出國報告（出國類別：參加國際會議）

2017 APEC 優良查驗登記管理 (GRM)法規科學訓練卓越中心 (CoE) 先期研討會 (Pilot Workshop) 會議報告

2017 APEC RHSC Regulatory Science Center of Excellence (CoE) for Good Registration Management (GRM) - Pilot Workshop

服務機關：衛生福利部食品藥物管理署
姓名職稱：黃琴嘵科長
派赴國家：墨西哥國墨西哥市
出國期間：106 年 6 月 24 日至 6 月 30 日
報告日期：106 年 9 月

摘要

APEC 生命科學創新論壇 (LSIF: Life Science Innovation Forum)之法規協和指導委員會 (RHSC: Regulatory Harmonization Steering Committee)選定出六個主要的工作領域 (The RHSC’s Priority Work Areas, 簡稱 PWAs) 作為法規協和的優先主題，其中「優良查驗登記管理 (Good Registration Management)」由我國與日本共同主導 (Champion Economy)，在 2020 年前以階段性的模式促成由學術或教育訓練機構主辦之 APEC 法規科學訓練卓越中心 (APEC LISF RHSC Training Centers of Excellence for Regulatory Science，簡稱 CoE)，培訓 APEC 各會員經濟體的法規科學種子師資，以 train the trainer 的概念培育出更多的法規人才，以便在亞太區域內深植法規協和。

美國醫療法規學會台灣分會 (RAPS Taiwan Chapter)辦理「2016APEC 優良查驗登記管理法規科學訓練卓越中心 (CoE) 先期研討會 (Pilot Workshop」成果豐碩，2017 年 2 月 24 日 RAPS Taiwan Chapter (美國醫療法規學會台灣分會) 與食藥署(TFDA)聯名獲得 2017 APEC RHSC 支持，正式通過成立「APEC 優良查驗登記管理法規科學訓練卓越中心:APEC LISF RHSC Training Center of Excellence for Regulatory Science for Good Registration Management」。這項成果是食藥署在國際合作上的重要突破，食藥署與 LSIF 簽署合作備忘錄，每年針對 APEC 會員經濟體舉辦優良查驗登記管理相關訓練活動。

墨西哥 COFEPRIS CoE 獲得 APEC RHSC 允准，於 2017 年 6 月 26 日至 6 月 28 日在墨西哥市舉辦「2017 APEC 優良查驗登記管理法規科學訓練卓越中心 (CoE) 先期研討會 (Pilot Workshop) 」。食藥署黃琴嘵科長暨 RAPS Taiwan Chapter 林稟彬博士奉指派，代表 Chinese Taipei，以 APEC RHSC GRM Roadmap Champion Economy 及 full GRM CoE 的身份發表演講及座談分享分享經驗，促進 GRM CoE 間之交流合作，並評估本次 COFEPRIS GRM CoE Pilot Workshop 之作業是否符合「APEC LSIF RHSC CoE Operating Model and Guidelines」所設定標準，做為日後是否可以通過 full GRM CoE 申請之重要參考。

關鍵詞：APEC、生命科學創新論壇、法規協和指導委員會、優良查驗登記管理、法規科學訓練卓越中心、先期研討會、COFEPRIS、墨西哥市

內容

壹、背景介紹

一、亞太經濟合作 (Asia-Pacific Economic Cooperation，簡稱 APEC)

係於 1989 年開始設立，為亞太區域內促進各區域經濟成長與發展的論壇，目前總共有 21 個會員經濟體。我國於 1991 年以「Chinese Taipei」的名稱加入。各成員國以會員經濟體 (或會員體，Member of Economy) 的身份參加。APEC 會議屬於「論壇」 (Forum) 形式，尊重各成員國間開放與互相的對話進而達成決議。每年的 APEC 會議由一個會員經濟體擔任主辦。

二、生命科學創新論壇 (Life Science Innovation Forum，簡稱 LSIF)法規協和指導委員會 (Regulatory Harmonization Steering Committee，簡稱 RHSC)

APEC 會議包含許多不同主題的論壇， LSIF 為 APEC 下討論公衛及生命科學相關議題的論壇。LSIF 論壇成立之首要目的為支持創新生命科學的發展與應用，以促成區域內的全民健康。此論壇聚集了各經濟會員體衛生機構官員、產業界與學界的代表，共同關注與討論創新生命科技發展的新知與衛生健康政策相關的倡議。近年來由於體認到醫藥品法規協和化 (harmonization/convergence) 相關於醫藥品上市的速度與人民健康的重要性，RHSC 於 2008 年時成立，致力於促成亞太區域內醫藥品法規的協和，TheAPEC Harmonization Center(AHC) 於 2008 年時在韓國首爾成立，依據策略性的指導原則，RHSC 願景在 2020 年可以促進區域內的醫藥法規協和。

三、 RHSC 六個主要工作領域 (The RHSC’ s Priority Work Areas, 簡稱 PWAs)

作為法規協和的優先主題，各 PWAs 皆制定出需遵行的工作路徑圖 (Implementation Roadmap)。目前之工作領域如下列，且已分配給多個國際團隊來負責主導，作為法規協和的優先主題：

- 日本與泰國共同主導：多邊臨床試驗及優良臨床規範 (GCP)查核 (Multi

Regional Clinical Trials and Good Clinical Practices Inspections)

- 韓國主導：藥品與醫材安全監視 (Pharmacovigilance & Medical Device Vigilance)
- 韓國主導：生技醫療藥物 (Biotherapeutics)
- 新加坡主導：細胞及組織治療 (Cell and Tissue-based Therapies)
- **中華台北與日本共同主導：優良查驗登記管理 (Good Registration Management)**
- 美國主導：全球供應鏈完整性 (Global Supply Chain Integrity)

四、APEC 法規科學訓練卓越中心 (APEC LSIF RHSC Training Centers of Excellence for Regulatory Science，簡稱 CoE)

RHSC 希冀採用永續的法規科學訓練方式來促進 APEC 經濟國區域各項優先工作領域之法規協和，在 2020 年前以階段性的模式促成由學術或教育訓練機構主辦之 APEC 法規科學訓練卓越中心 (Training Centers of Excellence for Regulatory Science，簡稱 CoE)，為各項優先工作領域提供適切之法規科學訓練課程，培訓 APEC 各會員經濟體的法規科學種子師資，以 train the trainer 的概念培育出更多的法規人才，以便在亞太區域內深植法規協和。

五、我國正式成為「APEC 優良註冊管理法規科學訓練卓越中心」

2011 年 7 月 18 日 RAPS 台灣分會成立。2016 年 2 月於 2016APEC RHSC 會議提案「APEC 優良註冊管理法規科學訓練卓越中心先期研討會」。2016 年 8 月於 2016 APEC RHSC 會議提報「APEC 優良註冊管理法規科學訓練卓越中心先期研討會」規劃。2016 年 11 月 15 日-17 日 APEC 優良註冊管理法規科學訓練卓越中心先期研討會(APEC GRM CoE Pilot Workshop) 在台北市盛大舉行成功。 2017 年 2 月 24 日食藥署(TFDA)與 RAPS Taiwan Chapter (美國醫療法規學會台灣分會)

聯名獲得 2017APEC RHSC 支持通過正式成立「APEC 優良註冊管理法規科學訓練卓越中心: APEC LSIF RHSC Training Center of Excellence for Regulatory Science (CoE) for Good Registration Management (GRM)」。

貳、過程與目的

墨西哥 COFEPRIS CoE 向 APEC RHSC 申請，獲准在墨西哥國墨西哥市主辦 2017 APEC 優良查驗登記管理法規科學訓練卓越中心 (CoE) 先期研討會 (Pilot Workshop)，於 2017 年 6 月 26 日至 6 月 28 日在墨西哥市喜來登飯店 (Sheraton Mexico City Maria Isabel Hotel)舉行。

一、行程安排

時間	行程
6 月 24 日-25 日	台北至墨西哥
6 月 26 日-28 日	出席 2017 APEC RHSC Regulatory Science Center of Excellence (CoE) for Good Registration Management (GRM) - Pilot Workshop
6 月 29 日-30 日	墨西哥返台北

二、參與目的：

(一) 、 代表 Chinese Taipei 以 APEC RHSC GRM Roadmap Champion Economy 及 full GRM CoE 的代表身份擔任 Plenary Speaker 及 Panel Discussion 之 Panelist 分享經驗。

(二) 、 代表 Chinese Taipei 以 GRM Roadmap Champion Economy 的身份評估本次 COFEPRIS CoE Pilot Workshop 之作業是否符合「APEC LSIF RHSC CoE Operating Model and Guidelines」所設定標準，做為日後是否可以通過 full GRM CoE 申請之重要參考。

(三) 、 代表 Chinese Taipei 了解 COFEPRIS CoE 直接將我方 2016 GRM CoE

Pilot Workshop 資料翻譯成西班牙語的情況。

(四) 、 同行 RAPS TW 代表亦於會中分享該組織辦理 CoE 之經驗分享，鼓勵與會經濟體善用資源、促進各 GRM CoE 間之交流合作。

參、會議內容

墨西哥 COFEPRIS 大致依我方 2016 年 11 月於中華台北主辦 (CoE) for Good Registration Management (GRM) - Pilot Workshop 核心課綱規劃此 GRM CoE 先期訓練課程，訓練對象主要包括墨西哥及拉丁美洲國家智利、巴西、哥斯達黎加。此次先期研討會 (Pilot Workshop)課程結束後，即上網公開訓練教材，並且建立專家網絡供學員諮詢或討論 GRM 相關問題。COFEPRIS CoE 期望有機會能夠於 2017 年獲 RHSC 認可成為正式的 CoE。

Sessions	演講人
Day 1 09:00 - 09:30 Opening	Chyn-Liang (Cindy) Huang (TFDA)
Day 1 09:40 - 10:00 C1.1 Lecture 1: The APEC 2020 Roadmap to Promote GRM and the Core Curriculum of the GRM Training Program	Chyn-Liang (Cindy) Huang (TFDA)
Day 2 08:00-17:30 A1 A2 A3 Applicant Session	Dr. Bing Bing Lin (RAPS Taiwan Chapter)
Day 2 08:00-17:30 R1 R2 R3 R4 Reviewer Session	Chyn-Liang (Cindy) Huang (TFDA)

Day 3 09:30 - 09:45 C5.1 Lecture 1: RAPS Regulatory Competency Model Framework.	Dr. Bing Bing Lin (RAPS Taiwan Chapter)
Day 3 10:15 - 11:00 C5.3 Panel Discussion to discuss issues and challenges for building, developing or and or implementing a competency model for good registration management	Panelist: Chyn-Liang (Cindy) Huang (TFDA) Dr. Bing Bing Lin (RAPS Taiwan Chapter)
Day 3 15:00 - 15:30 C5.6 Lecture 1:Chinese Taipei FDA Pilot APEC GRM program experience	Chyn-Liang (Cindy) Huang (TFDA)

肆、心得與建議

一、持續與 APEC 會員經濟體的法規交流合作

我國於 2016 年 2 月獲 APEC RHSC 會議認可「APEC 優良註冊管理法規科學訓練卓越中心先期研討會」後，同年 11 月 15 日至 17 日舉辦 APEC GRM CoE Pilot Workshop 成功，獲各國佳評。2017 年 2 月 24 日本署與 RAPS Taiwan Chapter (美國醫療法規學會台灣分會)聯名獲得 RHSC 支持通過正式成立「APEC 優良註冊管理法規科學訓練卓越中心: APEC LSIF RHSC Training Center of Excellence (CoE) for Regulatory Science for Good Registration Management (GRM)」，此為我國長期參與 RHSC 各項活動所獲得的國際認同之一。 優良註冊管理法規科學訓練卓越中心先期研討會

為永續發展我國與 APEC 會員經濟體的法規交流合作，除繼續參 APEC 與 RHSC 相關會議外，身為 APEC GRM Roadmap 的推動經濟體，除了負責訂定相關核心課綱外，另一責任工作為輔導及確認已經 APEC 核定的先期卓越中心所辦理的各項活動皆符合規定辦理。如此次應邀赴墨西哥藉由分享我國去年辦理先期研討會之經驗，並了解該先期研討會之活動內容是否依核心課程宗旨設計其內容。

二、持續推動 APEC 優良查驗法規管理(GRM)，以達 APEC 2020 指標

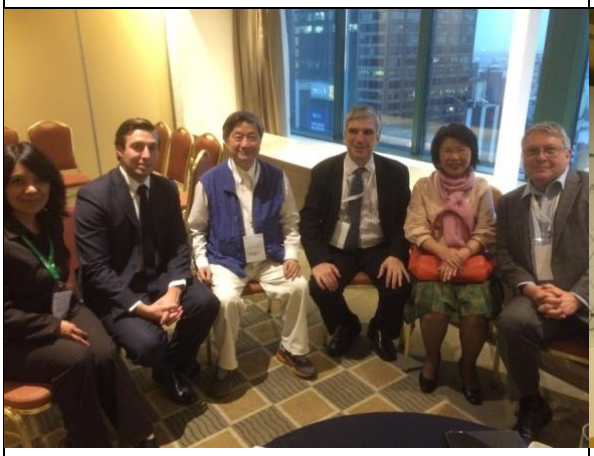
除了為 APEC GRM 的 Champion Economy，食藥署同時與 RAPS TW 共為正式 GRM CoE。每年除了舉辦相關研討會，培訓優良查驗登記管理種子師資，以利將相關教育訓練及規範的落實推廣至所有 APEC 會員經濟體。今(2017)年的訓練活動將於 10 月 31 日至 11 月 2 日在台北辦理，歡迎 APEC 各會員經濟體成員參加。

此外，透過辦理訓練活動，與各 CoE 之經驗分享與交流互動，促進優良查驗登記管理作業規範之推動，皆利於 2020 年有效完成路徑圖的最終績效指標評估，實質促進 APEC 的區域法規協和。

伍、會議翦影

所有講員合照

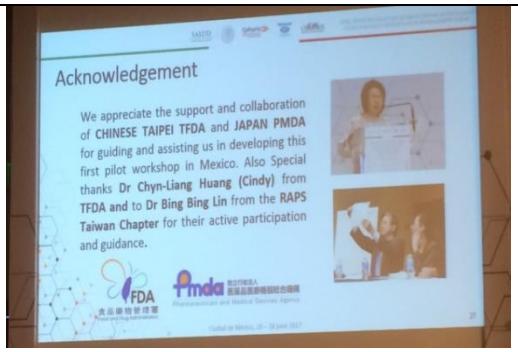
Dr. Mario Alanis arza(COFEPRIS)



歡迎茶會

Panel Discussion

Plenary Speaker 黃琴嘵科長



Special acknowledgement

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2017 APEC RHSC Regulatory Science Center of Excellence (CoE) for Good Registration Management (GRM) - Pilot Workshop
June 26-28, 2017 - Sheraton María Isabel CDMX Hotel, Mexico – DRAFT PROGRAM

SESSION DAY 1	SUBJECT COMMON SESSION	TIME	LECTURE	OBJECTIVE	CHAIR OF SESSION	SPEAKERS		ROOM
						Institution	Name	
C0	Registration	08:00 – 09:00						Fiestas
	Opening	09:00 - 09:30	Opening	Each institution will deliver a statement of 2 to 3 mn. To welcome participants, explain their participation and interest to the activity	Maestro de ceremonias (Jorge Romero)	COFEPRIS SECRETARIAT DEL SALUD CHINESE TAIPEI, TFDA; AMIIF, CANIFARMA, ANAFAM, OPS/OMS	Hilda Chavez, SS. (COFEPRIS / *FOMENTO, CAS, FS)* Chyn-Liang (Cindy) Huang (TFDA) AMIIF CANIFARMA OPS/OMS	
	Objectives of the workshop and workshop information	09:30 - 09:40	C0.1.1.Workshop objectives and expectations. C0.1.2.Administrative and logistic announcement about the workshop.	-Introduction of the general objectives and expectations of the GRM workshop -information to all participants about organization.	Mario Alanis, Director General IC COFEPRIS, International Cooperation	COFEPRIS CoE	Evencio Ramirez (Objectivos) Enrique Arriaga (Administration & Logisitics)	
C1	Basic concept of Good Registration Management (GRM)	09:40 - 10:00	C1.1 **Lecture 1**: The APEC 2020 Roadmap to Promote GRM and the Curriculum Design of this Pilot Workshop.	To understand the goal and specific activities of the APEC 2020 Roadmap to Promote GRM.		CHINESE TAIPEI, TFDA	Chyn-Liang (Cindy) Huang (TFDA)	
		10:00 - 10: 30	COFFEE BREAK					Independencia B
		10:30 -11:00	C1.2 **Lecture 2**: Background of GRM and high level principles and processes of Good Review Practice (GRevP) & Good Submission Practice (GSubP).	To understand the historical background and basic concept of GRM and high level principles and processes of GRevP and GSubP.	Mario Alanis, Director General IC COFEPRIS, International Cooperation.	COFEPRIS CoE	Lahouari Belgharbi	
		11:00 -11:20	C1.3 **Lecture 3**: How to build quality onto the regulatory submission and review process? and how can these be measured?	To understand how quality is built upon the process of regulatory review and providing feedback about survey undertaken in APEC economies about the needs.		CIRS	Lawrence Liberty	
		11:20 - 11:30	Wrap up and Q&A	Participants will raise questions or request clarification about the lectures delivered		Chair of the session	Mario Alanis, Director	

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SESSION DAY 1	SUBJECT COMMON SESSION	TIME	LECTURE	OBJECTIVE	CHAIR OF SESSION	SPEAKERS		ROOM
						Institution	Name	
C2	An overview of the good review	11:30 - 11:50	C2.1 **Lecture 1**: An overview of Good Review : GRevP : Today and the Future GRevP Document Key Principles	To understand the principles of Good Review Practices (GRevP), as well as the historical background and basic concepts of GRM.	Ma de la Luz Lara Mendez Executive Director of Registration and Licencing CAS	COFEPRIS CoE	Lahouari Belgharbi (COFEPRIS)	
		11:50 - 12:10	C2.2 **Lecture 2**: The Challenge of Making Good Review Practices a Reality	Share experience from regulatory systems on their experience in registration systems (CIRS risk based evaluation model).		CIRS	Lawrence Liberty	
		12:10- 12:30	C2.3 **Lecture 3**: Management of the Review and Quality System	Show performance standards during the conduct of reviews through organized and integrated tasks to ensure quality during the review process.		COFEPRIS CAS CCAYAC	Q. Adriana Martínez, Veronica Vega Segura	
		12:30 - 13:00	Wrap up and Q&A	Participants will raise questions or request clarification about the lectures delivered		Chair of the session	Philip M. Budashewitz or Patricia Pineda	
		13:00 - 14:00	**LUNCH BREAK**					Independencia B
C3	An overview of the good submission	14:00 - 14:30	ICE BREAKING /STRETCHING ACTIVITY	Ensure focus and attention of participant for the afternoon sessions	Justin Duarte Pine Director, International Affairs Biotechnology Innovation Organization, BIO:ORG	CYPRESS, Comunicación	Miquel Ramírez	Fiestas
		14:30- 14:40	C3.1.**Lecture 1**: Why applicants need to use and implement Good Submission Practices (GSubP)?	Understand the importance of implementing GSubP principles for achieving Good Submission.		ABBVIE	Lina María Olmos Solanilla	
		14:40- 15:00	C3.2 **Lecture 2**: What is "quality of submission"? -Practice with participants	Explain through practices what are the critical elements that determine the quality of the dossier to achieve good quality submission.		ROCHE	Anabelle Castro	
		15:00 - 15:10	C3.3 **Lecture 3**: Outline of Good Submission Practices (GSubP) -Guideline for Applicants	Introduce the GSubP guideline for applicants and understand tits intended objectives		BIO.ORG, USA	Justin Duarte Pine	
		15:10 - 15:20	C3.4 **Lecture 4**: Summary	Reviewing the key elements of knowledge delivered through the Good Submission Practices (GSubP)		ABBVIE	Lina María olmos olanilla	
		15:20 - 15:30	Wrap up and Q&A	Participants will raise questions or request clarification about the lectures delivered		Chair of the session	Justin Duarte Pine	
		15: 30 - 16:00	**COFFEE BREAK**					Independencia B

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SESSION DAY 1	SUBJECT COMMON SESSION	TIME	LECTURE	OBJECTIVE	CHAIR OF SESSION	SPEAKERS		ROOM
						Institution	Name	
C4	Effective communication for GRM	16:00 - 16:30	C4.1 **Lecture 1**: Effective communication for GRM	Understand the fundamentals (concept and principles) for ensuring an effective communication for GRM	Esther Ávila Head of Latin America, Worldwide Safety & Regulatory- Innovative PFIZER	CYPRESS, Comunicación	Miguel Ramírez,	Fiestas
		16:30 - 17:30	C4.2 **Case study Case study on** : Effective communication for GRM	Understand the importance of communication between applicants and regulatory authorities throughout the registration process case study.		BAYER and CYPRESS, Comunicación	Kim Quantance and Miguel Ramírez	
		17:30 - 17:40	Wrap up and Q&A	Participants will raise questions or request clarification about the lectures delivered		Chair of the session	Esther Ávila	
		18:00 - 19:00	**Organizer meeting (private)**	**Organizer meeting to review next day and get feedback about the day**				**Caza A**
		19:00 - 22:00	**Cocktail for all registered participants**	**Welcome al participants**				**Angel A, Piso 19**

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SESSION DAY 2	SUBJECT APPLICANT SESSION	TIME	LECTURE	OBJECTIVE	CHAIR OF SESSION	SPEAKERS		ROOM
						Institution	Name	
A1	Management of submission: planning of application and how to prepare application dossier	08:00 - 08:15	A1.1 **Lecture 1**: What do we want?	Understand the dossier preparation process in order to achieve an efficient preparation including the relevant documentation with the objective to ensure high quality expectations.	Mike Tagliaferi Director, Worldwide Safety & Regulatory Operations PFIZER	ABBVIE	Paul Dearden	Fiestas
		08:15 - 08:30	A1.2 **Lecture 2**: What do we need?			GSK	Arturo González	
		08:30 -08:45	A1.3 **Lecture 3**: How we do it?			NOVARTIS	María Anotienta Roman	
		0845 – 10:15	IN FIESTA ROOM A SPECIAL EVENT WILL BE ORGANISED TO ACCOMODATE THE VISIT OF THE REPRESENTATIVES OF THE MINISTRY OF HEALTH AND FEDERAL COMMISSIONER DURING THE INTERNATIONAL WEEK.					Fiestas
			COFFEE BREAK					Independencia B
A2	Management of submission: preparation of applicant dossier/ practice: how to prepare application dossier	10:15 - 10:40	A2.1 Lecture 1: Dossier Preparation and + supporting tools	Understand what is a well-structured, clearly written and complete dossier for ensuring high quality and timely review. Using supporting tools	Mike Tagliaferi Director, Worldwide Safety & Regulatory Operations PFIZER	ANAFAM	Dagoberto Cortes Cervantes	Fiestas
		10:40 - 11:00	A2.2 Lecture 2: How to build quality within the regulatory process of submission	Updating participants about building quality within the regulatory process submission process an how this can be monitored		JANSSEN	Norma Loza	
		11:00 – 11:30	A2.2 Lecture 3: SOP for dossier preparation	Understand what is a well-structured, clearly written and complete dossier for ensuring high quality and timely review. Using shared experience through existing SOP.		SERVIER	Luz Zermeño	
		11:30 - 13:30	A2.3 **Case study** on dossier preparation	Understand and identify what information is needed to reach a level of certainty to solve scientific and administrative issues and to be able to meet the established requirements.		NOVARTIS	Maria Antonieta Roman	
		13:30 - 14:30	LUNCH BREAK					Independencia B
		14:30 – 15:30	ICE BREAKING /STRETCHING ACTIVITY	Ensure focus and attention of participant for the afternoon sessions	Liliana Hernández	CYPRESS, Comunicación	Miguel Ramírez	Fiestas
		15:30- 16:00	A3.1 **Lecture 1**: Overview of the fundamentals for effective communication.	Understand the fundamental (concept, principles and key elements) to ensure effective communication with the interested party		ELY LILLY and CYPRESS, Comunicación	Teresita Olivo and Miguel Ramírez	

2017 APEC RHSC Regulatory Science Center of Excellence (CoE) for Good Registration Management (GRM) - Pilot Workshop
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SESSION DAY 2	SUBJECT APPLICANT SESSION	TIME	LECTURE	OBJECTIVE	CHAIR OF SESSION	SPEAKERS		ROOM
						Institution	Name	
A3	Management of submission: effective communication	16:00 - 16:30	A3.2 **Lecture 2**: Explain effective communication 2.	Group discussions: apply the fundamental of effective communication during the submission process.	Director de Asuntos Regulatorios en Boehringer Ingelheim	ELY LILLY and CYPRESS, Comunicación	Teresita Olivo and Miguel Ramírez	
		16:30 – 16:45	COFFEE BREAK					
		16:45 - 17:30	A3.3 **Case study Case study on** : Effective communication for GRM	Understand how fundamental of effective communication are applied during submission process to ensure optimal output.		ABBVIE and CYPRESS, Comunicación	Cristina Mota and Miguel Ramírez	Fiestas
		17:30 - 18:00	Wrap up and Q&A	Participants will raise questions or request clarification about the lectures delivered		Chair of the session	Liliana Hernández	
		18:00 - 19:00	Organizer meeting (private)	Organizer meeting to review next day and get feedback about the day				Caza A

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SESSION DAY 2	SUBJECT REGULATOR SESSION	TIME	LECTURE	OBJECTIVE	CHAIR OF SESSION	SPEAKERS		ROOM
						Institution	Name	
R1	Managing the review: good review practices (GrevP)	08:00 - 08:10	ICE BREAKING / TRETCHING SESSIONS	Aimed to increase attention and focus in order to prepare the brain and body to enjoy the training sessions of the day	Philip M. Budashewitz USFDA	CYPRESS, Comunicación	Miguel Ramírez	Embajadores
		08:10 - 08:20	R1.1 **Lecture 1**: Overview of review management based on the WHO Good Review Practice (GRevP) Guidelines for Regulatory Authorities.	Principles of quality management and standard operating procedures in the stages of the review process		COFEPRIS (CoE)	Lahouari Belgharbi	
		08:20 – 08:45	R1.2 **Lecture 2**: Experience sharing from different Regulatory Authorities used project management, quality management and standard operating procedures in managing the review a) Mexico - COFEPRIS b) Chile – ANAMED (not confirmed) c) Brazil – ANVISA (not confirmed)	• Introduce principles of a safety and efficacy review. • Explain basic concepts of critical thinking in decisions made by the regulatory authority. • Share important considerations in the review process for decision making by the regulatory authority.		Country experience: a) COFEPRIS b) ANVISA c) ANAMED	a) COFEPRIS (Ivan Calderon Lojero, CAS) b) ANVISA c) ANAMED, Christian Barrueto, ANAMED	
		08:45 - 10:15	IN FIESTA ROOM A SPECIAL EVENT WILL BE ORGANISED TO ACCOMODATE THE VISIT OF THE REPRESENTATIVES OF THE MINISTRY OF HEALTH AND FEDERAL COMMISSIONER DURING THE INTERNATIONAL WEEK.					Fiestas
			COFFEE BREAK					Independencia B
		10:15 - 11:15	R1.3 **Lecture 3**: Sharing experiences between different RNAs: Questions to answer? *1. What are the current practices in managing the review among different economies?* *2. What are the challenges in managing the review among different economies?* *3. What are the gaps in managing the review among different economies?* *4. How to effectively utilize project management, quality management, standard operating procedures, and review process stages in managing the review?*	Share important considerations in the review process for decision making by the regulatory authority. **Methodology**: Each group will wrap up the findings into a presentation that will feedback the main points regarding the current practices, gaps and challenges in managing the review	Philip M. Budashewitz USFDA			Embajadores

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SESSION DAY 2	SUBJECT REGULATOR SESSION	TIME	LECTURE	OBJECTIVE	CHAIR OF SESSION	SPEAKERS		ROOM
						Institution	Name	
R2	Review personel – critical thiniking	11:30 - 12:45	R2.1 **Case study –** a) Dengue vaccines b) Biotechnological Orphan Drug medicines	Case study to learn about critical thinking based on two specific products	Rodolfo Cruz CNQFB	COFEPRIS ,SANOFI, IPN, CMNO-IMSS.	Ivan Calderon Lojero, (CAS), Dr. Gilberto Castañeda Hernández, Dr. en C. José Elías García Ortiz	**Embajadores**
		12:45 - 13:30	R2.2. **Panel discussion**: COFEPRIS, SANOFI, UNAM, CNQFB (if you cannot participate kindly confirm your non participation).	Discussion and exchange with product evaluation experts on the lessons learned, issues and challenge during review process and critical thinking.		Chair of the Session	Rodolfo Cruz CNQFB	
		13:30 - 14:30	**LUNCH BREAK**					
R3	Conducting the review	14:30 - 15:00	ICE BREAKING /STRETCHING ACTIVITY	Ensure focus and attention of participant for the afternoon sessions	ANCF Inés Fuentes	CYPRESS, Comunicación	Miguel Ramirez	**Embajadores**
		15:00 - 15:30	R3.1 **Lecture 2**:.Conducting the review from pharmacokinetic reviewer's perspectives.	Introduction of PK's review points.		UNAM	Helgi Jung	
		15:30 - 16:30	R3.2 **Case study**: Recombinant protein	Case study to learn about critical thinking of PK's review points		IPN	Emilio Medina Rivero	
		16:30 –17:00	**COFFEE BREAK**					
R4	Conducting the review: effective communication including communication fundamentals	17:00 - 17:15	R4.1 **Lecture 1**: Overview of the fundamentals for effective communication.	Understand the fundamental (concept, principles and key elements) to ensure effective communication with the interested party	Jorge Romero, FOMENTO.	CYPRESS, Comunicación	Miguel Ramirez	
		17:15 - 17:30	R4.2 **Lecture 2**: Sharing experiences between different National Regulatory Agencies on effective communication: • Country experience : a) Mexico – COFEPRIS b) Chile – ANAMED c) Brazil - ANVISA	Learning from country experience in developing an applying effective communication during review process to ensure optimal output.		COFEPRIS (Lauro Misael , TAPVS/UNAM. a)Mexico – COFEPRIS b) CHILE – ANAMED c)BRAZIL - ANVISA	COFEPRIS (CIS), ANVISA, Christian Barrueto, ANAMED	

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SESSION DAY 2	SUBJECT REGULATOR SESSION	TIME	LECTURE	OBJECTIVE	CHAIR OF SESSION	SPEAKERS		ROOM
						Institution	Name	
		17:30 - 18:30	R4.3 Case of study	Understand how fundamental of effective communication are applied during review process to ensure optimal output.		CYPRESS, Comunicación and COFEPRIS CIS	Miguel Ramirez and Adriana Contreras	
		18:30- 19:00	Organizer meeting (private)	Organizer meeting to review next day and get feedback about the day				Caza A

2017 APEC RHSC Regulatory Science Center of Excellence (CoE) for Good Registration Management (GRM) - Pilot Workshop
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SESSION DAY 3	SUBJECT COMMON SESSION	TIME	LECTURE	OBJECTIVE	CHAIR OF SESSION	SPEAKERS		ROOM
						Institution	Name	
C5	Development of the GRM training program in each economy and workshop evaluation	09:00 - 09:30	Summary report from previous days from both groups sessions	Listen to summary from both Groups Sessions and raising questions or clarifications about the previous 2 days of training including discussion about the recommendations for the next workshops.	CNQFB-COMECEF Graciela Aguilar	Applicants and Regulators Group representatives	Each group will designate a Speaker to report to the common session	Fiestas
		09:30 - 09:45	C5.1 **Lecture 1**: RAPS Regulatory competency model framework.	Understand the RAPS competency model proposed for regulatory professionals..		COFEPRIS CoE	Lahouari Belgharbi	
		09:45 - 10:15	C5.2 **Lecture 2**: Sharing experience of Applicants and Reviewers in addressing knowledge and competencies gaps. a) OPS/OMS b) CHILE	Sharing experience of applicants and reviewers from institution that have developed a strategy to address gap knowledge and competencies		CHILE OPS/OMS	Christian Barrueto, ANAMED Cecilia Acuna	
		10:15 - 11:00	C5.3 **Panel Discussion** to discuss issues and challenges for building, developing or and or implementing a competency model for good registration management **Panel members**: AMIIF, ANAFAM, UNAM , CNQFB,, Cámara De Comercio Británica Ac, OPS, UC Berkeley, TFDA (if you cannot participate kindly confirm your non participation).	Discuss what is the outline of concrete and immediate actions to address the gap knowledge and competencies meet by regulators and regulatory professionals in the industry and other relevant organisations: • *What do we need: Are there different needs?* • *What do we want: what is the priority?* • *Do we know the best practices documented?* • *Can we apply these models?* • *What are the obstacles and Challenges* • *Do we need to build up a network or system for sharing these models experiences?* • *Recommendations: How to move forward to implement it?*		AMIIF, ANAFAM, , UNAM , CNQFB, Cámara De Comercio Británica Ac, OPS, UC Berkeley, TFDA,	Fernando Fon, Dagoberto Cortes, Socorro Alpizar, Rivelino Flores, Louise Batchelder, Maria Cecilia Acuña, Veronica Miller, Chyn-Liang (Cindy) Huang,	
		11:00 – 11:30	**COFFEE BREAK**					
		11:30 – 12:30	C5.4 **Lecture 1**: Rolling out the GRM training in each economy.	Understand the planning required for documenting: • *Through each organization the existing knowledge in GRevP and GSubP.* • *Indicate also the commitment to implement the knowledge gained to improve the current practices.* • *Recommend action it happen.*	Veronica Miller , Berkeley, School of Public Health, University of	AMIIF, AMID	Fernando Fon or and Sandra Lijia Gonzalez	

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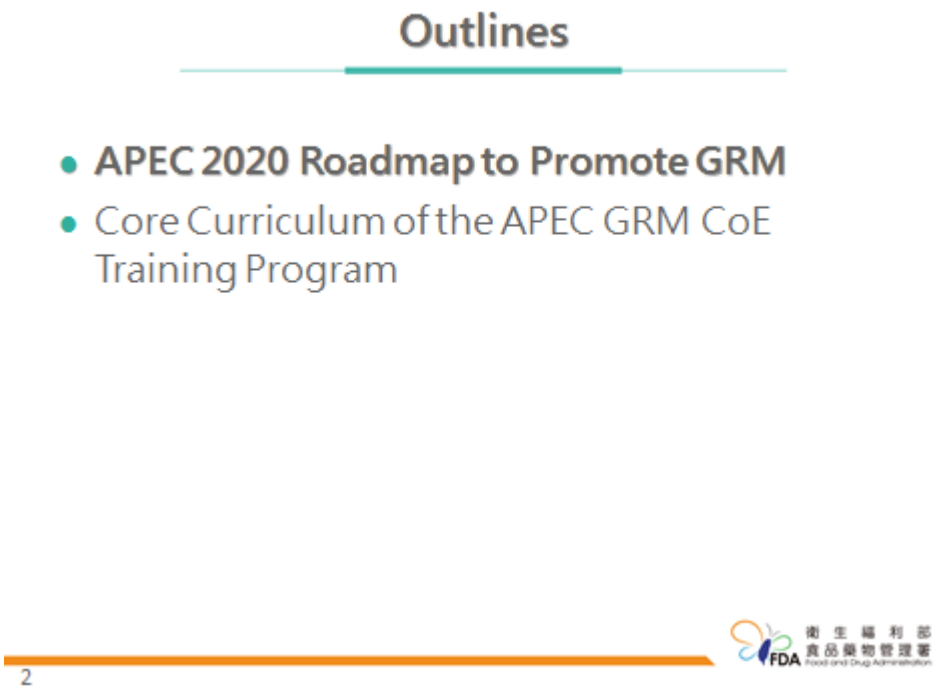
SESSION DAY 3	SUBJECT COMMON SESSION	TIME	LECTURE	OBJECTIVE	CHAIR OF SESSION	SPEAKERS		ROOM
						Institution	Name	
		12:30 - 13:00	C5.5 **Lecture 5**: Introduction to the GRevP and GSubP Training Manuals and discussions for its improvement	• Presentation of the content of the training manual • Discussion on how to improve it.	California	COFEPRIS CoE	Martha Garcia	
		13:00 - 14:00	Wrap up and Q&A	Participants will raise questions or request clarification about the lectures delivered		Chair of the Session	Veronica Miller	
		14:00 - 15:00	**LUNCH BREAK**					Independencia B
		15:00 – 15:30	C5.6 **Lecture 1**:Chinese Taipei FDA Pilot APEC GRM program experience	Share Chinese Taipei on the development and implementation of the APEC GRM pilot program.		Chinese Taipei, FDA	Chyn-Liang (Cindy) Huang (TFDA)	
		15:30 – 16:30	C5.7. **Lecture 1**: Evaluation and results of the workshop.	To present the workshop evaluation feedback from the different commons and specific sessions with regulators and applicants.	Mario Alanis, Director General IC COFEPRIS, International Cooperation.	COFEPRIS CoE	Marcos Daniel	
		16:30 - 17:00	**COFFEE BREAK**					
CLOSING		17:00 - 17:30	**Closing APEC GRM pilot workshop**		Maestro de ceremonias	COFEPRIS	Jorge Romero	

二、本次簡報資料

(一) The APEC 2020 Roadmap to promote GRM and the core curriculum of the training program.



Concept of the GRM

Promote Efficient Registration Process for Medical Products

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Goal of the GRM roadmap and each key element

- Promote the concept of Good Registration Management (GRM)
- Enhance mutual trust for regulatory convergence among the APEC member economies by 2020

Regulatory Harmonization Steering Committee

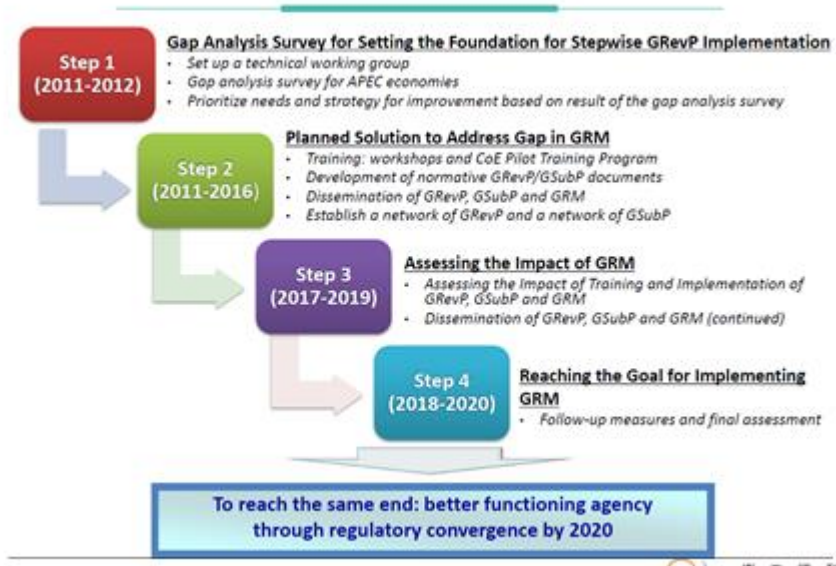
APEC

Life Sciences Innovation Forum

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** aswell as its management.

4

Specific Activities and Timeframe of the GRM Roadmap



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

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

PWA Champions: Chinese Taipei & Japan

CoEs:

- TFDA/RAPS Taiwan Chapter
- COFEPRIS (pilot)

Networks of CoEs for a topic area are possible

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Step 1: Gap Analysis (1)

- Most practices are currently evolving and are applied on an **informal basis.**
- Most agencies have developed **SOPs and guidelines** and **use a variety of training methods.**

✓ **CIRS** conducted a gap analysis survey among 14 APEC regulatory agencies in 2011 and 2012.

Common Approach to Regulatory Review

- ☐ Build **trust and confidence** in each agency's processes
- ☐ Setting the stage for **work sharing**
- ☐ Bringing **consistency and transparency** to the review process

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Step 1: Gap Analysis (2)

- **GSubP:** Several articles addressed the issue of quality of application submissions
  - ✓Indicate necessity of promotion of **GSubP by applicants** & **GRevP by regulatory authorities**

- ☐ Independent Evaluation of FDA's First Cycle Review Performance–Retrospective Analysis Final Report. January 2006 (by Booz Allen Hamilton Inc.)
- ☐ Characterizing Good Review Practices: A Survey Report Among Agencies of APEC Member Economies. TIRS 47(6) 678-683, 2013
- ☐ Building Quality into Regulatory Activities: What does it mean? June 2006 (by CMR International

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Step 2: Planned Solution to Address Gap in GRM (1)

(1) Training: Workshops and CoE Training Programs

- **GRevP training workshops** in Chinese Taipei (2011-2012)
- **GRM CoE Pilot Training Program** including GRevP and GSubP was held in November 2016 in Chinese Taipei

(2) Develop Normative GRevP/GSubP Documents

- **"Good review practices: guidelines for national and regional regulatory authorities"** was published by WHO in 2015.
- **"Good submission practice (GSubP): guideline for applicants"** was endorsed by APAC in 2015 and by APEC RHSC in 2016.

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APEC Good Review Practice Workshop on Medical Products

APEC Regulatory Harmonization on Medical Devices
Good Review Practices: A Key Enabler in Promoting Quality Decision-making
June 25, 2010at Grand Hyatt Hotel, Taipei

APEC Good Review Practice Workshop on Pharmaceuticals
November 3-5, 2010 at Cheng Yung-Fa Foundation, Taipei

APEC Good Review Practice Workshop on Medical Products
October 12-14, 2011 at Cheng Yung-Fa Foundation, Taipei

APEC Advanced Workshop of Good Review Practice on Medical Products
November 6-8, 2012 at the Great Roots Forestry Spa Resort, New Taipei City

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Step 2: Planned Solution to Address Gap in GRM (2)

(3) Dissemination of GRevP, GSubP and GRM

- Presentations in national/international conferences and workshops

(4) Establish Networks of GRevP and GSubP

- The networks may include experts and competent organizations.

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Step 3: Assessing the Impact of GRM

Dissemination of GRevP, GSubP and GRM (continued)

Continue dissemination activity of through national/international conferences and workshops.

Assessing the Impact of Training and Implementation

- Initiate the **training of trainers** for reviewers and applicants.
- **Extend the CoE training program** to full-scale, continue assessing the outcomes of training, and evaluate the impact of implementation.

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Step 4: Reaching the Goal for Implementing GRM

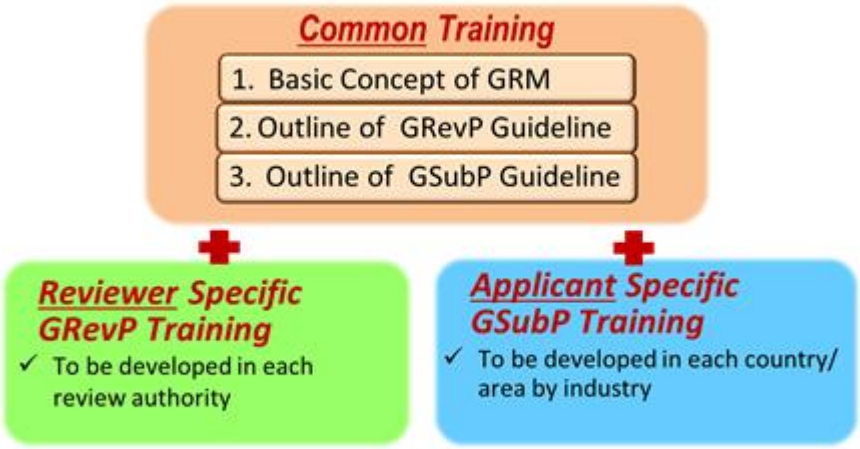
■ Follow-up Measures and Final Assessment

- **Take follow-up measures** according to the outcome of annual assessment conducted in Step 3.
- **Conduct final assessment** and prepare a final assessment report for the outcomes of the GRM roadmap.

Outlines

- APEC 2020 Roadmap to Promote GRM
- **Core Curriculum of the APEC GRM CoE Training Program**

Structure of GRM Training



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Learning objectives and core curriculum were developed based on GRevP guidelines and GSP guidelines

GRevP Guidelines (WHO)

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

GSP Guidelines (APEC RHSC)

Table of Contents

1. INTRODUCTION
2. **PRINCIPLES OF A GOOD SUBMISSION**
3. **MANAGEMENT OF SUBMISSION**
   - Planning for Submission
   - Preparation and Submission of Application Dossier
   - Quality Check
4. **COMMUNICATIONS**
   - Communications with the Review Authorities
   - Communication within Applicants' Organization
5. **COMPETENCY AND TRAINING**
   - Core Competency of Applicants
   - Training and Capacity Building
6. GLOSSARY
7. REFERENCE

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Learning Objectives

To learn the followings for implementation of GRM:

- The principles of GRevP and GSubP
- What is needed for regulators to accomplish good review
  - Conducting and managing the review
  - Good communication with applicants
  - Competency for regulators
- What is needed for applicants to accomplish good application
  - Planning and preparation of application dossier
  - Good communication with regulators
  - Competency for applicants

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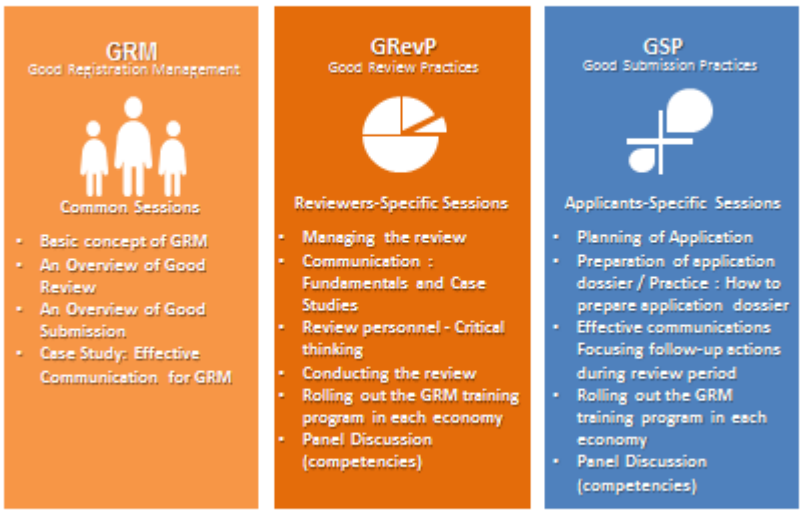
Core Curriculum



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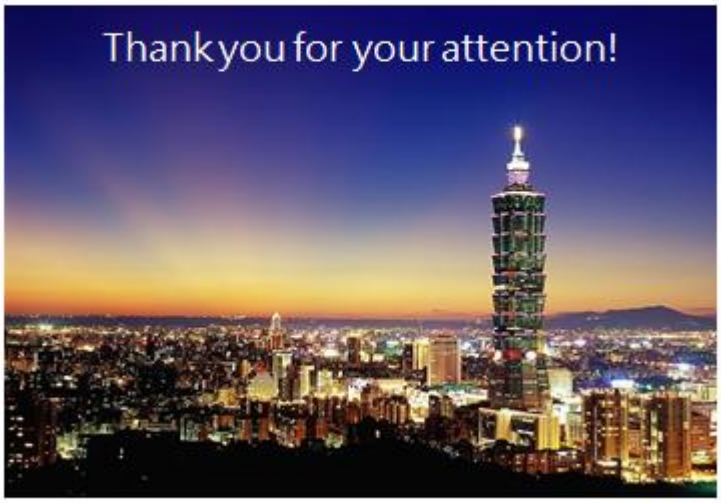


Performance Indicators (GRevP)

1. Roadmap Outputs

Below is a checklist of deliverables upon the successful completion of this roadmap:

1) Good review practices: guidelines for national and regional regulatory authorities. WHO Technical Report Series, No. 992, 2015, Annex 9
2) Materials and reports from "2011 APEC Good Review Practice Workshop on Medical Products" and "2012 APEC Advanced Workshop of Good Review Practice on Medical Products"
3) Training curriculum and materials or e-learning targeting on training of regulators
4) Related documents based on each step of the roadmap, including gap analysis survey reports, final assessment survey report, and progress reports
5) Final assessment report on the impact of this roadmap in promoting GRevP

Performance Indicators (GRevP)

2. Measurable Outcomes

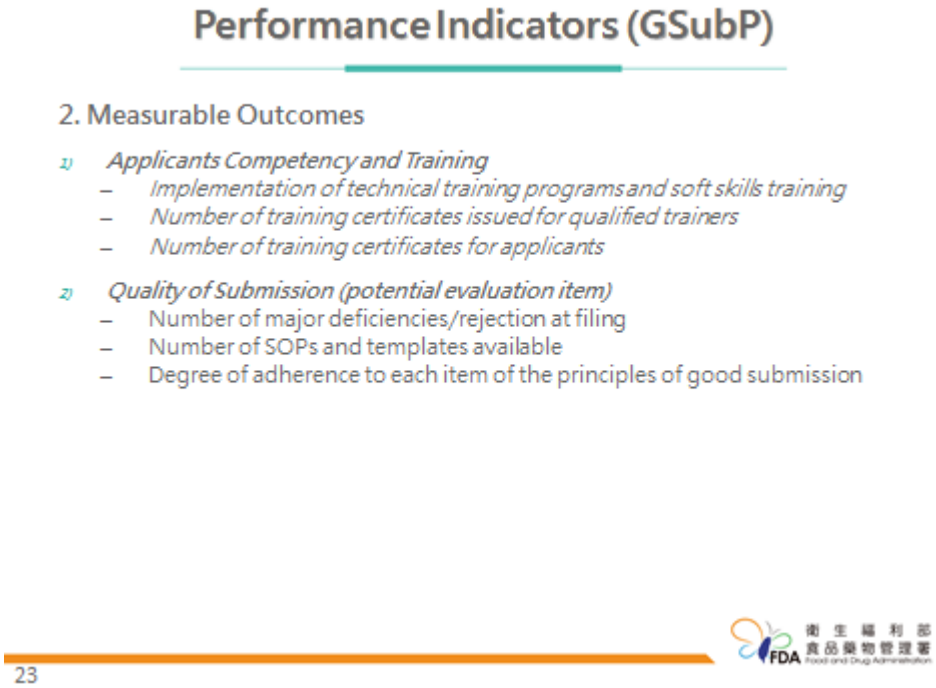
1) *Reviewer Competency and Training*
   - Implementation of technical training programs and soft skills training
   - Number of training certificates issued for qualified trainers
   - Number of training certificates for regulators
2) *Use of Templates and Procedures*
   - Number of SOPs and templates available
   - Degree of adherence required for following SOP
3) *Transparency, Consistency, Predictability and Timeliness*
   - Number/ Type of information accessible by public online
   - Involvement of stakeholders
   - Establish checkpoints and set target timelines for review, and determine how many reviews have met these targets
   - Adoption of peer review
   - Establishment of a quality system

Performance Indicators (GSubP)

1. Roadmap Outputs

Below is a checklist of deliverables upon the successful completion of this roadmap:

1) GSubP Guideline Document for Applicants
2) Training curriculum and materials or e-learning targeting on training of applicants
3) Trainer's manual or handbook (Instructions for trainers on how to conduct training for applicants)
4) Related documents based on each step of the roadmap such as survey report and progress report
5) Final assessment reports on the impact of this roadmap in promoting GSubP



(二) The outcomes of 2016 APEC GRM CoE pilot workshop-experience sharing from TFDA.

Outline

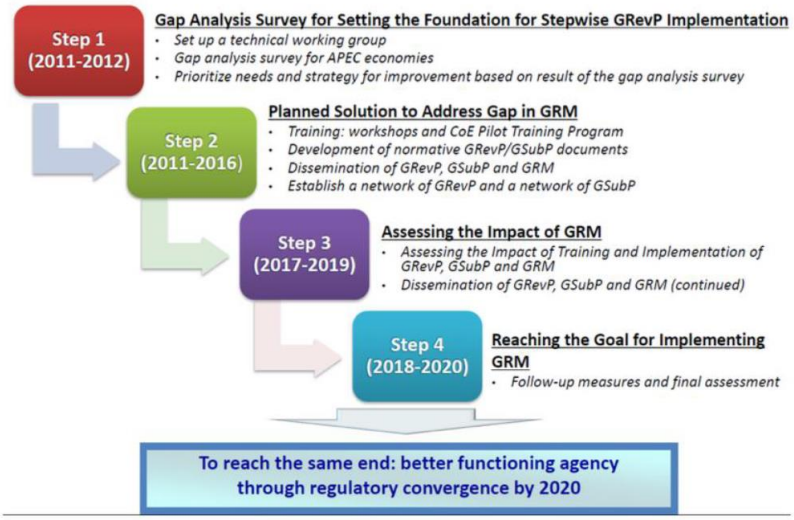
- Promotion of Good registration Management (GRevP and GSubP) in APEC
- 2016 APEC GRM CoE Pilot Workshop
- Conclusion and Future Plan

Goals of the APEC GRM roadmap and each key element

- **GRM:**
  - A concept to promote efficient registration process for medical products by promoting GRevP and GSupP 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 Practice (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 Time frame of the GRM Roadmap



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.
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.**

2016 APEC GRM CoE Pilot Workshop

Workshop co-organizers

APEC LSIF Regulatory Harmonization Steering Committee

Food and Drug Administration, Ministry of Health and Welfare, Taiwan (Chinese Taipei)

Pharmaceuticals and Medical Devices Agency, Japan

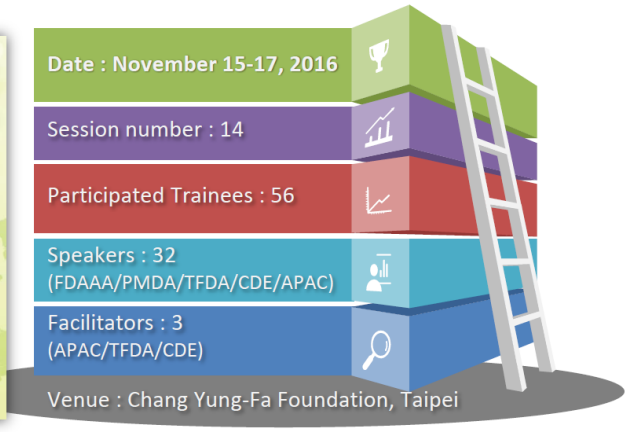
Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs

Asia Partnership Conference of Pharmaceutical Associations

APEC Harmonization Center

Regulatory Affairs Professionals Society (RAPS)
RAPS Taiwan Chapter

2016 APEC GRM Regulatory Science Center of Excellence Pilot Workshop



RAPS REGULATORY AFFAIRS PROFESSIONALS SOCIETY

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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

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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

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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 regulators to accomplish good application
- Planning and preparation of application dossiers
- Good communication with regulators
- Competency for applicants

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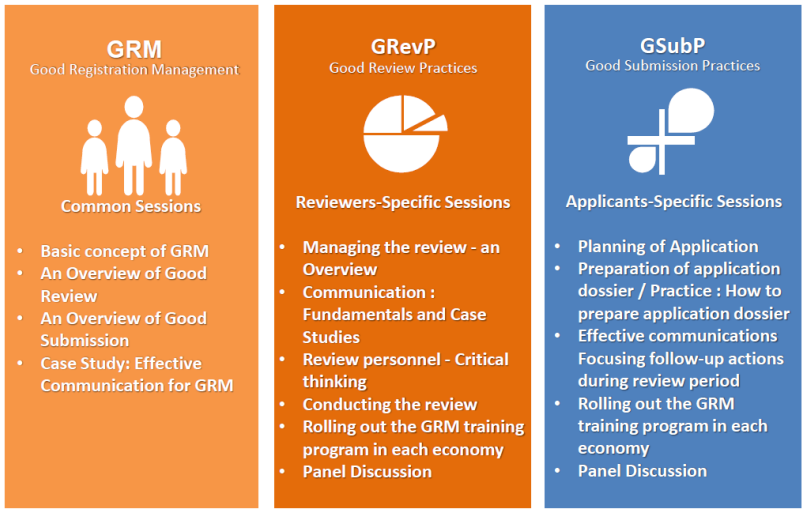
Core Curriculum



Program of 2016 GRM Pilot Workshop

Day 1	Day 2		Day 3	
Common Sessions	***Reviewer Sessions***	***Applicant Sessions***	***Reviewer Sessions***	***Applicant Sessions***
Basic Concept of GRM	Managing the review	Planning of application	Review personnel – Critical thinking	Communication during review period
Overview of Good Review/ Submission	Communication: Fundamentals & Case studies	Prep of application dossiers	Conducting the review	
Effective Communication of GRM			Rolling out the GRM in each economy	Rolling out the GRM in each economy
			Common Session Panel discussion on competency	

Group photo of all GRM participants

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Workshop photos

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Onsite Survey: 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.

Onsite Survey: 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%)

Onsite Survey: 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%)

Onsite Survey: 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%)

Onsite Survey: 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%)

Feedback from Onsite Survey (1)

Feedback from 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

Feedback from Onsite Survey (2)

Feedback from Applicants

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

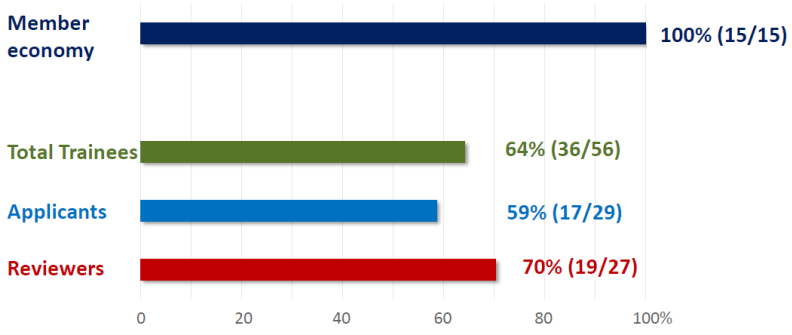
Applicants
Communication
Planning for submission
QC & Dossier Preparation
Case study & group discussion are very good.
All topics
The tools, the exercises.
Section A3. Effective communications - Focusing follow-up actions during review period / Practice: Case study of how to handle inquires

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

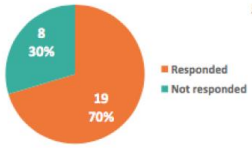
Follow-up survey 2 months after the pilot (1)

Response rate

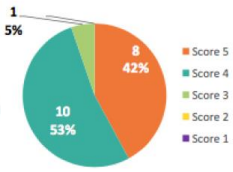


Follow-up survey 2 months after the pilot (2)

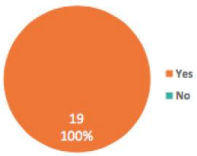
Reviewers



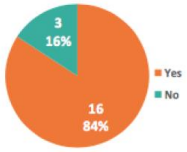
(1) Response rate 19/27 (70%)



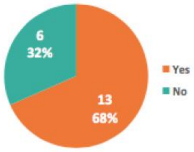
(2) Very helpful in improving review practices 18/19 (95%)



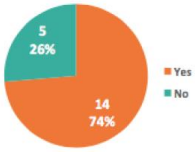
(3) Will recommend colleagues to participate in the workshop 19/19 (100%)



(4) Take action to promote GRM 16/19 (84%)



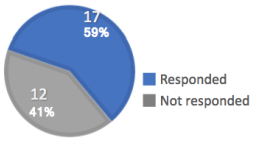
(5) Plan to conduct local training 13/19 (68%)



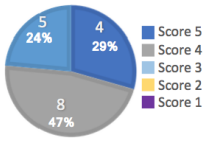
(6) Will use the training manuals to organize training 14/19 (74%)

Follow-up survey 2 months after the pilot (3)

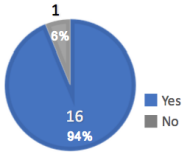
Applicants



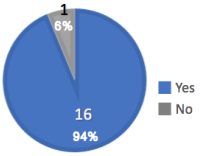
(1) Response rate 17/29 (59%)



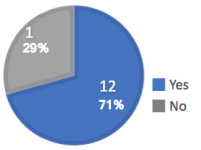
(2) Very helpful in improving submission practices 12/17 (71%)



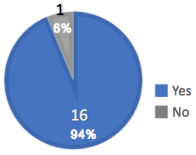
(2) Will recommend colleagues to participate in the workshop 16/17 (94%)



(4) Take action to promote GRM 16/17 (94%)



(5) Plan to conduct local training 12/17 (71%)



(6) Will use the training manuals to organize training 16/17 (94%)

Conclusion and Discussion

- It was a successful CoE pilot with
  - good partnership and collaboration,
  - significant interactive elements, such as interactive discussions, group discussions, case studies, and practices,
  - good rating and overall satisfaction, and
  - Endorsement as a formal CoE by APEC RHSC under the partnership of TFDA and RAPS Taiwan Chapter
- 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”.

Challenges from Organizer's Perspectives

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

Upcoming Event

Program of 2017 GRM Pilot Workshop

<table>
<tr><th>Day 1</th><th colspan="2">Day 2</th><th>Day 3</th></tr>
<tr><td colspan="2">Common Session
Keynote speech: Basic Concept of GRM

Overview of Good Review/ Submission

Experience sharing from different APEC member economies</td><td rowspan="2">Reviewer Session

Review personnel – Critical thinking

Communication: Fundamentals & Case studies</td><td rowspan="2">Applicant Session

Prep of application dossiers

Communication during review period</td><td rowspan="2">Common Session

Communication
-Practices and interactive discussions between reviewers and applicants

Panel discussion on competency

Rolling out the GRM in each economy</td></tr>
<tr><td>Reviewer Session

Managing & Conducting the review</td><td>Applicant Session

Planning of application

Special Considerations and Case Studies for Management of Submission for Generic Drug Applications</td></tr>
</table>

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Food and Drug Administration Ministry of Health and Welfare

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