PMDA Update

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Session 03

DIA

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Expectations for CM

- Opportunities:
  - To avoid poor quality product with PAT etc.
    → Prevention of drug shortage problem
  - To avoid scale-up issues
    → Rapid development
  - To operate multiple scales and dosage manufacturing
    → Personalized medicines
  - To reduce inventory
    → Cost reductions

PMDA would like to encourage industry to introduce the innovative manufacturing technology.

Innovative Manufacturing Technology Working Group (IMT-WG)

- Has been established in PMDA since July, 2016.
- Purpose
  - To establish PMDA's perspective on the latest technologies of pharmaceutical quality control
  - To propose a new regulatory framework for the pharmaceutical quality control by the new technologies
  - To draft guidelines
- Members
  - Senior Scientist (for Quality); Dr. Yoshihiro Matsuda
  - From Office of New Drugs
  - From Office of Manufacturing/Quality and Compliance
  - From Office of Regulatory Science

IMT-WG Activity Plan

- To organize face-to-face meeting(s) with FDA and EMA
- To visit continuous manufacturing sites
- To discuss with stakeholders including industries and academia
- To collaborate with a national research project on pharmaceutical quality control
- To publish a draft points-to-consider document about CM in spring, 2017

Clarification for CM Implementation

A draft Points-to-Consider document.

- We are focusing on 4 topics
  - Control Strategy
  - Batch/Lot Definition
  - Process Validation
  - Stability Test

Next Step

- How to gain experience of CM?
- How to share our experience of CM?
- How to encourage industries?
- How to return profits to patients?

Let’s move forward!

Ask