).**

This introductory workshop is designed to provide participants with a guided tour through the statistical design of experiments (DOE), acceptance sampling and statistical; process control (SPC).

The material presented in the workshop is based on the second edition of: *Modern Industrial Statistics with applications in R, MINITAB and JMP* by Kenett and Zacks, Wiley 2014 (http://eu.wiley.com/WileyCDA/WileyTitle/productCd-1118456068.html. Real life examples and simulations will be provided using JMP.

Workshop agenda:

9:00	Introduction to QbD and the New Process Validation Guideline
9:30	**Design of Experiments (DOE)**
11:15	**Coffee Break**
11:45	**Acceptance Sampling**
14:00	**Lunch Break**
14:45	**Statistical Process Control (SPC)**
16:30	Closure

כינוס ירושלים הרביעי בנושא רוקחות תעשייתית, ניהול סיכונים ותכנון
Quality by Design

20 ו-21 במאי 2014 בקריית אדמונד ספרא, ק. גבעת רם של האוניברסיטה העברית בירושלים

<u>ההשתתפות בסדנה של ה 22.5.2014 ללא עלות אבל מחייבת רישות מוקדם</u>

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The 4rd Jerusalem Conference on Quality and Pharma Sciences

20-21st May, 2014 at the Hebrew University of Jerusalem,
Edmond J. Safra Campus, Givat Ram

Conference participation fees, per person: 500 ₪ (student 250 ₪); Single day: 350 ₪

Participation in the special workshop on 22/5 is free but requires pre-registration

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