出國報告（出國類別：會議）

出席 2017 年 CIRS「第一屆優化藥政法規單位審查效率年會」及「透過風險評估促進新藥審查效率工作坊」會議 報告

服務機關：衛生福利部食品藥物管理署

姓名職稱：王兆儀組長、張連成副研究員

派赴國家：巴西

出國期間：106.03.04-106.03.11

報告日期：106.04.27

摘要

世界衛生組織了解各國家在品管理環境與體系擁有不同的資源和能力，儘管資源有限，但重複工作的情況依然存在。在成熟的機構中，越來越多的藥品審查是發展優先考慮基於風險的決策方法。在新藥管理的生命週期中實施基於風險的決策，可解決從臨床前到臨床試驗，以及藥品製造過程風險和產品上市後的安全等複雜性議題。考量世界尚許多中低收入國家法並沒有完善的藥政管理體系與審查能量，足以提供有效的醫藥品法規支持，延宕藥品的審查與核准，或使品質低、安全性有疑慮的產品流入市場，產生藥物不良反應，浪費醫療成本，甚至降低具醫療迫切需求之病人使用藥品，損及病人健康與權益。本次研討會以過去 CIRS 全球發展研究成果，以及優良法規與審查作業規範為基礎，著重於對新藥審查流程進行風險優先排序，討論審查和決策中利用基於風險的分層評估方法，以及機構間，跨機構和區域整合的意義。在第一天的 1st Annual OpERA Forum 中，討論優化法規單位效能計畫(OpERA，Optimising Efficiencies in Regulatory Agencies)，該計畫將提供適當工具，協助法規單位依據其編制、任務及時效，追蹤測量法規單位內部審查程序之表現，減少不必要之程序或時間浪費，強化藥品審查與管理效能。各國藥政與審查單位於會上藉由經驗分享、資訊交換，了解各國藥品管理所面臨的議題、分享各國經驗與看法、討論 OpERA 計畫未來發展。第二天開始的 8th Annual CIRS Regulators’ Forum 則是考慮藥品研發全球化趨勢，邀請 WHO 專家共同討論，各國法規單位如何相互合作，避免重複建置審查能量，共同協助開發中國家，以風險評估為基礎，建立決策程序。第三場「Facilitating the review of new medicines through risk-based evaluations: How can a stratification process be utilised to achieve an effective use of resources?」工作坊，則是討論藥品審查與決策之優先序位，如何藉由科學基礎進行風險評估，討論實際運行的決策框架，促使審查程序更有效率，增進病人使用藥品之可近性。

關鍵字: 湯森路透集團藥政科學創新中心（CIRS ，Centre for Innovation in Regulatory Science）優化法規單位效能計畫（OpERA，Optimising Efficiencies in Regulatory Agencies）

Abstract

The World Health Organization identifies that the current regulatory landscape as having different capacities yet duplicating work despite limited resources. As countries develop regulatory capabilities a more risk-based approach in evaluation has been suggested instead of the common prescriptive approach. Mature agencies have seen an increase in development of prioritized, risk-based approaches to decision making. A risk-based approach can be implemented across the life cycle of new medicines addressing both compliance and product risks from preclinical to clinical trials, as well as the manufacturing process and inspection. Many emerging national regulatory agencies (NRAs), especially those in low and middle-income countries (LMICs), do not have the systems, skills and capabilities in place to provide effective and efficient regulatory support. This results in delays in medicine reviews and approvals, an increased likelihood of poor quality medicines entering the market, and delays in patient access to critical medicines especially where there is an unmet medical need. This workshop builds on previous CIRS global research data as well as the work being undertaken by groups in the area of Good Regulatory and Review Practices and focuses on risk-based prioritization of the review process for new medicines. The aim is to discuss the utilization of a risk based stratification evaluation approach in review and decision-making, and what this means within an agency, across agencies and for regional alignments. CIRS invites national representatives or reviewers to discuss OpERA (Optimising Efficiencies in Regulatory Agencies) in the 1st Annual OpERA Forum. The program will provide appropriate tools to assist regulatory units in tracking the performance of the internal review process of regulatory units in accordance with the preparation, task and timeliness, reducing unnecessary procedures or wasting time, and enhancing drug review and management effectiveness. At the meeting, National drug administration and review organizations, by experience sharing, exchange of information, and developing an understanding the problems faced by drug management, will discuss the future development of the OpERA program. The 8th Annual CIRS Regulators' Forum, which starts the next day, will consider the trend of globalization of pharmaceutical research and development. WHO experts discussed national regulatory units cooperation to avoid duplicating work and reviewing assistance to developing countries, risk assessment, and the establishment of decision-making procedures. The third workshop, " Facilitating the review of new medicines through risk-based evaluations: How can a stratification process be utilised to achieve an effective use of resources?" discussed the priority order of drug review and decision making, scientific basis for risk assessment, and the actual operation of the decision-making framework. These topics all aim to promote more efficient review processes and enhance the drug accessibility.

Key words：CIRS (Centre for Innovation in Regulatory Science)、OpERA (Optimising Efficiencies in Regulatory Agencies)

目次

目的

湯森路透集團藥政科學創新中心（Centre for Innovation in Regulatory Science，CIRS）為國際中性獨立組織，成立目的為鼓勵醫藥品創新研究，建立以科學為基礎的全球化法規環境，討論醫療科技評估 (Health Technology Assessment, HTA) 政策，促使更多病人獲得安全有效的治療。

本次研討會以過去 CIRS 全球發展研究成果，以及優良法規與審查作業規範為基礎，著重於對新藥審查流程進行風險優先排序，討論審查和決策中利用基於風險的分層評估方法，以及機構間，跨機構和區域整合的意義。

CIRS 由 Dr Neil McAuslane 及 Mrs Prisha Patel 於 2016 年 11 月 11 日上午 10 時 30 分拜會本署，討論其最新優化法規主管機關審查效率計畫 (OpERA: Optimising Efficiencies in Regulatory Agencies)，以及 2017 年規劃舉辦活動期程，雙方就臺灣藥政改革進展與審查效率進行交流，並邀請王兆儀組長於 2017 年 3 月 8 日巴西聖保羅市舉辦之「Facilitating the review of new medicines through risk-based evaluations: How can a stratification process be utilised to achieve an effective use of resources?」工作坊擔任講座。

過程

一、 行程

<table>
<tr><th></th><th>106.3.4-5</th><th>106.3.6</th><th>106.3.7</th><th>106.3.8</th><th>106.3.9</th><th>106.3.10-11</th></tr>
<tr><td>上午</td><td rowspan="2">啟程</td><td>會議準備</td><td>1st Annual OpERA Forum (Ⅱ)</td><td>Workshop * Session 1</td><td rowspan="2">Workshop* Session 3</td><td rowspan="2">返程</td></tr>
<tr><td>下午</td><td>1st Annual OpERA Forum (Ⅰ)</td><td>8th Annual CIRS Regulators' Forum</td><td>Workshop* Session 2</td></tr>
</table>

OpERA：Optimising Efficiencies in Regulatory Agencies

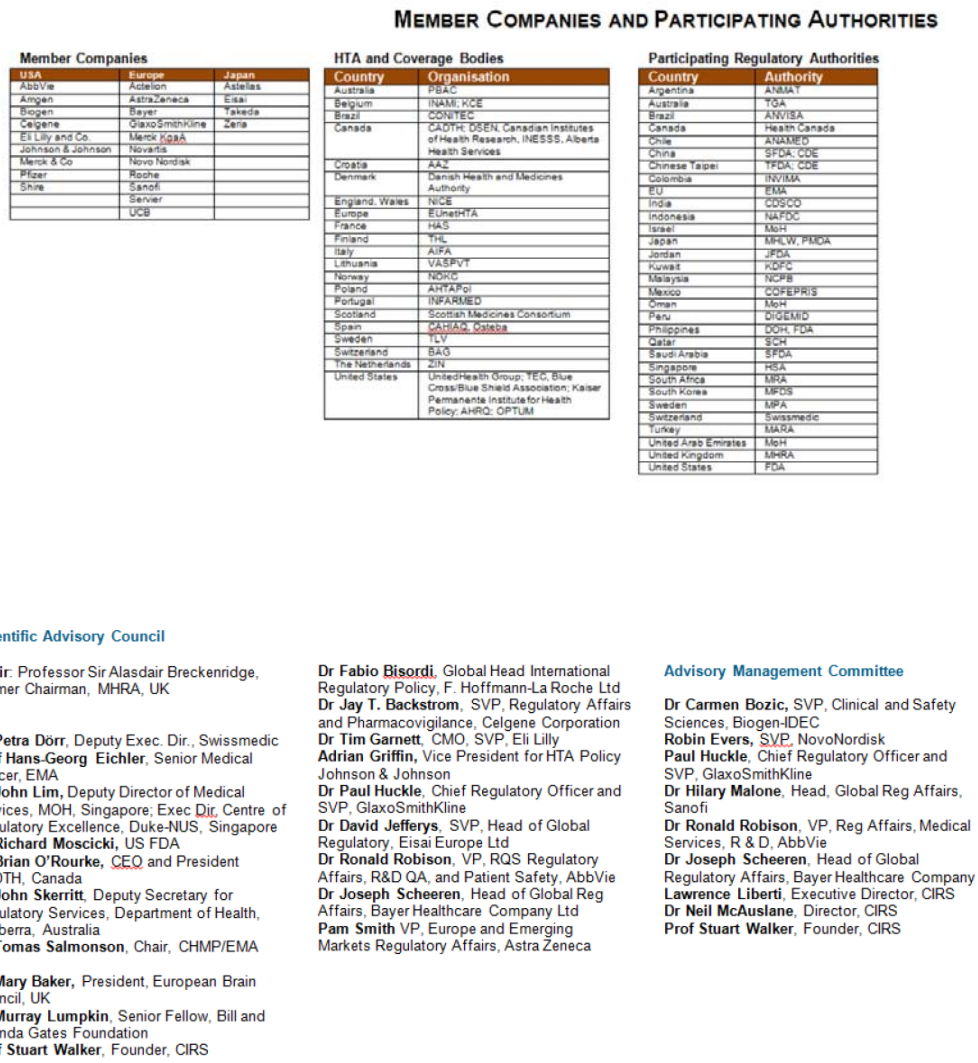
Workshop *：Facilitating the review of new medicines through risk-based evaluations: How can a stratification process be utilised to achieve an effective use of resources?

二、會議情況

(一) 1st Annual OpERA Forum

1. Introduction

湯森路透集團藥政科學創新中心（Centre for Innovation in Regulatory Science，CIRS），主要會員及諮詢委員會組成如下圖。



MEMBER COMPANIES AND PARTICIPATING AUTHORITIES

Member Companies

USA	Europe	Japan
AbbVie	Actelion	Astellas
Amgen	AstraZeneca	Eisai
Biogen	Bayer	Takeda
Celgene	GlaxoSmithKline	Zeria
Eli Lilly and Co.	Merck KgaA	
Johnson & Johnson	Novartis	
Merck & Co	Novo Nordisk	
Pfizer	Roche	
Shire	Sanofi	
	Servier	
	UCB	

HTA and Coverage Bodies

Country	Organisation
Australia	PBAC
Belgium	INAMI; KCE
Brazil	CONITEC
Canada	CADTH; CDEN; Canadian Institutes of Health Research; INESSS; Alberta Health Services
Croatia	AAZ
Denmark	Danish Health and Medicines Authority
England, Wales	NICE
Europe	EUnetHTA
France	HAS
Finland	THL
Italy	AIFA
Lithuania	VASPVT
Norway	NOKC
Poland	AHTAPol
Portugal	INFARMED
Scotland	Scottish Medicines Consortium
Spain	CAHIAG; Osteba
Sweden	TLV
Switzerland	BAG
The Netherlands	ZIN
United States	UnitedHealth Group; TEC; Blue Cross/Blue Shield Association; Kaiser Permanente Institute for Health Policy; AHRQ; OPTUM

Participating Regulatory Authorities

Country	Authority
Argentina	ANMAT
Australia	TGA
Brazil	ANVISA
Canada	Health Canada
Chile	ANAMED
China	SFDA; CDE
Chinese Taipei	TFDA; CDE
Colombia	INVIMA
EU	EMA
India	CDSCO
Indonesia	NAFDC
Israel	MoH
Japan	MHLW; PMDA
Jordan	JFDA
Kuwait	KDFC
Malaysia	NCPB
Mexico	COFEPRIS
Oman	MoH
Peru	DIGEMID
Philippines	DOH; FDA
Qatar	SCH
Saudi Arabia	SFDA
Singapore	HSA
South Africa	MRA
South Korea	MFDS
Sweden	MPA
Switzerland	Swissmedic
Turkey	MARA
United Arab Emirates	MoH
United Kingdom	MHRA
United States	FDA

Scientific Advisory Council

Chair: Professor Sir Alasdair Breckenridge, Former Chairman, MHRA, UK

Dr Petra Dörr, Deputy Exec. Dir., Swissmedic
Prof Hans-Georg Eichler, Senior Medical Officer, EMA
Dr John Lim, Deputy Director of Medical Services, MOH, Singapore; Exec Dir, Centre of Regulatory Excellence, Duke-NUS, Singapore
Dr Richard Moscicki, US FDA
Dr Brian O'Rourke, CEO and President CADTH, Canada
Dr John Skerritt, Deputy Secretary for Regulatory Services, Department of Health, Canberra, Australia
Dr Tomas Salmonson, Chair, CHMP/EMA

Dr Mary Baker, President, European Brain Council, UK
Dr Murray Lumpkin, Senior Fellow, Bill and Melinda Gates Foundation
Prof Stuart Walker, Founder, CIRS

Dr Fabio Bisordi, Global Head International Regulatory Policy, F. Hoffmann-La Roche Ltd
Dr Jay T. Backstrom, SVP, Regulatory Affairs and Pharmacovigilance, Celgene Corporation
Dr Tim Garnett, CMO, SVP, Eli Lilly
Adrian Griffin, Vice President for HTA Policy Johnson & Johnson
Dr Paul Huckle, Chief Regulatory Officer and SVP, GlaxoSmithKline
Dr David Jefferys, SVP, Head of Global Regulatory, Eisai Europe Ltd
Dr Ronald Robison, VP, RQS Regulatory Affairs, R&D QA, and Patient Safety, AbbVie
Dr Joseph Scheeren, Head of Global Reg Affairs, Bayer Healthcare Company Ltd
Pam Smith VP, Europe and Emerging Markets Regulatory Affairs, Astra Zeneca

Advisory Management Committee

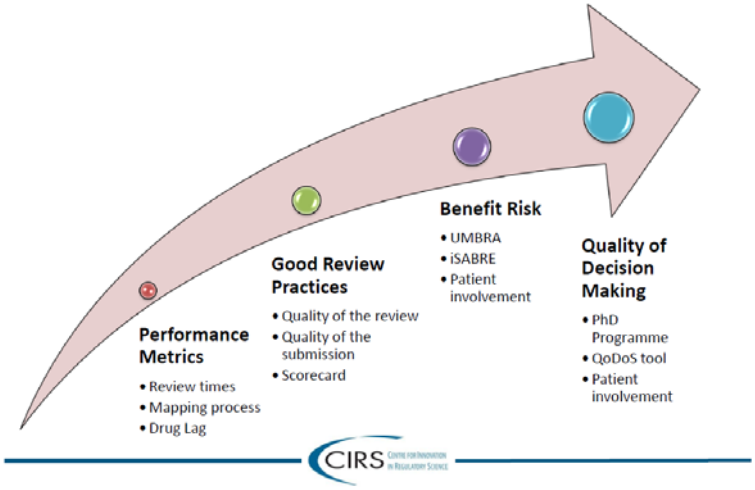
Dr Carmen Bozic, SVP, Clinical and Safety Sciences, Biogen-IDEC
Robin Evers, SVP, NovoNordisk
Paul Huckle, Chief Regulatory Officer and SVP, GlaxoSmithKline
Dr Hilary Malone, Head, Global Reg Affairs, Sanofi
Dr Ronald Robison, VP, Reg Affairs, Medical Services, R & D, AbbVie
Dr Joseph Scheeren, Head of Global Regulatory Affairs, Bayer Healthcare Company
Lawrence Liberti, Executive Director, CIRS
Dr Neil McAuslane, Director, CIRS
Prof Stuart Walker, Founder, CIRS

2. OpERA Programm 緣起

CIRS 長期針對於全球醫藥品的研發與應用進行研究，主軸分為建立全球發展(Global Development)與健康科技評定(Health Technology Assement)兩大重點，並規劃 workshop、seminar 或 research project 等系列活動。其中，全球發展的目的在於調整全球遞件申請程序，並解決已開發和發展中司法管轄區的審查要求所帶來的挑戰，健康科技評定(Health Technology Assement)部分，主要在通報不良反應和影響市場准入，需要確定早期藥物開發中可以建立的因素，與藥政管理要求一致，凸顯新療法的價值。

藉由蒐集、綜合處理及分析數據，在藥品研發過程中提醒公司或機構流程與時效，同步建立基準，再針對特殊主題或程序採行深入調查，將能管理不確定因素並增進可預測性。另外，CIRS 辦理各類研討會、論壇活動，邀請各國藥政主管部門經驗分享、腦力激盪，希望促進藥政管理體系框架建立、增進審查程序透明化，運用科學邏輯強化新藥週期管理之決策品質。

在審查效率的促進議題上，強調主管部門應加強與產業對話，獲取充分且正確的訊息，推動優良送件/審查作業規範，與區域法規協和或審查合作。CIRS 的工作從性能指標到決策的自然演進如下圖所示。



3. Current status of OpERA programme

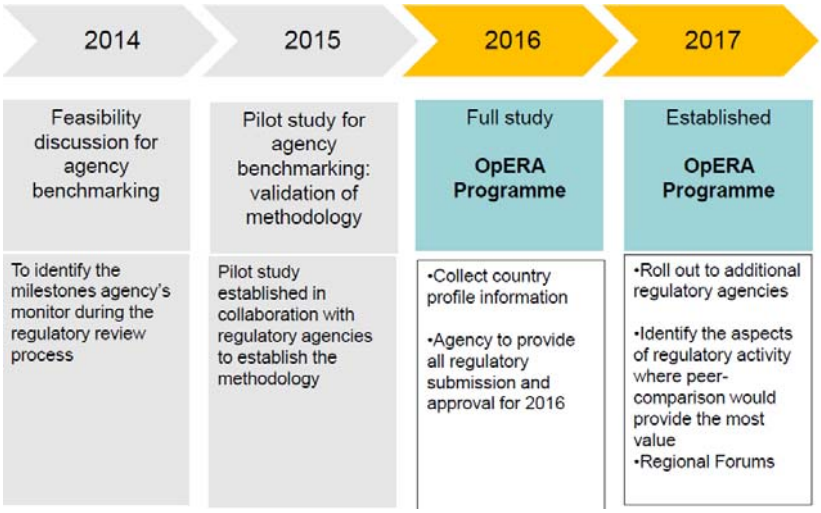
OpERA programme 是 2013 年由 CIRS 發起的持續多年期計畫，包括 ANVISA、SFDA、NADFC 等衛生主管部門均參與此一計畫，計畫目的在支持國家衛生主管部門發展的資訊需求，協調收集和評估參與機構內各項流程特徵的數據，以協助衛生主管部門定義並實現績效目標，優化流程效率。另也提供可幫助整合國家衛生主管部門追蹤評估審核績效的工具，優化工作流程，包括：潛在的審查和核准時間的減少，而不會影響產品的安全、有效與品質。獨立的 CIRS 贊助的計畫部分由 Bill＆Melinda Gates 基金會(BMGF)長期資助。

CIRS 與國家衛生主管部門合作，對藥品上市流程進行持續性、系統性的評估，鼓勵每個機構遵守其標準作業流程，收集到的數據分析後，將回饋幫助調整標準作業流

程，針對績效目標加以改進，為決策者和其他利益相關者提供溝通成果和需求，並與其他國家衛生主管部門相比較，了解各區域對藥品管理的做法和成果，成果將以論文期刊、研討會、工作坊等形式發表，也邀請全球醫藥衛生機構例如：世衛組織/泛美衛生組織，BMGF，區域藥品研發管理卓越中心等機構一同討論，期待提出有助於全球醫藥品發展的策略方法。

CIRS 開發標準化方法可以確定影響管理績效的關鍵特徵，提供國家衛生主管部門特定報告並與全球比較、分享資料，鼓勵各國衛生主管部門採取良好的管理措施。至於什麼樣的時間和資源才能參加該計劃呢? 依據目前已參與計畫之機構的經驗，參與 OpERA 計畫不會增加任何重大的工作量。CIRS 將與每個機構合作，確定其內部時程表，亦可提供實施和支持 OpERA 計畫所需的資源，提供資金與人力資源（例如實習生，學生），參與該計畫無須額外負擔經費，此外，本計畫由 CIRS 和 BMGF 支付培訓班旅費和住宿費用。

OpERA 提供簡單的工具和持續支持，包括：標準化國家概況和良好的審查指標，用於收集時間軸和其他指標數據的表單，安全的線上系統，以持續收集數據和報告，所有資訊均嚴格保密，除非代理機構特別書面同意，不會將任何數據與任何第三方分享。計畫實施期程如下圖所示。



未來將著重於確定數據收集資源需求的支持，特別對 2016 年核准的藥品，例如：新成分新藥、疫苗和生物製劑、治療愛滋病毒，結核病和瘧疾的學名藥等進行數據收

集。初步分析結果將在年度 OpERA 會議討論，同時就國家報告與亞洲區域會議討論主題進行全面了解。

4. Utilising Regulatory Science to Build Trust in Reliance Models

Dr. Lawrence Liberti (CIRS Executive Director)介紹利用管理科學建立信任模型，CIRS 所採取的模式除大規模數據收集分析外，亦邀請各國產官學研專家辦理研討會，討論最新藥品管理趨勢，自 2009 年起，曾經辦理相關活動及主題整理如下圖。

	Year	Location	Topics
1	2009	Geneva	Changes and challenges to the EM regulatory environment: a 5-year projection
2	2011	Tokyo	Barriers and enablers to regulatory efficiencies
3	2011	Kuala Lumpur	Barriers and enables of GRevP
4	2013	Beijing	Quality decision making: an EM perspective
5	2014	Lima	Identifying and building GRevP
6	2015	Taipei	Assessing agencies' review processes, performance metrics and BR assessment
7	2016	Kuala Lumpur	Using metric to measure regulatory processes and practices to facilitate the licensing of new medicines
8	2017	Sao Paulo	Using regulatory science to build trust in reliance models

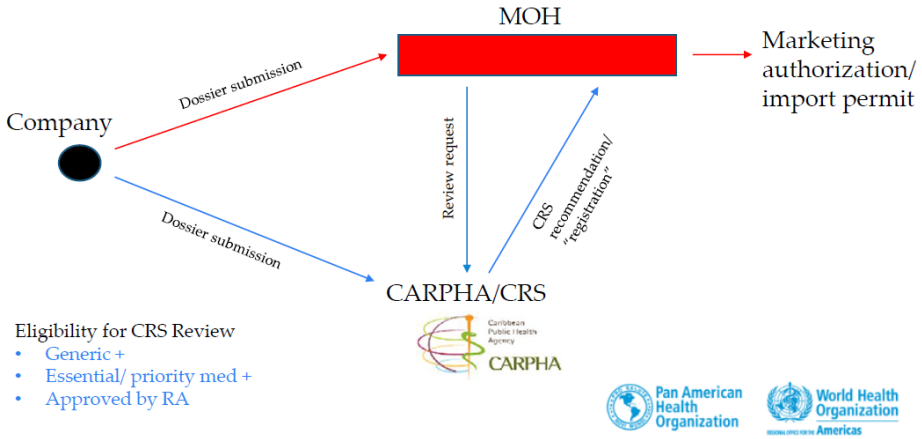
CIRS 工作採每 3 年一個週期，下一個週期（2018-2019-2020）的主題正在研擬中，本次論壇將徵求各位與會者意見並納入參考，目前策略將著重於解決：管理和 HTA / Access 問題的匯合、公司和機構加快全球發展和管理評估的最佳做法、病人於藥物開發的角色、發展中國家與已開發國家的藥品管理環境所面臨的特殊問題。

5. Caribbean Community Regulatory Efforts Regional Approaches to Risk Based Evaluation

Dr .Charlie Preston 為 PAHO/WHO 藥品和其他健康技術加強管理系統之顧問，於會議介紹加勒比共同體藥品管理的風險評估方法，考量加勒比海地區國家審查能量不足，產品上市積案嚴重、上市後風險控管機制逐步建立中、市面上偽劣藥物辨識與稽查專業人力不足，更嚴重的還有東加勒比國家組織（OECS）還未能擁有藥品管理體系，

世界衛生組織與 BMGF，提供專業人員與資金，建立藥品管理制度(Caribbean Regulatory System)、培訓專業人士。初步流程如下圖所示。

辛巴威共和國藥品管理部門，Ms Gugu Mahlangu 也介紹南部非洲發展共同體在藥品管理的合作。



6. KEY OUTCOMES OF OpERA ACTIVITIES

巴西 ANVISA 衛生專家 Ana Carolina Moreira Marino 分享該單位參加 CIRS 的經驗。CIRS 的專案經理 Prisha Patel 與科技務門負責人 Neil McAuslane，報告 OpERA 計畫數據蒐集實務經驗。

(二) Facilitating the review of new medicines through risk-based evaluations workshop

1. Risk-based approaches to the evaluation of new medicines: What does this mean and why should countries consider such an approach?

Mike Ward 目前擔任 WHO 基本藥物、健康產品管理體系協調員，以視訊方式說明國家衛生主管部門正在面臨越來越大的壓力，如何提高績效，促進及時獲得安全，有效和優質的藥物和其他衛生技術是 WHO 關切的重要議題。由於全球化，日益複雜的技術和日益增長的公眾期望，這項任務變得更具挑戰性，這些挑戰在中低收入國家（LMIC）更為嚴重。

世衛組織長期以來，輔導 LMIC 制定規範和標準、促進管理融合和協調、培訓和能力建設、通過協作，依賴和認可來支持資源的最佳利用，迄今為止的經驗有助於表徵這些舉措在加速國內管理決策中的利益，挑戰和潛在的發展。

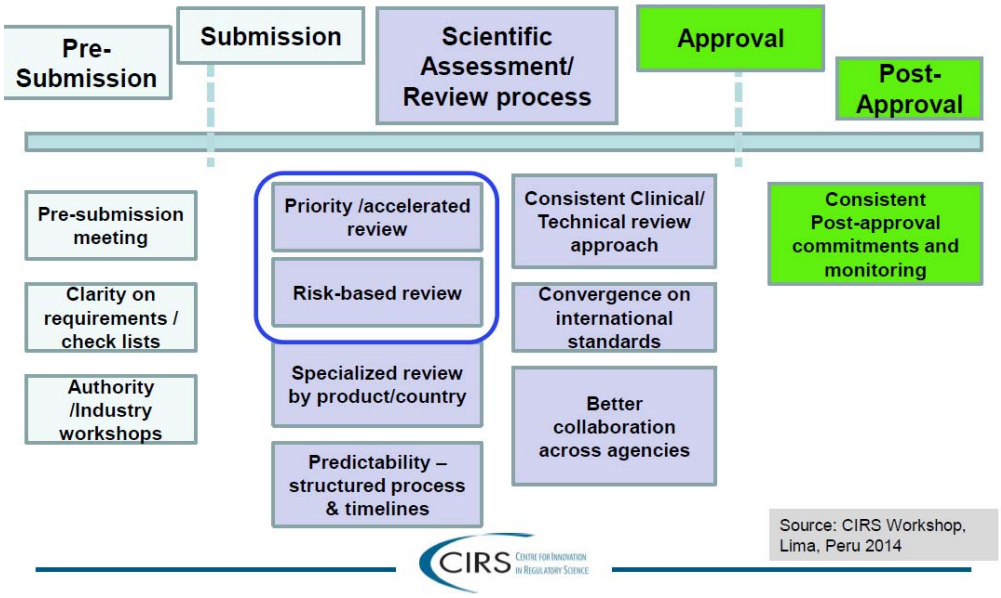
無效率的管理制度將危及消費者的利益，所有藥政管理體系應以科學為依據，尊重

國際標準，採取互利互惠，衡量公共衛生益效益的有效措施。

相互協作需要多方溝通協調，獨立個人和組織基於共同目的相互結合，可以實現單方面難以實現的目標，而合作的關鍵成功因素有：合作的動力應來自內部發起，合作關係應立足於高級管理/機構支持和投資、相互信任和尊重、良好的溝通、明確角色和指定職責、形式化的關係、專業功效，以及充足的資源分配。

2. What are the different risk-based evaluation models/approaches that agencies can consider or adopt? What are their main advantages and possible barriers?

公平獲得藥物是所有病人的權利，對於已經確認安全性和有效性的產品，其他司法管轄區的病人應該期望及時獲得，快速的管理授權不應限於初始評估受益的司法管轄區，需要一個框架，採取靈活的系統，提供及時評估安全有效的藥物，同時保護所有司法管轄區的公共衛生，理想的醫藥管理途徑如下圖所示。



Primary FRP 意指促進產品開發，審查和核准的途徑；通常採取獨立審查，加速核准與評估程序，優先審查突破性治療藥品。

Reliance 意指一個管轄機構的藥品政策可以考慮由另一個管轄機構或其他信託機構代為履行。

Recognition 意指例行接受另一管理機構或其他信託機構的行政裁決，認可符合 A 國藥品管理要求的證據，亦足以滿足 B 國家的要求。

風險分層方法的考慮因素包括：適當的風險評估和風險管理應納入審查的一部分、需要建立決策的能力，並思考哪些領域可以委託其他機構辦理，合作決策的透明系統方式，並決定在哪個地區投資專門成為區域/全球管理體系。

建議使用 FRP 的四步框架方法：

步驟 1：環境準備的 4 個領域（n = 33）（社會和管理環境；能力和能力；決策工具；後授權能力；

步驟 2：有效使用標準（n = 27）（原子能機構援助和驗收標準;審查過程要素;決策標準;授權後和脫離接觸活動；

步驟 3：給予機構評估工具準備和能力(基於步驟 1 和 2 評估;泛美衛生組織清單; CPP 依賴;提交透明度; GRevP;培訓）；

步驟 4：為機構確定使用最相關的 FRP 提供途徑。

總之，主要和次要 FRP 提供了有效應用管理資源的重要選擇，主要 FRP 的組合與縮短的開發、審查時間有關，通過評估環境，能力和能力機構可以確定適當使用基於風險的二級 FRP，特別是新興的國家，信任和認可方式將在次級 FRP 中發揮越來越大的作用，CIRS 提出的四步框架可以作為確定適當使用 FRP，以提供及時評估和公平獲取安全有效的藥物好處的基礎。

接下來由新加坡 HAS、澳洲衛生部、Bill & Melinda Gates Foundation、印尼 NADFC、Taiwan FDA、瑞士 Council for International Organizations of Medical Sciences (CIOMS), 巴西 ANVISA 等代表，分享各國在風險評估管理與合作的經驗，本署由藥品組王兆儀組長獲大會邀請，以「Good Registration Management (GRP and GSP) as critical components to enabling agencies to undertake a risk based review process」發表演講。產業界則有衛采製藥歐洲資深副總裁 Dr David Jefferys 以藥品產業角度，提出區域審查模式的優勢和主要障礙。

心得及建議

評估和了解利益風險是機構評估和依賴其他機構決策的關鍵 ，CIRS 一直在與使用不同審查模式的機構合作，利用利益風險架構和匯總文件系統，研究如何能夠做出合理決策。其發展出的指導決策者的原則包括：Selecting、Organising、Understanding、Summarising、Communicating，建議採行有效策略、健全組織架構、完善審查系統、強化科學審查與人員培訓等措施環環相扣，相輔相成。

參加此次會議，學習到 CIRS 發展出一套特有的系統，可與各國衛生主管部門合作，收集審查與管理數據，檢視內部標準作業流程的缺失，進一步參考先進國家制度予以改善。醫藥產業，藥政管理和衛生技術評估機構在整個藥物生命週期中作出的決定，對於確保及時獲得安全有效的藥物至關重要，先進國家不斷加強對藥物研發決策的品質方面的研究，風險利益評估的價值在於以科學為基礎的知識管理，建立系統化、透明化且持續的決策模式，與民眾、產業進行有意義、持續不間斷的溝通。本次活動也有許多專家針對 CIRS 研討會主題，建議對決策過程的質量進行評估，未來 CIRS 會將其納入年度計畫重點。

Good Registration Management (GRM)是結合 Good Review Practices (GRevP)和 Good Submission Practice (GSubP)的上位概念，主要目的為促進藥品研發與查驗登記上市審查效率，亦為主管單位建構基於風險評估概念的科學審查流程的關鍵，本次會議本署王兆儀組長分享台灣透過亞洲太平洋經濟合作會議(APEC) LSIF Regulatory Harmonization Steering Committee (RHSC)平台，首先倡議並推行之 Good Registration Management (GRP and GSP)規劃，以及2016年在台灣舉辦「APEC GRM Regulatory Science Center of Excellence Pilot Workshop」之成果，其中 Good Review Practices (GRevP)已獲得 WHO 認可並發布為國家或地區藥品審查單位的指導基準，充分顯示我國多年來推動提升藥品審查效能之努力，獲國際先進製藥國家及 CIRS 重視，未來更將藉由亞太經合組織法規科學卓越培訓中心(APEC Training Center of Excellence for Regulatory Science (CoE))，以教育訓練或研討會議方式，邀請各國主管部門代表參與討論，逐步實施或加強藥品研發與上市過程之審查品質，提升藥政主管部門績效、可預測性和透明度，促進醫療產品審查過程之

效率，推動區域醫藥品法規及管理體系之整合。

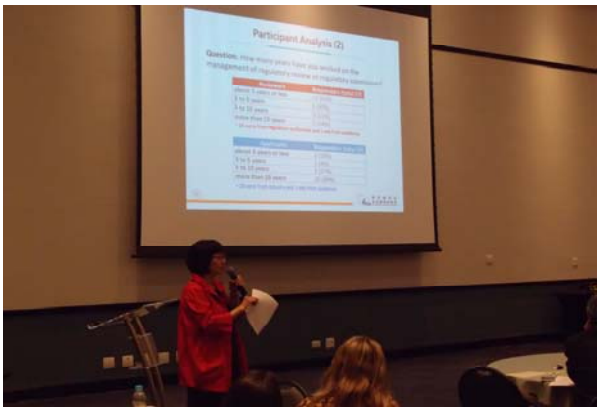
另外，WHO 專家也說明 WHO 與 BMGF 協助中低收入國家（LMIC）的進展，台灣在醫藥管理體系建構上一直採取國際標準，經過多年的努力建構與國際接軌之藥政管理體系，已具備獨立審查能力，同時在藥品不良反應通報、HTA 等持續加強，未來可持續將台灣經驗與世界各國分享。我國為世界的成員，理應享有參與 WHO 討論醫藥衛生管理各項議題的基本權力，尤其防疫與醫藥品可近性關係到全球健康照護系統的健全與完整，更應以務實態度進一步推動有意義參與(Meaningful Participation)世界衛生組織各項專業活動，推動參與世界衛生組織，爭取成為世界衛生大會觀察員。

附錄一 會議照片

一、參加會議人員合影

二、Lawrence Liberti, MSc, RPh, RAC 介紹OpERA

三、王兆儀組長受邀演講，並與Prof Sir Alasdair Breckenridge (Professor Former Chair, MHRA, UK)合影



CIRS Centre for Innovation in Regulatory Science

***Op*timising *E*fficiencies in *R*egulatory *A*gencies**

1st Annual OpERA Forum

Agenda

6th & 7th March 2017

Sao Paulo Airport Marriott Hotel

CONFIDENTIAL

CIRS- Centre for Innovation in Regulatory Science
The Johnson Building, 77 Hatton Garden, London EC1N8JS, England

INTRODUCTION

Many emerging national regulatory agencies (NRAs), especially those in low and middle-income countries (LMICs), do not have a robust complement of systems, skills and capabilities in place to provide effective and efficient regulatory support. This results in delays in medicines reviews and approvals, an increased likelihood of poor quality medicines entering the market, and delays in patient access to critical medicines especially where there is an unmet medical need. This problem has been identified by the agencies and other stakeholders and CIRS is committed to building regulatory capacity among these agencies.

However, in order to effectively embed these processes, the agencies need to not only be given the tools, but need to be measured as to the outcomes of their implementing these processes. To support these agencies in developing their capacity, CIRS have developed a multi-year project initiated in 2013 with the input of regulatory agencies from Asia, Latin America, Africa and the Middle East. The programme name, OpERA (Optimising Efficiencies in Regulatory Agencies) is a global programme, available to all regulatory agencies irrespective of their size, mission or maturity. The OpERA programme provides the tools that help regulators integrate a practice of tracking and measuring regulatory performance within their agencies. This promotes continuous improvements and opportunities for work optimisation including potential reductions in review and approval times.

As part of the OPERA programme, CIRS holds an annual forum with the regulatory agencies participating to come together to learn about tools that will build their regulatory capacity, through the mutual development and implementation of a metrics collection process by which agency progress can be measured, and provides for mechanisms to communicate results back to emerging NRAs to provide a continuous learning feedback loop.

OBJECTIVES OF THE FORUM

- To provide a forum for discussion with and among regulatory agencies about the stated topics
- To allow agencies to share their views and learnings
- To learn from and discuss the OpERA programme and to make recommendations on developing the programme and next steps.

The agenda for this meeting is presented in the follow pages, and over two half days starting on 6th March with lunch at 1pm in the Jupiter Room.

1st Annual OpERA Forum

Day 1: 6th March 2017

13:00	**Lunch**	
KEY OUTCOMES OF OPERA ACTIVITIES		
14:00	**Chairman's Introduction**	**Lawrence Liberti,** Executive Director, CIRS
14:30	**Introduction to OpERA Programme**	**Prisha Patel,** Manager, Global Development Programme, CIRS
15:00	**Current status of OpEra programme**	
15:30	**Feedback from OpERA regional meetings**	
	CARICOM	**Dr Charlie Preston,** Advisor, Regulatory Systems Strengthening for Medicines and Other Health Technologies , PAHO/WHO, Trinidad
	ZaZiBoNA	**Gugu Mahlangu** , Director General, Medicines Control Authority, Zimbabwe
16:00	**Break**	
ASSESSING AGENCIES REVIEW PROCESS THROUGH KEY PERFORMANCE METRICS		
16:30	**Agency experience with the OpERA programme for monitoring their agency's improvement initiatives**	**Ana Carolina Moreira Marino Araújo**, Health Regulation Expert, ANVISA, Brazil
17:00	**Summary of day one**	**Lawrence Liberti,** Executive Director, CIRS
17:15	**Close of meeting**	
19:00	**Reception and Dinner**	

Day 2: 7th March 2017

08:30	**Summary from day one meeting**	**Lawrence Liberti,** Executive Director, CIRS
MAXIMISING THE VALUE OF PARTICIPATING IN THE OPERA PROGRAMME.		
08:45	**Practicalities of OpERA data collection** - Introduction to data collection processes	**Prisha Patel,** Manager, Global Development Programme, CIRS
09:15	**Implementing an efficient and effective data collection process: What are the considerations?**	**All participants**
09:45	**Break**	
10:15	**Examples of analyses and how they have been used by agencies**	**Neil McAuslane,** Scientific Directors, CIRS
10:45	**Report output discussion** - Discussion on core analysis - Identify additional analysis that are value to all agencies - Feedback mechanisms (regional visits, forums, reports)	**Prisha Patel,** Manager, Global Development Programme, CIRS
11:30	**The way forward** - 2017 OpERA programme - Long terms communications	**Lawrence Liberti,** Executive Director, CIRS **All Participants**
12:00	**Close of Meeting**	

Workshop

Facilitating the review of new medicines through risk-based evaluations: How can a stratification process be utilised to achieve an effective use of resources?

8 - 9 MARCH 2017

PROGRAMME

Sao Paulo Airport Marriott Hotel, Sao Paulo, Brazil

The official language of the workshop will be English due to the international representation of the participants

CENTRE FOR INNOVATION IN REGULATORY SCIENCE

The Johnson Building, 77 Hatton Garden, London EC1N 8JS, UK, Telephone: +44 (0) 207 433 4247 Email: ghepton@cirsci.org

Organisers

Neil McAuslane: nmcauslane@cirsci.org, Prisha Patel: ppatel@cirsci.org,

Lawrence Liberti: lliberti@cirsci.org

Draft: V8 – 21Oct16

Facilitating the review of new medicines through risk-based evaluations: How can a stratification process be utilised to achieve an effective use of resources?

The current regulatory landscape is one of differing resources and capacities among agencies, yet a common feature as identified by World Health Organization is their engagement in duplicative work despite resources limitations. Indeed, the majority of the WHO member states do not have fully functional effective regulatory systems, leading to regulatory gaps and differing practices and functions. As the development of new medicines and advanced therapies becomes increasingly important, very few agencies have the needed advanced skills and mature regulatory systems to conduct a relevant review of these. So the challenge over the next 10 years will be the efficient evaluation of the same global products across many jurisdictions, despite very different capabilities and overall socioeconomic development.

However, as countries develop their regulatory capabilities it is being suggested that they evolve more to a risk-based evaluation approach and away from the more common prescriptive approach wherein every agency repeats a full review. Indeed across mature agencies we have seen the increasing development of prioritised risk-based approaches to decision making. Risk-based decision making is an area that addresses both compliance risks as well as product risks and can be implemented across the life cycle of new medicines from preclinical, through the oversight of clinical trials, as well as the manufacturing process and inspections, addressing the type of evidence required and review conducted for marketing authorisation, through to postmarketing compliance and review of variations.

In regard to the review of new medicines not only are countries looking to improve access through conditional or accelerated approvals for products to address serious and life-threatening diseases for which there are few, if any, effective therapies, but many agencies are also looking to leverage/rely on work undertaken by reference agencies to help inform their own regulatory decision-making. This enables them to stratify the evaluations of new medicines by using verification or abridged processes (which can be informed by prior assessments), thereby focusing their resources on the benefit-risk and suitability assessment of the product for their jurisdiction and on other value-added activities within their jurisdiction that only they can perform.

Indeed, the continuing limitations of adequate resources within regulatory agencies have the potential to drive greater focus toward risk-based evaluation, focusing on what is locally critical (ie, value-added) vs. what can be leveraged/relied upon from other trusted authorities, leading to improved allocation of scant local resources and improved patient availability This can be seen in the increasing role of WHO prequalification and its collaborative and joint review processes with NRAs, or where regional alignment or work-sharing initiatives are being developed. These approaches allow agencies time to build their regulatory technical capacity in line with their mission and funding, but at the same time enable patient access to good quality medicines that are safe and effective. However, implementation of these prioritisation approaches face a number of challenges including legal, political, methodological, cultural and organizational. These can be helped by having appropriate decision making frameworks and practices in place.

This workshop will build on previous CIRS global development workshops as well the work being undertaken by various groups in the areas of Good Regulatory and Review Practices *and will focus specifically on the risk-based prioritization of the review process for new medicines*. The aim will be to discuss the utilization of a risk based stratification evaluation approach to review and decision making, and what this means within an agency, across agencies and for regional alignments.

Workshop Objectives

- Identify the **current risk-based prioritisation evaluation models of decision making being used for the review of medicines** and what are believed to be the benefits and hurdles of utilising these in the review of new medicines
- Discuss **the frameworks and decision making practices that need to be in place to enable** effective and efficient prioritised risk-based decision-making
- Make recommendations on practical and acceptable review models to **evolve and ensure success of risk based evaluation approaches of decision making** that allow agencies to focus on value-added activities and provide timely patient availability to good quality medicines that are safe and effective. .

Style and Participation

Following the agreed practices for CIRS Workshops, the meeting participation is by invitation to maintain a size that encourages a neutral environment that promotes productive dialogue and networking. We aim to advance the debate and discussion around the subject of the Workshop and to produce constructive recommendations based on the Workshop activities.

Organisers
Neil McAuslane: nmcauslane@cirsci.org, Prisha Patel: ppatel@cirsci.org,
Lawrence Liberti: lliberti@cirsci.org

Draft: V8 – 21Oct16

Day 1: 8th March 2017

08:30 Registration

Session 1: Models and approaches to risk-based review and decision making: Advantages and barriers to stratification	
09:00	**Chair's welcome and introduction** **Prof Hans-Georg Eichler,** Senior Medical Officer, European Medicines Agency
09:05	**Country welcome and introduction** **Patrícia Oliveira Pereira Tagliari**, Head of International Affairs Office, ANVISA
09:10	**Risk-based approaches to the evaluation of new medicines: What does this mean and why should countries consider such an approach?** *What are the underlying principles, policy tools and support needed to promote the stratified, risk-based evaluation approaches? What aspects need to be considered (e.g. legal, cultural and organizational)?* **Mike Ward**, Coordinator, Regulatory Systems Strengthening, Essential Medicines and Health Products, World Health Organization
09:30	**Discussion**
09:40	**What are the different risk-based evaluation models/approaches that agencies can consider or adopt? What are their main advantages and possible barriers?** **Lawrence Liberti**, Executive Director, CIRS
10:00	**Discussion**
10:10	**Introducing risk-based evaluation methods into the review process – Practical experience and key considerations** **Agnes Chan,** Director of Therapeutic Products Branch, Health Sciences Authority, Singapore
10:30	**Discussion**
10:40	**Break**
11:10	**Work-sharing versus information sharing – What are the practical consideration an Agency needs to consider?** **Adj Prof John Skerritt**, Deputy Secretary, Department of Health, Australia
11:30	**Discussion**
11:40	**Stakeholder perspectives: Why should agencies establish risk-based approaches and how could stakeholders enable the process? NGO perspective** **Dr Shyam Bhaskaran,** Program Officer, Regulatory Affairs, Bill & Melinda Gates Foundation, USA
12:00	**Discussion**
12:10 *12:30*	**Country approaches to risk-based evaluation – Prioritisation based on reference agency approval: What are the opportunities and barriers within their country?** **Agency Viewpoint** - Colombia – **Dr Javier Guzman**, Director General, INVIMA **Agency Viewpoint** - Indonesia – (Path I, II and III) – **Togi Junice Hutadjulu**, Director of Drugs and Biological Product Evaluation, NADFC
12:50	**Discussion**
13:00	**Lunch**

Day 1 cont: 8th March 2017

SESSION 2: What are the practical frameworks that agencies have or need to have in place to adopt multiple pathways to prioritise medicines evaluation?	
14:00	**Chair's Introduction** **Dr Petra Dörr,** Head of Communication and Networking, Deputy Director, Swissmedic
	Regional Approaches to Risk-Based evaluation – Rationale, considerations, opportunities and barriers. How are these maximising capacity, enabling competence and improving patient access to new, safe and effective medicines?
14:05	**European Centralised System (EMA)** – **Dr Tomas Salmonson,** Chair CHMP, EMA
14:20	**Caribbean Community (CARICOM)** – **Dr Charlie Preston**, Advisor, Regulatory System Strengthening in Medicines and Other Health Technologies, PAHO, Trinidad
14:35	**ZaZiBoNa** - **Gugu Mahlangu**, Director-General, Medicines Control Authority, Zimbabwe
14:50	**What do companies see as the advantages and barriers in regard to regional alignment review models?** **Dr David Jefferys,** Senior Vice President, Global Regulatory, Government Relations, Public Affairs and European Product Safety, Eisai Europe Ltd, UK
15:05	**Discussion**
15:25	**Break**
	What tools and agency activities can be put in place to facilitate risk-based evaluation-based approaches?
15:55	**Utilization of a systematic structured benefit-risk or decision making framework to enable consistency within and across agencies** **Dr Neil McAuslane,** Scientific Director, CIRS
16:15	**Communication and transparency of decision making by agencies - How can assessment reports, inspection reports, and other work products of other agencies be used most effectively?** **Mario Alanis Garza,** Director General de Asuntos Internacionales, COFEPRIS, Mexico
16:35	**Good Registration Management (GRP and GSP) as critical components to enabling agencies to undertake a risk based review process** **Joyce Wang,** Director, Division of Medicinal Products, Food and Drug Administration, Chinese Taipei
16:55	**Discussion**
17:05	**Prioritisation: Balancing the evidence available within the submission and local jurisdictional requirements – What are the practical/scientific issues that agencies face?** **Claudiosvam Martins Alves de Sousa,** Manager, Office of Safety and Efficacy Assessment of Synthetic Drugs, ANVISA, Brazil
17:25	**Managing safety post-approval: What do agencies using risk-based approaches need to consider?** **Dr Lembit Rägo**, Secretary-General**,** Council for International Organizations of Medical Sciences (CIOMS), Switzerland
17:45	**Discussion**
17:55	**Introduction to Roundtable Discussions**
18:15	**End Day one**
19:00	**Reception**
19:30	**Dinner**

Day 2: 9th March 2017

SESSION 3: ROUNDTABLE DISCUSSIONS	
08:30	**Roundtable Discussions. Each roundtable is asked consider both qualitative and quantitative issues. Please review, debate and make recommendations for the following:** **Roundtable A:** *What are main criteria utilised in defining "risk based" and what needs to be the key considerations ?* **Chair: Catherine Parker,** Director General, Biologics and Genetic Therapies Directorate, Health Canada **Rapporteur: Jorge Azar,** Area Regulatory Director LA, AstraZeneca, USA **Roundtable B:** *What are the main internal considerations, policy challenges and opportunities for individual agencies to incorporate a risk stratification-based decision making approach to the review of new medicines?* **Chair: Adj Prof John Skerritt**, Deputy Secretary, Department of Health, Australia **Rapporteur: Dr Catherine Burgess,** Senior Director, Head of Emerging Markets Regulatory Affairs – Pipeline, Takeda, USA **Roundtable C:** *What are the main internal considerations, policy challenges and opportunities for agencies need to address in order to take a regional approach to the joint/shared review of new medicines?* **Chair: Lauhouari Belgharbi,** Director General, Center of Excellence For Regulatory Sciences (RS), Good Regulatory Practices (GRP) and Good Regulatory Management (GRM), COFEPRIS, Mexico **Rapporteur: Gugu Mahlangu**, Director-General, Medicines Control Authority, Zimbabwe **Roundtable D:** *What are companies looking for in agencies or regions that might use a risk evaluation based approach – what would a successful system look like?* **Chair: Dr Janet Vessotskie,** Head of Americas, Regulatory Policy and Intelligence, UCB, USA **Rapporteur: TBC** **Roundtable E:** *Managing Risk Post-Approval: What are the roles and responsibilities of the company, agency and other stakeholders?* **Chair: Prof Hans-Georg Eichler,** Senior Medical Officer, European Medicines Agency **Rapporteur: Lisa Ruiz,** Senior Director, Latin America Area Regulatory Affairs, AbbVie, USA
12:30	**End of roundtable discussions and Lunch**
14:00	**Chair's Introduction - Prof Sir Alastair Breckenridge**
14:05	**Feedback by roundtable rapporteurs and discussion.**
15:05	**Panel reflection from roundtable session – What are the next steps in the implementation of risk-based evaluations, by jurisdiction or regionally?** **Viewpoints from:** **Dr David Jefferys,** Senior Vice President, Global Regulatory, Government Relations, Public Affairs and European Product Safety, Eisai Europe Ltd, UK **Dr Charlie Preston,** Advisor, Regulatory System Strengthening in Medicines and Other Health Technologies, PAHO, Trinidad **Renato Porto**, Director, ANVISA **Dr Petra Dörr,** Head of Communication and Networking, Deputy Director, Swissmedic **Dr Shyam Bhaskaran**, Program Officer, Regulatory Affairs, Bill & Melinda Gates Foundation, USA
16:20	**Chairman's summary and close of Workshop**

Facilitating the review of new medicines through risk-based evaluations:
How can a stratification process be utilised to achieve an effective use of resources?

Good Registration Management (GRP and GSP) as critical components to enabling agencies to undertake a risk based review process

Chao-Yi (Joyce) Wang
Director, Division of Medicinal Products, TFDA

Sao Paulo, Brazil
8 March 2017

衛生福利部 食品藥物管理署 Food and Drug Administration
http://www.fda.gov.tw/

Outline

- Promotion of Good Registration Management (GRP and GSP) in APEC
- GRP and GSP are critical components to enabling agencies to undertake a risk based review process
- Future Direction

Goals of the APEC Good GRM roadmap and each key element

- GRM:
  - A concept to promote efficient registration process for medical products by promoting GRevP and GSubP cooperatively
- Goals of Roadmap:
  - To promote the concept of GRM
  - To enhance mutual trust for regulatory convergence among the APEC member economies by 2020

Good Review Practices (GRevP)	Good Submission Practice (GSubP)
To strengthen the **performance**, **predictability**, and **transparency** of regulatory agencies through the implementation or enhancement of GRevP and quality measures stepwise in each interested APEC economy.	To enhance the **quality** and **efficiency** of the medical product registration process by **improving the quality of submission** as well as its management.

Specific Activities and Timeframe of the GRM Roadmap

Step 1 (2011-2012)

Gap Analysis Survey for Setting the Foundation for Stepwise GRevP Implementation

- *Set up a technical working group*
- *Gap analysis survey for APEC economies*
- *Prioritize needs and strategy for improvement based on result of the gap analysis survey*

Step 2 (2011-2016)

Planned Solution to Address Gap in GRM

- *Training: workshops and CoE Pilot Training Program*
- *Development of normative GRevP/GSubP documents*
- *Dissemination of GRevP, GSubP and GRM*
- *Establish a network of GRevP and a network of GSubP*

Step 3 (2017-2019)

Assessing the Impact of GRM

- *Assessing the Impact of Training and Implementation of GRevP, GSubP and GRM*
- *Dissemination of GRevP, GSubP and GRM (continued)*

Step 4 (2018-2020)

Reaching the Goal for Implementing GRM

- *Follow-up measures and final assessment*

To reach the same end: better functioning agency through regulatory convergence by 2020

Milestones of the GRM Roadmap

Year	Milestone
2011	Good Review Practice (GRevP) was endorsed as a priority work area (PWA) by APEC LSIF-RHSC. Chinese Taipei was endorsed as the champion.
2013	APEC 2020 Roadmap for GRevP on Medical Products was endorsed by RHSC.
2014	Good Submission Practice (GSubP) was endorsed as a PWA by RHSC.
2014-2015	**Good review practices: guidelines for national and regional regulatory authorities was adopted and published by WHO.**
2016	**Good Submission Practice Guideline for Applicants was endorsed by RHSC.** **GRevP and GSubP were merged as a PWA entitled Good Registration Management (GRM).** A combined roadmap was endorsed by RHSC. Chinese Taipei and Japan were endorsed as the co-champions. **RAPS Taiwan Chapter was endorsed as a Center of Excellence (CoE) for GRM pilot program by RHSC. A CoE Pilot Workshop was held in Taipei in Nov 2016.** Mexico Cofepris was endorsed as a CoE for GRM pilot program by RHSC.
2017	**TFDA in partnership with RAPS Taiwan Chapter was endorsed as a formal APEC GRM CoE by RHSC.**

Good review practices: guidelines for national or regional regulatory authorities (WHO)

Annex 9

Good review practices: guidelines for national and regional regulatory authorities[1]

Background

The good review practices (GRevP) guidelines for regulatory authorities emanate from a partnership between the Asia-Pacific Economic Cooperation (APEC) Regulatory Harmonization Steering Committee (RHSC) and the World Health Organization (WHO). This is the first set of guidelines of its kind globally and addresses an important gap identified at the 2012 International Conference of Drug Regulatory Authorities (ICDRA). Although the RHSC does not directly produce guidelines, contributing to WHO guidelines is in line with the RHSC's principle of working with appropriate partners to achieve common objectives.

In June 2013 the RHSC convened an expert working group with WHO representation to develop a draft GRevP document, intended to cover both medicines and medical devices, for submission to WHO in early 2014. The draft document subsequently underwent the required WHO consultation process with a view to its further development into WHO guidelines for adoption by the Expert Committee on Specifications for Pharmaceutical Preparations and the Expert Committee on Biological Standardization. This led to these new GRevP guidelines for regulatory authorities adopted by the WHO Expert Committee on Specifications for Pharmaceutical Preparations at its forty-ninth meeting.

[1] Asia-Pacific Economic Cooperation (APEC) Regulatory Harmonization Steering Committee (RHSC) good review practices (GRevP) with the participation of Working Group Members representing the regulatory authorities (RAs) from the economies of Australia, Canada, Taipei (China), Japan, Republic of Korea, Saudi Arabia, Singapore, United States of America, and representatives of the Center for Innovation in Regulatory Science (CIRS), and the Food and Drug Administration Alumni Association International (FDAAA).

Table of contents

1. Introduction
2. Glossary
3. **Principles of a good review**
4. **Managing the review**
   - Project management • Quality management
   - SOPs • Review process stages
5. **Communications**
   - Intra-agency • Interagency • With applicants
   - With external experts • With the public
6. **Review personnel**
   - Reviewer expertise, competencies and training
   - Critical thinking
7. **Conducting the review**
   - Key elements in defining a review strategy
   - Applying the review strategy

Bibliography

GSubP Guideline for Applicants (APEC RHSC)

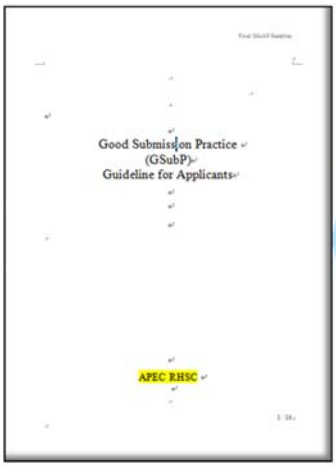


Table of contents

APEC Center of Excellence

The Vision

- A sustainable platform for promoting regulatory convergence, capacity and cooperation in areas of medical products
- Science and best practice focus

The Approach

- Partnership of academia, regulators and industry to deliver and maintain educational programs
- Benefit must be realized by all 3 partners
- Oversee & certify performance via APEC RHSC and AHC

Benefits of CoE Model

- Sustainable
- Offloads execution to training experts

Concept Model for APEC Training Center of Excellence for Regulatory Science (CoE)

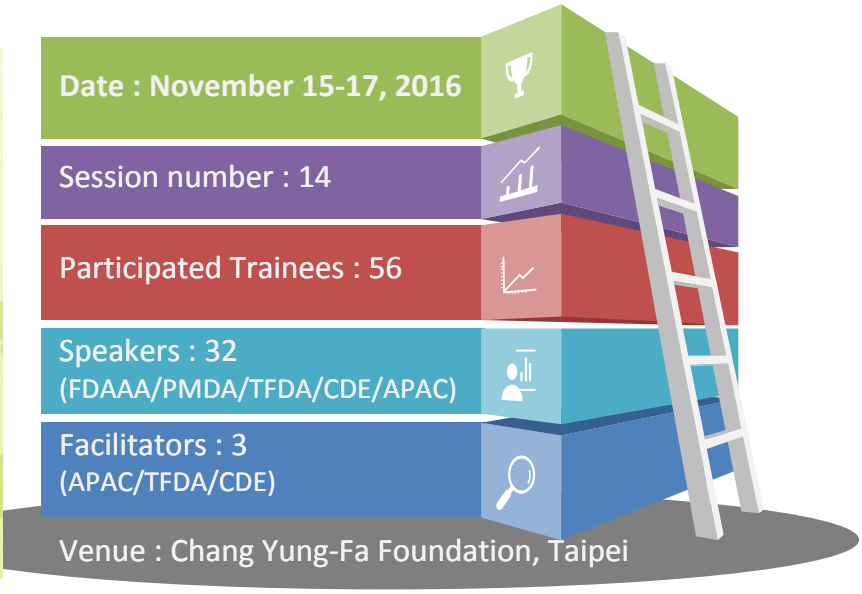
Topic-focused CoEs Hosted by Academic Institutions or Organizations with Appropriate Expertise

- **Champion economies:** Chinese Taipei & Japan
- **CoE:** (1) TFDA & RAPS Taiwan Chapter, (2) COFEPRIS

Networks of CoEs for a topic area are possible

衛生福利部 食品藥物管理署 FDA Food and Drug Administration

2016 APEC GRM Regulatory Science Center of Excellence Pilot Workshop



衛生福利部 食品藥物管理署 FDA Food and Drug Administration

Learning Objectives

Principles

- The principles of Good Review Practices (GRevP) and Good Submission Practices (GSubP)

Good Review

- What is needed for regulators to accomplish good review
  - Conducting and managing the review
  - Good communication with applicants
  - Competency for regulators

Good Submission

- What is needed for applicants to accomplish good application
  - Planning and preparation of application dossier
  - Good communication with regulators
  - Competency for applicants

衛生福利部 食品藥物管理署 FDA Food and Drug Administration

Core Curriculum

Curriculum developed based on GRevP guidelines and GSubP guidelines

GRM
Good Registration Management

Common Sessions

- Basic concept of GRM
- An Overview of Good Review
- An Overview of Good Submission
- Case Study: Effective Communication for GRM

GRevP
Good Review Practices

Reviewers-Specific Sessions

- Managing the review
- Communication : Fundamentals and Case Studies
- Review personnel - Critical thinking
- Conducting the review
- Rolling out the GRM training program in each economy
- Panel Discussion (competencies)

GSubP
Good Submission Practices

Applicants-Specific Sessions

- Planning of Application
- Preparation of application dossier / Practice : How to prepare application dossier
- Effective communications Focusing follow-up actions during review period
- Rolling out the GRM training program in each economy
- Panel Discussion (competencies)

衛生福利部 食品藥物管理署 FDA Food and Drug Administration

Group photo for all workshop participants

衛生福利部 食品藥物管理署 FDA Food and Drug Administration

Workshop photos

Case studies

Lectures

Group discussion

衛生福利部 食品藥物管理署 FDA Food and Drug Administration

Participant Analysis (1)

Total GRM Trainees
Chile (1)
China (3)
Hong Kong (2)
Indonesia (3)
Japan (2)
Korea (2)
Malaysia (3)
Mexico (2)
Papua New Guinea (2)
Peru (1)
Philippines (3)
Singapore (3)
Thailand (5)
Taiwan (23)
Vietnam (1)
56 APEC delegates
15 APEC member economies

Applicant-specific sessions

Applicants
China (3)
Hong Kong (2)
Japan (2)
Korea (2)
Malaysia (2)
Philippines (3)
Singapore (3)
Thailand (3)
Taiwan (9)
29 APEC delegates
9 APEC member economies

Reviewer-specific sessions

Reviewers
Chile (1)
Indonesia (3)
Malaysia (1)
Mexico (2)
Papua New Guinea (2)
Peru (1)
Thailand (2)
Taiwan (14)
Vietnam (1)
27 APEC delegates
9 APEC member economies

Participant Analysis (2)

Question: How many years have you worked on the management of regulatory review or regulatory submission?

Reviewers	Responders (total 27)
about 3 years or less	11 (41%)
3 to 5 years	8 (30%)
5 to 10 years	3 (11%)
more than 10 years	5 (18%)

- 26 were from regulatory authorities and 1 was from academia.

Applicants	Responders (total 29)
about 3 years or less	3 (10%)
3 to 5 years	1 (4%)
5 to 10 years	5 (17%)
more than 10 years	20 (69%)

- 28 were from industry and 1 was from academia

Effectiveness Analysis

General Satisfaction with the Workshop

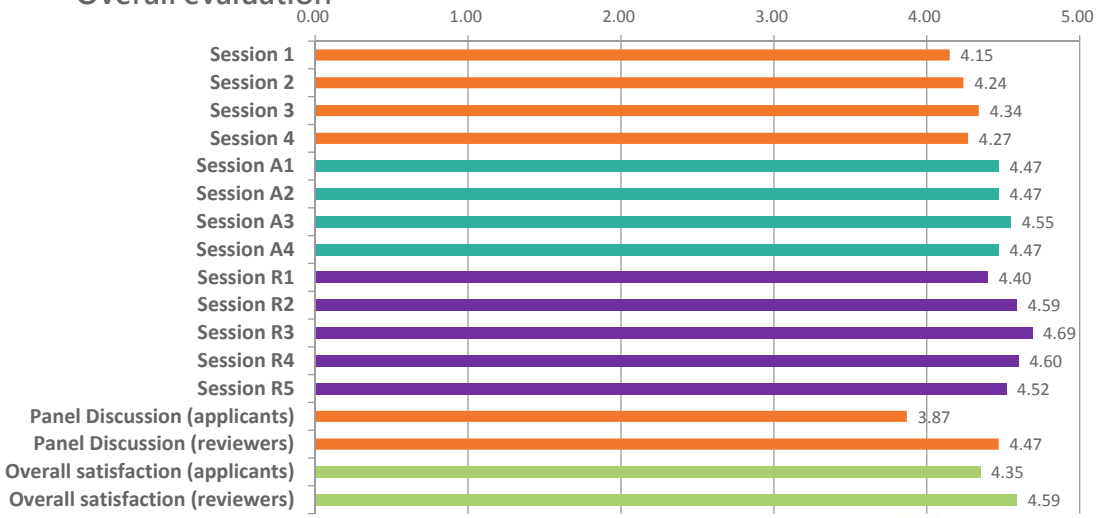
General Satisfaction	Response Average	Responders (response rate)
Were level and amount of pre-training materials adequate?	4.33	42 (75%)
Did the workshop enhanced your understanding of GRM concept?	4.49	42 (75%)
Were your expectations for this workshop met?	4.33	42 (75%)
Overall satisfaction	4.48	42 (75%)

Scale 1 = Poor and 5 = Excellent
Average rating score is above 4. The pilot is considered with good satisfaction.

衛生福利部 食品藥物管理署 FDA Food and Drug Administration

Curriculum Analysis

- Onsite survey was conducted to rate each session in terms of
  - The adequacy of training materials
  - The adequacy of the time allocation for this session
  - Facilitation and presentation of the content
  - Overall evaluation



衛生福利部 食品藥物管理署 FDA Food and Drug Administration

Curriculum Analysis (1)

Rating for Common Sessions

Common Sessions	Session 1 Basic concept of GRM		Session 2 An Overview of Good Review		Session 3 An Overview of Good Submission		Session 4 Case Study: Effective Communication for GRM	
	Response Average	Responder (response rate)	Response Average	Responder (response rate)	Response Average	Responder (response rate)	Response Average	Responder (response rate)
The adequacy of training materials	3.96	33 (59%)	4.03	33 (59%)	4.18	33 (59%)	4.21	33(59%)
The adequacy of the time allocation for this session	4.27	33 (59%)	4.30	33 (59%)	4.24	33 (59%)	4.27	33(59%)
Facilitation and presentation of the content	4.12	33 (59%)	4.21	33 (59%)	4.27	33 (59%)	4.24	33(59%)
Total evaluation	4.15	33 (59%)	4.24	28 (50%)	4.34	32 (57%)	4.27	33(59%)

衛生福利部 食品藥物管理署 FDA Food and Drug Administration

Curriculum Analysis (2)

Rating for Reviewer-Specific Sessions

Reviewers-Specific Sessions	Session R1 Managing the review - an Overview		Session R2 Communication : Fundamentals and Case Studies		Session R3 Review personnel - Critical thinking		Session R4 Conducting the review		Session R5 Rolling out the GRM training program in each economy	
	Response Average	Responder (response rate)	Response Average	Responder (response rate)	Response Average	Responder (response rate)	Response Average	Responder (response rate)	Response Average	Responder (response rate)
The adequacy of training materials	4.36	22 (76%)	4.45	22 (76%)	4.60	23 (79%)	4.47	23 (79%)	4.47	23 (79%)
The adequacy of the time allocation for this session	4.40	22 (76%)	4.54	22 (76%)	4.60	23 (79%)	4.52	23 (79%)	4.52	23 (79%)
Facilitation and presentation of the content	4.40	22 (76%)	4.59	22 (76%)	4.69	23 (79%)	4.52	23 (79%)	4.52	23 (79%)
Total evaluation	4.40	22 (76%)	4.59	22 (76%)	4.69	23 (79%)	4.60	23 (79%)	4.52	23 (79%)

衛生福利部 食品藥物管理署 FDA Food and Drug Administration

Curriculum Analysis (3)

Rating for Applicant-Specific Sessions

Applicants-Specific Sessions	Session A1 Planning of Application		Session A2 Preparation of application dossier / Practice : How to prepare application dossier		Session A3 Effective communications Focusing follow-up actions during review period		Session A4 Rolling out the GRM training program in each economy	
	Response Average	Responder (response rate)	Response Average	Responder (response rate)	Response Average	Responder (response rate)	Response Average	Responder (response rate)
The adequacy of training materials	4.36	22 (76%)	4.36	22 (76%)	4.7	20 (69%)	4.44	18 (62%)
The adequacy of the time allocation for this session	4.40	22 (76%)	4.36	22 (76%)	4.45	20 (69%)	4.42	19 (65%)
Facilitation and presentation of the content	4.5	22 (76%)	4.27	22 (76%)	4.5	20 (69%)	4.47	19 (65%)
Total evaluation	4.47	21 (72%)	4.47	22 (76%)	4.55	20 (69%)	4.47	19 (65%)

Curriculum Analysis (3)

Rating for Panel Discussion on Regulatory Professionals' Competencies

Session A5/R6 Panel discussion	Response Average	Responder (response rate)
The adequacy of training materials	4.26	37 (66%)
The adequacy of the time allocation for this session	4.17	39 (69%)
Facilitation and presentation of the content	4.25	39 (69%)
Total evaluation	4.22	39 (69%)

衛生福利部 食品藥物管理署 FDA Food and Drug Administration

Feedback from Trainees (Applicants)

Topics/presentations of the 2016 pilot workshop most useful to trainees

Applicants
Communication
Planning for submission
QC & Dossier Preparation
Case study & group discussion are very good.
All topics
The tools, the exercises.
Section A3. Effective communications - Focusing follow-up actions during review period / Practice: Case study of how to handle inquires

Topics/areas trainees would like to see in the future GRM workshop

Applicants
Effective communication
More case studies: implementation of GRM, submission to regulatory authorities among Asia/US/EU
Interactive sessions between reviewers and applicants
Others: tools for improving quality of submissions, project management, risk management, critical thinking

Feedback from Trainees (Reviewers)

Topics/presentations of the 2016 pilot workshop most useful to trainees

Reviewers
Critical thinking, Communication
Rolling out the GRM training program in each economy
Case studies
Group discussion
All topics
Conducting the review
Managing the Review

Topics/areas trainees would like to see in the future GRM workshop

Reviewers
Critical thinking in risk/benefit considerations, different product areas, review disciplines and post-approval modifications
Communication
Interactive sessions between reviewers and applicants
Others: effective tools and approaches used for GRevPs, key aspects to perform a review

Challenges from Organizers' Perspectives

- Provide a curriculum which meets the need of all individual trainees with variability in background.
  - For Applicant-Specific Sessions, case studies were provided based on the experiences of **well-resourced companies** which focus on registration of new drugs.
  - For Reviewer-Specific Sessions, participants are from different APEC member economies with **different levels of regulatory sophistication** and with **focus in different review disciplines**.
- Provide more opportunities for regulators and applicants to efficiently interact with each other.

Conclusion from the Pilot Workshop

- It was a successful CoE pilot with
  - good partnership and collaboration,
  - significant interactive elements, such as interactive discussions, group discussions, case studies, and practices, and
  - good rating and overall satisfaction.
- For the future training program, we plan to
  - create more collaborative sessions to allow trainees from industry to talk to regulators,
  - provide more case studies and interactive discussions, and
  - put more emphasis on the topics of "communication" and "critical thinking".

Expected impacts of GRM to enabling agencies to undertake a risk based review process

- **Good submission practices enable applicants to**
  - understand the principles of a good submission,
  - strengthen their core competency in understanding of risk-benefit analysis, and
  - clarify the nature of benefits and risks of the products when preparing for submission.
- **Good review practices enable regulators to**
  - understand the principles of a good review,
  - strengthen their knowledge and skills of risk-based analysis for reviewing a medical product application,
  - strengthen their competency in critical thinking when granting authorization,
  - determine if the application permits a conclusion about benefits and risks, and
  - apply the review strategy to understand the benefit–risk profile of the medical product.
- **Good Registration Management (GRP and GSP) could serve as critical components to enabling agencies to undertake a risk based review process.**

Future Direction

APEC CoE

- Become a formal APEC GRM Center of Excellence (endorsed by RHSC in Feb 2017)
- To host annual training events for APEC member economies

Train-the-trainer

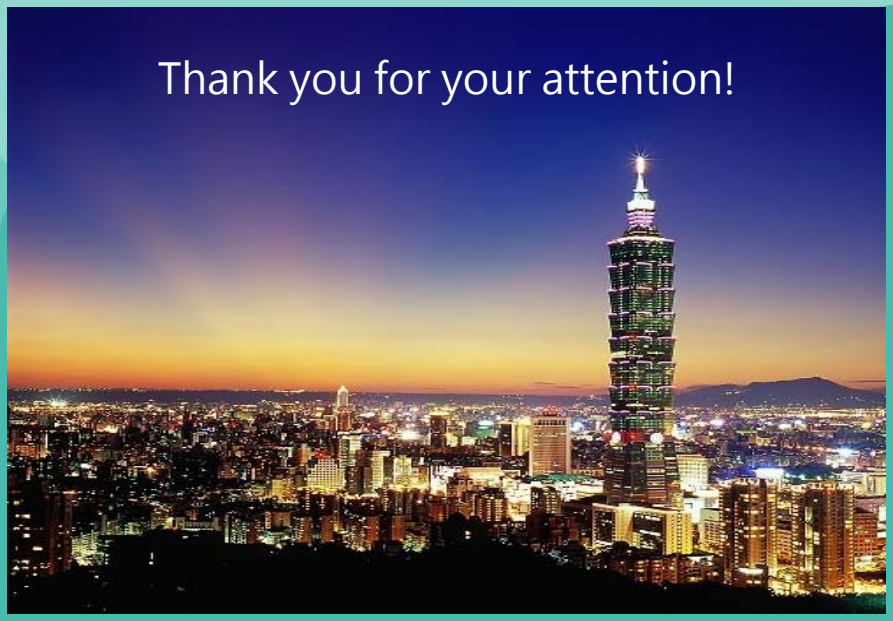
- Trainees are expected to develop and deliver local training in their respective APEC member economies

Objective and Goal

- Dissemination of GRM to promote efficient registration process for medical products and regulatory convergence in APEC

衛生福利部 食品藥物管理署 FDA Food and Drug Administration

Thank you for your attention!



衛 生 福 利 部
食 品 藥 物 管 理 署
Food and Drug Administration

http://www.fda.gov.tw/