WEBINARS | COMPLIANCE SERIES

Regulated Health Products in South Africa	2020 Schedule[1]			Product Portfolio Focus									
				Medicines					Medical Devices				
Webinar Topics	**Date**	**Time**	**Duration**	**RP**	**RAP**	**RAA**	**PVO**	**GxP**	**AR**	**RAP**	**RAA**	**VO**	**GxP**
1. Health Products Regulation: The Act, The Councils & The Processes	11.03	12:00	1,5 hrs	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
2. Health Products Regulation: The Past, Present & Future – Category A Medicines	18.03	12:00	1 hr	✓	✓	✓	✓	✓	✗	✗	✗	✗	✗
3. Health Products Regulation: The Past, Present & Future – Category D Medicines	01.04	12:00	1,5 hrs	✓	✓	✓	✓	✓	✗	✗	✗	✗	✗
4. Health Products Regulation: The Past, Present & Future – MDs	15.04	12:00	1,5 hrs	✗	✗	✗	✗	✗	✓	✓	✓	✓	✓
5. Health Products Regulation: References | Websites , Guidelines & Circulars	22.04	12:00	2 hrs	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
6. Classification of Health Products – Borderline Products	29.04	12:00	2,5 hrs	✓	✓	✗	✗	✗	✓	✓	✗	✗	✗
7. Registration Process Flow & Evaluation Procedures – Category A Medicines	06.05	12:00	1 hr	✓	✓	✓	✗	✗	✗	✗	✗	✗	✗
8. Registration Process Flow & Evaluation Procedures – Category D Medicines	13.05	12:00	1 hr	✓	✓	✓	✗	✗	✗	✗	✗	✗	✗
9. The Registration Dossier, Registration Guidelines & Due Diligence – Category A Medicines	20.05	12:00	2 hrs	✓	✓	✗	✗	✗	✗	✗	✗	✗	✗
10. The Registration Dossier, Registration Guidelines & Due Diligence – Category D Medicines	27.05	12:00	2 hrs	✓	✓	✗	✗	✗	✗	✗	✗	✗	✗
11. Submission Ready Documentation & Regulatory Writing	03.06	12:00	1,5 hrs	✓	✓	✓	✓	✓	✗	✗	✗	✗	✗
12. Dossier Maintenance – Conversions, Updates & Variations	10.06	12:00	1,5 hrs	✓	✓	✓	✓	✓	✗	✗	✗	✗	✗

[1] Webinars run on Wednesdays from 12:00. Scheduling is subject to change. If a session is postponed, it will be postponed to the following Wednesday, causing a week's shift in the schedule. It is recommended to block all Wednesdays for the duration of the series, irrespective of portfolio, for the event of a postponement occurring.

RPs = Responsible Pharmacists & Regulatory Affairs Managers | RAPs = Regulatory Affairs Pharmacists / Professionals | RAAs = Regulatory Affairs Assistants | P-|VOs = Pharmaco|Vigilance Officers | GxP = Good Practice – Compliance Officers for Applicants/HCRs

Cat A = Human Category A Medicines | Cat D = Human Category D Medicines | CMs DS & Health Supplements | ARs = Authorised Representatives & Regulatory Affairs Managers | MDs = Medical Devices: IVDs & Non-IVDs

381 Rossouw Street | Murrayfield | 0184
Pretoria | Gauteng | South Africa

Tel: +27 (0)12 803-6223 /-5955 /-1039

www.mra-regulatory.com

Registration enquiries email training@mra-regulatory.com

Regulated Health Products in South Africa	2020 Schedule[1]			Product Portfolio Focus									
				Medicines					Medical Devices				
Webinar Topics	**Date**	**Time**	**Duration**	**RP**	**RAP**	**RAA**	**PVO**	**GxP**	**AR**	**RAP**	**RAA**	**VO**	**GxP**
13. Regulatory Information Management over Lifecycle	24.06	12:00	1,5 hrs	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
14. Creating eCTD Baselines	15.07	12:00	1,5 hrs	✓	✓	✓	✗	✗	✗	✗	✗	✗	✗
15. Managing correspondence with a Regulator	29.07	12:00	1,5 hrs	✓	✓	✓	✗	✗	✓	✓	✓	✓	✓
16. The Registration Certificate, Conditions of Registration & Maintaining Compliance	05.08	12:00	2 hrs	✓	✓	✓	✓	✓	✗	✗	✗	✗	✗
17. GMP, RA, Vigilance & Data Integrity – The Compliance Pillars	19.08	12:00	2 hrs	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
18. Periodic Product Reviews – Quality, RA & Vigilance	26.08	12:00	2 hrs	✓	✓	✓	✓	✓	✗	✗	✗	✗	✗
19. Risk Management for Applicants / HCRs	02.09	12:00	2 hrs	✓	✓	✓	✓	✓	✗	✗	✗	✗	✗
20. Managing the RA Department	09.09	12:00	2 hrs	✓	✓	✗	✗	✓	✓	✓	✗	✗	✓
21. Pharmacovigilance Requirements | Local & International	16.09	12:00	2 hrs	✓	✓	✓	✓	✗	✗	✗	✗	✗	✗
22. Vigilance Requirements | Local & International	30.09	12:00	2 hrs	✗	✗	✗	✗	✗	✓	✓	✓	✓	✓
23. Pharmacovigilance Plan | Development & Implementation	14.10	12:00	2 hrs	✓	✓	✓	✓	✗	✗	✗	✗	✗	✗

[1] Webinars run on Wednesdays from 12:00. Scheduling is subject to change. If a session is postponed, it will be postponed to the following Wednesday, causing a week's shift in the schedule. It is recommended to block all Wednesdays for the duration of the series, irrespective of portfolio, for the event of a postponement occurring.

RPs = Responsible Pharmacists & Regulatory Affairs Managers | RAPs = Regulatory Affairs Pharmacists / Professionals | RAAs = Regulatory Affairs Assistants | P-|VOs = Pharmaco|Vigilance Officers | GxP = Good Practice – Compliance Officers for Applicants/HCRs

Cat A = Human Category A Medicines | Cat D = Human Category D Medicines | CMs DS & Health Supplements | ARs = Authorised Representatives & Regulatory Affairs Managers | MDs = Medical Devices: IVDs & Non-IVDs

381 Rossouw Street | Murrayfield | 0184
Pretoria | Gauteng | South Africa

Tel: +27 (0)12 803-6223 /-5955 /-1039

www.mra-regulatory.com

Registration enquiries email training@mra-regulatory.com

Regulated Health Products in South Africa	2020 Schedule[1]			Product Portfolio Focus									
				Medicines					Medical Devices				
Webinar Topics	**Date**	**Time**	**Duration**	**RP**	**RAP**	**RAA**	**PVO**	**GxP**	**AR**	**RAP**	**RAA**	**VO**	**GxP**
24. Vigilance Plan | Development & Implementation	28.10	12:00	2 hrs	✘	✘	✘	✘	✘	✓	✓	✓	✓	✓
25. Pharmacovigilance Submissions	04.11	12:00	1,5 hrs	✓	✓	✓	✓	✘	✘	✘	✘	✘	✘
26. Vigilance Reporting	11.11	12:00	1,5 hrs	✘	✘	✘	✘	✘	✓	✓	✓	✓	✓
27. Managing Section 21 Exemptions	25.11	12:00	1 hr	✓	✓	✓	✓	✘	✓	✓	✓	✓	✓
28. Creating Requests for Designation – Borderline Products	02.12	12:00	1 hr	✓	✓	✘	✘	✘	✓	✓	✘	✘	✘
				39,5 hrs	39,5 hrs	30 hrs	25 hrs	20,5 hrs	22 hrs	22 hrs	16,5 hrs	16,5 hrs	18,5 hrs

[1] Webinars run on Wednesdays from 12:00. Scheduling is subject to change. If a session is postponed, it will be postponed to the following Wednesday, causing a week's shift in the schedule. It is recommended to block all Wednesdays for the duration of the series, irrespective of portfolio, for the event of a postponement occurring.

RPs = Responsible Pharmacists & Regulatory Affairs Managers | RAPs = Regulatory Affairs Pharmacists / Professionals | RAAs = Regulatory Affairs Assistants | P-|VOs = Pharmaco|Vigilance Officers | GxP = Good Practice – Compliance Officers for Applicants/HCRs

Cat A = Human Category A Medicines | Cat D = Human Category D Medicines | CMs DS & Health Supplements | ARs = Authorised Representatives & Regulatory Affairs Managers | MDs = Medical Devices: IVDs & Non-IVDs