

MEDICINES CONTROL COUNCIL



eCTD Go-live in South Africa

TO ALL APPLICANTS

The Medicines Control Council (MCC) went live with eCTD for New Chemical Entities on 01 April 2016, and the intended go-live date for generic applications is 02 January 2017.

With lessons learned in the pilot phase the specifications and validation requirements have been changed. These will be published shortly, and will be presented to industry at a workshop in October 2016.

You are invited to attend a one-day workshop on either Tuesday, 18 October 2016, or Wednesday, 19 October 2016, in the Civitas Building, Auditorium, Podium Level, 42 Thabo Sehume Street, Pretoria.

As space is limited, we request that a maximum of three delegates per company attend, preferably only two, of which one should have a sound knowledge of regulatory processes, and the other of IT.

The agenda and registration form can be accessed at: 18 October www.xing-events.com/MCC-Oct18
19 October www.xing-events.com/MCC-Oct19

Please register as soon as possible, but not later than 10 October 2016.

Enquiries: Mrs E Taute 012 395 8034

Proposed agenda:

Time	Topic	Speaker
9:00 – 9:30	Welcome and Key Note address	Mrs JE van Oudtshoorn, MCC
9:30 – 11:00	eCTD basics	Dr Silke Nolkemper, Christine Hirt - EXTEDO
11:00 – 11:20	Coffee break	
11:20 – 13:00	New M1 for ZA including live demo	Dr Silke Nolkemper, Christine Hirt - EXTEDO
13:00 – 14:00	Lunch	<i>Only tea and coffee provided</i>
14:00 – 15:00	Experiences from Pilot from Agency perspective	Estelle Taute, Director: Operations & Administration, MCC
15:00 – 15:30	Experiences from Pilot from Industry perspective	Anita Smal, ABEX Pharmaceutica
15:30 – 16:00	Q&A session	All

DR JC GOUWS
REGISTRAR OF MEDICINES