Collaboration on Practical GCP Inspection activities between TFDA and MHLW/PMDA

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Ryosuke SAKAI

Office of Non-clinical and Clinical Compliance

Pharmaceuticals and Medical Devices Agency

Task

TFDA and MHLW/PMDA agreed that the importance and necessity **to set discussion place** and **share information** between GCP experts in this field.

Short term purpose
- To promote **confidence building measures** on GCP inspection result

Long term purpose
- To make a **platform to exchange information** of GCP inspection
- Utilization of **GCP inspection result** by TFDA and MHLW/PMDA

Necessary Task

- Mutual understanding on GCP regulation
- Confirmation on the practical GCP inspection level

Progress

1. Face-to-face meetings
- ✓ May 2015 & July 2016 (Taiwan)

2. Teleconferences
- ✓ Total 11 teleconferences since March 2015

3. Exchanged Documents
- ✓ GCP-related regulations (including procedures)
- ✓ Questionnaires for GCP inspections (New drugs & generics)

4. Practical understandings
- ✓ Observed inspection
    - in Japan by TFDA (August 2015)
    - in Taiwan by PMDA (October 2015)
- ✓ Classroom & field lectures for BE study, etc. by PMDA (September 2016)

5. Others
- ✓ Lecture by PMDA in 2016 Conference on Good Clinical Practice (July 2016 in Taiwan)

Achievements & Future proposal

1. Mutual understanding
- ✓ Understood the regulations & procedures for GCP inspection by information sharing
- ✓ Confirmed the practical GCP inspection level through the observation of inspections & discussions

2. Platform for exchanging information
- ✓ Smooth communication could be done between each contact persons

1. Keep channel
- ✓ TFDA & PMDA will communicate using this channel when necessary
- ✓ TFDA & PMDA will discuss when specific topic is appeared.

2. Regular meeting (including teleconference)
- ✓ Will be able to shift to Review WG

(Ref.) 'Next steps and future' in 2015 meeting

- **Identify and seek to avoid gaps using the cases**
    - such as GCP inspection for same protocol
    - such as GCP inspection on simultaneous application product

- **Create information exchange platform on practical GCP inspection**

- **Create GCP inspection training at PMDA to provide its practical GCP knowledge**

- **Collaborate on common challenge for Clinical Quality Management System**