

ROLLING TRAINING CALENDAR | 2017 – 2018

SHORT COURSES IN REGULATORY AFFAIRS FOR:	May	June	July	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	April
COMPANY EXECUTIVES & BOARD MEMBERS [2 Days]						11 12					13 14	
REGULATORY AFFAIRS MANAGERS [RAMs] RESPONSIBLE PHARMACISTS [RPs] [3 Days]			4 5 6							06 07 08		
REGULATORY AFFAIRS ASSISTANTS [3 Days]				15 16 17						20 21 22		
REGULATORY AFFAIRS PHARMACISTS [3 Days]						17 18 19						10 11 12
PHARMACOVIGILANCE OFFICERS [2 Days]				1 2							7 8	
GXP FOR APPLICANTS / HOLDERS OF CERTIFICATES OF REGISTRATION [3 Days]		7 8 9					7 8 9					
REGULATORY DOCUMENTS AUTHORIZING & EDITING [2 Days]							1 2		16 17			
REGISTRATIONS FOR AFRICA [3 Days]			18 19 20						23 24 25			

Please remember to book your seat by the **latest 2 weeks prior to the training date** to avoid disappointment.
Complete the **REGISTRATION FORM** and email to training@mra-regulatory.com with the attached particulars.

Changes from previous calendar: **Rescheduled** **New**



REGULATORY AFFAIRS MANAGERS [RAMs] | RESPONSIBLE PHARMACISTS [RPs]

TRAINING AGENDA

DAY 1

Topic		
1.	Medicine Regulation: The Act, The Councils & The Process	AM
2.	Medicine Regulation: The Past, Present & Future	AM - PM
3.	Medicine Regulation: References Websites , Guidelines & Circulars	PM

DAY 2

Topic		
1.	The Registration Dossier, Registration Guidelines & Due Diligence	AM
2.	The Registration Certificate, Conditions of Registration & Maintaining Compliance	PM

DAY 3

Topic		
1.	GMP, RA & PV – The Compliance Trinity	AM
2.	Managing the RA Department	PM

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[REGISTRATION FORM](#)



**REGULATORY AFFAIRS PHARMACISTS
TRAINING AGENDA**

DAY 1

Topic Medicine Regulation		
1.	The Act, The Councils & The Process	AM
2.	The Past, Present & Future	AM
3.	Registration Process Flow & Evaluation Procedures	PM
4.	References Websites , Guidelines & Circulars	AM

DAY 2

Topic		
1.	Understanding the Registration Dossier	AM
2.	Due Diligence	PM

DAY 3

Topic		
1.	Submission Ready Documentation & Regulatory Writing	AM
2.	Medicine Registration Certificate & Conditions of Registration	AM - PM
3.	Dossier Maintenance	PM

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**REGULATORY AFFAIRS ASSISTANTS
TRAINING AGENDA**

DAY 1

Topic		
1.	Medicine Regulation: The Act, The Councils & The Process	AM
2.	Websites , Guidelines & Circulars	PM

DAY 2

Topic		
1.	The Registration Dossier, Registration Guidelines & Creation of Electronic File Structures	AM
2.	Preparing Submission Copies and Maintaining in-house Filing	PM

DAY 3

Topic		
1.	Post-Screening Copies and Medicines Control Council (MCC) Communications	AM
2.	Dossier maintenance and life-cycle management	PM

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PHARMACOVIGILANCE OFFICERS TRAINING AGENDA

DAY 1

Topic		
1.	The “What?”, “Why?” and “Where?” of Pharmacovigilance	AM

DAY 2

Topic		
1.	PV Requirements Local & International	AM
2.	PV Plan Development & Implementation	PM

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REGULATORY DOCUMENTS | AUTHORING & EDITING

TRAINING AGENDA

DAY 1

Topic		
1.	ICH & MCC Guidelines	AM
2.	PDF Editing <ul style="list-style-type: none"> • ICH Compliance Requirements • MCC Compliance Requirements • Exercises 	PM

DAY 2

Topic		
1.	Microsoft Word – Exercises <ul style="list-style-type: none"> • Creation of Regulatory Affairs Templates • Leveraging MS Word functionalities • Exercise 	AM – PM

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REGISTRATION FORM

Please complete the following booking particulars and return them to training@mra-regulatory.com:			
Title, Name & Surname			
Qualification			
Designation/Job Description			
Employer/Company Name			
Contact Details	Email		Mobile

Interested in Attending:	Cost:	<input checked="" type="checkbox"/>	Training Dates
Please tick (✓) Training Course Title(s) and indicate the preferred date as per the Training Calendar	COMPANY EXECUTIVES & BOARD MEMBERS [2 days]	R 7,100.00	
	REGULATORY AFFAIRS MANAGERS [RAMs] RESPONSIBLE PHARMACISTS [RPs] [3 days]	R 8,900.00	
	REGULATORY AFFAIRS ASSISTANTS [3 days]	R 8,900.00	
	REGULATORY AFFAIRS PHARMACISTS [3 days]	R 8,900.00	
	PHARMACOVIGILANCE OFFICERS [2 days]	R 7,100.00	
	GMP FOR APPLICANTS / HOLDERS OF CERTIFICATES OF REGISTRATION [3 days]	R 8,900.00	
	REGULATORY DOCUMENTS AUTHORIZING & EDITING [2 days]	R 7,100.00	
	REGISTRATIONS FOR AFRICA [3 days] *** New ! ***	R 8,900.00	

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Complete the **REGISTRATION FORM** and email to training@mra-regulatory.com with the attached particulars.

Please complete the following booking particulars and return them to training@mra-regulatory.com :	
Title, Name & Surname	
Dietary Requirements	Please mark if applicable: Vegetarian <input type="checkbox"/>
Please Note:	<p>MRA Regulatory Consultants (MRA) will provide a standard meal – vegetarian/non-vegetarian depending on the selection made above.</p> <p>A microwave is available to heat any special meals that a delegate may require and can bring along.</p> <p>Trainees are required to be at the training venue by 08:45 for a planned finish at 16:30. Training takes place at MRA Regulatory Consultants (MRA)'s office.</p> <p>Parking is available at own risk, at the MRA Regulatory Consultants office.</p>
Terms & Conditions:	<p>Certificates of attendance are issued on the last day of training, at the time of closure. A Training Register is kept for record purposes. Certificates are not issued if the trainee has not attended/been present for the entire training, irrespective of the reason for not being able to do so.</p> <p>Trainees are required to comply with MRA's IT and office policies.</p> <p>In the event that a delegate does not arrive for the programme or event and no written cancellation has been received and confirmed by MRA 7 (seven) working days prior to the commencement of the programme or event, the full fee remains payable or will not be refunded.</p> <p>Provided that the delegate has notified MRA 7 (seven) working days prior to the commencement of the programme or event, the delegate shall be entitled to postpone attending the programme or event to a future date subject to these Terms and Conditions remaining binding and in full force and effect.</p> <p>Programme details are given in good faith, however MRA reserves the right to change the programme or event content and presenters or to cancel a programme or event and will notify all registered delegates accordingly should this occur. The full programme or event fees will be refunded if the programme or event is cancelled by MRA.</p> <p>All course materials provided for the duration of the learning programme are the copyrighted works of MRA, and are provided for the sole use of the delegate attending the course in question. Reproduction, distribution or modification of the course material is strictly prohibited.</p> <p>MRA accepts no liabilities with respect to damage to property, vehicles or personal harm or injury. The trainee and his/her employer will hold MRA, its affiliates and staff harmless in this regard.</p>

Please complete the following booking particulars and return them to training@mra-regulatory.com :			
Title, Name & Surname			
	MRA reserves the right to refuse admission to any programme or event, should payment for the delegate's attendance not have been received, or should the delegate be suspected of being a health or safety risk to other delegates and to the facilitator or seen to be a disruption to the other delegates in attendance.		
Signed in acknowledgement of the above:			
Signature:		Date:	



Kindly complete the attached particulars for invoicing purposes:

COMPANY DETAILS:

FULL COMPANY NAME (PTY / CC / TRUST)

TRADING NAME

COMPANY REGISTRATION NUMBER

COMPANY'S VAT REGISTRATION NO.

PHYSICAL ADDRESS

POSTAL ADDRESS

CONTACT PERSON (NAME AND SURNAME)

CONTACT PERSON'S DESIGNATION

E-MAIL ADDRESS (PROJECT CONTACT)

TEL NO.

FAX NO.

MOBILE NO.

FINANCE DEPARTMENT:

CONTACT PERSON (NAME & SURNAME)

CONTACT PERSON'S DESIGNATION

E-MAIL ADDRESS (FINANCIAL CONTACT)

TEL NO.

FAX NO.

MOBILE NO.

Proof of payment is required to confirm the booking. Please send this together with the completed forms.

A VAT invoice can be issued ahead of payment if required. Please indicate this in your mail.