

# Advanced Good Clinical Practice (GCP) for Clinical Trial Professional

2 & 3 September, 2026

7:30 AM - 11:30 AM | Indonesia, Thailand, Vietnam, Cambodia, Laos

8:30 AM - 12:30 PM | Singapore, Malaysia, Philippines, Hong Kong, Taiwan  
Zoom Webinar



## Strengthening Excellence in Clinical Research Through International Best Practices

Designed for investigators, study teams, and clinical research professionals, this interactive online program provides a practical understanding of Good Clinical Practice (GCP), ethical principles, regulatory requirements, and investigator responsibilities essential for conducting high-quality clinical research.

Conducted in collaboration with IASMED, the program combines DIA's global perspectives, real-world case studies, and interactive discussions to help participants strengthen compliance, enhance study quality, and improve confidence in clinical trial conduct.

## Key Learning Topics

### Roles & Responsibilities

- Clinical Trial Lifecycle
- Roles of Investigators & Study Teams
- Sponsors, CROs & Institutions
- IRB/IEC Oversight
- Drug Development Overview

### GCP, Ethics & Regulations

- ICH GCP Principles
- Human Subject Protection
- Ethical Conduct
- Informed Consent
- Regulatory Compliance

### Effective Study Conduct

- Study Preparation & Initiation
- Subject Recruitment & Retention
- Safety Monitoring & Reporting
- Study Documentation & Data Integrity
- Study Close-out & Inspection Readiness

## Who should attend?

### Clinical Research Professionals

- Principal Investigators
- Sub-Investigators
- Clinical Research Associates (CRAs)
- Clinical Research Managers
- Study Coordinators
- Research Nurses

### Industry Professionals

- Sponsor Representatives
- CRO Professionals
- Regulatory Affairs Professionals
- Pharmacovigilance Professionals

### Oversight & Academia

- Ethics Committee (IRB/IEC) Members
- Clinical Research Unit Personnel
- Academic Researchers

## Live Online Training with Recording Access

Registered participants will receive access to the session recordings, allowing them to review the content or catch up on any sessions they are unable to attend live.

To register, please visit the link below or scan the QR code.

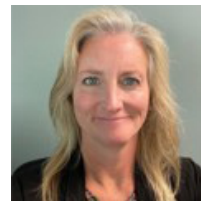
## REGISTER NOW



DIA Korea  
Korea@DIAGlobal.org

DIA Global Center: Washington, DC, USA | Basel, Switzerland | Beijing, China | Horsham, PA, USA | Mumbai, India | Tokyo, Japan | Seoul, Korea

## FACULTY INFORMATION



### Lynn King, MHA

Consultant,  
Cornerstone Clinical Research Consulting,

#### United States

- 25+ Years of Experience in Clinical Research & Drug Development
- Extensive Experience Across Pharmaceutical Companies, CROs & Research Sites
- Expert in GCP, Clinical Trial Operations & Regulatory Compliance
- Certified Trainer & Professional Coach

## DIA MEMBERSHIP

Join DIA now to save on future meetings and to enjoy the benefits of membership for a full year:  
[www.DIAGlobal.org/Membership](http://www.DIAGlobal.org/Membership)

To view the benefits of the membership, please click the link.

DIA volunteers, members, and staff provide a comprehensive catalogue of conferences, workshops, training courses, scientific publications, and educational materials, throughout the year, all around the world.

[DIAGlobal.org](http://DIAGlobal.org)

## AGENDA | Advanced GCP for Clinical Trial Professional - 2 & 3 September, 2026

| Session Agenda                                                                  | DAY 1 (2 September)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|---------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Welcome &amp; Objectives</b>                                                 | Welcome & Objectives <ul style="list-style-type: none"> <li>• Learning objectives review</li> <li>• 3-5 question poll</li> </ul>                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Module 1: Regulatory Landscape &amp; ICH E6(R3) Update</b>                   | <ul style="list-style-type: none"> <li>• GCP Overview</li> <li>• Evolution from GCP E6(R2) to E6(R3): key changes and rationale</li> <li>• Risk-based quality management (RBQM) principles embedded in R3</li> <li>• Interplay with FDA regulations (21 CFR 50, 54, 56, 312), EU CTR, and local requirements</li> <li>• Ethics Committee &amp; IRB Reviews</li> </ul>                                                                                                                                          |
| <b>Module 2: Investigator Responsibilities &amp; Oversight</b>                  | <ul style="list-style-type: none"> <li>• Investigator Responsibilities overview</li> <li>• Adequate resources, delegation of authority, and supervision standards</li> <li>• Sub-investigator and delegation log best practices</li> <li>• Investigator oversight of vendors/CROs — what “adequate oversight” looks like</li> <li>• Common inspection findings related to investigator oversight</li> <li>• Case study discussion: Recent Investigator 483s; Examples of GCP gaps at clinical sites</li> </ul> |
| <b>Module 3: Audit Trends &amp; Corrective &amp; Preventive Actions (CAPA)</b>  | <ul style="list-style-type: none"> <li>• Delegation logs</li> <li>• FDA findings trends review</li> <li>• Key factors in creating CAPAs</li> </ul>                                                                                                                                                                                                                                                                                                                                                             |
| <b>Module 4: Case Study Review</b>                                              | <ul style="list-style-type: none"> <li>• Example of Investigator findings and how to manage</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Q&amp;A</b>                                                                  | <ul style="list-style-type: none"> <li>• Live Q&amp;A, participant-submitted questions addressed</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                    |
| Session Agenda                                                                  | DAY 2 (3 September)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Introduction</b>                                                             | <ul style="list-style-type: none"> <li>• Review Day 1</li> <li>• Agenda review for Day 2</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Module 5: Informed Consent — Advanced Issues</b>                             | <ul style="list-style-type: none"> <li>• Consent process overview</li> <li>• Consent for vulnerable populations (cognitively impaired, pediatric, emergency research)</li> <li>• Electronic informed consent (eConsent): regulatory expectations</li> <li>• Reconsent triggers and documentation of the consent process (not just the form)</li> <li>• Handling consent deviations and capacity concerns</li> </ul>                                                                                            |
| <b>Module 6: Risk-Based Monitoring, Data Integrity &amp; Quality Management</b> | <ul style="list-style-type: none"> <li>• Critical-to-quality (CtQ) factors and risk assessment at study start-up</li> <li>• ALCOA+ principles and source data verification vs. source data review</li> <li>• Data integrity in EDC/eSource systems; audit trail review responsibilities</li> <li>• Deviation/violation management: classification, CAPA, and reporting timelines</li> </ul>                                                                                                                    |
| <b>Module 7: Safety Reporting &amp; Inspection Readiness</b>                    | <ul style="list-style-type: none"> <li>• SAE/AE reporting responsibilities and timelines (regional and local regulation; investigator vs. sponsor obligations)</li> <li>• Preparing for regulatory inspections and sponsor audits: documentation readiness</li> <li>• GCP deficiencies and how to avoid them</li> <li>• Keys to successful CAPAs</li> <li>• Case Study: Findings &amp; CAPA actions</li> </ul>                                                                                                 |
| <b>Module 8: Vendor &amp; Site Oversight</b>                                    | <ul style="list-style-type: none"> <li>• Clinical trial site monitoring</li> <li>• Vendor monitoring and oversight (sites and global CROs; mention importance of contract review)</li> </ul>                                                                                                                                                                                                                                                                                                                   |
| <b>Summary/Q&amp;A</b>                                                          | <ul style="list-style-type: none"> <li>• Live Q&amp;A, participant-submitted questions addressed</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                    |

**REGISTRATION FORM** : Register online or forward to DIA Korea  
Korea@DIAglobal.org

## DIA Webinar

Advanced Good Clinical Practice (GCP) for Clinical Trial Professional  
2 & 3 September 2026 | Zoom Webinar

## REGISTRATION

Register online at the link [HERE](#) or complete this registration form and email to our Korea Office

DIA will send participants a confirmation letter within 10 business days after receipt of their registration.

### Registration Fee: USD 150

The registration fee for this course is the same regardless of DIA membership status. Registration fee includes full admission to virtual course, electronic access to training course materials. Please note that the full amount must be received by DIA by commencement of the course to get the electronic access to the material. If you wish to register for both the Protocol Development Training and the Advanced GCP for Clinical Trial Professionals course, please select "Both Trainings" from the table below, complete this registration form, and email it to DIA Office Korea@DIAglobal.org.

|                                                         | REGISTRATION FEE (USD)       |
|---------------------------------------------------------|------------------------------|
| 2-3 Sep   Advanced GCP for Clinical Trail Professionals | <input type="checkbox"/> 150 |
| 4 Sep   Protocol Development                            | <input type="checkbox"/> 100 |
| 2-4 Sep   Both Trainings                                | <input type="checkbox"/> 250 |

### Please check the applicable category:

☐ Academia ☐ Government ☐ Industry

Last Name

First Name

Degrees

☐ Dr. ☐ Mr. ☐ Ms.

Job Title

Company

Address (As required for postal delivery to your location)

City

State

Zip/Postal

Country

email **Required for confirmation**

Phone Number **Required**

## DIA MEMBERSHIP- Special Offer!!

Enjoy \$30 off DIA membership now! (regularly USD 180 → **USD 150 now**).

Join a DIA member and enjoy discounted member registration rates for other DIA programs.

Use promo code "RMP30" when joining membership online.

To purchase membership and registration together, contact Korea@DIAglobal.org

☐ I **DO** want to be a DIA member

☐ I **DO NOT** want to be a DIA member

To view the benefits of the membership, please click the link.

## CONTACT INFORMATION

### DIA

email:

Korea@DIAglobal.org

Eunah.Cha@DIAglobal.org

www.diaglobal.org

## DIA Terms and Conditions

### CANCELLATION POLICY: On or before 2 August, 2026

**Administrative fee that will be withheld from refund amount: the administrative fee that will be withheld from refund amount is 25 % of the delegate fee**

Cancellations must be in writing and be received by the cancellation date above. Registrants who do not cancel by that date and do not attend will be responsible for the full registration fee paid.

You may transfer your registration to a colleague at any time but **membership is not transferable**. Please notify DIA of any such substitutions as soon as possible. Substitute registrants will be responsible for nonmember fee, if applicable.

### EVENT STREAM AND RECORDING

If you attend a DIA event, we make video and audio recordings of events (both face to face and online) that may include your participation in the event, including your image, questions and comments. To view our full photography and video recording policy, click [here](https://www.diaglobal.org/general/photography-policy). (https://www.diaglobal.org/general/photography-policy)

### PRIVACY STATEMENT

The personal information you request will be used for the purpose of sending conference information from DIA. In addition, in the web conference, we will use the information with the name of the company or organization and the name of everyone who participates, and it will be used for networking with participants, related parties, exhibiting companies for the period and about two weeks after the event. By submitting this application form, it is interpreted that you have consented to the above handling of personal information, but if you do not agree, please contact DIA.

By signing below I confirm that I agree with DIA's Terms and Conditions of booking. These are available from the office or online by clicking [here](https://www.diaglobal.org/general/photography-policy). (https://www.diaglobal.org/general/photography-policy)

Signature

Date

## PAYMENT OPTIONS

Register online at [www.DIAglobal.org](http://www.DIAglobal.org) or check payment method.

### ☐ BANK TRANSFER:

**You will receive an invoice with bank information detail by email after registration completion.**

*All local and overseas charges incurred for the bank transfer must be borne by payer.*

### ☐ CREDIT CARD (VISA OR MASTERCARD OR AMEX ONLY)

☐ **VISA** ☐ **MC** ☐ **AMEX** Exp. (mm/yy) \_\_\_\_\_

Card No. \_\_\_\_\_

Cardholder Name \_\_\_\_\_

Signature \_\_\_\_\_