



## 2025/2026 FINANCIAL YEAR - SAAPI WORKSHOPS

### WORKSHOPS ARE PROPOSED AND SUBJECT TO CHANGE

WORKSHOP CODE	DATE	TOPIC	DESCRIPTION	TRAINER	VENUE	SESSION TIMES	COST
25-26/01VLS	30-Jan-26	Vector LS Blue Flame Hot Topic (Free Workshop for SAAPI Members) Re: Application Portal (2 hour session)	A run through on the application portal - from creating new applications to submitting variations and responses	Dr. Madelein Terblanche - Vector Life Sciences	Online MS Teams	09h00 to 11h00	Members: Free Non-Members: R250
25-26/09PC	4-Feb-26	Structure of a comprehensive PQS: Session 1	Content of a PQS and Regulatory References / How to compile a SMF and a Quality Manual and a VMP / How to compile an effective SOP - Back to Basics/ How to compile a PQS record - Link to SOP / How to Compile a PQS Register / GDP overview	Rosemary Kietzmann - PharmaConsult	Online MS Teams	09h00 to 12h15	Members: R1 300 Non-Members: R1 544
25-26/02VLS	10-Feb-26	From Chaos to Clarity - Crafting Submission-Ready Documents for your eCTD	Learn how to transform everyday regulatory documents into structured, validation-ready files that glide through publishing and review	Dr. Madelein Terblanche - Vector Life Sciences	Online MS Teams	09h00 to 13h00	Members: R1 600 Non-Members: R1 900
25-26/10PC	11-Feb-26	Structure of a comprehensive PQS: Session 2	Conducting Effective Self-Inspections and Certification Requirements for the Internal Auditor	Rosemary Kietzmann - PharmaConsult	Online MS Teams	09h00 to 12h15	Members: R1 300 Non-Members: R1 544
25-26/31IH	18-Feb-26 to 19 Feb-26	Medical Device: QMS ISO 13485	Medical Device Quality Management System - ISO 13485	Simone Rudolph-Shortt - ISOHealth SA	Online MS Teams	09h00 to 13h00	Members R3 200 Non-Members R3 800
25-26/27IH	24-Feb-26	Medical Devices: Quality Management System - Requirements for Medical Devices	What is a Quality Management System & Understanding and Implementing the ISO13485 Requirements	Simone Rudolph-Shortt - ISOHealth SA	Online MS Teams	09h00 to 13h00	Members: R1 600 Non-Members: R1 900
25-26/21MCA	25-Feb-26	MCA	Code of Practice for the Marketing of Health Product	Dr Belinda Meyer/ Val Beaumont/ Lize Cronje - Marketing Code Authority	Online MS Teams	09h00 to 11h00	Members: R500 Non-Members: R500
25-26/28IH	26-Feb-26	Medical Devices: Quality Auditing Techniques - Medical Devices	How to implement an Audit Programme / How to do an Audit & Key ISO 13485 Considerations	Simone Rudolph-Shortt - ISOHealth SA	Online MS Teams	09h00 to 13h00	Members: R1 600 Non-Members: R1 900
25-26/44SAAPI	3-Mar-26	Stock Outs and Supply Chain	Free Webinar - Evening Session	SAAPI EXCO	Online MS Teams	19h00 to 20h00	PSSA Members: Free Non-Members: R250

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25-26/11PC	4-Mar-26	Structure of a comprehensive PQS: Session 3	Quality Management Review reporting, effectiveness checking and continuous improvement initiatives and Sr Managements role in Quality Reviews / Compiling a TQA for various categories of supplier	Rosemary Kietzmann - PharmaConsult	Online MS Teams	09h00 to 12h15	Members: R1 300 Non-Members: R1 544
25-26/03VLS	10-Mar-26 to 11-Mar-26	Busting the Myths of eCTD - eCTD basics	Discover how the eCTD comes together, from modules to lifecycles and envelopes - the foundation for every compliant submission	Dr. Madelein Terblanche - Vector Life Sciences	Online MS Teams	09h00 to 13h00	Members R3 200 Non-Members R3 800
25-26/30PC	17-Mar-26	cGWP and cGDP for RPs, QA Personnel and Operational Management		Rosemary Kietzmann - PharmaConsult	Online MS Teams	09:00 to 13:00	Members: R1 600 Non-Members: R1 900
25-26/32IH	18-Mar-26 to 19-Mar-26	Implementing a QMS for Medical Devices		Simone Rudolph-Shortt - ISOHealth SA	Online MS Teams	09h00 to 13h00	Members R3 200 Non-Members R3 800
25-26/37IH	31-Mar-26	Medical Devices: Risk Management Short Course		Simone Rudolph-Shortt - ISOHealth SA	Online MS Teams	09h00 to 13h00	Members: R1 600 Non-Members: R1 900
25-26/26TZ	7-Apr-26 to 8-Apr-26	Variations	Variations	Salma Ismail - Twinz Regulatory Consultants	Online MS Teams	09h00 to 13h00	Members R3 200 Non-Members R3 800
25-26/04VLS	15-Apr-26	Green Tick Guaranteed: Outsmarting eCTD Validation Hurdles the Smart Way	Unpack SAHPRA's validation criteria, learn how to troubleshoot errors, and leave with your own checklist for a flawless technical screening	Dr. Madelein Terblanche - Vector Life Sciences	Online MS Teams	09h00 to 13h00	Members: R1 600 Non-Members: R1 900
25-26/36IH	21-Apr-26	Medical Device: Vigilance Adverse Incident Recall Short Course		Simone Rudolph-Shortt - ISOHealth SA	Online MS Teams	09h00 to 13h00	Members: R1 600 Non-Members: R1 900
25-26/29PC	22-Apr-26 to 23-Apr-26	QA for QC Laboratories	Includes preparation activities for managing external audits of the Laboratory	Rosemary Kietzmann - PharmaConsult	Online MS Teams	09h00 to 13h00	Members R3 200 Non-Members R3 800
25-26/45SAAPI	5-May-26	African Medicines Agency (AMA)	Free Webinar - Evening Session	SAAPI EXCO / Gina Partridge	Online MS Teams	19h00 to 20h00	PSSA Members: Free Non-Members: R250
25-26/12PC	6-May-26	Understanding Core PQS Elements - Theory and Practical Sessions: Session 1	Deviations / Root Cause Analysis	Rosemary Kietzmann - PharmaConsult	Online MS Teams	09h00 to 12h15	Members: R1 300 Non-Members: R1 544
25-26/05VLS	13-May-26	ZA eCTD in Action: Real Lessons, Real Mistakes, Real Mastery	A practical, hands-on session walking through real-world submission scenarios - what works, what fails, and how to avoid the common traps	Dr. Madelein Terblanche - Vector Life Sciences	Online MS Teams	09h00 to 13h00	Members: R1 600 Non-Members: R1 900

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25-26/33IH	14-May-26 to 15-May-26	Regulatory Requirements for Medical Devices		Simone Rudolph-Shortt - ISOHealth SA	Online MS Teams	09h00 to 13h00	Members R3 200 Non-Members R3 800
25-26/38IH	19-May-26	QMS GMP Device vs Medicines Short Course		Simone Rudolph-Shortt - ISOHealth SA	Online MS Teams	09h00 to 13h00	Members: R1 600 Non-Members: R1 900
25-26/13PC	20-May-26	Understanding Core PQS Elements - Theory and Practical Sessions: Session 2	Corrective and Preventative Actions (CAPA) / and Change Management	Rosemary Kietzmann - PharmaConsult	Online MS Teams	09h00 to 12h15	Members: R1 300 Non-Members: R1 544
25-26/22MCA	27-May-26	MCA	Approval of Promotion material, sponsorships, meetings & events	Dr Belinda Meyer/ Val Beaumont/ Lize Cronje - Marketing Code Authority	Online MS Teams	09h00 to 11h00	Members: R500 Non-Members: R500
2026F / 2026D	10-Jun-26 to 11-Jun-26	<b>2026 SAAPI Conference</b> (Hybrid)	Expanding Pharma Borders: Transcending Limits, Transforming Lives	SAAPI	CSIR Pta	08h00 to 16h00	Visit <a href="http://www.saapi.org.za">www.saapi.org.za</a>
25-26/39IH	18-Jun-26	Medical Devices: Labelling (ID) & Traceability Short Course		Simone Rudolph-Shortt - ISOHealth SA	Online MS Teams	09h00 to 13h00	Members: R1 600 Non-Members: R1 900
25-26/06VLS	23-Jun-26 to 24-Jun-26	The Lifecycle Symphony: Orchestrating New Applications, Renewals & Baselines with Precision	Master the art of Lifecycle Management - understand how to create, renew, update, and close sequences without missing a beat	Dr. Madelein Terblanche - Vector Life Sciences	Online MS Teams	09h00 to 12h00	Members: R2 400 Non-Membmers R2 850
25-26/34IH	25-Jun-26 to 26-Jun-26	Medical Devices: Validation of Health Products		Simone Rudolph-Shortt - ISOHealth SA	Online MS Teams	09h00 to 13h00	Members R3 200 Non-Members R3 800
25-26/40IH	8-Jul-26	PMS vs Vigilance Conversation (2 hour session)		Simone Rudolph-Shortt - ISOHealth SA	Online MS Teams	09h00 to 11h00	Members: R800 Non-Members: R950
25-26/41IH	14-Jul-26	Role of RP, AR, LH (Meds and MD) and QMS Rep Conversation (2 hour session)		Simone Rudolph-Shortt - ISOHealth SA	Online MS Teams	09h00 to 11h00	Members: R800 Non-Members: R950
25-26/07VLS	22-Jul-26	When Change Knocks: Navigating Variations Without Losing Your Rhythm	Learn how to handle Variations seamlessly, keeping traceability, structure, and compliance intact through every change cycle	Dr. Madelein Terblanche - Vector Life Sciences	Online MS Teams	09h00 to 13h00	Members: R1 600 Non-Members: R1 900
25-26/35IH	28-Jul-26	Medical Devices: Technical File (vs CTD) short course		Simone Rudolph-Shortt - ISOHealth SA	Online MS Teams	09h00 to 13h00	Members: R1 600 Non-Members: R1 900

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25-26/14PC	29-Jul-26	Understanding Core PQS Elements - Theory and Practical Sessions: Session 3	Quality Risk Management	Rosemary Kietzmann - PharmaConsult	Online MS Teams	09h00 to 12h15	Members: R1 300 Non-Members: R1 544
25-26/23MCA	5-Aug-26	MCA	Code of Practice for the Marketing of Health Product	Dr Belinda Meyer/ Val Beaumont/ Lize Cronje - Marketing Code Authority	Online MS Teams	09h00 to 11h00	Members: R500 Non-Members: R500
25-26/15PC	12-Aug-26	Understanding Core PQS Elements - Theory and Practical Sessions: Session 4	Annual Product Quality Review (APQR) Sourcing of data and compilation process; review process / Batch Release requirements for FPP to the SA Market	Rosemary Kietzmann - PharmaConsult	Online MS Teams	09h00 to 12h15	Members: R1 300 Non-Members: R1 544
25-26/16PC	19-Aug-26	Understanding Key Quality Assurance Activities in Industrial Pharmaceutical Facilities: Session 1	Supplier/Vendor/CMO Management - Qualification and Approval for Outsourced Activities / External cGXP Auditing - includes qualification process for internal auditors	Rosemary Kietzmann - PharmaConsult	Online MS Teams	09h00 to 12h15	Members: R1 300 Non-Members: R1 544
25-26/46SAAPI	26-Aug-26	Project Management and Time Management	Free Webinar - Evening Session	SAAPI EXCO	Online via MS Teams	19h00 to 20h00	PSSA Members: Free Non-Members: R250
25-26/17PC	2-Sep-26	Understanding Key Quality Assurance Activities in Industrial Pharmaceutical Facilities: Session 2	Tech Transfer - Includes Protocols, Launch Readiness and link to the registered regulatory dossier (eCTD) Quality Sections	Rosemary Kietzmann - PharmaConsult	Online via MS Teams	09h00 to 12h15	Members: R1 300 Non-Members: R1 544
25-26/18PC	9-Sep-26	Understanding Key Quality Assurance Activities in Industrial Pharmaceutical Facilities: Session 3	Introduction to GEP / Quality and Validation - Facilities, Utilities and Equipment, Includes Facility Design / Product Process Validation (PV) - Includes Product Performance Qualification (PPQ) and Continuous Process Verification - Includes Re-Validation	Rosemary Kietzmann - PharmaConsult	Online via MS Teams	09h00 to 12h15	Members: R1 300 Non-Members: R1 544
25-26/08VLS	16-Sep-26	Behind the XML Curtain: Unpacking the Secrets of the eCTD 3.1 Specification Engine	Step into the advanced technical heart of eCTD - explore envelopes, metadata, and specifications that power the submission ecosystem	Dr. Madelein Terblanche - Vector Life Sciences	Online via MS Teams	09h00 to 13h00	Members: R1 600 Non-Members: R1 900
25-26/42IH	22-Sep-26	ISO vs MDSAP and reliance Conversation (2 hour session)		Simone Rudolph-Shortt - ISOHealth SA	Online via MS Teams	09h00 to 11h00	Members: R800 Non-Members: R950
25-26/25MCA	30-Sep-26	MCA	Code of Practice for the Marketing of Health Products	Dr Belinda Meyer/ Val Beaumont/ Lize Cronje - Marketing Code Authority	Online via MS Teams	09h00 to 11h00	Members: R500 Non-Members: R500
25-26/19PC	28-Oct-26 to 29-Oct-26	Responsible Pharmacist - Role and Responsibilities for an Industrial Pharmacy RP or Deputy RP of a Manufacturer or HCR (Applicant Facility)	Overview of the shorter workshop topics covered during the year	Rosemary Kietzmann - PharmaConsult	Online via MS Teams	09h00 to 13h00	Members R3 200 Non-Members R3 800

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25-26/24MCA	4-Nov-26	MCA	Approval of Promotional Material, sponsorshis, meetings and events	Dr Belinda Meyer/ Val Beaumont/ Lize Cronje - Marketing Code Authority	Online via MS Teams	09h00 to 11h00	Members: R500 Non-Members: R500
25-26/43IH	11-Nov-26	Supplier Management, Outsourcing and QA Agreement (& PMS) conversation (2 hour session)		Simone Rudolph-Shortt - ISOHealth SA	Online via MS Teams	09h00 to 11h00	Members: R800 Non-Members: R950
25-26/20PC	18-Nov-26 to 19-Nov-26	Annual cGMP Refresher		Rosemary Kietzmann - PharmaConsult	Online via MS Teams	09h00 to 13h00	Members R3 200 Non-Members R3 800
25-26/47SAAPI	25-Nov-26	Labelling Harmonisation	Free Webinar - Evening Session	SAAPI EXCO	Online via MS Teams	19h00 to 20h00	PSSA Members: Free Non-Members: R250