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#1 Introduction of fast-track development / review process for drugs for serious diseases with high frequency or those specifically seen in Asia											
Summary of current condition	There is a Special review process for IND review of Innovative Drugs. There is a fast track review and approval for NDA of drugs for AIDs, tuberculosis.	There is no formal priority review system.	There is no formal priority review system.	There is no priority system. The review following the timeline of registration (100 or 150 or 300 working days).The orphan drug will evaluate within 100 working days.	The priority review system exists for drugs treating serious and life-threatening disease. The orphan drug system exists. - Less than 50,000 in Japan - Subsidy payment , Priority consultation, Preferential tax treatment, Priority review, Extension of re-examination period	The priority review system exists for Anti-AIDS agent, anti-cancer agent, new drug, agent for disease for which treatment is not possible with existing therapies(due to development of resistance, etc), certain products which are designated by Minister of MFDS, etc (ref: MFDS notification 2013-238, article 58)	Fast-track review may be considered for critical/life-threatening diseases like cancer, HIV etc. where there is no alternative available. Regulatory Authority has set fast-track criteria and once an application is accepted for fast-track, they will target to review and make an approval decision in 6 months.	The priority review system exists for serious diseases and life-threatening conditions.	No established system for fast-track or priority review is in place. On a case-by-case basis, the request can be made to the authority for consideration.	The priority review system exists for NCEs treating serious disease with unmet medical needs. TFDA estimated 1/3 reduction of reviewing time. Pre-NDA evaluation is required. The accelerated review system exists for NCEs treating serious disease with unmet medical needs or orphan drugs. Also, if the disease indicated by the candidate drug is urgently needed for treatment but it is difficult to import or manufacturer such drug, it fulfills accelerated approval procedure. Pre-NDA evaluation is required.	The priority review system exists for drugs required for national public health problem solving such as anti-cancer, anti-HIV drug and the drug which mainly research and develop in Thailand.
Additional information and/or analysis	The following products are subject of Special Review Process 1. Drugs derived from plants, animals and minerals which are not yet launched in China 2. Novel chemical and biological products which are not licensed worldwide 3. New drugs which have obvious clinical advantages, e.g. drugs for treatment of AIDS, tumour and orphan diseases 4. New drugs for diseases which hava no effective treatment currently In 2011, CDE issued "Announcement on Access to Special Approval Procedure for Registration of Anti-Tuberculosis Drug Resistance" to apply Special Review Process to drugs for drug-resistant tuberculosis.		On case by case basis, CDSCO will issue an import license for small quantities of a new drug without Registration Certificate based on the legal basis for compassionate use.	BPOM (NADFC) may grant authorization for the use and import of unauthorized medicinal products through Special Access Scheme (SAS), a type of compassionate use program.	The proority review is applied to the following categories of drugs. 1. Orphan drug 2. AIDS drugs approved in overseas 3. Drugs to which "Extraordinary Approval" is given 4. Drugs or additional indications already approved in overseas and their efficacy and safety are well recognized in public 5. Other drug having clinical usefulness for serious diseases as defined in the PFSB/ELD Notification No.0901/1 dated September 1, 2011		The applicant need to submit a request letter to NPCB (BPFK) supported with appropriate justifications for fast-track review. Applications for a Special Import Permit may be considered for compassionate use of an unregistered product, usually on a named patient basis. The Ministry of Health is also finalising a special procedure for orphan drugs.	"special lane" review process is a separate and speeded up process for the evaluation and final regulatory action on application for drug registration. The "special lane" is applied to the products under seven categories and meet criteria as described in the Memorandum Circular No. 5 s 1990. The review time for "special lane" product is not more than 90 working days.	For NDAs submitted via the abridged evaluation route, the applicant may request for priority review for a life-saving drug if there are unmet medical needs. The following states the criteria that will be considered for priority review: a) The drug is intended for treatment of a serious life-threatening condition and demonstrates the potential to address local unmet medical needs, as defined by: - the absence of a treatment option; or, - the lack of safe and effective alternative treatment and the drug would be a significant improvement compared to available marketed products, as demonstrated by i. evidence of increased effectiveness in treatment, prevention, or diagnosis;or ii. elimination or substantial reduction of a treatment-limiting drug reaction. b) Disease conditions that are of local public health concerns will be given primary consideration for priority review. Currently these include: - cancer; and, - infectious diseases: dengue, tuberculosis, hepatitis and malaria.	Refer to DOH Announcement No. 0991416281: Announcement on Two Guidelines "A Streamlined Inspection and Registration Review Process for New Drugs" "A Priority Review Mechanism for Inspection and Registration of New Drugs" Expected review timeline in accelerated or priority review is 100 WD without sub-committee review and 130 WD with sub-committee review.	Priority review or accelerated approval will be applied to the following drugs categories: - Drugs to prevent or treat the diseases that are the current health problems in Thailand or major problem to Thai population or serious diseases that is Life-threatening e.g. AIDS's treatment, Anti-Cancer drug including the life saving drugs and other drugs which meet the criteria of the Thai FDA etc. - Drugs developed or studied in Thailand and accepted by Thai FDA that it should be priority reviewed.
Issues and problems	Expansion of Special Review process to established priority review system is desired especially for drugs to treat serious diseases specifically seen in China	Need to introduce proprity review system for drugs which have strong public needs	Need to introduce proprity review system for drugs which have strong public needs	Need to introduce proprity review system for drugs which have strong public needs		Sometimes due to the additional data request from MFDS, it takes time to get approval as soon as expected.	There is no clear written guideline for fast-track review process		No clear written guidance exists. The review timeline for abdridged is 180 WD. However there is no clear definition review timeline for priority review will be shorter than 180 WD.		Though the priority review system exists, in real practice, it does not meet the timeline. No difference in registration requirements and process from other product groups'.
#2 Acceptance criteria of clinical trial data											
Summary of current condition	Global / MRCT clinical data for chemical drugs are acceptable, but Chinese P3 and PK data is indispensable. For biologicals, global / MRCT clinical data is unacceptable at this moment. <Requirement> 1. Chemical Drug: the minimum number of Chinese subjects should not less than 100 per arm. 2. Therapeutic Biological products: Chinese Subjects should be not less than 300 per arm 3. PK data for Chinese population is needed.	The overseas clinical trial data is acceptable. Bridging data are not required.	Clinical data in Indian population is required except few life saving therapeutic categories which is at the discretion of the regulatory agency.	Overseas clinical trial data is acceptable, as long as it is aligned with ICH and/or WHO guideline. Local regulatory trials is required for new pyschotropics and drug for family planning program /	Foreign clinical trial data have been accepted with bridging strategy and global clinical trial in Japan. But PMDA requires Japanese patient clinical data and PK data except anti-HIV drug.	For new drug application, bridging data is mandatory.	Overseas clinical trial data is acceptable, as long as it is aligned with ICH and/or WHO guidance, and accepted by the major reference countries. Local regulatory trials is not required.	Overseas clinical trial data is accepted.	Clinical data conducted overseas is acceptable for NDA submission. Generally, clinical data in a specific population is not requested but may be needed on a case-by-case basis.	IND studies conducted in other countries are well accepted in Taiwan NDA dossier. With appropriate ethnical justification (Bridging Study Evaluation), no local trial is mandatory in case the company provides two CPPs from 10A reference countries. If only one CPP is provided, company needs to involve Taiwan in at least one of the global IND study (Phase I or II or III). In case no CPP is provided, company needs to involve Taiwan in at least two IND studies (Phase I + III or Phase II + III). Each phase has lower limit of Taiwanese patient number recruited in the study statistical scheme.	It depends on the expert, mostly they accept foreign data.
Additional information and/or analysis											There is observation, however, that if clinical trial data also conducted in Thailand, the expert may accept that data more easily.
Issues and problems						The number of Korean subject is the key topic/issue.					
#3 Establishment of DMF (Drug Master File) system											
Summary of current condition	China has not established DMF system for Drug Substance and Packaging material and they still need to be registered. In 2012. China published Provisions on Strengthening Supervision & Administration of Pharmaceutical Excipients. However, there is no guideline on how to implement this provision.		DMF is optional, one could submit document as per CTD (Note: it does not mean DMF system as in other countries.)	DMF is mandatory on API since Jan 2014 of NCE or provide CMC documents of API	The amended Pharmaceutical Affairs Law, which went into effect on April 1, 2005, has introduced the new drug master file system under which manufactures of drug substances and other products can register manufacturing information on their products in order to protect their intellectual properties from marketers and other parties, simplify data attached to applications for marketing approval.	DMF is mandatory on APIs since 2002. And the scope of DMF is i) API of New drug ii) Certain APIs(208 APIs which are designated by Minister of MFDS iii) human placenta originated API. Applicable to drug substances only.	The DMF is currently a requirement under registration of Active Pharmaceutical Ingredients. Phase 1 started for NCE registrations in Jan 2012. This may be replaced by a CEP or full details of Part II S ACTD. Regulatory control of active pharmaceutical ingredient (API) is applicable to all pharmaceutical products either locally manufactured or imported, excluding biologics, health supplements and natural products.	The DMF is a requirement in the submission for product registration, especially for the new drugs, of which is based on the ASEAN Common Technical Requirements. In some instances, the Philippine FDA also recognizes and accepts the DMF based on the ICH dossier. Yes, it is mandatory.	DMF is part of the product registration requirements but a CEP issued by EDQM can also be accepted in lieu of a DMF. DMF is only applicable to drug substance (DS)	Taiwan health authority designed 4-stage implementation plan of DMF to be required for all existed and new APIs. First stage started in May 2013, including 10 widely used APIs and all NCEs. According to the plan, final (4th) stage shall be accomplished in 2018 to cover ALL APIs used in Taiwan market. Packaging materials and excipients are not included in this project.	Currently only DMF of finished product is required and for the new site, which has never been registered in Thailand. (Site master file is required for new site accreditation. For DMF, it is requested by the expert case by case.)
Additional information and/or analysis							Phase 2 will also be implemented for Generics (Scheduled Poison) as given below: New Generics: Parenterals by 1 July 2014, Oral dosage forms by 1 July 2016, All other dosage formsby: 1 July 2018 Existing Products: At registration renewals for Parenterals by 1 July 2015, Oral dosage forms by 1 July 2017, All other dosage forms by 1 July 2019. (Submission of required documents to be done 1 year before product licence expiry.)				

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Issues and problems	1) The responsibility between the suppliers of drug substance, Packaging material and excipient and Drug Products manufacturer is not clarified under the current system. 2) If the supplier doesn't want to release confidential data to the DP manufacture, this will provide challenge to the review of DP application. 3) High cost and time-consuming to register DS, packaging material and new excipient. 4) Furthermore, unreasonable registration requirement is (similar as a NDA) also great hurdle for industry development in these areas.					・Data request based on the global standard (3 batch data on residual solvent, etc) ・Review period(shorten the review period from 120 days to ??) ・Linkage between DMF and change of product approval (label change): duplicated data ・And basically MFDS is planning to expand the scope of DMF to all APIs	There may be difficulties in the implementation of the Generic phase, eg for API suppliers/ manufacturers in the Generic phase to provide the required data/documents. The industry is working on issues to be raised to the HA.		Issues with the closed part of the DMF are sent directly by the DS manufacturer to HA. The applicant is sometimes not aware of correspondences between the health authority and the manufacturer.	1) Strict reviewing requirement, detail technical documents was requested and lengthy reviewing time. 2) Low approval rate (36% according to the latest statistical number) 3) Delay of other application / reviewing timeline due to hugely increase of both industry / health authority manpower. 4) Unclear management policy of DMF and Drug license that each DMF applied to.	
#4 Acceptance of USP, EP and JP as harmonized pharmacopeia											
Summary of current condition	CHP (Chinese Pharmacopoeia) is the standard pharnacopoeia.	BP, USP, EP and JP are accepted. In-house specification for NCE would be accepted by DOH.	If a DP/DS is official in the Indian Pharmacopoeia(IP) than must conform to IP if not official in IP than BP/USP/EU Pharmacopoeia standards are to be followed	Standard Pharmacopoeia : Indonesian Pharmacopeia Other accepted Pharmacopoeia : USP/NF, BP, EP, JP.	JP (Japanese Pharmacopeia) is the standard pharmacopoeia. USP and EP are acceptable.	Standard : KP Accepted : JP, Ph. Eur(EP), USP(NF), BP, Deutshces Arzneibuch, Pharmaacipee Francaise	The main pharmacopieal references are BP and USP. Others are JP and EP.	JP, USP/NF, EP, BP, PP (Philippine Pharmacopoeia) are accepted	BP, EP, USP, JP are well recognized and accepted.	Accepted pharmacopoeia are JP, EP, USP/NF. USP, EP and JP are fully adopted in Taiwan as standard reference. APIs / DPs already listed in these pharmacopeias and mandatory to follow these specifications and test methods.	USP, BP, IP, Thai-pharmacopoeia, EP are accepted.
Additional information and/or analysis											
Issues and problems	1) Although ChP is evaluating the harmonized pharmacopoeial tests published in ICH Q4B, the process appears to be slow when adopting those tests. 2) Monographs adopted by ChP 2010 were mainly based on generic drug products manufactured in China and in most cases without full consideration of drug development, safety and efficacy demonstrated by innovators' products.		If a drug is included in Indian Pharmacopoeia, companies have to meet IP. So harmonization with USP/EP would be of immense value.		When using the non-harmonized test methods etc. , PMDA requests the detail of description in Japanese.			The challenge is faced where drug substances are sourced from some Asian Jurisdictions that do not follow this format.			JP has been under Thai FDA consideration for a while, but so far no progress. Hard copy of pharmacopoeial monograph is required for submission. Referring "current pharmacopeia" is unaccepted. Year of the pharmacopoeia must be specified in registration documents.
#5 Clarification of package insert(PI) and label requirements											
Summary of current condition	The required contents are described in SFDA order 24. The contents Should be written in Chinese.	English or English and Chinese, requirements decribed in Guidelines on the Labelling of Pharmaceutical Products	The required contents are described in rule 96 & Schedule D2 of the Drug and Cosmetic Rules 1945. PI and packaging labels should be written in English.	New guideline 2011 for labeling prescription drug : request to provide Package insert (English or Indonesia), Patient Information Leaflet (Indonesian), outerbox should following packaging requirement (name of the product, active substance, volume, indication, contraindication, dosage and administration, storage condition, manufacturing name & address , imported by,) also retail price, Registration number, Harus dengan resep dokter, Logo of prescription drug. In the label, after product name should follow active substance names, Label also following regulation on registration. Guideline for OTC : inner box and all product information should be in Indonesian language.	The required contents are described in Article 50 of the Pharmaceutical Affairs Act. The contents Should be written in Japanese.	Language : Korean Requirement : Follow Article 56 of the Pharmaceutical Affairs Act and in Article 69~71 of the Enforcement regulation of Safety on Pharmaceutical Products, etc.	The labeling content is stated in Drug Regulatory Guidance Document. The labeling for pharmaceutical products are in English or Bahasa Malaysia.	The required contents are described in Generic Labeling Law. The contents Should be written in English. (see A.O. 55, series 1988)	Language: English. Refer to: GUIDANCE ON MEDICINAL PRODUCT REGISTRATION IN SINGAPORE APPENDIX 6 POINTS TO CONSIDER FOR SINGAPORE LABELLING	The required contents are described in Article 20 of "drug review and registration guideline". The contents should be written in English and Chinese.	Follow ASEAN labeling requirements Thai language required for - category of drug - expiration date - special warning
Additional information and/or analysis							Consumer Medication Information Leaflet or Patient Information Leaflet (PIL) is compulsory for products which are self-administered by patients, including: a) Scheduled poisons b) Over-the-Counter, OTC products c) Herbal products; and health supplements with high claims (disease risk reduction).				
Issues and problems	PI: 1. There is only physician PI, no Patient PI. 2. The trade name can not be used to the PI and Label of generic products. 3. The PI for same products (original and generic) from different manufacturer are different. Packaging label:1. The trade name can not be used to generic products. 2. The registration License number has to be put on the label. 3. There are size and position requirement for trade name (if have) and general name.				The content of the description to PI and the label is clarified, and there is little problem. PI doesn't often reach doctors because the prescription out of hospital has increased, and it will be necessary to consider the method of the communication of drug information.	During the process of the PI change, MFDS accepts short grace period(0 or 1 month) therefore it is hard to manage the label change, importing and supply of the product	There are often country-specific statements to be included in the PI which adds to additional work and cost for artwork and packaging management, etc. The PIL is required in English and Bahasa Malaysia and in a standard format defined by the HA. The PIL requirement was extended to a large range of products in 2013 however the HA allowed a dead-line extension later. As the requirement is presently for the PIL to be posted online at the HA's website, the industry do not have issues with inclusion of the PIL as additional material in the actual pack.	There is no exclusivity in terms of PI text and this is not fair since the we believe that each company must have their PI based on their own study data. The Generic Labeling Requirements are still currently used but the FDA is working on the updating of this guideline.		Mixed version from US, EU approved packaging insert, not easy for future maintain and update	
#6 Clarification of Risk Management Plan (RMP) requirements and implementation process											
Summary of current condition	CDE is researching the guideline for RMP but not yet officially implemented. RMP is required for IND submission for Innovative Drugs. For the product which is accepted for special review procedure, Risk Management and Implementation Plan should be submitted at NDA.	RMP is one of the mandatory requirements for NCE registration	RMP is not mandatory requirement in India	RMP is not required yet. RMP regulation will establish later on.	The RMP Guidance was released by MHLW on April 11, 2012. It is mandatory to all NCEs and New biological products.	RMP(or REMS) is not mandatory in Korea, however some products(e.g., a few of new drug, orphan drug) have been requested to submit the REMS to MFDS. And MFDS has a plan to set up a regulation on REMS upcoming future	RMP is included in the registration guidelines for Biologicals. It has first been implemented for Biosimilars, and requests for new Biological molecules has also been noted.	The establishment and submission of a RMP for each product (for registration and registered) is now mandatory. This is required by the PHL FDA.	RMP is only required for selected products. This will be communicated to the applicant during evaluation of product registration and added as a product licensing condition. From experience, RMP from reference agencies like US REMS and EU RMP are required at filing for NDA and line extension filing as per local regulatory guideline.	TFDA made official announcement of RMP Guidance in April 2012. It is mandatory to all NCEs or New biological products submitted NDA without any reference country CPPs (non-CPP submission), and domestic R&D NCEs. TFDA may request RMP to other NCEs or biologics as well during NDA reviewing process depends on risk level of the drug's safety profile.	RMP is voluntary for NCE, but mandatory for one biotech drug (Erythropoietin). Required for some specific group. Ex. Thalidomide. It is requested by the experts case by case.
Additional information and/or analysis									RMP/REMS may be requested but its assessment guideline is not clear.(past case)		

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Issues and problems					We should watch the reeview process of RMP by PMDA.			The PHL FDA does not have a template for the RMP so companies which do not have established RMPs may have difficulty in complying with the requirement. Even for innovator companies, the Global RMPs may sometimes be more comprehensive than the listed details in the PV guideline so it would be appreciated that PHL FDA issues a guiding template for local use.		1) Needs time to improve implementation details. 2) Requirement of RMP during NDA reviewing process may cause delayed approval time.	
#7 Acceptance of NDA dossier in internationally harmonized format and language											
Summary of current condition	ICH-CTD format is only accepted for limited types of NDA application of Chemical drugs. For biologics, ICH-CTD format is not accepted. All the NDA dossier should be in Chinese. If the original information is in English, full Chinese translation and original English version both are needed.	CTD can be accepted. All NDA dossiers can be in English.	ICH CTD is accepted in India NDA dossier is accepted only in English.	ACTD format is required. Dossier in English is acceptable.	We have the J-CTD format which harmonized with ICH-CTD. Japanese translation is necessary on module 1 and 2 . English is acceptable on module 3-5.	ICH-CTD is acceptable in Korea(mandatory on new drug, optional for other products) and MFDS has a plan to receive the CTD data on generics as well. Korean translation is necessary on module 1 and 2. Ebglish is acceptable on module 3-5.	All applications are made in ASEAN CTD format. Online submission is with the ACTD format in the electronic submission system. Our regulatory authority accepts the NDA submission in English or Bahasa Malaysia. Any text in foreign language must be translated to English. Queries may be received from the authority in our local language but the response may still be provided in English.	Application data for new drugs have to be handled by the ASEAN CTD format. Besides, ICH-CTD can be accepted. NDA dossier must be in English.	Both ICH-CTD and ACTD are accepted. All dossier documents should be in English. Any text in foreign languages should be translated to English.	CTD format has been announced by TFDA in July 2012 and mandatory applied to NCE application since Nov. 2012. Non-NCE and generic drug applications should follow CTD format, starting from July 2014. All NDA dossiers can be in English.	ICH-CTD is accepted only for NCE and Biotech products. We do need to submit ACTD-mapping document. Dossier in English is acceptable . The labeling and package insert will need to be translated into Thai.
Additional information and/or analysis											
Issues and problems						MFDS is reviewing the possibility to accept the e-CTD/CDISK.					
#8 Introduction or reinforcement of electronic submission system for NDA											
Summary of current condition	Chinese CFDA/CDE planned to introduce electronic submission system for NDA.		No electronic submission system for NDA		There is the electronic submission system for NDA. At present, the paper submission is also acceptable.	There is a electronic submission system for NDA (http://ezdrug.mfds.go.kr/index.jsp) and also MFDS is planning to adopt the e-CTD based on the pilot study in 2014	Electronic submission has been implemented.	Electronic submission is partly implemented now and the direction of FDA is to have a full implementation with regards to LTO and Product registration.	An electronic submission system is in place for NDA. All new NDA has to be done via the electronic submission system.	TFDA have electronic submission system for NDA as an option.	
Additional information and/or analysis	Paper submission is mandatory, but electronic application form should be downloaded from CFDA web site. Application form and electronic summary documents should be submitted electronicaly. Pilot program of electronic submission intiated from June 2013. It requires application submission of in pdf (but not eCTD). The program first started with CDE's intra-net submission through the specific PC in CDE. On-line application is planned in near future.	Paper submission is required. In case of many technical documents, soft copy is suggested to be submitted by reviewers.	CDSCO is not yet ready to accept full electronic submission, but voluntarily accepts it only for Biologics. Two sets of soft copies in pdf in CD-ROM are required along with papaer submission at CTA/NDA.	The standard form off application submisssion is still paper copy. Applicants need to submit full paper dossier together with electronic submission of general information through BPOM/NADFC on-line system. One person for each company should be assigned ID number. eCTD is not yet accepted.	Both eCTD and hard copies are accepted as official NDA dossier. Submission in eCTD is encouraged. In 2012, 93 out of 101 submissions were made in eCTD.	Registration dossier should be submitted electronically containing application, supporting documents. Original document is also required in case of certificates such as CPP. eCTD will be required in near future.	Product registration application are to be done via the on-line QUEST system. (QUEST is an acronym for Quality, Efficacy & Safety.) Applicant should obtain an account on the system to access it for applications. The Drug Registration Guidance Document (DRGD) provides notes for on-line application form. Online submission was started in 2002 with the QUEST2 System. An upgraded QUEST3 system was set up later in 2010.	FMC 2013-001 took effect from feb 2013, Guidelines on the Submission of LTO and CPR Application with Electronic Copy. The objective is to minimize the influx and accumulation of records in FDA. In addition to hard copy, electronic dossier (in pdf) is also required.	The application submission should be in electronic format, and HSA accepts applications only through PRISM on-line system. CTD parts (ICH or ACTD) can be attached to PRISM section 7 or submitted in CD/DVD. hard copies are only required for certificates which need proof of authenticity.	Electornic submission is not mandatory but recommended by TFDA.Eiither eCTD or electronic dossier in pdf are accepted. eCTD builder tool and manual are available. For Modile 1, MOHW has issued the Electronic Submission Backbone File (ESBF) specifications, and other Modules can be in ICH eCTD. At present there is no on line submission system, and submission needs to be made with CD-ROM.	Electronic submission is not yet available in Thailand. It is in pilot project.
Issues and problems	At the moment, the sponsor need submit hard copy NDA dossier to CFDA at first, and submit the electronic NDA dossier to CDE thereafter. It is not the real electronic submission. And there is no guideline for e-submission in China up to now.				The eCTD submission should become mandatory, and the paper submission for expert discussion and Drug Committee should be unnecessary.	Improve the system stability and easy usage and check-up the process	Presently both QUEST 2 and 3 are being used for different application types but have posed more technical problems in recent years, and a semi-manual process is being implemented for the time-being. A new and improved system is being developed currently and expected to be ready in 2016.		The system provides fields for the applicant to populate for the administrative part. Attachments are uploaded or sent via CD format for the quality and technical parts of the dossier. Improvements can be made to enhance the stability of the system and make it up to date.	The current e-filing system has not yet mature; it still has potential to improve technically	
#9 Understanding & Implementation of QbD											
Summary of current condition	There is no QbD guideline. In general the QbD principle in ICH Q8 is accepted. There is very limited experience in QbD filing and review in China.		There is no QbD guideline. They accept submission as per ICH Q8.		There is QbD guideline in Japan.	Until now, there is no QbD guideline. However MFDS organized the TFT including industry to review the QbD.	There is no QbD guideline yet. Malaysia as an ASEAN member state is working with the ACCSQ-PPWG on this area. At the 20th ACCSQ-PPWG the proposed Annex C of the ASEAN Process Validation Guidelines, which refers to “Quality by Design as an Alternative Approach to Process Validation”, is still being revised after the TWG discussion. The revised version (v1.5) will be discussed further at subsequent PPWG meetings. It was noted that the region may not be ready yet and it was agreed at the 20th Meeting that there is a need for capacity building in the area of Quality by Design.	The FDA is still working on understanding and recognizing the QbD principle. Some companies are already using this on their dossier.”	Authority accepts QbD principle in ICH Q8 guideline. Singapore as an ASEAN member state is working with the ACCSQ-PPWG on this area. The proposed Annex C of the ASEAN Process Validation Guidelines, which refers to “Quality by Design as an Alternative Approach to Process Validation”, is still being revised by ASEAN.	Authority accepts QbD principle in ICH Q8 guideline.	QbD guideline is in Annex C of ASEAN Process Validation Guideline. The FDA has no plan to adopt it yet.
Additional information and/or analysis											
Issues and problems									As with all ASEAN member states, there is possibility the HA would need time to be experience with QbD implementation.		According to current regulation, any changes made to manufacturing of the product require FDA approval. There may be constraint for QbD implementation in Thailand.