COURSE INDEX & PROGRAMME CATALOGUE

GCP Training Programme

Good Clinical Practice Foundation · **ICH-GCP E6(R2) Aligned** · **12 Modules** · **30 Learning Hours** · **CPD Certified**

12	30	ICH-GCP E6(R2)	CPD Certified
CORE MODULES	LEARNING HOURS	ALIGNED	ACCREDITED

PROGRAMME OVERVIEW

The Yoshe Clinical Academy GCP Training Programme equips clinical research professionals with a thorough grounding in Good Clinical Practice principles, regulatory frameworks and the ethical standards governing clinical trials. Aligned with ICH-GCP E6(R2) and applicable national legislation, this 30-hour programme delivers 12 structured modules covering the complete lifecycle of GCP-compliant trial management — from study set-up and informed consent through to safety reporting and investigational medicinal product management.

COURSE MODULE INDEX — 12 MODULES, 30 HOURS

NO.	MODULE TITLE	DURATION
01	**Introduction to Health and Social Care Research** Research governance, the UK/EU/US research environment	2 hrs
02	**Clinical Trial Types and Phases** Phase I–IV, observational and interventional designs	2 hrs
03	**Fundamentals of ICH-GCP** Origins, scope and application of the guideline	2 hrs
04	**Principles of Good Clinical Practice (ICH-GCP)** The 13 core principles in practice	2 hrs
05	**Regulatory and Legislative Framework — Approvals** Competent authority and ethics approvals	3 hrs
06	**Informed Consent Process** Process, documentation and re-consent	3 hrs
07	**Study Set-Up and Management** Roles & responsibilities of IRB/IEC, Sponsor and Investigator	6 hrs
08	**Safety and Adverse Events Reporting** AE, SAE and expedited reporting obligations	2 hrs
09	**Data Collection and Documentation** Essential records, source data and ALCOA+	2 hrs
10	**Investigator's Brochure (IB)** Content, updates and site-level use	2 hrs
11	**Clinical Trial Protocol and its Amendment** Protocol structure, amendments and deviations	2 hrs
12	**Introduction to GCP — IMP Management** Receipt, storage, accountability and return	2 hrs
TOTAL PROGRAMME — 12 Modules		**30 Hrs**

PARTICIPANT PROFILE & DELIVERY

WHO SHOULD ATTEND

- Clinical Research Associates (CRAs)
- Clinical Research Coordinators (CRCs)
- Investigators and site staff
- Sponsor / CRO clinical operations teams
- Data management and regulatory personnel
- New entrants to clinical research

DELIVERY FORMATS

- Live Online — instructor-led sessions
- In-Person — site or training centre
- Blended — eLearning plus live workshops
- CPD accredited and formally assessed
- Global delivery capability (US, UK, EU, India)
- Certificate of completion with CPD hours recorded

REGULATORY ALIGNMENT

- **ICH-GCP E6(R2)** — Good Clinical Practice
- **Declaration of Helsinki** — ethical principles
- **US FDA** — 21 CFR Parts 50, 56 & 312
- **UK** — MHRA & HRA, UK Clinical Trials Regulations
- **EU** — Clinical Trials Regulation 536/2014
- **Data Privacy** — UK/EU GDPR and US HIPAA

PROGRAMME NOTES

> Duration figures are indicative; actual delivery time varies with group size and interactive content. All modules are delivered in compliance with ICH-GCP E6(R2) and relevant national regulatory frameworks. Module durations are confirmed upon programme scheduling.

ENROLMENT & ENQUIRIES

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