



CONTACT FOR BOOKINGS/QUERIES:

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** Please note courses will only be held if for:*

- 1 day course; a minimum of 5 attendees register
- 2-5 day course; a minimum of 10 attendees register.

**DISCOUNTS
&
COMPANY
SPECIFIC
TRAINING**

- Discounts for group bookings available
- Discounts for multiple course bookings also available
- Tailor made company specific training available

For more details visit:
www.twinztraining.com

23 JANUARY 2019

INSPECTION READINESS

1 day course

- SAHPRA/MCC and SACP Legislation
- Legal Compliance during an inspection.
- PICS Guideline

06 FEBRUARY 2019

**REQUIREMENTS FOR
SPECIFIC SADC
ENGLISH SPEAKING
AFRICAN COUNTRIES**

1 day course

Comprehensive training on the regulatory requirements in specific African countries Botswana, Namibia, Zimbabwe, Zambia, Mozambique, Malawi, Mauritius, Ghana, Nigeria, Kenya, Uganda, Tanzania and Ethiopia.

**13 FEBRUARY 2019
SOUTH AFRICAN
AMENDMENTS/
VARIATION
REQUIREMENTS**

1 day course

Current regulatory requirements in order to meet SAHPRA/MCC requirements for various variations to the South African Dossier.
-Compilation of the Amendment Schedule

**27 FEBRUARY 2019
VARIATIONS TO
MARKETING
AUTHORISATIONS IN
THE EU**

1 day course

- An introduction to the European Commission system for Variations
- The Current Variations
- Regulations of the EC and procedures in practice
- Review of latest requirements
- Pharmaceutical and Clinical Variations
- Practical advice on the preparation and submission of variation applications

**05 – 06 MARCH 2019
PROFESSIONAL
INFORMATION AND
PATIENT INFORMATION
LEAFLET TRAINING**

2 day course

Compilation of the professional information and patient information leaflet with the implications of the latest published regulations.

- South African Legislation
- SAHPRA/MCC guidelines
- ZA CTD requirements
- Amendments & General information
- SR-PINS
- USRNS
- Safety & Medicine Safety Alerts
- Relevance of CCDS & PSURs/ PBRER
- Referencing System