ART LINK

Professional Regulatory Affairs

GCC Certification Programme

RAPS RAC-Drugs 2026 Aligned | 72 CPD Hours | 16 Modules
Abu Dhabi (In-Person) & Online (Limited Seats)

Location

Abu Dhabi

Date

November 2026

Every Saturday,
10:00 AM – 2:00 PM

16	72	4	20
MODULES	CPD HOURS	MONTHS	MAX SEATS

ART LINK

Professional Regulatory Affairs

GCC Certification Programme

RAPS RAC-Drugs 2026 Aligned | 72 CPD Hours | 16 Modules

Abu Dhabi (In-Person) & Online (Limited Seats)

16	72	4	20
MODULES	CPD HOURS	MONTHS	MAX SEATS

ABU DHABI | NOVEMBER 2026 | EVERY SATURDAY, 10:00 AM – 2:00 PM

Programme Overview

The Art Link CEM Professional Regulatory Affairs GCC Certification Programme is Abu Dhabi's first RAPS RAC-Drugs aligned certification for pharmaceutical regulatory professionals. This comprehensive 16-module programme equips participants with globally recognised regulatory knowledge and deep GCC-specific expertise covering all six Gulf regulatory authorities.

The programme is structured around the RAPS RAC-Drugs 2026 Exam Content Framework across all four domains, Strategic Planning, Submissions, Post-Marketing, and Collaboration, with an additional layer of GCC regulatory context not available in any other regional programme.

Why Join This Programme?

01

RAPS RAC-Drugs Exam Preparation

Every module is mapped to the RAPS RAC-Drugs 2026 Exam Content Framework. A full 120-question mock exam is included in the final session.

02

GCC Deep Dive - Unique to This Programme

Dedicated sessions on all six GCC regulatory authorities: UAE MOHAP/DOH, Saudi SFDA, Qatar MOPH, Bahrain NHRA, Kuwait MOH, and Oman TRC.

03

RAC-Certified Expert Faculty

Sessions delivered by practising regulatory affairs professionals holding the RAPS RAC-Drugs credential and active GCC industry experience

04

Printed Participant Workbook

Every registered participant receives a professionally printed workbook with all 16 modules, key definitions, GCC focus sections, and practice questions.

05 **Flexible Delivery - Abu Dhabi & Online**

Attend in-person in Abu Dhabi (Saturday sessions) or join via live online stream. Recordings available for 48 hours after each session.

06 **Certificate + Digital CPD Badge**

Receive the Art Link CEM Certificate of Completion with RAPS RAC alignment stated, plus a digital Credly badge for your LinkedIn profile.

Who Should Attend

Regulatory Affairs Professionals

Validate your expertise and prepare for the RAPS RAC-Drugs exam.

Health Authority Staff

Understand the industry perspective on regulatory submissions and dossier preparation.

Pharmacists

Transition into regulatory affairs one of the fastest-growing roles in GCC healthcare.

Fresh Pharmacy Graduates

Build a competitive edge for regulatory affairs roles in the GCC pharma market.

QA / QC Professionals

Expand into regulatory science and understand the full submission landscape.

Clinical Research Professionals

Understand regulatory requirements for clinical trial submissions and IND/CTA applications.

Medical Affairs Teams

Gain regulatory knowledge for labelling, submissions, and post-marketing work.

Regulatory Consultants

Update GCC knowledge and earn CPD hours supporting client compliance work.

Programme Details

Programme Title	Professional Regulatory Affairs - GCC Certification
RAPS Alignment	RAC-Drugs 2026 Exam Content Framework - All 4 Domains
Number of Modules	16 Modules (comprehensive curriculum)
Total CPD Hours	72 hours (64 contact + 8 hours assessment & review)
Duration	4 months - November 2026 to February 2027
Session Schedule	Every Saturday - 10:00 AM to 2:00 PM (Abu Dhabi time)
Delivery Formats	In-Person: Abu Dhabi (hotel venue) | Online: Live Zoom with breakout rooms
Language	English instruction | Arabic summary notes provided
Class Size	MAXIMUM 20 PARTICIPANTS - Limited seats available
Assessment	Module quizzes + GCC Case Study + 120-question RAC-style Mock Exam
Certificate	Art Link CEM Certificate of Completion + Digital CPD Badge (Credly)
Entry Requirement	Art Link CEM Certificate of Completion + Digital CPD Badge (Credly)
First Session	Saturday, 1 November 2026

Programme Curriculum 16 Modules

All 16 modules are aligned with the RAPS RAC-Drugs 2026 Exam Content Framework. Each module includes core content, GCC-specific regulatory context, a session activity, and practice questions.

01

Regulatory Affairs Fundamentals & Global Framework

Global authorities (FDA, EMA, ICH, WHO, GCC), product lifecycle, RAPS Code of Ethics, GCC-DR system

02

Regulatory Strategy & Product Classification

Regulatory pathways (NDA, MAA, ANDA, biosimilar), feasibility assessment, risk-benefit analysis, expedited pathways

03

Drug Development - Nonclinical & Clinical

ICH M3(R2), toxicology, Phase I–III clinical trials, IND/CTA preparation, ICH E-series GCP

04

Quality - CMC & GMP

ICH Q-series, pharmaceutical development, GMP frameworks (FDA, EU, WHO, GCC), Drug Master Files

05

Common Technical Document (CTD) & eCTD

ICH M4 CTD structure (Modules 1–5), eCTD technical requirements, regional CTD variations, GCC e-submission

06

New Drug Applications - US FDA

NDA 505(b)(1), 505(b)(2), ANDA; FDA review process; Complete Response Letter; REMS; post-approval supplements

07

Marketing Authorization - EU (EMA)

Centralized, decentralized, and MRP procedures; SmPC; PIL; EU post-authorization variations; 5-year renewal

08 **GCC Drug Registration - Deep Dive**
All 6 GCC authorities in depth: UAE MOHAP/DOH, SFDA, MOPH, NHRA, Kuwait MOH, TRC; GCC centralized procedure; Module 1

09 **Generics, Biosimilars & Special Products**
Bioequivalence (80-125% CI criterion), FDA 351(k) biosimilar pathway, EMA biosimilar guidelines, OTC switch, herbals

10 **Pharmacovigilance & Drug Safety**
ADR definitions, causality assessment, ICSR reporting (7-day/15-day rules), PSUR/PBRER, RMP, GCC PV obligations

11 **Labelling, Advertising & Promotion**
FDA PLR format, EU SmPC, GCC bilingual labelling, MLR review, off-label prohibition, digital promotion guidelines

12 **Post-Approval Changes, Variations & Renewals**
FDA supplements (PAS, CBE-30, CBE-0), EU variations (Type IA/IB/II), GCC variation requirements, renewal timelines

13 **Product Recalls, Safety Actions & Risk Management**
FDA Class I/II/III recalls, DHPC 'Dear Doctor' letters, root cause analysis (5-Why, Fishbone), CAPA systems

14 **Collaboration, Inspections & Interfacing**
FDA Type A/B/C meetings, GMP inspection readiness, Form 483 response, cross-functional RA advisory role

15 **Regulatory Intelligence, Ethics & Career Development**
Regulatory monitoring tools, RAPS Code of Ethics applied, AI in regulatory affairs, RAC certification pathway

16 **Comprehensive Review & 120-Question Mock Exam**
Full domain review, high-yield exam facts, exam technique, 120-question RAC-style mock examination and debrief

Investment & Fees

EARLY BIRD PRICE

AED 8,500

Registeration before 15 October 2026

STANDARD PRICE

AED 9,500

Registration after 15 October 2026

What Is Included	All 16 modules |Printed participant workbook| Session recordings access (48hrs) | Module quizzes |120-question mock exam | Certificate of Completion |Digital Credly CPD badge
Group Rate	AED 8,000 per person for groups of 3 or more from the same organisation - company invoice available
Online Participants	Same fee applies for online attendance - you save on travel and accommodation
Corporate In-House	Custom delivery for teams of 10+ at your premises - from AED 40,000 for the full programme. Contact us for a proposal.
Payment Methods	Bank transfer | Cheque payable to Art Link CEM LLC | Credit card
Payment Terms	50% deposit upon registration to confirm your seat | Balance due 2 weeks before the programme starts
Cancellation Policy	Full refund if cancelled 4+ weeks before start | 50% refund 2-4 weeks before |Transfer to next cohort within 2 weeks
VAT	Prices are exclusive of VAT where applicable

Seats Are Limited

- MAXIMUM 20 PARTICIPANTS
- 90+ expressions of interest received
- Secure your place before the cohort fills

How To Register

1. Visit artlinkcem.com/ra-certification and complete the online registration form
2. Submit a copy of your educational qualifications and current CV (1 page)
3. Receive confirmation of acceptance within 2 business days
4. Pay 50% deposit to secure your place — seat only confirmed upon payment
5. Receive your welcome pack, pre-reading materials, and Zoom link 2 weeks before start
6. Attend the optional online orientation session — Friday 31 October 2026 (6:00 PM)

Contact Us

WhatsApp / Phone
+971 552212749

Email
training@artlinkcem.com

Website
www.artlinkcem.com

Address
Abu Dhabi, UAE |Licence CN-5129677

Registration Page
www.artlinkcem.com/ra-certification

LinkedIn
linkedin.com/company/artlinkcem

Programme Director
Dr. Rania Tayseer Mustafa Aldweik
Associate Professor

ART LINK CEM

Building Regulatory Excellence in the GCC

training@artlinkcem.com
www.artlinkcem.com
+971 552212749

Abu Dhabi, UAE | Licence CN-5129677