

COURSE BROCHURE · COHORT 1

CMC Drug Development Accelerator

The end-to-end CMC course most pharmaceutical professionals never get.

8
MODULES

2 hrs
PER SESSION

2
IDENTICAL SESSIONS
(ATTEND ONLY ONE)

Jul 13
START DATE

✓
CERTIFICATE OF
COMPLETION

How Sessions Work: Each module runs across **2 identical sessions** — Monday 11 AM–1 PM PDT · Tuesday 5–7 PM PDT. Attend only one session per module — whichever fits your schedule and time zone.

WHO IS THIS COURSE FOR

Wherever you are in your career — this course gives you the CMC picture most people never get.

- ▶ Early-career scientists and PhD graduates building their CMC foundation
- ▶ Professionals transitioning into CMC from clinical, research, or QA functions
- ▶ Leaders whose career growth has brought CMC into their portfolio
- ▶ Working CMC scientists who want cross-modality perspective beyond their specific function

Prerequisite: Background in chemistry, biology, pharmacy, or pharmaceutical sciences. No prior CMC experience required.

WHY THIS COURSE EXISTS

CMC expertise is usually learned the hard way — through years of trial and error and scattered, informal mentorship. Talented scientists build deep functional skills, but rarely get structured exposure to how those skills connect to the bigger development picture. This course closes that gap, building the cross-functional CMC fluency that typically takes a decade — in a fraction of the time.

ICH guidelines are dense. Textbooks get you lost in the weeds. And nobody shows you the one thing that changes everything:

Your goal post is the IND and the BLA. Build backwards from there.

If you know exactly what data regulators need to approve a filing — you can build your development program backwards from that. Less guessing. Less rework. Faster timelines. And ultimately, patients waiting less time for medicines that can help them.

COURSE CURRICULUM — 8 MODULES

July 13 – September 1, 2026 · 2 identical sessions per module (attend only one) · Mon 11 AM–1 PM PDT · Tue 5–7 PM PDT

#	MODULE TITLE	KEY TOPICS	LIVE DATES
1	Orientation & Drug Development Framework	Drug dev continuum · NCE/NBE/ATMP · IND/BLA/NDA · eCTD · Phase-appropriate CMC · AI/ML intro	Jul 13–14
2	Quality by Design: QTPP to Control Strategy	QTPP · CQA/CPP · Design space · ICH Q8/Q9/Q10/Q11/Q14 · QbD case: GLP-1 peptide & mAb	Jul 20–21
3	Drug Modalities: Small molecules, Peptides (GLP-1), mAbs, ADCs, mRNA, Cell & Gene Therapy	mAb CMC · ADC conjugation · mRNA/LNP · CAR-T · Gene therapy vectors · Peptide/GLP-1 analogues	Jul 27–28
4	Analytical Method Development & Validation	ICH Q2(R2)/Q14 · Method lifecycle · Potency assays · Characterization techniques · AI in analytics	Aug 3–4
5	Drug Manufacturing	Cell culture · Purification · Fill-finish · Small molecule synthesis · CDMO management · GLP-1 mfg	Aug 10–11
6	Specifications, Stability, Release Testing & Process Validation	ICH Q6A/B/Q1/Q5C · Shelf-life · Release testing · Process validation lifecycle (ICH Q8 Stage 1–3) · CPV	Aug 17–18
7	CMC Regulatory Submissions, Lifecycle & Advanced Topics	Module 3 authoring · QOS · Post-approval changes · Continuous mfg (ICH Q13) · AI/ML in CMC · CDMO oversight	Aug 24–25
8	Capstone — Student Project Presentations	Students present CMC learnings applied to their own drug development project · Certificate of Completion awarded	Aug 31–Sep 1

CAPSTONE PROJECT & CERTIFICATE OF COMPLETION

This course doesn't end with a passive exam. In Module 8, every student presents CMC learnings applied to their own drug development project — demonstrating real mastery, not just attendance. All participants who complete the program receive a **Certificate of Completion from PharmiOnyx LLC**, suitable for your LinkedIn profile and professional portfolio. Course materials remain accessible for 2 years after completion — so you can revisit modules, reference slides, and apply the content as your career evolves.

SESSION SCHEDULE — ALL 8 MODULES

2 identical sessions per module — attend only one. All times in PDT (Pacific Daylight Time).

⚠ Schedule update: The previous **Slot B (Tuesday 6:00–8:00 AM PDT)** is no longer offered. Only the two slots below are available.

Slot A · Monday 11:00 AM – 1:00 PM PDT **Slot C · Tuesday 5:00 – 7:00 PM PDT**

MODULE	SLOT A · MON 11 AM – 1 PM PDT	SLOT C · TUE 5 – 7 PM PDT
Module 1 Orientation & Drug Development Framework Jul 13–14, 2026	Mon Jul 13	Tue Jul 14

MODULE	SLOT A · MON 11 AM – 1 PM PDT	SLOT C · TUE 5 – 7 PM PDT
Module 2 Quality by Design: QTPP to Control Strategy Jul 20–21, 2026	Mon Jul 20	Tue Jul 21
Module 3 Drug Modalities: Small molecules, Peptides (GLP-1), mAbs, ADCs, mRNA, Cell & Gene Therapy Jul 27–28, 2026	Mon Jul 27	Tue Jul 28
Module 4 Analytical Method Development & Validation Aug 3–4, 2026	Mon Aug 3 Scotland Bank Holiday · all slots run	Tue Aug 4
Module 5 Drug Manufacturing Aug 10–11, 2026	Mon Aug 10	Tue Aug 11
Module 6 Specifications, Stability, Release Testing & Process Validation Aug 17–18, 2026	Mon Aug 17 India Independence Day (Aug 15) · all slots run	Tue Aug 18
Module 7 CMC Regulatory Submissions, Lifecycle & Advanced Topics Aug 24–25, 2026	Mon Aug 24	Tue Aug 25
Module 8 — Capstone Student Project Presentations · Certificate Awarded Aug 31 – Sep 1, 2026	Mon Aug 31 UK Bank Holiday · all slots run	Tue Sep 1 Course Concludes

Bank holidays noted for participant awareness — all sessions run as scheduled regardless of regional holidays.

WHAT MAKES THIS COURSE DIFFERENT

6 Modalities in One Course Small molecule · GLP-1 peptide · mAb · ADC · mRNA · Cell & Gene Therapy. Most courses cover one. This covers all of them.	IND/BLA as the Goalpost Every module is structured backwards from regulatory filing requirements — so you always know why you're doing what you're doing.	AI/ML Woven Throughout Artificial intelligence and machine learning appear in relevant modules as a current practitioner tool — not a separate add-on topic.
Capstone Project No passive exam — students apply everything to a real drug development project and present their work.	Practitioner-Built Built from 20+ years across Covance, Takeda, Aquestive Therapeutics, CSL Behring, and AbbVie.	Certificate of Completion Formal certificate from PharmiOnyx LLC — shareable on LinkedIn and your professional portfolio. Plus 2-year access to all course materials after completion.

PRICING — COHORT 1 EARLY BIRD

Early bird pricing valid through July 6, 2026. Standard rate of \$599 per person applies after July 6.

Professionals

PACKAGE	EARLY BIRD	PER PERSON	STANDARD	DISCOUNT
1 Professional	\$479	\$479	\$599	20% off standard rate
Group of 2 Professionals	\$838 total	\$419 each	\$599 each	30% off standard rate
Group of 3 Professionals	\$1,257 total	\$419 each	\$599 each	30% off standard rate

Students & Graduate Trainees

PACKAGE	EARLY BIRD	PER PERSON	STANDARD	DISCOUNT
1 Student	\$359	\$359	\$599	40% off standard rate
Group of 2 Students	\$598 total	\$299 each	\$599 each	50% off standard rate
Group of 3 Students	\$897 total	\$299 each	\$599 each	50% off standard rate

Registering a Larger Group? Combine Packages.

The per-person rate stays consistent regardless of how you combine packages. Examples:

GROUP SIZE	HOW TO REGISTER	TOTAL COST	PER PERSON	SAVING VS STANDARD
4 Professionals	2 × Group of 2	\$1,676	\$419 each	\$720 total
4 Students	2 × Group of 2	\$1,196	\$299 each	\$1,200 total
5 Professionals	Group of 2 + Group of 3	\$2,095	\$419 each	\$900 total
5 Students	Group of 2 + Group of 3	\$1,495	\$299 each	\$1,500 total
6 Professionals	2 × Group of 3	\$2,514	\$419 each	\$1,080 total
6 Students	2 × Group of 3	\$1,794	\$299 each	\$1,800 total

For groups larger than 6 or mixed professional/student teams, contact us for a custom quote at pharmionyx.com

ABOUT THE INSTRUCTOR

Ashraf Raza, PhD

Principal CMC Consultant
PharmiOnyx LLC
20+ Years in Pharmaceutical
CMC

Covance

Takeda

Aquestive Therapeutics

CSL Behring

AbbVie

Dr. Raza has spent two decades working across the full drug development continuum — from early discovery through commercial lifecycle management. His experience spans analytical method development and validation, QC, CDMO and testing lab oversight, global regulatory submissions across FDA, EMA, and ICH frameworks, and CMC strategy for both small molecules and complex biologics.

His PhD specialization in Hydrogen-Deuterium Exchange Mass Spectrometry (HDX-MS) and subsequent work in PK/TK profiling, redox biology, and vaccine development gave him a scientific foundation that bridges bench science and regulatory strategy.

This course represents what Dr. Raza wishes had existed at the start of his own career — the framework, the context, and the regulatory goalpost that nobody shows you.

Ready to get the full CMC picture?

Cohort 1 begins July 13, 2026. Register before July 6 to lock in early bird pricing.

pharmionyx.com/courses