Thailand

Panel Discussion [Thailand]

in APAC 2019

To encourage scientific and risk based approach to stability study for post approval change (PAC) in "Thailand" at the present status,

Question 1: ***Do you accept "stability commitment"* at the PAC review if the scientific and risk based approach can assure the shelf-life and storage conditions (Yes or No) ?***

** "Stability commitment" is to initiate or complete ongoing, long-term stability testing on post-change batches.*

If Yes,	What guideline, justification or methodology of scientific and risk based approach based do you accept it now?
1	ASEAN Variation Guideline
2	ASEAN Guideline on Stability of Drug Product
3	A risk assessment report that justifies stability commitment

If No,	What guideline, justification or methodology based do you not accept it now?
Obs. 1	
Obs. 2	
Obs. 3	
Obs. 4	...

Any other comments regarding the current your requirements for stability commitment (if any)

When submitting post approval variations, the data of commitment batches may be requested depending upon types of variations.

To encourage scientific and risk based approach to stability study for post approval change (PAC) in "Thailand" in the future,

Question 2: ***Will* you *accept "stability commitment"* at the PAC review if the scientific and risk based approach can assure the shelf-life and storage conditions in the future (Yes or No) ?***

If Yes,	What are required/changed if you can accept it in the future?
1	A risk assessment report should explain how the presented data demonstrate that the risk was addressed or showing how the risk was evaluated, i.e., how it justifies stability commitment.
2.	A comparative stability study of the results of studies on changed and unchanged API/FPP (pre- and post-approval).

If No,	What obstructions will you not accept it in the future?
Obs. 1	
Obs. 2	
Obs. 3	

Any other comments regarding the future requirements for stability commitment (if any)

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APAC

To encourage scientific and risk based approach to stability study for post approval change (PAC) in "Thailand",

Question 3: ***Do you have any concerns or discussion points to accept a "stability commitment" with scientific and risk based approach?***

Please note that, ***depending upon types of post-approval variations***, stability commitment generally may be sufficient for assuring stability or storage conditions or shelf life of the post-approval batches.

In certain cases, especially for major post-approval changes, the data of commitment batches (full or partial) may be requested (if any problems appear with the stability studies).

In general, science- or risk-based approaches may be used to justify stability commitment at the PAC. However, under certain circumstances where risk-based justification may not provide sufficient assurance, some stability data of post-approval change batches may be requested at the submission of post-approval change, along with a commitment letter to complete a long-term stability test.

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