



S A Pharmaceutical Regulatory Affairs Association
 P O Box 2909
 Randburg 2125
 R.S.A.
 Telephone: (011) 928 8856
 Telefax: (011) 974 7787

AGENDA

DATE: 15 September 2010
VENUE: Bytes Conference Centre (Midrand)

<i>Topics to be covered and speakers</i>		<i>Time allocation</i>
<i>Registration</i>		<i>08:00 – 09:00</i>
Introduction and welcome	Marie McLellan (for Dorcas Peta)	09:00 – 09:10
<i>The ZA CTD – It's a piece of cake!</i> A presentation on the Structure and Regulatory requirements of the ZA CTD as compared to the EU CTD	Hilde Rodseth DRA Pharmacist Boehringer Ingelheim (Pty) Ltd	09:10 – 09:50
<i>Proof of the pudding is in the eating!</i> An Applicant's experience with compilation of a paper-based ZA CTD	Penny Slabbert DRA Pharmacist Boehringer Ingelheim (Pty) Ltd	09:50 – 10:30
<i>Spring inspired "High tea"</i>		<i>10:30 – 11:15</i>
<i>A touch of indigestion?</i> Industry comments on the ZA CTD guidelines	Abeda Williams PIASA	11:15 – 11:45
Clarification and discussion of the MCC's CTD and eCTD roadmap	Estelle Taute Director Ops and admin (MCC)	11:45 - 12:15
Presentation on a software system for industry use for the CTD: <ul style="list-style-type: none"> • General overview of CTD • Best practices when considering moving over to CTD (and eCTD) • Document management 	Michael Schulz (Lorenz)	12:15 – 13:00
<i>Lunch</i>		<i>13:00 – 14:30</i>