Recent Efforts of Quality Assurance for Pharmaceuticals in Japan

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On-site Inspection Trend

- Risk assessment for products types, dosage form, manufacturing processes etc.
- Assessment based on inspection reports which received from PIC/S participating authority
- Assessment and information acquired at API Program
- MRA with EU resulted in simplification of inspection

★Increase inspections at Asia area

★Enhance number of domestic inspections

→ Unannounced inspections

Increase joint inspection with prefectures

Information Exchange at API Program

API Program : Program to rationalize international GMP inspections of active pharmaceutical ingredients/active substances manufacturers

◆Purpose

To foster greater international collaboration and information sharing to help better distribute inspection capacity, allowing more sites to be monitored, conducting more effective inspections and reducing duplication.

◆Participating Countries and Organizations

Australia, Canada, Denmark , EDQM, France, Ireland, Italy, United Kingdom, U.S.A., EMA, WHO, Japan

Mutual Recognition Agreement with EU

2004 2013 2014 2016 2018

- MRA between the EU (15 countries) and Japan were concluded (Scoped only non-sterile products)
- On-site assessment by EU for exemption of the EU's regulatory control applicable to APIs exported from Japan
- Japan was listed to the exemption of the EU's regulatory control applicable to APIs
- On-site assessment by the PIC/S for the PIC/S membership
- Became the PIC/S membership (45th country)
- Expands MRA scoped EU countries from 15 to 28
- Extends MRA scope to sterile products, APIs and biologicals including vaccines

PMDA Asia Training Center

GMP Area

Established in April 2016

- Mock inspection at the manufacturing site
- Collaboration with PIC/S
  - December 2016 at Toyama (Solid dosage form)
  - July 2017 at Yamaguchi (Vaccine)
  - November 2018 at Tochigi (API for Biotech)

Ranking of Critical and Major Deficiencie

Increasing “Documents and records management” deficiencies in 2016

Ranking	2014	2015	2016
	Items	Items	Items
1	Validation	Validation	Documents and Records
2	Documents and Records	Documents and Records	Cross Contamination
3	Cross Contamination	Deviation control	Validation
4	Deviation control	Cross Contamination	Change control
5	API and starting material handling	Change control	Deviation control
6	QMS	Manufacturing process	Maintenance of facility
7	Maintenance of facility	Maintenance of facility	QMS
8	Training	Training	API and starting material handling
9	Release management	Cleaning Validation	Cleaning Validation
10	Supplier management	Annual Product Review	Release management
	Stability test		

Thank you for your attention.

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