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

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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)
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
• 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