

**2024/2025 FINANCIAL YEAR - SAAPI WORKSHOPS**

**WORKSHOPS ARE PROPOSED AND SUBJECT TO CHANGE**

DATE	TOPIC	DESCRIPTION	TRAINER	VENUE	SESSIONS/TIMES	PRICE
04-Feb-25	Pharmaceutical Quality System Elements (PQS Elements) Quality Risk Management	How to compile a QRA and maintain a living QRM Register	PharmaConsult - Rosemary Kietzmann	Online	08h30 - 11h00	Members: R1 000 Non-Members: R1190
06-Feb-25 & 07-Feb-25	QMS for Medical Devices		ISOHealth - Simone Rudolph Shortt	Online	09h00 - 13h00	Members: R3 200 Non-Members: R3 800
11-Feb-25 & 12-Feb-25 & 13-Feb-25	GWP/GDP	GWP and GDP - Legal Provision, Guiding Principles, Good Pharmacy Practice, SA GWP, GDP for Medical Products WHO and PIC/S. Contractual Activities -SLA and Technical Agreements, Customer Verification, Organization and Management, Personnel, Premises and Equipment, Operations, Complaints/ Returns/ Suspected falsified products and Recalls	ZA Med Consulting - Fleur Hartman	Online	09h00 - 13h00	Members: R4 800 Non-Members: R5 700
18-Feb-25	PQS Elements - Quality Issues	Deviations and audit observations & Investigations - using RCA and how to use RCA tools	PharmaConsult - Rosemary Kietzmann	Online	08h30 - 11h00	Members: R1 000 Non-Members: R1190
19-Feb-25 & 20-Feb-25	Business English Writing		Own Your World - Yuver	Online	09h00 - 13h00	Members: R3 200 Non-Members: R3 800
25-Feb-25	Introducing HTA	Health Technology Assessment	Syenza - Dr. Joao Carapinha	Online	09h30 - 10h30	Members: Free Non-Members: R250
28-Feb-25	MCA		MCA - Val Beaumont	Online	09h00 - 11h00	R500
04-Mar-25	PQS Elements - CAPA Management & Change Management	Compile CAPAs and related Change Controls with Effective Checks	PharmaConsult - Rosemary Kietzmann	Online	08h30 - 11h00	Members: R1 000 Non-Members: R1190
11-Mar-25 & 12-Mar-25	GWP/GDP: Role of RP	Role of RP in Wholesale and Distribution of Meds and SK Substances - Legal Provision, Pharmacy Act, Guiding Principles, GPP and SA GWP.	ZA Med Consulting - Fleur Hartman	Online	09h00 - 13h00	Members: R3 200 Non-Members: R3 800
18-Mar-25	PQS Elements - Compiling a Technical Quality Agreement (TQA)	Compiling a Technical Quality Agreement (TQA) - for various types of suppliers/ vendors	PharmaConsult - Rosemary Kietzmann	Online	08h30 - 11h00	Members: R1 000 Non-Members: R1190
19-Mar-25	HTA - Workshop 1	Introduction to Health Technology Assessment (HTA) and Health Economics and Outcomes Research, Economic Analysis of Medicines and Medical Devices, Budget Impact Analysis	Syenza - Dr. Joao Carapinha	Online	09h30 - 13h30	Members: R1 600 Non-Members: R1 900
25-Mar-25 & 26 Mar-25	Medical Device: QMS Auditing Techniques		ISOHealth - Simone Rudolph Shortt	Online	09h00 - 13h00	Members: R3 200 Non-Members: R3 800
09-Apr-25 & 10-Apr-25	Variations	Variations to Market Authorisations: SAHPRA & EU Guidelines & Requirements	Twinz - Salma Ismail	Online	08h30 - 12h30	Members: R3 200 Non-Members: R3 800
22-Apr-25 & 24-Apr-25	Health Products Risk Management		ISOHealth - Simone Rudolph Shortt	Online	09h00 - 13h00	Members: R3 200 Non-Members: R3 800
06-May-25	PQS Elements - Compiling a Self Inspection Schedule and checklists	Compile Self-Inspection schedule and checklists integrated with Data Integrity principles used in the Verification Process	PharmaConsult - Rosemary Kietzmann	Online	08h30 - 11h00	Members: R1 000 Non-Members: R1190
07-May-25	HTA - Workshop 2	Decision Analysis and Economic Modeling; Real-World Examples and Practical Skills; Critiquing Health Economics and Outcomes Research Articles	Syenza - Dr. Joao Carapinha	Online	09h30 - 13h30	Members: R1 600 Non-Members: R1 900

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13-May-25 & 14-May-25	Validation for Medical Devices		ISOHealth - Simone Rudolph Shortt	Online	09h00 - 13h00	Members: R3 200 Non-Members: R3 800
20-May-25	PQS Elements - FP Transport Validation requirements	FP Transport Validation requirements - from site of manufacturer to local receiving FP warehouse - transport requirements for Distribution contractor, imported batch to batch verification requirements	PharmaConsult - Rosemary Kietzmann	Online	08h30 - 11h00	Members: R1 000 Non-Members: R1190
21-May-25 & 22-May-25	cGXP Inspection Readiness - HCR Applicant Facilities	cGXP Inspection Readiness for HCR (Applicant) Facilities - Review current requirements, practical emphasis on how to prepare for the audit (Health Authority and Customer audits) ; How to compile responses - use of PQS System, recommended documentation; How to conduct effectiveness checks	PharmaConsult - Rosemary Kietzmann	Online	08h30 - 12h30	Members: R3 200 Non-Members: R3 800
28-May-25	MCA		MCA - Val Beaumont	Online	09h00 - 11h00	R500
10-Jun-25	PQS Elements - Structure of a comprehensive PQS & Good Documentation Practice	PQS Elements - <b>Structure of a comprehensive PQS and Good Documentation Practice</b>	PharmaConsult - Rosemary Kietzmann	Online	08h30 - 11h00	Members: R1 000 Non-Members: R1190
11-Jun-25 & 12-Jun-25	Medical Device: Post Marketing Surveillance/Vigilance/Adverse Incidents		ISOHealth - Simone Rudolph Shortt	Online	09h00 - 13h00	Members: R3 200 Non-Members: R3 800
19-Jun-25 & 20-Jun-25	GWP/GDP: Self Inspection and External Audits of outsourced activities		ZA Med Consulting - Fleur Hartman	Online	09h00 - 13h00	Members: R3 200 Non-Members: R3 800
24-Jun-25	PQS Elements - Batch Record Release & Annual Product Quality Review	Batch Record Release review process and Annual Product Quality Review process related to batch release	PharmaConsult - Rosemary Kietzmann	Online	08h30 - 11h00	Members: R1 000 Non-Members: R1190
08-Jul-25 & 09 Jul-25	Managing Effective Business Meetings		Own Your World - Yuver	Online	09h00 - 13h00	Members: R3 200 Non-Members: R3 800
22-Jul-25	Tech Transfer Process & Compiling Protocols	Tech Transfer Process and Compiling Protocols - from dossier to living product - includes product process and analytical method Tech Transfers - Compiling a TTP. (CMO and MAH (Applicant) focussed approach	PharmaConsult - Rosemary Kietzmann	Online	08h30 - 12h30	Members: R1 600 Non-Members: R1 900
23-Jul-25 & 24 Jul-25	Medical Device: Regulatory Affairs & Documentation		ISOHealth - Simone Rudolph Shortt	Online	09h00 - 13h00	Members: R3 200 Non-Members: R3 800
29-Jul-25	Qualification and Validation Requirements	Qualification and Validation requirements for equipment and product processes - compiling a VMP, PVP and PVR (CMO and MAH (Applicant) focussed approach	PharmaConsult - Rosemary Kietzmann	Online	08h30 - 12h30	Members: R1 600 Non-Members: R1 900
30-Jul-25 & 31 Jul-25	QA for QC	Good Laboratory Practice (Contract Laboratories and CMO Production sites with own Laboratories (non - MA Holders)	PharmaConsult - Rosemary Kietzmann		08h30 - 12h30	Members: R3 200 Non-Members: R3 800
06-Aug-25	MCA		MCA - Val Beaumont	Online	09h00 - 11h00	R500
13-Aug-25 & 14-Aug-25	Responsible Pharmacists - Roles and Responsibilities	Full overview of all requirements - including RPs for Applicants and Manufacturing Sites	PharmaConsult - Rosemary Kietzmann	Online	08h30 - 12h30	Members: R3 200 Non-Members: R3 800
19-Aug-25 & 20-Aug-25	Medical Device: QMS Non-Conformance / Deviation CAPA		ISOHealth - Simone Rudolph Shortt	Online	09h00 - 13h00	Members: R3 200 Non-Members: R3 800

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26-Aug-25 & 27-Aug-25	Bioequivalence	Bioequivalence studies & relevance within the medicinal product registration dossier-innovator & generic	Twinz - Salma Ismail	Online	08h30 - 12h30	Members: R3 200 Non-Members: R3 800
02-Sep-25 & 03-Sep-25	Module 3 CTD		Twinz - Salma Ismail	Online	08h30 - 16H30	Members: R6 400 Non-Members: R7 600
09-Sep-25	cGMP for Supply Chain Personnel		PharmaConsult - Rosemary Kietzmann	Online	08h30 -12h30	Members: R1 600 Non-Members: R1 900
10-Sep-25 & 11-Sep-25	Procurement and Sale of Health Products	Approved product; Qualification of suppliers and customers; Receipt, storage and supply; Handling of complaints, returns, suspected falsified medical products and recalls	ZA Med Consulting - Fleur Hartman	Online	09h00 - 13h00	Members: R3 200 Non-Members: R3 800
16-Sep-25 & 17-Sep-25	Medical Device: Implementation of QMS		ISOHealth - Simone Rudolph Shortt	Online	09h00 - 13h00	Members: R3 200 Non-Members: R3 800
30-Sep-25	cGMP for Pharmaceutical Management	cGMP for Pharmaceutical Management (target groups CEOs/ MDs/ Site Heads/ Allied Departmental Managers etc)	PharmaConsult - Rosemary Kietzmann	Online	09h00 - 12h00	Members: R1 200 Non-Members: R1 425
08-Oct-25 & 09-Oct-25	Client Services (Training)		Own Your World - Yuver	Online	09h00 - 13h00	Members: R3 200 Non-Members: R3 800
14-Oct-25 & 15-Oct-25	GWP/GDP: Licensing and Good Documentation Practices	Licensing and GDP - Quality System Documentation - Site and Device Master Files, Quality Manual, SOPs and QS records	ZA Med Consulting - Fleur Hartman	Online	09h00 - 13h00	Members: R3 200 Non-Members: R3 800
21-Oct-25 & 22-Oct-25	Medical Device: QMS Auditing Techniques		ISOHealth - Simone Rudolph Shortt	Online	09h00 - 13h00	Members: R3 200 Non-Members: R3 800
29-Oct-25 & 30-Oct-25	Annual cGMP Refresher	Annual cGMP Refresher - Target group - Local Manufacturers	PharmaConsult - Rosemary Kietzmann	Online	08h30 - 12h30	Members: R3 200 Non-Members: R3 800
05-Nov-25	MCA		MCA - Val Beaumont	Online	09h00 - 11h00	R500
18-Nov-25 & 19-Nov-25	QMS for Medical Devices		ISOHealth - Simone Rudolph Shortt	Online	09h00 - 13h00	Members: R3 200 Non-Members: R3 800
02-Dec-25 & 03-Dec-25	Medical Device QMS Auditing Techniques		ISOHealth - Simone Rudolph Shortt	Online	09h00 - 13h00	Members: R3 200 Non-Members: R3 800