COURSE INDEX & PROGRAMME CATALOGUE

Global Regulatory Training Programme

US FDA · UK MHRA/HRA · EU CTR 536/2014 · **29 Modules** · **81 Learning Hours** · **CPD Certified**

29	81	FDA · MHRA EMA	3 Workshops
MODULES	LEARNING HOURS	MULTI-JURISDICTION	ASSESSED PRACTICALS

PROGRAMME OVERVIEW

The Yoshe Clinical Academy Global Clinical Trial Regulatory Training Programme spans 29 structured modules covering the full spectrum of international regulatory frameworks, including the US FDA, UK MHRA/HRA and EU CTR 536/2014. Designed for regulatory affairs professionals and clinical operations teams working across multiple jurisdictions, the programme equips participants to navigate multi-jurisdictional submissions, safety reporting obligations, CTIS workflows and inspection-readiness activities, and concludes with three assessed practical workshops.

COURSE MODULE INDEX — 29 MODULES, 81 HOURS

NO.	MODULE TITLE	DURATION
01	**Introduction to Clinical Research Regulations** ICH-GCP, Declaration of Helsinki, roles & responsibilities	2 hrs
02	**Regulatory Lifecycle of a Clinical Trial** Feasibility through to archiving	2 hrs
03	**Essential Documents and ISF / eTMF Management** Filing standards and completeness	3 hrs
04	**Ethics Committees and IRB / REC / IEC Submissions** Submission routes and ongoing obligations	3 hrs
05	**Informed Consent Regulations** Patient-facing document requirements	2 hrs
06	**Translation, Version Control and Document Compliance** Controlled document practice	2 hrs
07	**US FDA Regulatory Framework** IND, Forms FDA 1572, 3454 / 3455	4 hrs
08	**US IRB Submissions, Amendments and Continuing Review** Lifecycle of US ethics oversight	3 hrs
09	**US Site Activation Package and Regulatory Binder Setup** Start-up documentation	3 hrs
10	**UK Clinical Trial Framework** MHRA, HRA, REC and IRAS	3 hrs
11	**UK IRAS and HRA Submission Process** Practical submission workflow	3 hrs
12	**UK MHRA CTA and Safety Reporting** Authorisation and expedited reporting	3 hrs
13	**UK Site Green Light and NHS R&D Approvals** Capability and capacity confirmation	2 hrs
14	**EU Clinical Trial Regulation 536/2014** Scope, transition and obligations	3 hrs
15	**CTIS System Navigation and User Roles** Access, roles and workspace structure	2 hrs
16	**CTIS Part I and Part II Submissions and RFIs** Dossier assembly and response handling	4 hrs
17	**CTIS Substantial Modifications and Transparency Rules** Publication and deferral rules	2 hrs
18	**AE, SAE and SUSAR Reporting (US, UK, EU)** Multi-jurisdictional safety obligations	3 hrs
19	**DSUR and Annual Safety Reporting** Periodic reporting requirements	2 hrs
20	**Protocol Deviations, GCP Breaches and CAPA Management** Escalation and remediation	3 hrs
21	**GDPR and Data Privacy in Clinical Research** UK/EU GDPR in trial operations	2 hrs
22	**Clinical Trial Agreements, DPAs and Confidentiality** Contractual and data-processing terms	2 hrs
23	**Regulatory Tracking Systems and CTMS** Tracking submissions and approvals	2 hrs
24	**eTMF Systems and Filing Best Practices** Inspection-ready TMF management	2 hrs
25	**Audit and Inspection Readiness** FDA, MHRA and EMA inspections	4 hrs
26	**Audit Response and Regulatory CAPA Process** Findings, responses and closure	3 hrs
27	**CTIS Mock Submission Workshop** Practical, assessed workshop	4 hrs
28	**IRAS and IRB Practical Form Completion** Practical, assessed workshop	4 hrs
29	**Regulatory Inspection Role Play and Final Assessment** Capstone assessment	4 hrs
TOTAL PROGRAMME — 29 Modules		**81 Hrs**

PARTICIPANT PROFILE & DELIVERY

WHO SHOULD ATTEND

- Regulatory affairs professionals
- Clinical operations and CRA teams
- Sponsor and CRO regulatory leads
- eTMF and document management teams
- Quality assurance and compliance staff
- Site coordinators in regulated studies

DELIVERY FORMATS

- Live Online — instructor-led sessions
- In-Person — site or training centre
- Workshop and role-play assessments
- CPD accredited and formally assessed
- Global delivery capability (US, UK, EU, India)
- Certificate of completion with CPD hours recorded

REGULATORY ALIGNMENT

- **US FDA** — 21 CFR Parts 11, 50, 54, 56 & 312
- **UK** — MHRA, HRA, REC and IRAS
- **EU** — Regulation (EU) No 536/2014 and CTIS
- **ICH** — E6(R3) GCP, E2A / E2F safety reporting
- **Data Privacy** — UK/EU GDPR and US HIPAA
- **Records** — 21 CFR Part 11 and EU GMP Annex 11

PROGRAMME NOTES

Workshop and role-play sessions (modules **27–29**) include practical assessments modelled on real-world regulatory submissions. The programme covers US FDA, UK MHRA/HRA and EU CTR 536/2014 requirements in parallel, with region-specific tracks available. Module durations are confirmed upon programme scheduling.

ENROLMENT & ENQUIRIES

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