Summary of questionnaire about BE studies

Change item	Country A	Country B	Country C	Country D	Country E	Country F
Q1 *Dosage form*	Yes/in vivo ·need clinical study(MA) to change dosage form ·Not appricable to biowaiver	Yes/in vivo ·need BE study to change dosage form ·Class I, not narrow therapeutic drug, and dissolution rate is >85% within 15min	Yes/other ·need clinical study to change from fine granule to tablet, narrow therapy index, modified-release ·No change to the percentage and rapid of API in to system circulation	Yes/in vivo or vitro ·need BE study to change modified-release ·refer to SUPAC/ASEAN varidation guideline ·BCS Class I		Yes/in vivo or vitro ·need BE study(MA) to depend on BCS Class of API ·need BE study to modified-release ·BCS Class I & III
Q2 *Strength*	Yes/in vivo or vitro ·basically, need BE study to change strength ·change composition is low	Yes/in vitro ·basically, need in vitro study to change strength ·narrow therapeutic index or class IV need to BE study ·lower strength	Yes/other ·need clinical study to higher strength, narrow therapy index, controlled release ·in vitro study: lower strength, same site and same formulation ratio ·N/A	Yes/in vivo or vitro ·depend on dose proportionate ·BCS Class I		Yes/in vivo or vitro ·need BE study(MA)to depend on BCS Class of API ·need to BE study to the highest strength ·need BE study to modified-release ·BCS Class I & III
Q3 *Formulation change*	Yes/in vivo ·need clinical study to formulation change ·Not appricable to biowaiver	Yes/in vivo ·need BE study to major formulation change ·in vitro study need to minor formulation change	Yes/other ·in vitro study: change excipient component, narrow therapy index, ClassIV, coating weight ·No criteria of justification on BE waiver	Yes/in vivo or vitro? ·refer to SUPAC/ASEAN varidation guideline ·BCS Class I	Yes/in vivo or vitro ·need BE study(MA) to major change	Yes/in vivo or vitro ·need BE study(MA) to new excipient change ·need to in vitro study to same function excipient change(SUPAC GL) ·need BE study to modified-release ·BCS Class I & III
Q4 *API change*	Yes/in vitro ·need in vitro study .	Yes/in vivo or vitro ·need BE study to narrow therapeutic drug ·Normally, need in vitro study	Yes/other ·need BE study to mfg. site change ·in vitro study: process change ·No criteria of justification on BE waiver	Yes/in vivo or vitro? ·refer to SUPAC/ASEAN varidation guideline	Yes/in vitro ·need in vitro study to mfg. site/process of API	Yes/in vivo or vitro ·refer to ASEAN varidation guideline ·need BE study(MA) to API form change depend on BCS Class ·form change of BCS Class I & III API
Q5 *Excipient change*	Yes/in vivo or vitro ·need BE study or in vitro study according to change level .	Yes/in vivo or vitro ·need BE study or in vitro study according to change level .	Yes/other ·in vitro study: change excipient component, narrow therapy index, ClassIV, coating weight ·No criteria of justification on BE waiver	Yes/in vivo or vitro? ·refer to SUPAC/ASEAN varidation guideline		Yes/in vivo or vitro ·refer to SUPAC/ASEAN varidation guideline ·BCS Class I & III
Q6 *Mfg. site*	Yes/in vitro or No ·need in vitro study or batch analysis according to change level .	Yes/in vivo or vitro ·need BE study or in vitro study according to change level .	Yes/other ·need BE study ·No criteria of justification on BE waiver	Yes/in vitro ·refer to SUPAC/ASEAN varidation guideline	Yes/in vitro ·need in vitro study	Yes/in vivo or vitro ·need in vitro study to same formulation and mfg. equipment/process ·BCS Class I & III
Q7 *Batch size*	Yes/in vitro or No ·in vitro study: more than 10 times ·batch analysis: less than 10 times .	Yes/in vitro or No ·in vitro study: more than 10 times ·batch analysis: less than 10 times .	Yes/in vitro ·in vitro study: more than 10 times ·batch analysis: less than 10 times ·No criteria of justification on BE waiver	Yes/in vitro ·refer to SUPAC/ASEAN varidation guideline	Yes/in vitro ·need in vitro study	Yes/in vitro ·need in vitro study
Q8 *Mfg. equipment*	Yes/in vitro or No ·in vitro study: influence on product quality ·batch analysis: no influence on quality .	Yes/in vitro or No ·in vitro study: influence on product quality ·batch analysis: no influence on quality .	No	Yes/in vitro ·refer to SUPAC/ASEAN varidation guideline	Yes/in vitro ·need in vitro study	Yes/in vitro or No ·need in vitro study to mfg. principle change or major process change ·Normally no need
Q9 *Mfg. process*	Yes/in vivo or vitro or No ·need BE study or in vitro study or batch analysis according to change level .	Yes/in vivo or vitro ·need BE study or in vitro study according to change level .	Yes/other ·in vitro study ·No criteria of justification on BE waiver	Yes/in vitro? ·refer to SUPAC/ASEAN varidation guideline	Yes/in vivo or vitro ·need BE study(MA) to major change	Yes/in vivo or vitro ·refer to SUPAC/ASEAN varidation guideline ·BCS Class I & III