**[Programme](http://www.dissolutionconference.co.za/index.php/programme)**

**DAY 1 (Monday 2nd December, 2013)**

**WELCOME AND MESSAGE**

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| **8.15** | **Welcome** |
|  | **Professor Isadore Kanfer, Chair: Organizing Committee** |
|  | **Message** |
|  | **Professor Rod Walker, Dean of Pharmacy** |

**DISSOLUTION TESTING**

***Session Chair: Mr Mike Aereboe***

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| **8:30 – 9:15** | **Updates on Dissolution/Drug Release Testing in the US Pharmacopeia** |
|  | **Speaker:         Dr.E.Stippler (USA-USP)** |
| **9:15 -10.00** | **The New USP Chapter 1092 Dissolution Method Development and Validation** |
|  | **Speaker:            Dr. Johannes Krämer (Germany)** |
| **10:00 -10.30** | ***Question & Answer Session*** |
|  | ***Moderator: Dr Mike Skinner*** |
| **10.30 -11.00** | ***~ Tea Break ~*** |

***Session Chair: Ms Samantha Mukozhiwa***

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| **11.00 -11.45** | **Qualification of Dissolution Apparatus** |
|  | **Speaker:          Dr.E.Stippler (USA-USP)** |
| **11:45 -12.30** | **Automation in Dissolution** |
|  | **Speaker:             Mr Knitter (Erweka)** |
| **12.30 -1.00** | ***Question & Answer Session*** |
|  | ***Moderator: Prof Rod Walker*** |
| **1.00- 2.15** | ***~ Lunch Break ~*** |

***Session Chair: Dr Raimar Löbenberg***

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| **2.15 -3.00** | **USP Chapter 1088 – from the Workbench Perspective** |
|  | **Speaker:          Dr. Johannes Krämer (Germany)** |
| **3.00 – 3.45** | **Bioperformance Dissolution Standards** |
|  | **Speaker:          Dr.G.Amidon (University of Michigan, USA)** |
| **3.45 -4.15** | ***~ Tea Break ~*** |

***Session Chair: Mr Pedzisai Makoni***

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| **4.15 – 5.00** | **Drug Product Performance – Continuing Equivalence** |
|  | **Speaker:          Dr. E. Stippler (USA-USP)** |
| **5.00- 5.45** | ***Questions & Answer Session*** |
|  | ***Moderator: Prof Izzy Kanfer*** |
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|  | **END OF DAY 1** |

**DAY 2 (Tuesday 3rd December, 2013)**

**BIOEQUIVALENCE TESTING – CURRENT REGULATORY ASPECTS**

**(USA, Canada, Europe and South Africa)**

***Session Chair: Ms Ashmita Ramanah***

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| **8.30 – 9.00** | **Prediction of “Food Effects” using Dissolution Testing** |
|  | **Speaker:             Dr. R. Löbenberg (University of Alberta, Canada)** |
| **9.00 -9.30** | **USP Flow-Through Apparatus (Apparatus 4): Applications** |
|  | **Speaker:          Dr. E. Stippler (USA-USP)** |
| **9.30 – 10.00** | **Bioequivalence Requirements for Market Approval of Generic Drug Products in South Africa: Current Guidelines** |
|  | **Speaker:           Prof. R.B.Walker (Rhodes University)** |
| **10.00 -10.30** | ***Questions & Answers Session*** |
|  | ***Moderator: Dr Johannes Krämer*** |
| **10.30 -11.00** | **~ Tea Break ~** |

***Session Chair: Dr Mike Skinner***

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| **11.00 -11.30** | **New Canadian Guidelines for Bioequivalence** |
|  | **Speaker:           Dr.M.Ducharme (Health Canada)** |
| **11.30 -12.00** | **Options for the Bioequivalence Assessment of Topical Products** |
|  | **Speaker:             Prof. I.Kanfer (Rhodes University)** |
| **12:00 -12:30** | ***Questions & Answers Session*** |
|  | ***Moderator: Mr Mike Aereboe*** |
| **12:30 -2:00** | **~ Lunch Break ~** |

***Session Chair: Prof Rod Walker***

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| **2:00 -2:30** | **Biosimilars: Regulatory Requirements for Market Approval** |
|  | **Speaker:           Dr. M.Ducharme (Health Canada)** |
| **2:30 -3:00** | **International Bioequivalence Recommendations** |
|  | **Speaker:             Dr. B.Davit (Merck Researcjh Labs, USA)** |
| **3:00 -3.30** | **Dissolution evaluation in the Office of Generic Drugs** |
|  | **Speaker:           Dr. B.Davit (Merck Research Labs, USA)** |
| **3:30 – 4:00** | **~ Tea Break ~** |

***Session Chair: Dr Murray Ducharme***

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| **4:00 -4:30** | **Bioequivalence & Biowaivers – A WHO update** |
|  | **Speaker:           Dr J.Gordon (WHO)** |
| **4:30 – 5:00** | **BCS and Beyond – Limitations and Steps Towards Harmonization** |
|  | **Speaker:             Dr.G.Amidon (University of Michigan, USA)** |
| **5:00 – 5.30** | **FDA Generic Drug Products User Fees (GDUFA): Background and Implications** |
|  | **Speaker:           Dr Lane Christensen (FDA)** |
| **5:30 – 6:00** | ***Questions & Answers Session*** |
|  | ***Moderator: Prof Rod Walker*** |
|  | **Closing Remarks** |