History of APAC ATIM-TF Session

April 2021

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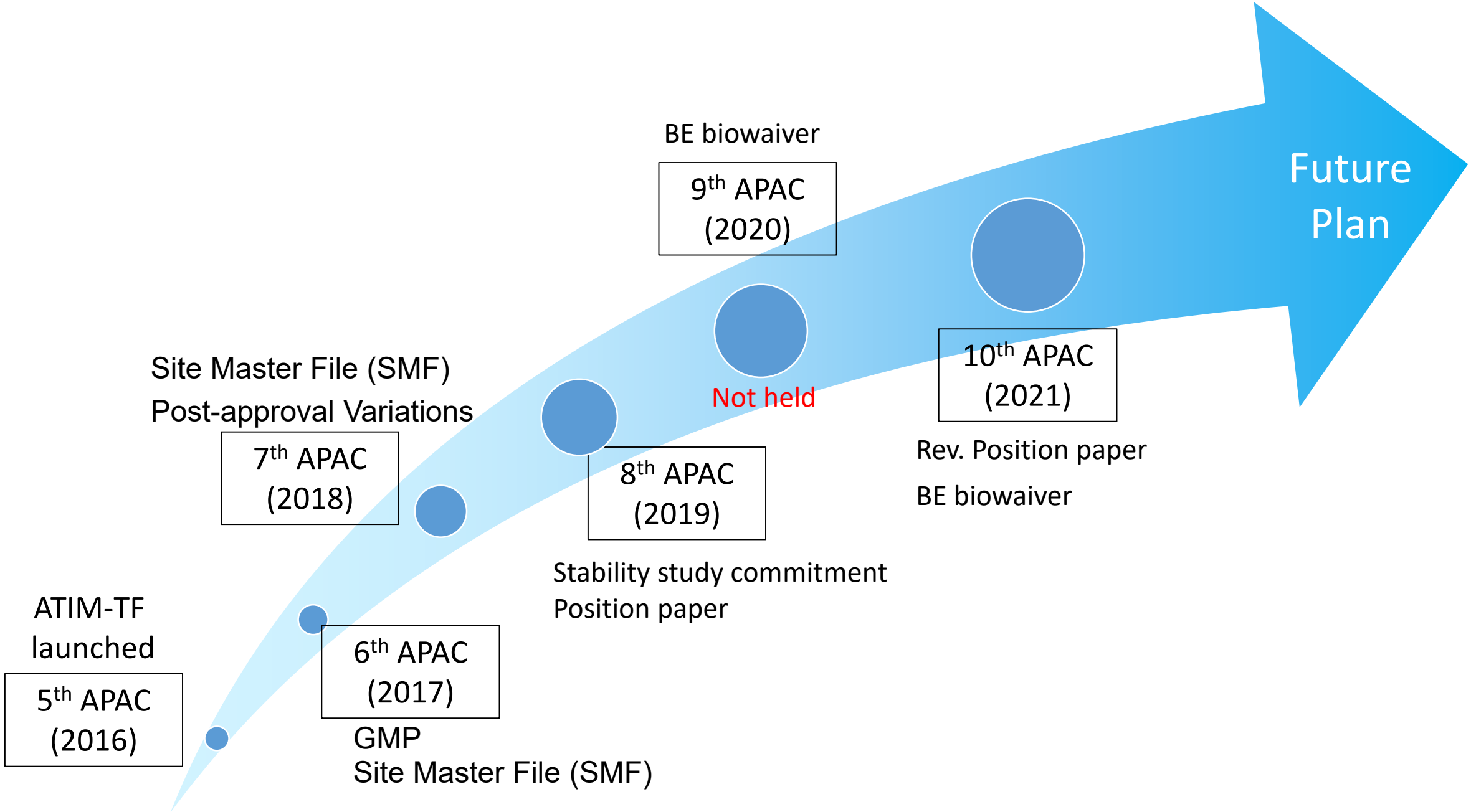
Asia Partnership Conference of Pharmaceutical Associations



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Concept of ATIM (Access To Innovative Medicine)

ATIM Focus

- Innovation of new drug is the driving force to fulfil the unmet medical needs. IP(Intellectual Property), forms the foundation for innovation, and is most important to improve ATIM.
- In addition to DA & RA, APAC will further discuss the possibility to set up a new EWG or project team.

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5th APAC ATIM session summary

The below sessions were held to share the current regulatory situation from the view of harmonization.

- Implementation of International Regulatory Harmonization Strategy(Regulatory Science Initiative : RSI)
- Korean healthcare Strategy for the Improvement of Access to Innovative medicine
- Healthcare System Reform & Innovative Medicine in China
- Report of APEC Harmonization Center Activities
- ASEAN Regulatory Harmonization
- UHC(Universal Health Coverage) Expansion & Innovative medicine Position

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6th APAC ATIM session summary

At the ATIM sessions, GMP was on the agenda for the first time. We heard a report on the evaluation process, especially inspections and SMF (Site Master File) / PMF (Plant Master File), from each Asian regulatory authority. At the panel discussion, we were able to clarify different perspectives of each country, and had fruitful discussions for improving the efficiency of our evaluation process.

- Current and Future of GMP compliance assessment by Korean, Taiwan, Thailand, Indonesia and Japan.

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7th APAC ATIM session summary

Site Master File (SMF)

- Regulators and Industries have reviewed the SMF template, and reached consensus to use it.
  (SMF template would be informed & discussed in PIC/S Committee Meeting in Geneva as regional initiative actions.)

Post-approval Variations

- In the 7th APAC meeting, each difference of the post approval variation fields was confirmed, especially for CMC & stability parts.

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8th APAC ATIM session summary

The post-approval change procedure by stability study commitment

- JPMA proposed the ‘position paper’ to accomplish APAC mission, including the post-approval change procedure.
- The position paper recommends the procedure for change application to employ stability commitment, instead of the submission of newly collected stability data throughout the shelf life at the time of change application. Discussion was made on this point with the participants in ASEAN.
- All the authorities participated in a panel discussion (Malaysia, Thailand and Indonesia) agreed to consider this commitment procedure based on the science and risk based approach, by keeping regulatory science justification for the commitment.
- PMDA introduced PACMP (Post-Approval Change Management Protocol) pilot program, starting from April 2018 in Japan.

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9th APAC ATIM session summary
(Not held due to COVID-19)

Recommendation and Proposals

- There are several points to consider the benefit of applying new ICH guideline M9;
  - BE biowaiver based on BCS(Biopharmaceutics Classification System) can contribute the faster development, avoid unnecessary exposure of healthy patient during BE, and efficient review of formulation change in pre- and post- submission.
  - Adaptation of the concept and risk based approach, this may also reduce the financial impact of the drug development by the industry, consequently the region may benefit from the faster introduction on the innovative drug with less pricing burden.
  - With development ICH guideline, how can we adopt new BCS and its method, to harmonize the procedure to adopt BCS approvals.

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10th APAC ATIM session 2 Recommendation and Proposals

1. Implement mutual understanding and commitment approach could be applied for the change management using the tools such as PACMP and BCS.
2. Increase opportunities for dialogue and collaboration between industry and regulators to discuss integrated science and risk based approaches to have regulatory flexibility for the Product Lifecycle Management and to support the stability of the product.

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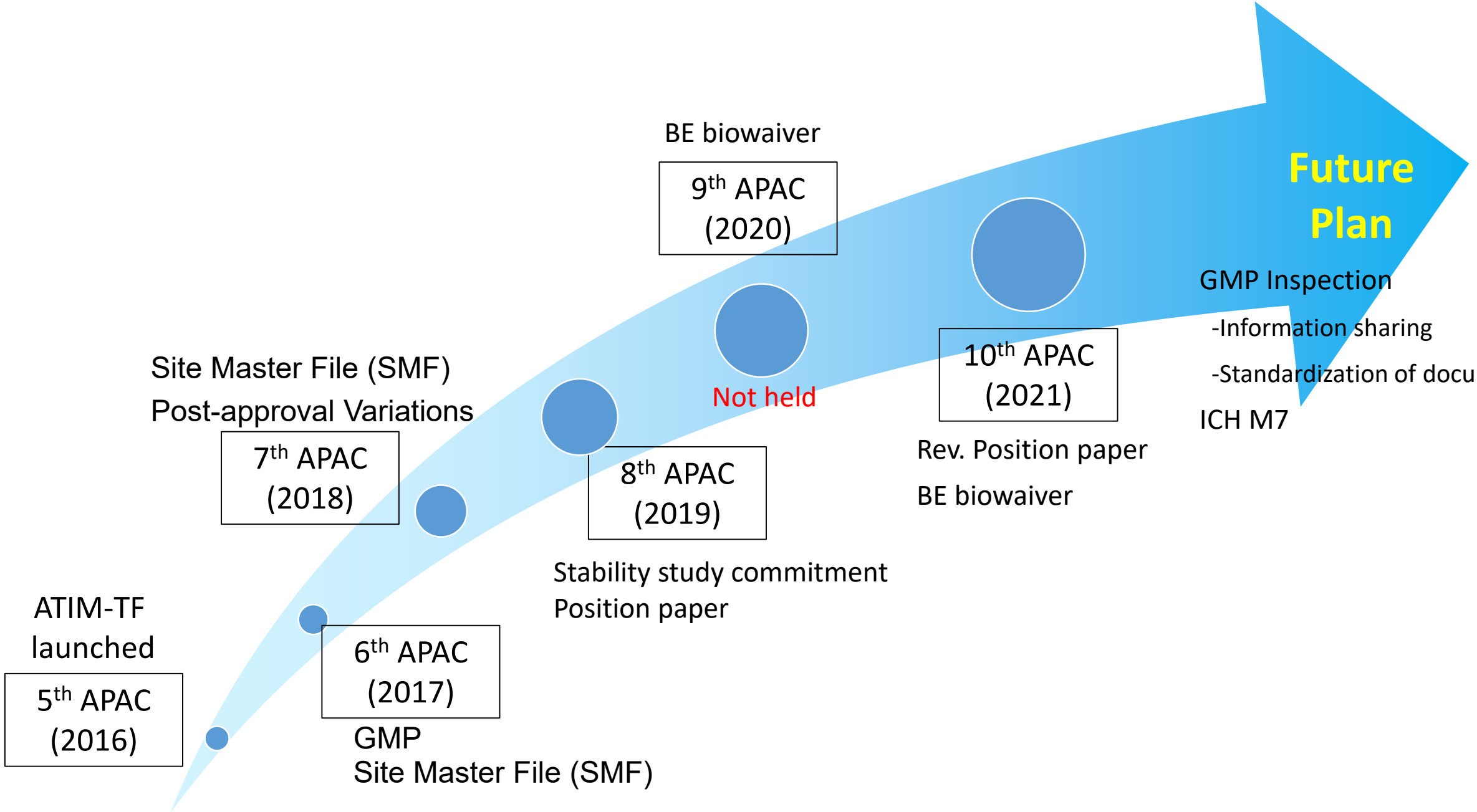

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