PMDA Update

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Session 03
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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

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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
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!