Training components for GCP inspectors in PMDA

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Office of Conformity Audit, PMDA
Content

1. Conformity inspection in the training program for newcomers to PMDA

2. The training programs for new members of the conformity audit office

3. The training programs for foreign regulatory officers
PMDA Staff Size

- Administrative part
- Safety Department
- Review Department

Year: 2004 to 2013
Training program for newcomers to PMDA

• Intended for all newcomers including GCP inspectors.
• Consisting of lectures and case studies.
• Covering broad topics such as process of drug development, review and approval process, GCP and related regulations and guidelines, post-marketing safety measures, etc.
• Taking about 30 days to finish the program.

✓ Conformity inspection and GXP for data integrity are important topics in the program.
Conformity inspection in the program (1)

• Introducing the concept of GCP and the pharmaceutical affairs act.
  Ethical and scientific quality standard for designing, conducting, recording, and reporting trials.

• Presenting data integrity standards for product applications.
  Accuracy: Accurate preparation of dossier based on the results of analyses and studies
  Completeness: Description of results which cast no doubt on quality, efficacy or safety
  Retention: Retention of the original data
Conformity inspection in the program (2)

Major activities in the Office of Conformity Audit

✓ Consultation
  • Before application

✓ Inspection
  • Application-based

✓ Enlightening activities
  • GCP workshop with sponsors, medical institutions, CRO, SMO, etc.

✓ Promoting international activities
Conformity inspection in the program (3)

Case study from the Office of Conformity Audit

✓ Informed consent
  • Vulnerable subjects
  • The role of a CRC/witness in taking the IC

✓ Institution Review Board
  • Composition of IRB members

✓ Selection of subjects
  • Deviation from the exclusion criteria
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Office of Conformity Audit, PMDA

Office Director

Office Deputy Director

- GCP On-site Inspection (Drugs team:21) (Devices team:7)
- Document-based Conformity Inspection (Drugs team:16) (Devices team:7)
- GLP Inspection (6)
- GPSP Inspection (13)

( ): The number of inspectors
Training program in Conformity Audit office

OJT (On the Job Training) is the main role.

✓ Inspectors are trained/educated by their mentors
✓ Checklists for on-site inspection are used as a reference
  • Preparation for the inspection
  • Inspecting procedures
✓ Reporting the inspection results in the office meeting is a good chance to train/educate inspector
✓ GCP workshop held yearly offers a learning opportunity
  • Intended participants (Sponsors, Medical institutions, CROs, SMOs, etc.)
  • Provide information on inspection (Purpose, Points to consider, Findings in recent inspections, etc.)
Checklist Utilization

Objective

• Inspectors can cover what they should review at least.

• Every inspector can review in the same way.

• Medical institution and/or sponsor can prepare for the inspection.
Checklist for the Institution
(Investigator, IRB, and Head of the Institution)

[ I ] Outline of the Medical Institution
  • Preparing the SOPs for clinical trial

[ II ] IRB
  • Using local IRB or other IRB
  • Preparing the SOPs, membership list, and minutes of meetings of the IRB
  • Composition of the IRB comply with GCP. (ex: at least five members, at least one member who is independent of the institution/trial site, etc.)
  • Conducting continuing review of each ongoing trial at least once per year
  • Reviewing all SAE reports from the investigator and safety reports from the sponsor appropriately

[ III ] Principal investigator
  • Preparing a list of the sub-investigators and the coordinators

[ IV ] Clinical trial management
  • All SAEs were reported to the sponsor, the IRB, head of the medical institution
  • PI documented any deviation from the protocol
  • The investigational product(s) were stored appropriately

[V] Informed consent
  • The written informed consent form includes necessary matters
  • Selections of the subjects are applicable

[ VI ] Case report form
  • Preparing accurate CRFs and signed by PI
### II-3. Composition of the IRB [Art. 28, para. 1]

- □ In compliance
- □ Capable of sufficient review the ethics and science  **Apr.98~**
- □ Consisting of at least 5 members
- □ At least one member whose primary area of interest is in a nonscientific area.
- □ At least one member who is independent of the institution/trial site.
Conclusion of GCP On-site Inspection

**Compliance:**
Acceptable as application dossier (indicate voluntary action, if necessary)

**Compliance with condition:**
Violation of GCP was found in a part of subjects
→ Acceptable as application dossier after excluding the data from NDA package

**Non-compliance:**
Violation of GCP was found generally and systematically
→ No reliability
→ Not acceptable as application dossier
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PMDA International Strategic Plan
(February, 2009)

Strengthening of cooperation and building of collaborative relations with the United States (US), the European Union (EU), Asian countries, and relevant international organizations
Capacity Building: **PMDA Training Seminars**

PMDA has held the training seminar since 2010 to provide educational opportunities of regulation system in Japan mainly for:

**Pharmaceuticals:**

1st **(Nov. 2010)** Reviewing of New Drugs  
(21 participants: China 6, Indonesia 8, Korea 3, Singapore 2, Taiwan 1)

2nd **(Dec. 2011)** GMP inspection  
(10 participants: Indonesia 4, Korea 5, India 1)

3rd **(Jan. 2013)** Post-Marketing Safety & Relief Services  
(18 participants: Indonesia 2, Korea 2, Singapore 5, Taiwan 2, Ukraine 6, Brazil 1)

4th **(Feb. 2014)** Reviewing of Generic Drugs  
(17 participants: Vietnam 4, Korea 3, Saudi Arabia 3, Taiwan 2, Indonesia 2, Yemen 1, Russia 1, WHO 1)

**Medical Devices:**

1st **(Mar. 2014)** Review and Safety  
(19 participants: Taiwan 4, Malaysia 4, Korea 3, Singapore 3, Uganda 1, Saudi Arabia 2, Hong Kong 1, Switzerland 1)
Trainings for individual Trainees

Medium-term training

- 2.5 months training for a CFDA reviewer – May~July 2010
- Three weeks’ training for three MFDS(ex-KFDA) officials on general issues - Dec 2011
- One month training for TFDA (Taiwan FDA) officials on Medical Devices – Feb 2012
- Five days training for NADFC (Indonesia) officials on review system – March 2013
- FDA (US) analyst: 6 months, 2013-2014
- NPBC (Malaysia) officials: 1 month, 2014 (forthcoming)
- Thai FDA (Thailand) officials: 5 days, 2014 (forthcoming)
Thank you for your attention!

Please contact us.
http://www.pmda.go.jp/