



PHARMERS ACADEMY - REGULATORY AFFAIRS MASTERCLASS SERIES

MASTERCLASSES & SHORT COURSE - LEARN RA IN AS LITTLE AS 4 DAYS

Introduction to regulatory affairs for beginners

The PHARMERS RA Masterclass Series is a groundbreaking initiative developed by PHARMERS ACADEMY to assist aspiring participants and beginners to know about RA and enter the industry with ease, confidence, and practicality. The lack of entry-level/ beginner practicals from industry experts was raised as a serious hindrance and barrier to RA (even from the regulator - SAHPRA). This course was then piloted mid 2020 and after a first, second and third round of classes with excellent feedback, we never looked back. With the latest addition to the format and classes (107-109 listed on the website available from June 2022) our ongoing online support is unmatched; participants have praised the simplistic yet thorough nature of the classes, stating how their objectives were reached with clear and concise understanding obtained. Many have now gone on to securing RA jobs and thriving in new roles as a result!

We focus on producing practical know-how & simulating the much-needed hiring criteria – real-life experience!

Masterclass series objectives

- ✓ To understand regulatory affairs comprehensively
- ✓ provide efficient learning through PHARMERS RA TOOLS
- ✓ To provide a step-by-step supportive learning environment
- ✓ To bring practical knowledge and application of working guidelines
- ✓ To provide much needed employability know-how & work experience
- ✓ To correctly apply RA to the pharmaceutical industry locally and globally
- ✓ To introduce RA laws, guiding principles & guidelines from various key authorities
- ✓ To apply one's pharmacy expertise to the dossier compilation process (where applicable)

The RA masterclass short course comprises of four masterclasses:

- ✓ Masterclass 101: Introduction to RA (regulatory affairs)
- ✓ Masterclass 102: Module 1 ZA + compilation exercise
- ✓ Masterclass 103: Modules 2/4/5 eCTD + compilation exercise
- ✓ Masterclass 104: Module 3 eCTD + compilation
+ optional Masterclass 104 (extended) additional compiling exercise

After ***completing the masterclass series***, you will be able to:

- ✓ Understand your personal RA affinity and job / work opportunities
- ✓ Compile your own dossier (m1-m5) and screen for outstanding information
- ✓ Mastery of local (SAHPRA) and international (EMA, ICH, EDQM, WHO, etc.) guides
- ✓ Understand what a drug dossier is, the components & available formats (MRF, MBR, CTD)
- ✓ Know the various laws, & guidelines that govern the registration of various medicines / types
- ✓ Understand the "Regulatory Affairs Story" and how it fits the local and international landscape
- ✓ Know the categories of medicine registration, and what the SAHPRA application process entails
- ✓ Know where to source dossier components / obtain necessary information required for an application

You will Need (estimated for the 101-104 short-course):

- Internet connectivity (+/- 10 hours)
- +/- 50 hours dedicated to self-study time
- A working device (desktop/ laptop computer)
- A WhatsApp/ phone number for any additional learning support

Course Tutor

Patricia Ngassam is a responsible and regulatory affairs pharmacist currently practicing in South Africa. After completing her master's in Applied Biopharmaceutical Biotechnology in the UK, she started her RA career years ago as an external evaluator for P & A at SAHPRA (evaluating dossiers for quality and bioequivalence), and later on became a technical advisory committee member to the CEO and evaluator team for SAHPRA. In the meantime, she also works as an RP (responsible pharmacist) and RA (regulatory affairs) pharmacist ensuring GMP compliance among others and compiling dossiers for submission to the national RRA (SAHPRA). With experience from both side of the regulatory coin, she now longs to assist enthusiastic and aspiring RA pharmacists to know and love RA & make the sectoral move and leap into RA with confidence. She presents eCTD compilation ABCs through these masterclasses (with practical examples, assessment, homework & certificates) and has created a unique learning hub for beginners.

Masterclass Course Outline

Day 1

Masterclass 101 - Introduction to Regulatory Affairs

Duration: approx. 1.5 hours + (3-4 self study hours)

Location: online

Additional Features: personality assessment/ SWOT, Homework, Assessment, Additional Guidance Resources

This introductory session spells everything out for you from a general and bigger perspective. It focuses in on the local (SAHPRA) and international (EMA, ICH, EDQM, WHO, etc.) guiding authorities by providing understanding on the four main components of regulatory affairs. Learn the basics of the product application process for and compiling a dossier. You will understand what, who, when, where and why RA is what it is! Commonly used jargon and key ideas/ concepts needed to grasp the essence of RA are also discussed. You will also determine if it is for you as a SWOT analysis is also done with examples to help participants relate personally.

Day 2

Masterclass 102 – Module 1 Compilation

Duration: 2.5 hours + (10 self study hours)

Location: online

Additional Features: PHARMERS m1 Tool, Assessment, Homework, Additional Guidance Resources

This detailed session starts with the first ADMINISTRATIVE module of a dossier compilation; the one outside of CTD. Terms, subsections, module, and nodes are all explained, and examples shown for each. SAHPRA guides are explained, and you will definitely grasp a good understanding of PI/PIL/ Label/ BTIF examples. Attachments of various kinds are also given to show the participants how to put this module together. Use the unique PHARMERS TOOL provided to START compiling straight away with an exercise / homework segment, an assessment and online support. Submit your work and get evaluated!

Day 3

Masterclass 103 – Modules 2/4/5 eCTD Compilation

Duration: 1.5 hours + (10 self study hours)

Location: online

Additional Features: PHARMERS 103 Tool, Assessment, Homework Additional Guidance Resources

These modules are straightforward and come as they are, with minimal compilation required (TOCs); Therefore, they can be bunched together into one session. Screening is simple; however, a few key principles still need to be understood. ICH/EMA guidelines relevant to all 3 modules are discussed with examples from Australian (TGA) and local

(SAHPRA) dossiers. Homework to screen / compile these modules is also available as well as subsequent online support. Submit your work and get evaluated. Additional resources (guides) also provided.

Day 4

Masterclass 104 – Module 3 eCTD Compilation

Duration: approx. 2.5 hours + (10 self study hours) (+10hrs extended)

Location: online

Additional Features: PHARMERS 104 Tool, Assessment, Homework, Additional Guidance Resources

This module represents the QUALITY part of a medicine dossier. You'll learn and understand how to carefully approach it during compilation. During the class, each node is discussed in detail and examples from international guidelines such as EMA/ICH are given. An Australian example is also shown (TGA). See and know what the attachments required are especially the SCORE document to be discussed. Get a chance to compile your very own module 3 at the end of the session using PHARMERS tool. Homework and online support are yours to help you submit your own. This class ends with an extended masterclass 104 segment where the second product application type is given to you to practice.

Who should attend

- ✓ Beginner RA pharmacist (wishing to Fast-track understanding)
- ✓ Aspiring RA pharmacist (currently in other sectors wishing to move)
- ✓ New RPs in industry (smaller company RP in an all-inclusive role including RA)
- ✓ Final year pharmacy students interested in the regulatory sector (intern/comserv)
- ✓ Pharmacists with RA duties or overlapping roles (seeking entry-level working knowledge)
- ✓ Junior evaluators (level 1) wishing to understand dossier compilation, screening, and evaluation

The Masterclass Series is available in 2 formats:

- Recorded classes available monthly online for up to 6 months (more affordable)
- 4 quarterly Live masterclass Series Sessions scheduled (~~March 1-7, June 1-7, September 1-9, November 1-9~~)

Bonus: At the end of the short course (101-104) as participants you will receive a complimentary CV + interview prep session at your chosen convenience (booked on website) to prepare you for an upcoming RA / RP interview.

Additional Training / Electives

Masterclass 105: New RPs Set up with RA roles (PQMS, Quality Standards, GMP etc.)

Masterclass 106: Variations & Conversions (MBR1/MRF1/CTD) formats (baseline in old dossier)

Masterclass 107: Complementary Medicines & Registration

Masterclass 108: Medical Devices & Registration

Masterclass 109: Biologicals & Biosimilars Medicines & Registration

Masterclass 110: Customized Training (depending on need)

Masterclasses are available in both formats as tabulated below. Enrolment typically closes 3 days before start of masterclasses. If you have an emergency or require custom training, please indicate so on the registration form comment section or select masterclass elective 110 for customized training and indicate specifications.

Note: All classes can be purchased separately, however in the short course, we apply a pre-requisite system to access the next class in the series. i.e. 101, then 102, then 103, then 104. This ensures best learning outcomes for participants.

Masterclass Options and Prices

Masterclasses Type	Masterclasses Name & Number	Recorded Masterclasses (1 st of Every Month)	Live Quarterly Masterclasses (On or before 25 th of Q3 & Q4)
Short Course	101 – Introduction to RA	R2200 / \$150	R3600 / \$230
	102 – Module 1 eCTD	R2200 / \$150	R3600 / \$230
	103 – Module 2/4/5 eCTD	R2200 / \$150	R3600 / \$230
	104 – Module 3 eCTD	R2200 / \$150	R3600 / \$230
	104 - Extended (2 nd eCTD Generic Exercise)	R2200 / \$ 150	R3600 / \$230
Elective	105 – PQMS, Documentation & Fundamentals	R3400 / \$230	R4500 / \$290
Elective	106 – Dossier Variations & Conversions	R3400 / \$230	R4500 / \$290
Elective	107 – Complimentary Medicines & Registration	R3400 / \$230	R4500 / \$290
Elective	108 – Medical Devices & Registration	R3400 / \$230	R4500 / \$290
Elective	109 – Biologicals, Biosimilars & Registration	R3400 / \$230	R4500 / \$290
Elective	110 – Customized Training	Cost will depend on specifications / need	

Please have a look at our website (www.pharmers.co.za) as well as our social media pages (Facebook and Instagram @pharmers.co.za) for other frequent updates, discounts, and info sessions.

Typical Duration

Recorded masterclasses are taken at your own time and convenience, therefore completion is also dependent on your own pace. The minimum amount of time is 4 days as that will assume one class is taken per day as with the live sessions, but the completion of self study, assessments, homework, and feedback is likely to take longer for most participants. On average a class per week is a reasonable time frame to expect. Many participants have taken up to 3 months to complete the short course 101-104. We however allocate up to 6 months from the start date to submit all requirements in order to provide support, feedback and certification (the complimentary cv + interview preparation session for 101-104 participants must also be booked within the six month deadline). Should a participant not meet these requirements they forfeit their certification.

Successful Completion

Upon completion of each masterclass and requirement, participants will receive completion certificates.

Academy Certification is subject to the following:

- Successful completion of homework (given statement)
- Successful completion of feedback form
- Successful completion of class assessment (65% class mark is considered a pass; a re-assessment will be provided for any participants who do not succeed on their first attempt)

A Premium Distinction Seal on the certificate is issued to participants who score 80% and higher!

Congratulations on taking this step; We are so excited to enroll and welcome you in!

REGISTRATION FORM

Please fill the registration form below and return to info@pharmers.co.za for an invoice to be generated for you.

Participant Title, Name, and Surname:		Current Position:	
Company:		Email:	
Contact Number:		Prospective Enrolment Start Date:	
Country:		City:	
RA Masterclasses Selection (please tick all boxes that apply to your desired enrolment)			
Type of class	Recorded	Live	Apply Discount Code
101			
102			
103			
104			
104 Extended (optional)			
105			
106			
107			
108			
109			
110			
Total number of classes		Other Comments:	
TOTAL payment due (IN R OR \$(US Dollar):			

Please Select A Payment Options			
One direct full payment		Two 50% installments over 2 months (by 1 st of both months) <small>(available for the 101-104/extended short course only)</small>	

Terms & Conditions:

Registration fees above include the following entitlements: entrance to sessions, registration pack, ongoing online support, links to additional resources. •Payments Terms; on the return of a registration form, full payment is required within 7 working days. Payment must be received prior to the event date. PHARMERS reserves the right to refuse entry into the course should full payment not have been received prior to the event date. Cancellations will be charged under the terms set out below. •Cancellations, no show, and substitutions: cancellations received in writing more than 21 days prior to the event being held carry a 50% cancellation fee. Should cancellations be received between 21 days and the date of the event, full course fees will be payable and non- refundable. Non-payment or non- attendance does not constitute cancellation. No shows will be charged the full registration fee. Cash back alternatives will not be offered, however, substitutions at no extra charge are welcome. •Alterations to the advertised package; PHARMERS reserves the right to alter this program without notice or penalty and in such situations no refunds or part refunds will be made. Alternative offers may be offered. Should PHARMERS permanently cancel an event, for any reasons whatsoever, the client shall be provided with a credit of the equivalent amount paid towards the cancelled event. In the event of a postponed or cancelled event PHARMERS will not be responsible for covering air fares, accommodation, and transportation. •Interest will be charged on all overdue amounts at a rate of three percent (3%) per month after thirty days. •In the event of PHARMERS instructing an attorney to enforce compliance with the terms here of, the above-mentioned company on the registration form agrees to pay such attorneys on an attorney and client scale and will be liable to pay the costs of letters of demand or any other cost involving cancellations or no shows to the event. PLEASE NOTE – PHARMERS HAS A NEW 10 DAY SATISFACTION GUARANTEE OR REFUND POLICY – if you experience all four of the following: feedback score less than 6 out of 10, unmet learning objectives of classes, failed one-on-one session on challenging area, unsatisfactory response to queries or questions then you are eligible for a full refund. Alternatively, the class which you struggle with may be reissued in an upcoming live or recording.

Participant / Delegate Signature: Date:

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