Under the patronage of his excellency
The Director General of the JFDA
Dr. Hayel Obaidat

The 2nd Symposium for
“Global Harmonization of Bioequivalence Requirements”

OCT 30th-31st 2017
ACDIMA
Amman-Jordan
events.acdima.com
The Globalization for better consolidation and utilization of industry resources

Since decades, bioequivalence is considered one of the key questions in new and generic drug product development and registration worldwide. At the same time, it is obvious that the regulations and jurisdictions still differ to certain extent from country to country and continent to continent, although the scientific basis for it is globally the same. This aspect, and the ongoing discussion on the suitability of reference products purchased from a specific country and their applicability for submissions in other countries or regions, create the necessity to conduct several only slightly different bioequivalence studies to get the same product authorized in various markets.

Scientific Sessions

Our selected session topics for this symposium, are:

- Debriefings on the harmonization landscape
- Multiple dose and two-stage design studies.
- Fixed-dose combinations products
- Inspections and audits

The topics of this Workshop were selected with the intention of identifying differences with realistic chances for harmonization based on the scientific basis. To achieve this objective, the BE-related topics selected for discussion include crucial issues concerning the need of multiple dose studies and two-stage studies. The discussion will throw lights on bioanalytical method regulatory updates and extra curricular requirements. Audits and inspection findings will be reflected on the symposium thematic talks to tackle the new wave over the scene. Based on the positive experience with the previous meeting in 2016, held in Amman, the organizers expect intensive discussions between the regulatory scientists of the involved agencies and the audience will yield better understanding between all stakeholders. In addition to the interactive sessions, a dedicated session will be allowed to have an open forum with the speakers and regulators to address other specific topics and particular questions.

The ultimate goal of the harmonization initiative applying a global approach, is that the recommendations arrived at, as to harmonized update of pertinent guidelines and regulations, will be properly considered. Contributions to it include experimental findings and experience-based view-points, presented by the global scientific community in the field.
Symposium for Global Harmonization on Bioequivalence Requirements

Dr. Hayel Obeidat
Director General of Jordan Food and Drug Administration
Symposium for Global Harmonization on Bioequivalence Requirements

SPEAKERS

Prof. Henning Blume
Chair, EUFEPS

Dr. Ridha BELAIBA
Pharmacokinetics Team leader / ANSM, France

Dr. Marina Fertek
Clinical assessor, Marketing authorization division, Czech Republic FDA.

Dr. Wesal Al Haqish
Drug Directorate director at Jordan Food and Drug Administration

Prof. Saleh Alsuwayeh
Professor / Saudi FDA

Dr. Mohammed Khalil
Director General, ACDIMA

Dr. Ahlam Abdelaziz
Pharmacist in Drug Registration Department at JFDA

Dr. Maha Jagheer
Head of Drug Registration Unit in JFDA

TIPS & TRICKS

- You can connect to WiFi through SSID: GHBR2 | Password: Me@#GHBR2.
- You can ask questions using your smart phone by connecting to www.sli.do and then entering GHBR2 to join.
- If you would like to speak up for your questions, you can request a wireless mic, or you can use your own mic app on your smart phone by connecting to KN310 Bluetooth device, please disconnect once you finish.

Read more on events.acdima.com
Symposium for Global Harmonization on Bioequivalence Requirements

SPEAKERS

Dr. Vit Perlik
Independent Consultant

Dr. Anders Fuglsang
Consultant & auditor

Dr. Loice Kikwai
Managing Partner / Ex-US FDA

Dr. Nabila Al Lawati
Director of the central QC laboratory and Ministry of Health of Oman

Dr. Saleem Al-Mahrouq
Head of Clinical Studies Division/ JFDA

Dr. Ehab AbuHamra
R&D Director
MS Pharma

Maria Caturla
CEO
Anapharm Bioanalytics

Dr. Marika Pečená
Managing Partner
Quinta-Analytica

TIPS & TRICKS

- You can check for the agenda on events.acdima.com
- You can download the speaker material from Slido or from the speaker page on events.acdima.com at the end of the day; password for the materials is #GHBR2.
- You may register for ONE-TO-ONE meeting with speakers on events.acdima.com/one-one-registration/.

Read more on events.acdima.com
# Symposium for Global Harmonization on Bioequivalence Requirements

**DAY 1/MONDAY 30 OCTOBER 2017**

## REGISTRATION & RECEPTION

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
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<tbody>
<tr>
<td>09:00-09:10</td>
<td>OPENING CEREMONY</td>
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<tr>
<td>09:10-09:30</td>
<td>WELCOME ADDRESSES</td>
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### JFDA:
Support of JFDA to the Harmonization

### EUFEP:
The Global Bioequivalence Harmonization Initiative Goals and challenges

### AUPAM:
Contribution by countries from Arab region

## SESSION I: Review of “Harmonization” world-wide endeavors

**Chair:** Wesal Al Haqish  | **Moderator:** Dr. Ridha Belaiba

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
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<tbody>
<tr>
<td>09:30-11:30</td>
<td>Summary of results of previous main conferences of the Global Bioequivalence Harmonization Initiative (GBHI)</td>
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<tr>
<td>10:00-10:20</td>
<td>Significance of harmonizing international bioequivalence guidelines local and regional Experience</td>
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<tr>
<td>10:20-10:40</td>
<td>Suggestions how to deal with individual “implausible” PK-data in BE studies</td>
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<tr>
<td>10:40-11:00</td>
<td>Regulatory perspective on BE with prodrugs in the region</td>
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### SESSION II: Multiple dose studies and two-stage design

**Chair:** Dr. Vit Perlik  | **Moderator:** Dr. Mohammad Khalil

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<thead>
<tr>
<th>Time</th>
<th>Event</th>
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<tbody>
<tr>
<td>11:30-13:30</td>
<td>Similarities and differences between international guidelines</td>
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<tr>
<td>12:00-12:30</td>
<td>Characterisation of bioequivalence of MR products: are steady state studies necessary?</td>
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<tr>
<td>12:30-13:00</td>
<td>Regulatory experience with steady state studies</td>
</tr>
<tr>
<td>13:00-13:30</td>
<td>Two-stage trials for BE. The Potvin designs, Challenges for CRO, Sponsor and Regulator &amp; how to achieve harmonization</td>
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### SESSION III: Bioanalytical validation – update of regulations needed?

**Chair:** Prof. Saleh Alsuwayeh  | **Moderator:** Prof. Dr. Henning Blume

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<thead>
<tr>
<th>Time</th>
<th>Event</th>
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<tbody>
<tr>
<td>14:30-16:00</td>
<td>Current regulations in Europe and the USA</td>
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<tr>
<td>15:00-15:30</td>
<td>Regulator considerations on bioanalytical issues</td>
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<tr>
<td>15:30-16:00</td>
<td>Suggestions for up-dating analytical validation requirements –a CRO perspective</td>
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### SESSION IV: In a nutshell: regulatory updates on bioequivalence landscape

**Chair:** Dr. Marina Fertek  | **Moderator:** Prof. Dr. Henning Blume

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
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<tbody>
<tr>
<td>16:30-17:15</td>
<td>Product specific guidelines, development of long acting injectables and introduction of draft guideline for locally applied products</td>
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<tr>
<td>17:15-17:30</td>
<td>Q &amp; A</td>
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<tr>
<td>17:30-18:00</td>
<td>General discussion with all speakers</td>
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<tr>
<td>18:00-19:00</td>
<td>Face to face / One to One meetings (Preregistration is required)</td>
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### SESSION V: Bioequivalence in case of fixed-dose combinations

<table>
<thead>
<tr>
<th>Time</th>
<th>Session Title</th>
<th>Chair</th>
<th>Moderator</th>
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<tbody>
<tr>
<td>09:00 - 09:25</td>
<td>Regulatory requirements of BE of FDC</td>
<td>Dr. Marina Fertek</td>
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<tr>
<td>09:25 - 09:50</td>
<td>Current regulations in Europe and the USA</td>
<td>Dr. Ridha Belaiba</td>
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<tr>
<td>09:50 - 10:15</td>
<td>Impact of formulation properties on drug-drug interactions and potential for interactions with alcohol</td>
<td>Prof. Henning Blume</td>
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<tr>
<td>10:15 - 10:40</td>
<td>Regulatory experience with BE of FDC</td>
<td>Dr. Marina Fertek</td>
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<tr>
<td>10:40 - 11:00</td>
<td>JFDA Perspective on FDC</td>
<td>Dr. Ahlam Abdelaziz</td>
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<td>11:00 - 11:30</td>
<td>Coffee Break</td>
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### SESSION VI: Intention, goals and experience with audits & inspections

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<tr>
<th>Time</th>
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<tbody>
<tr>
<td>11:30 - 12:00</td>
<td>Articulation of evaluation &amp; inspection in Europe-ANSM experience</td>
<td>Dr. Ridha Belaiba</td>
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<tr>
<td>12:00 - 12:30</td>
<td>Common inefficiencies submitted in the BE studies</td>
<td>Dr. Nabila Lawati</td>
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<tr>
<td>12:30 - 13:00</td>
<td>Clinical studies in Jordan and CRO inspection</td>
<td>Dr. Saleem Mahrook</td>
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<tr>
<td>13:00 - 13:15</td>
<td>Experience with inspections from Experts perspective</td>
<td>Dr. Anders Fuglsang</td>
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<tr>
<td>13:15 - 13:30</td>
<td>Experience with inspections from CRO perspective</td>
<td>Dr. Marika Pečená</td>
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<td>13:30 - 14:30</td>
<td>Launch Break</td>
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### SESSION VII: Dissolution and biowaiver hot topics

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<thead>
<tr>
<th>Time</th>
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<th>Chair</th>
<th>Moderator</th>
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<tbody>
<tr>
<td>14:30 - 15:15</td>
<td>Variability in comparative dissolution testing, and the use of BOOTSTRAP statistical method to calculate none biased f2 similarity factor</td>
<td>Dr. Ehab AbuHamra</td>
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<tr>
<td>15:15 - 16:00</td>
<td>Biowaiver in EU</td>
<td>Dr. Ridha Belaiba</td>
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<tr>
<td>16:00 - 16:30</td>
<td>Coffee Break</td>
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### SESSION VII: Panel Discussion

**Panelists:**
- Regulators: JFDA, EMA, SFDA, GCC, Algeria MOH, Tunis MOH, Sudan MOH, UAE MOH
- Speakers: Prof. Henning Blume, Prof. Saleh Alsuwayeh, Dr. Anders Fuglsang, Dr. Loice Kikwai, Dr. Mohammad Khalil, Dr. Ehab Abu Hamra, Dr. Rabab Tayyem

| Time       | Session Title                                                                 |                                            |                            |
|------------|-------------------------------------------------------------------------------|                                            |                            |
| 16:30 - 17:30 | Face to face meetings (Preregistration is required)                          |                                            |                            |
| 17:30 - 18:30 | Concluding Remarks & Closeout                                                 |                                            |                            |
Symposium for Global Harmonization on Bioequivalence Requirements

WELCOME TO OUR WORLD!

One to One Registration Form

Dr/Mr/Mrs/Miss/Ms:

First name:

Last name:

Day 1                                   Day 2

Speaker:

Email:

Easy Ways to register

- Please email us on events@acdima.com
- Give us a call on + 962 6 582 1618
- Visit our website: www.acdima.com/events
Symposium for Global Harmonization on Bioequivalence Requirements

BEHIND THE SCENES ORGANIZERS

Dr. Hiam Dabbas
• Public Relation Director / JFDA

Dr. Rabab Tayyem
• CEO / ACDIMA BioCenter

Dr. Mohammed Abu Fara
• MD / ACDIMA BioCenter

Eng. Eyad Habashneh
• Administrative Affairs / ACDIMA

Ahmed Al-Bustanji
• Public Relations / ACDIMA

Dr. Shams Waleed
• QA Officer / ACDIMA BioCenter

Eng. Mohammad Sarayreh
• Network Analyst / ACDIMA

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• Programmer / ACDIMA

Dr. Zaid Benni
• Strategic Planning / MS Pharma

Mohammad Al Mhsiri
• QA Officer / ACDIMA BioCenter