

# SAAPI Conference 2018

*"Right Time Right Now"*

## Conference Programme

Thursday, 04 October 2018

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<b>08:00</b>	<b>Registration &amp; Networking</b>
<b>09:00</b>	<b>Welcome and Introduction to Day 1</b> <i>Prof. Doug Oliver</i>
<b>09:10</b>	<b>Update from SAHPRA</b> <i>Prof Shabir Banoo - Technical Operations &amp; Regulatory Strategy Committee - SAHPRA</i>
<b>10:00</b>	<b>The Impact of Local and Global Regulations and Guidelines on the South African Clinical Trial Industry</b> <i>Ms Nicola Main - Clinical Research Manager - Cato Research and SACRA Vice - Chairperson</i>
<b>10:30</b>	<b>Questions and Round Table Discussion</b>
<b>10:45</b>	<b>Tea</b>
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<b>11:15</b>	<b>Role of the RP and QA in a Manufacturing Environment</b> <i>Mr Enos Motshitela – Inspectorate - SAHPRA</i>
<b>11:45</b>	<b>From Compliance Check to Quality Oversight</b> <i>Dr Georg Sindelar - Division Manager Qualification and Consulting - Chemengineering Business Design GmbH</i>
<b>12:45</b>	<b>Round Table Discussion</b>
<b>13:00</b>	<b>Networking Lunch</b>
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<b>14:00</b>	<b>Metrics &amp; KPIs - a Case Study</b> <i>Dr Georg Sindelar - Division Manager Qualification and Consulting - Chemengineering Business Design GmbH</i>
<b>15:00</b>	<b>Medical Devices: The Roles and Responsibilities of the Authorised Representative; Medical Device Regulations and Guidelines - Progress made and the way forward; and Product Surveillance and Reporting</b> <i>Ms Andrea Julsing Keyter - Deputy Director: Medical Devices - SAHPRA</i>
<b>15:30</b>	<b>Industry Perspective on the new Medical Device Regulations and Guidelines</b> <i>Ms Avanthi Bester - Regulatory Affairs Manager, Africa - BD</i>
<b>16:00</b>	<b>Cybercrime in South Africa - Specific Focus on the Medical Industry</b> <i>Ms Candice Sutherland - Cyber Insurance Underwriter - ITOO Special Risks</i>
<b>17:00</b>	<b>Close</b> <b>Networking Cocktail Function</b>

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**\*PLEASE NOTE: Topics, times and speakers are subject to confirmation and are therefore subject to change.**

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**Friday, 05 October 2018**

- 08:00**            **Registration & Networking**
- 09:00**            **Welcome and Introduction to Day 2**  
*Prof Doug Oliver*
- 09:10**            **International Society of Pharmaceutical Engineering (ISPE)**  
**Session 1 - Data Integrity**  
*Ms Alice Redmond - Vice President, European Operations*  
*Commissioning Agents, Inc. and Director - ISPE*
- 10:00**            **Title to be Confirmed**  
*Dr Anban Pillay - Deputy Director General - National Department of Health*
- 10:30**            **Tea (30 mins)**
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- 11:00**            **International Society of Pharmaceutical Engineering (ISPE)**  
**Session 2 – Pharma 4.0**  
*Ms Alice Redmond - Vice President, European Operations*  
*Commissioning Agents, Inc. and Director - ISPE*
- 11:50**            **Validation - Phase 1, Phase 2 and Phase 3 Approach (Unwrapping the FDA's new Guidance Document)**  
*Mr Dale Gyure - Independent Consultant - Far Sight Skills Development*
- 12:30**            **Round Table Discussion**
- 13:00**            **Lunch**
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- 14:00**            **Specialization - MPharm (Industrial Pharmacy) - An update**  
**Pharmacy Technicians and the Mid-Level Pharmacy Workforce**  
*Mr Amos Masango - Registrar/Chief Executive Officer - South African Pharmacy Council*
- 14:30**            **The Practical Implementation of the Marketing Code: Contracting HCPs, sponsorships and CPDs.**  
*Ms Suzette van Rooyen - Director Ethics and Compliance - Astellas Pharma*
- 15:10**            **Motivational Speaker**  
*Ms Arthie Moore - Ki Leadership Institute*
- 16:00**            **Closing Address**  
*Stavros Nicolaou - Senior Executive - Strategic Trade Dev, Strategic Trade - Aspen Pharmacare*
- 16:30**            **Closure and Departure**
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