ジャパン ライフサイエンスウィーク 2016
CPhI japan
国際医薬品原料・中間体展

Stable Supply and Quality Assurance of APIs for the Age of Market Share 80% of Generic Medicines

April 21, 2016

Pharma Planning Co., Ltd.
President　Kazuhito Takahashi

Classification of Manufacturers according to Site Inspections

◆**Drug and API Manufacturing Sites were classified as S,A,B,C,D to PMDA inspections (final evaluations based on level and number of incosistancies, and evaluations of subsystems)**

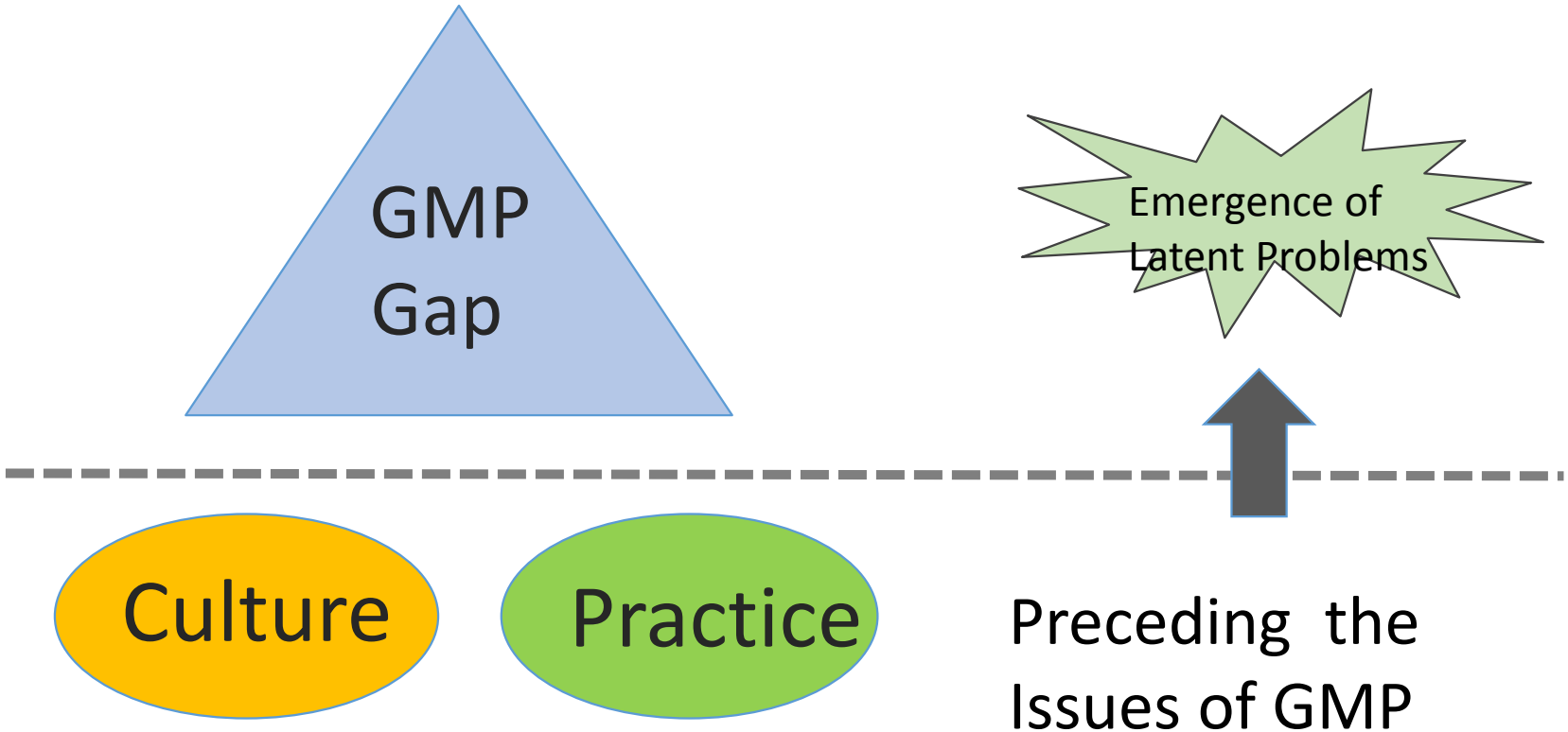
D：Uncomplient　C：Compliant but continuous control is required

Global Regions	On-Site Inspections Made 2007.12-2014.10	Classification		Total	Ratio of C&D(%)
		C	D		
Asia (except Japan)	273	80 (19)	7 (3)	87	32%
EU	127	7 (2)	0 (0)	7	6%
North America	88	8 (0)	1 (1)	9	10%
South America	6	1 (1)	0 (0)	1	17%
Japan	485	100 (28)	5 (5)	105	22%

- C,D ratio in Asia is still high
- Result D at renewal investigation is a big problem.

Source: PMDA

Issues with Overseas Manufacturers



Introduction of some cases: China

Chinese GMP Rule

「薬品生産品質管理規範（GMP）」
（衛生部令第79号　2011年3月施行）

(GMP for Drugs by　MOH)

It is fully comparable to those GMP regulations in Japan, US and EU.

Chinese Cases

Chinese GMP

（Rule is excellent）

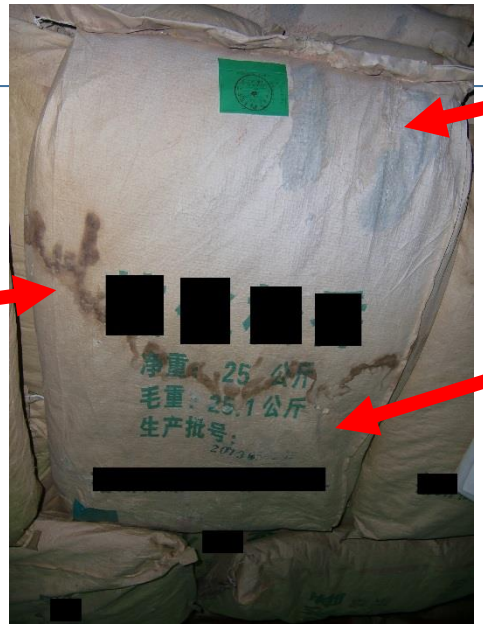
In reality・・・

There are companies judged to be uncompliant due to insufficiencies when they have domestic or global inspections.

Real Situation of a Manufacturing Site(an example)

In acceptance procedure, the established confirmation（checking and testing of substance name, lot numbers, appearance as to, breakage and filths, test certificates, etc.) is made, the receipt of goods and stored is normally made. But…..

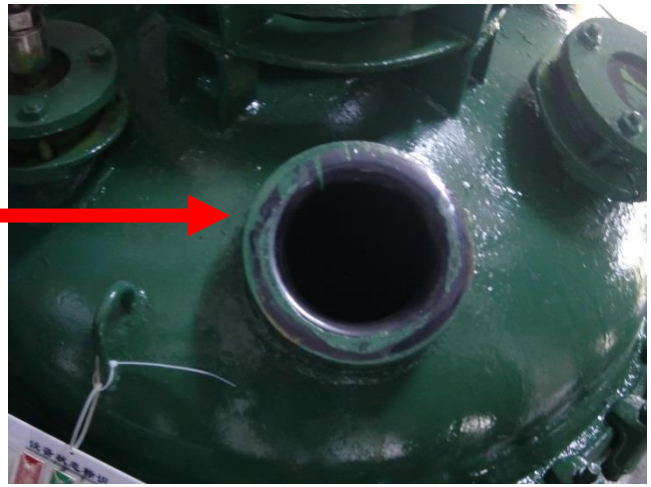
、



Real Situation of Manufacturing Site (an example)

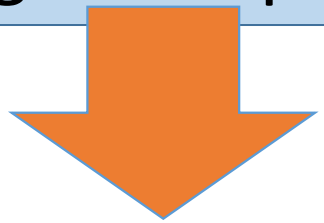
A synthetic reactor had smear and rust. Although repair was instructed, raw material charging hole is tainted with paint

The flange is tainted with paint.



Estimated Reasons

- GMP Culture's history or experience is short.
- Rationalism without Grounds
- Job-hopping of Responsible Employees



Culture

Practice

Proposal of Solutions for Issues

- Study Basic Practice of GMP

  -Not only ordinary workers but also responsible and Management people must learn GMP vigorously.

- Breakaway from Simple Mimicry from Advanced Countries

  -After studying GMP vigorously , it is important to proceed to develop better practice with what are important and what problems there are on your own.

Thank you
for your attention