Potential Areas for Improvement Of GMP Compliance Assessment

Suggestions from JPMA

Japan Pharmaceuticals Manufacturers Association (JPMA), Quality & Technology Committee

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APAC
Asia Partnership Conference of Pharmaceutical Associations

Agenda

1. Suggestions from JPMA
2. Experience of Product Application from Japan to Asian Authorities
3. Issues Related to Submitting Site Master Files (SMFs)
4. To Promote ATIM for People in Asia

Suggestions from JPMA: To Promote ATIM to People In Asia

Convergence of GMP Compliance Qualification Programs

- Convergence of document assessment programs for GMP compliance qualification is desired.
- The variety of the necessary documents is left to the discretion of each regulatory authority, however, contents of documents such as Site Master Files (SMFs) can be converged based on the PIC/S GMP guidelines/notes.
- Those documents will be created and assessed with shared understanding among regulatory authorities, among industry members, and between regulatory authority and the industry.
- With having a converged GMP compliance qualification program among the authorities, this will provide efficient use of time and resources
- And if successful, it will lead to shorter assessment of the GMP compliance qualification.

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Suggestions from JPMA (1)

A. Convergence of the Contents of Necessary Documents

1. It is desired that the necessary contents in SMF would follow the PIC/S SMF Guideline(*). (*)PE008-4"Explanatory notes for pharmaceutical Manufacturers on the preparation of a site master file"
   - Additional documents such as Plant Master File (PMF) or SMF based on regional requirement might be burden for industry because there are often cases that the content of such a SMF and PMF overlaps PIC/S SMF Guideline.

2. English will be used as the common language for documents of GMP compliance qualification.

Suggestions from JPMA (2)

B. Promoting Operational Efficiency in GMP Compliance Qualification

1. It is hoped to have a more transparent assessment process for GMP compliance qualification:
   - Additional documents are often requested in order to aid understandings of GMP inspector.
   - However, the scope of the documents tends to be wider than that in the on-site inspection.
2. To avoid loss of evaluation time, it is desired that manufacturing sites will be evaluated by risk-based approach regarding both evaluation of documents and request of additional documents.
3. Moreover, it is desired that GMP qualification status of a manufacturing site will be mutually recognized among the regulatory agencies.

Experience of Product Application from Japan to Asian Authorities

A Survey Conducted by JPMA

➢Purpose

- At the time of applying/supplying new drug to Asian authorities, some authorities request to submit SMF/PMF from the GMP related manufacturer.
- However the content of the document request is slightly different for each authority.
- The purpose of this survey to JPMA participating companies is to highlight the difference of thinking toward SMF/PMF and to search “common denominator” for faster supply of innovative medicine to people in Asia.

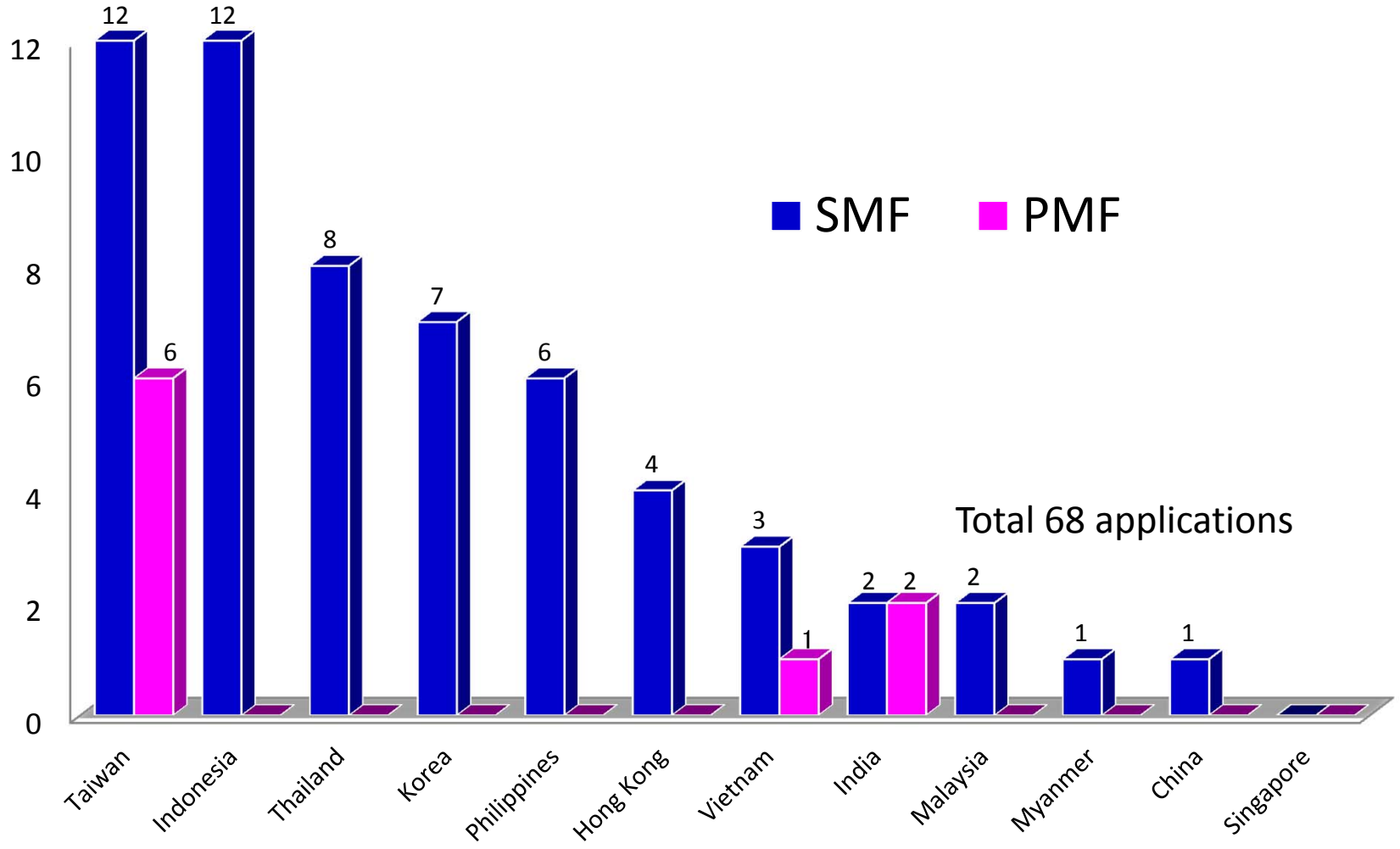
➢Survey participant

- Survey was conducted to JPMA member companies and we received responses from 29 companies based on submitted documents in the past four years.

➢Outline of the survey

- In total 68 cases of NDA application to APAC-participating authorities were reported (Including same product to multiple countries) .
- Countries that requested to submit SMF/PMF at the time of NDA application were examined.
- Cases of additional queries and data requested from regulatory authority
- Presence or absence of on-site inspection

Asian Authorities Requested SMF/PMF at the time of Product Application



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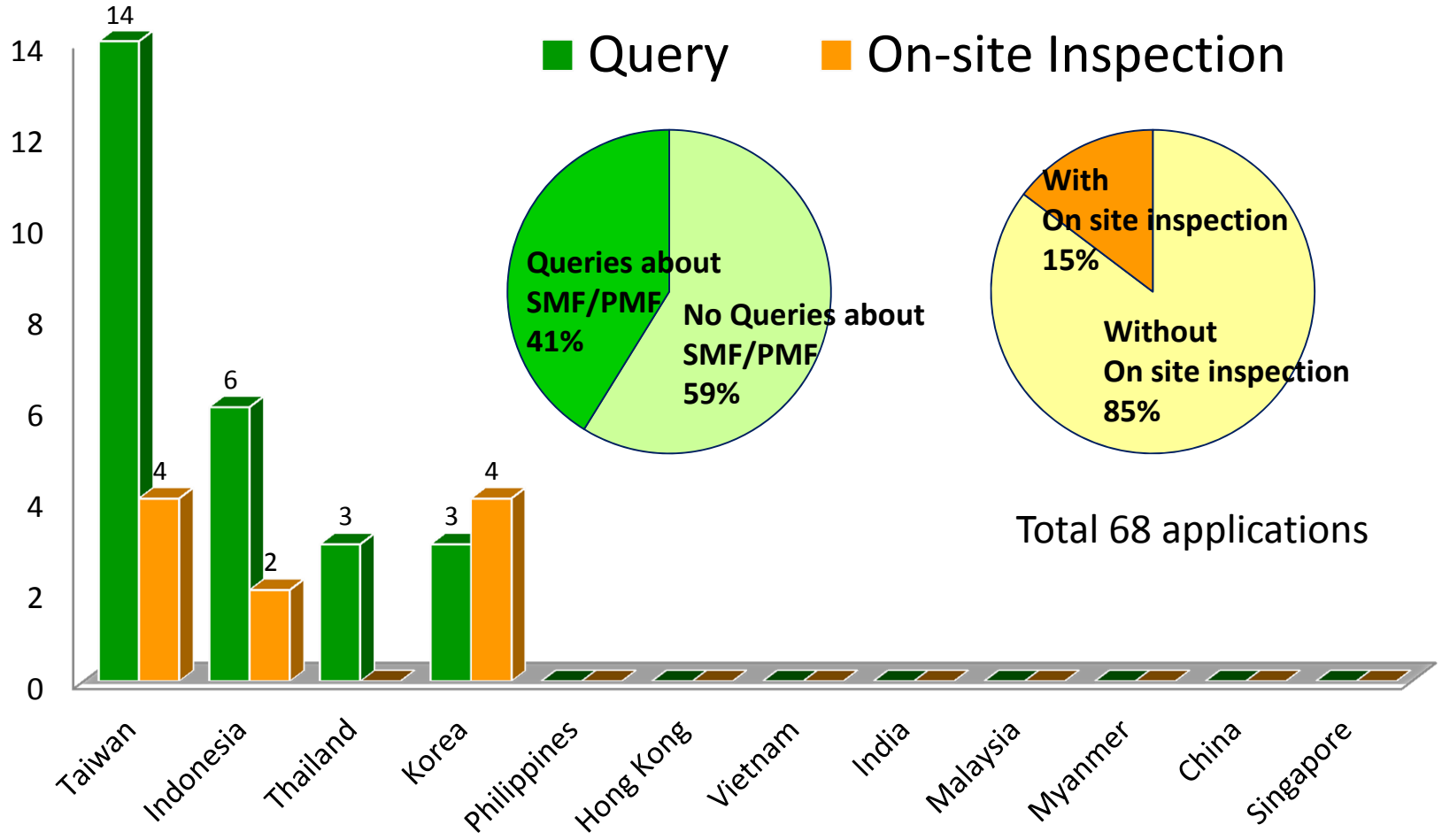
Issue Related To Submitting SMFs

- There are cases where regional guideline is followed to create SMFs.
- There are cases where PMF is required to submit at the time of new drug application. In some cases, PMF is required in addition to SMF
- Since required level of details of the SMF is not clear, there are cases where additional queries are made after the submission of the SMF.
- Other documents needed in addition to SMF for the GMP compliance qualification, are different for each regulatory authority. For example:
  - Checklist
  - Inspection Report
  - Additional data to PMF and periodical renewal of SMF
- There are only a few countries which require updating SMF.

Query about SMF/PMF
And related On-site Inspection



Query about SMF/PMF And related On-site Inspection

- Some regulatory bodies use submitted documents as the pre-reference for the on-site inspection.
- The condition/criterion for the selection of on-site inspection is not clear
- The relation between submitted documents and presence of on-site inspection is not clear.
- The process of GMP compliance assessment for manufacturing sites is not clearly defined.

To Promote ATIM for People in Asia

Convergence of GMP Compliance Qualification Programs

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- Those documents will be created and assessed with shared understanding among regulatory authorities, among industry members, and between regulatory authority and the industry.
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Forward-looking approach by the regulators is awaited, and the industry would like to make collaboration for its realization as much as possible.

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Thank you

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