出國報告（出國類別：參加國際會議）

2013 亞洲醫療器材法規調和會工作小組與英國倫敦大學衛生及熱帶醫學院聯合會議

(2013 Joint Meeting of AHWP WG1a and the London School of Hygiene and Tropical Medicine)

參加會議報告

服務機關：衛生署食品藥物管理局

姓名職稱：劉麗玲組長、楊士德研究技師

派赴國家：香港

出國期間：102 年 4 月 11 日 - 12 日

報告日期：102 年 6 月 20 日

摘要

亞洲醫療器材法規調和會(Asian Harmonization Working Party，簡稱 AHWP)係由亞洲及南美洲各國醫療器材法規主管機關與業者共同組成，為亞太地區推動醫療器材法規調和之重要組織，目前該組織會員國共有 23 個國家。AHWP 現任主席為沙烏地阿拉伯 Saudi Food and Drug Authority (SFDA)的 Dr. Saleh S. Al-Tayyar，副主席為本局醫療器材及化粧品組劉組長麗玲。AHWP 大會轄下設有秘書處及技術委員會，技術委員會共包含 7 個工作小組(Working Group, WG)及 1 個特殊任務小組(Special Task Group, STG)，劉組長亦擔任 WG1a-IVD (In Vitro Diagnostics) 工作小組主席，其主要任務係建立體外診斷醫療器材產品安全性及有效性評估，以及品質系統稽核等要項的國際共同基準規範，以協助各國醫療器材主管機關建立共識，採用相同體外診斷醫療器材管理模式，奠定國際間相互承認之基礎，以促進國際貿易之推動。

為加強開發中國家感染性疾病早期預防、診斷與治療的需求，英國倫敦大學衛生及熱帶醫學院 (London School of Hygiene and Tropical Medicine, LSHTM) 接受比爾蓋茲基金會（Bill & Melinda Gates Foundation）及加拿大國際衛生組織 (Grand Challenges Canada, GCC) 委託，透過劉組長副主席溝通協調，能夠積極與 AHWP WG1a 合作，共同研究並討論有關體外診斷醫療器材管理法規的國際調和化趨勢及價格取得合宜性（Affordable Access to In Vitro Diagnostics through Harmonization approaches，以下簡稱 AAIVD 計畫），期待能藉由建立完善的體外診斷醫療器材管理法規，提升開發中國家人民的健康水準。

本局醫療器材及化粧品組劉組長麗玲於去(101)年已赴香港參加相同會議，並於去(101)年執行並完成該會議所議定之相關工作，使得該計畫繼續得到 Grand Challenges Canada 一年半的經費支持，爰此該學院特別邀請劉組長於今（102）年 4 月 11 日至 12 日至香港參與旨揭會議，會中擔任亞洲體外診斷醫療器材法規論壇之主講人，該學院支付劉組長之機票及住宿費。

藉由參加此次會議，瞭解 AAIVD 計畫工作進度及未來規劃，並於會議中呈現由我國主導之 AHWP WG1a 小組工作成果，有利我國國際能見度之推廣，並進而促成我國療器材法規國際調和化之願景。

目　次

壹、背景

英國倫敦大學衛生及熱帶醫學院(London School of Hygiene and Tropical Medicine, LSHTM)所主導執行 AAIVD 計畫，由 Prof. Peeling 在 2012 年於 11 月 3-7 日在台北舉行的第 17 屆亞洲協調工作小組會議（AHWP）進行一場正式的演講。使得該計畫現已併入 AHWP WG1a 2012-14 年工作計劃。在這個計畫經過了一整天的研討會(101 年 11 月 6 日)，從產業、學術和衛生主管機關各界代表得到了豐富的回饋與寶貴意見。該計畫被視為是一個積極正面的策略來達成體外診斷醫療儀器國際法規之調和化。也有人建議並期待，這計畫將對在有些目前沒有醫療儀器管理的國家，準備在國內銷售的醫療設備之開始查驗登記是非常重要的工作。

建構在現有的基礎上，AHWP WG1a 同意與 LSHTM 合作進行 IVD 管理法規的國際調和，並同時執行在四大目標的先導計畫：共同的查驗登記送審表(common dossier submission)，製程品質查核(Quality system/facility inspection)，減少重複性臨床試驗(reduction in duplication of clinical trials)和上市後監測(post-marketing surveillance)。 AHWP 運用 GHTF 的指導文件為基本原則並深化成為亞洲會員國實際執行的管理法規準則，透過持續不斷的教育訓練，並會繼續努力與國際醫療儀器監管聯邦（IMDRF）在醫療器材法規調和這四個方面領域取得進展。

AAIVD 計畫已獲得第二階段的資助，其中主要重點是透過上述四大目標的領域，在非洲建立具規模的 IVD 管理法規先導計畫。本次會議舉行之目的是要了解如何建立於 AHWP 和加拿大國際衛生組織(Grand Challenges Canada, GCC)地區各方如泛非協調工作小組（Pan-African Harmonization Working Party, PAHWP）和拉丁美洲 IVD 協會（Latin America IVD Association , ALADDIV）之間的協同合作機制。也有計劃建立技術工作小組 (Technical working groups)，重點對 IVD 國際法規之調和化所相關的四大目標領域確定為優先執行。

貳、目的

這是第三次會議 LSHTM 和 AHWP WG1 小組針對 AAIVD 計畫的聯合會議。第一次會議於 2012 年 2 月 6 日至 7 日在香港舉行，第二次是在 2012 年 5 月在台北舉行。這第三次會議的會議目標是：

1. LSHTM 和 AHWP WG1 小組共同面對面討論並檢討 GCC 第 2 階段 AAIVD 計劃目標和工作項目。

2. 為了 GCC 所支持的計畫第二階段項目和 AHWP WG1 之間的合作、協調和基礎建設平台所作的集思廣益。

3. 以四大目標為出發點，要商定並確認 IVD 國際法規之調和化所需的工作進程時間表，里程碑和下一步的先導工作計劃

貳、議程

2013 亞洲醫療器材法規調和會工作小組與英國倫敦大學衛生及熱帶醫學院聯合會議於香港舉辦，為期共 2 天(4 月 11 日至 4 月 12 日)，會議議程如下：

4 月 11 日

Chair: Rosanna Peeling

14:00 – 14:05	Welcome	
14:05 – 14:30	Introduction to Phase 2 of the Grand Challenges Canada Project on Affordable Access to IVDs Meeting objectives and expected outcomes	Rosanna Peeling
14:30 – 15:00	Updates on The Asia Harmonization Working Party IVD subgroup work plans	Li-Ling Liu
15:30 – 15:45	Break	
15:45 – 17:00	GCC and AHWP IVD subgroup programme synergies and mechanism for collaboration: - Pan African Harmonization Working Party (PAHWP) progress and plans for 4 areas of harmonization: i) common submission template ii) quality system inspections iii) reduction in duplication of clinical trials iv) post-marketing surveillance - Twinning of TWGs - Capacity building plans	All
17:00 –18:00	Comments on the 3 IVD documents issued for WG01a	Jeffrey Chern
18:30	Group Dinner (Jasmine Chinese Restaurant, G-25 Festival Walk, Kowloon Tong)	

4 月 12 日

Chair: Li-Ling Liu

09:00 – 09:30	Recap of first day	Rosanna Peeling
09:30 – 10:30	Develop a workplan for piloting an IVD through the 4 areas targeted for harmonization with timelines and milestones	All
10:30 – 11:00	Break	
11:00 – 12:00	Develop a workplan for piloting an IVD through the 4 areas targeted for harmonization with timelines and milestones (cont'd)	All
12:00 – 12:30	Summary of meeting outcomes and next steps	All
13:00	Close of Meeting - Lunch	

肆、會議內容及心得

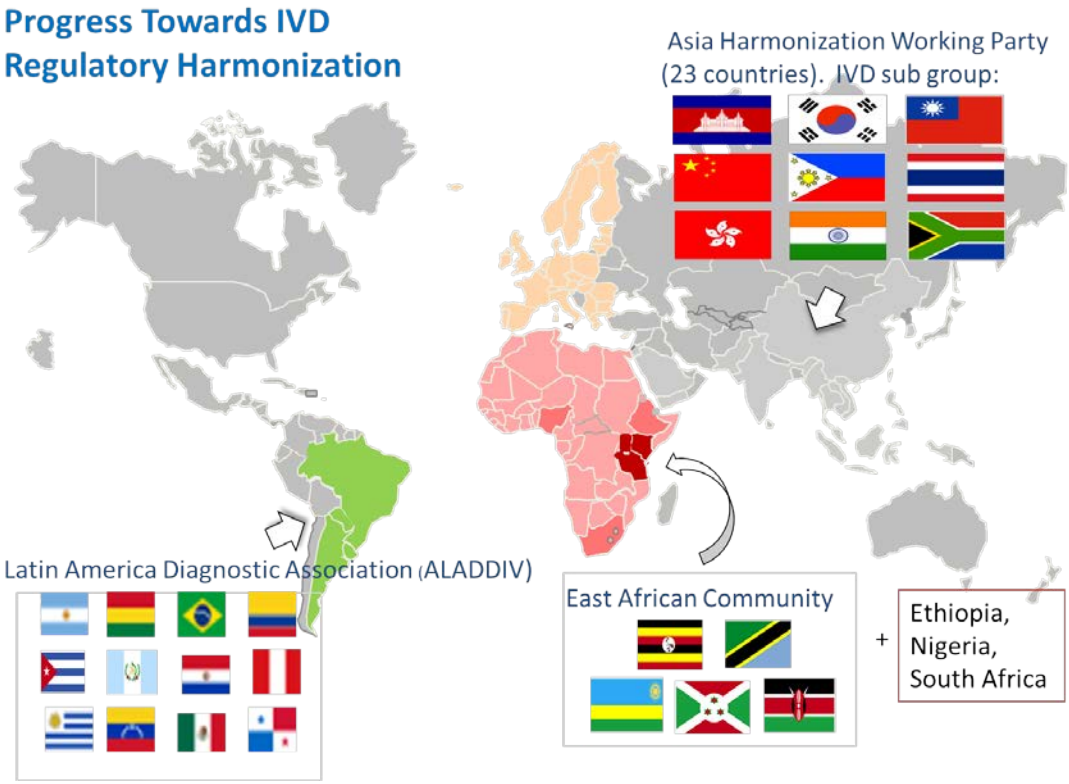
亞洲醫療器材法規調和會(Asian Harmonization Working Party，簡稱 AHWP)係由亞洲及南美洲各國醫療器材法規主管機關與業者共同組成，為亞太地區推動醫療器材法規調和之重要組織，AHWP 現任主席為沙烏地阿拉伯 Saudi Food and Drug Authority (SFDA)的 Dr. Saleh S. Al-Tayyar，副主席為本局醫療器材及化粧品組劉組長麗玲。

AHWP 大會轄下設有秘書處及技術委員會，技術委員會共包含 7 個工作小組(Working Group, WG)及 1 個特殊任務小組(Special Task Group, STG)，分別為 WG1 Pre-Market Submission and CSDT、WG1a IVDD、WG2 Post-Market Surveillance and Vigilance、WG3 Quality Management System、WG4 Quality System Audit、WG5 Clinical Safety/Performance、WG6 Capacity Building and Regulatory Training 以及 STG (N) Medical Device Nomenclature 等小組，本局醫療器材及化粧品組劉組長麗玲，除係 AHWP 副主席外，亦係 WG1a-IVDD 工作小組主席。

根據報告(Lewin Group. The value of diagnostics: Innovation, adoption and diffusion into health care. Falls Church, VA, Lewin Group, 2005)指出，醫學診斷項目占健康照護總支出有 1-2%，但診斷報告確影響 60-70%臨床決策。因此，體外診斷醫療器材研究發展、生產製造、臨床評估與審查上市已在全球生技產業中扮演相當重要的一環。其中，體外診斷醫療器材管理法規含概產品全生命週期(Total Product Life Cycle)之整體過程安全性及有效性，尤其是臨床評估對體外診斷醫療器材研發上市，具有關鍵性影響。為加強開發中國家感染性疾病早期預防、診斷與治療的需求，英國倫敦大學衛生及熱帶醫學院 (LSHTM) 接受比爾蓋茲基金會（Bill & Melinda Gates Foundation）及加拿大國際衛生組織 (Grand Challenges Canada, GCC) 委託，透過本局劉組長(AHWP 副主席以及 AHWP WG1a 主席)溝通協調，能夠積極與 AHWP WG1a 合作，共同研究並討論有關體外診斷醫療器材管理法規的國際調和化趨勢及價格取得合宜性（Affordable Access to In Vitro Diagnostics through Harmonization approaches，以下簡稱 AAIVD 計畫），期待能藉由建立完善的體外診斷醫療器材管

理法規，提升開發中國家人民的健康水準。

劉組長在領導 AHWP WG1 上完成的 2012 年工作成果，受到 LSHTM 方面重視與肯定，使得該 AAIVD 計畫繼續得到 Grand Challenges Canada 一年半的經費支持，本次會議舉行之目的是要了解如何以 AHWP WG1a 所建立 IVD 管理法規調合化為基楚，並持續和 LSHTM 在地區各方如泛非協調工作小組（PAHWP）和拉丁美洲 IVD 協會（ALADDIV）之間的協同合作機制(圖一)。這樣的國際合作，可讓 TFDA 立足亞洲，建立洲際 IVD 國際法規之調和化，對我國的外交工作有正面的意義。



圖一: 立足亞洲，建立洲際 IVD 國際法規之調和化

今(102)年 4 月 11 日至 12 日至香港生產力中心，本局劉組長率團代表 AHWP 副主席及 AHWP IVD Working Group 1a 與英國倫敦大學衛生及熱帶醫學院 Rosanne Peeling 教授雙方進行 Joint Meeting of AHWP WG1a and the London School of Hygiene and Tropical Medicine，本局劉組長領導本工作小組來全力支持此項跨洲的國際合作，並於聯合會議中達成幾項成果與共識:

1. 首先 Rosanne Peeling 教授介紹本次會議之議程及目地，之後給一個開場演講

(Keynote speech)，提到有些非州國家因缺乏行政法規與經驗來管理醫療器材，這樣使得民眾在一般超市或藥局容易買劣質的醫療器材，其安全及有效性令人擔憂，民眾的健康更是沒有受到保障。另一方面，具有好的 R&D 部門的公司依照產品的全生命週期所發展出優質的醫療器材，卻面臨當地政府缺乏行政法規以造成產品無法或延遲上市。為解決這些問題，LSHTM 找到問題根源在於需建立完整的醫療器材管理行政法規以及國際法規之調和化。IVD 醫療器材管理是首要的目標，因此 AAIVD 第二期計畫(圖二: GCC phase II)就以此而生。其經費來源與後續的支持，目前執行進度與成果，面臨的挑戰與契機，以及未來預定執行的四大目標(如表一)，來針對特定的 Point-of-care(POC) IVD 來促進並改善開發中國家之相關的 IVD 醫療器材法規調合:

- **To incentivise and accelerate innovation, we need to create more opportunities for interactions between industry, public health policy developers, regulators, and researchers/experts/users** :
  - Public health needs
  - Purpose of diagnostics and where diagnostics will be deployed (technology assessment/placement)
  - Target product profiles including performance expectations
  - Environmental requirements
  - where trade-offs are acceptable
- **Expected outcomes:**
  - **Streamlined regulatory approval process**:
    - Common dossier for review that the test is fit for purpose
    - Facility inspection: mutual recognition or recognition of third parties
    - Performance studies: standardised protocols, network of trial competent sites, joint review of data
  - **Reduced barriers to market entry for companies:**
    - better understanding of TPP and performance expectations
    - access to sites in disease endemic countries to optimise environment requirements of POC tests
    - access to trial sites which are competent to conduct performance studies using standardised protocols
    - more clarity on price point to make a business case for investment, including cost of regulatory approval (currently a major disincentive where regulatory systems are not transparent)
  - **Accelerated policy development/adoption and scale up:**
    - models for technology assessment and strategic placement of new technologies to ensure greatest impact and cost-effectiveness
    - policy development and scale up
    - post-market surveillance to assure the quality of tests and testing

圖二: GCC phase II

甲、 制定一套共同標準格式的查驗登記的送審表(common dossier for registration)

乙、　建立單一稽查系統來促進相互認定 QMS/GMP (facility inspection)

丙、　研擬特定的機制來避免重複的臨床測試 (Reduction of duplicated clinical trials)

丁、　發展 IVD 醫療器材之上市後品質監控系統 (Post-market surveillance)

Item	Status quo	Proposed Harmonisation model	Impact
Dossier for registration	Forms unique to each country	-Standardize template for registration: *Summary Technical Documentation* (STED) or *Common Submission Dossier Template (CSDT)*; -develop capacity for Good Review Practice	Save companies time and costs Standardised template easier to review and require less time
Facility Inspections	-ISO 13485 -Unique visits by NRAs; delay in approval due to long queues and high costs to companies	-adoption of common standard -mutual recognition of audits -recognition of third party audits	Shorten time to approval and reduce costs
Clinical Trials	Large number of trials conducted for each product	-Standardised trial protocol -Network of competent sites -Joint review of trial data but final approval country specific	-Approval in more countries with fewer trials; -clear and transparent path for approval -reduced costs for companies
Post-marketing surveillance	Limited capacity for identifying low quality products and product failures	-Network of evaluation sites act as sites for post-marketing surveillance	Ensure quality of tests post approval
Capacity building	Many countries do not regulate IVD; NRAs increasingly risk adverse	More streamlined approval process and keeping low quality products from entering the market	Better balance between risk vs benefit

表一: Standardization and Harmonization

雙方(AHWP WG1a 與 LSHTM)根據這四大目標及 2013AAIVD 計畫白皮書草稿，逐一且深入討論詳細的執行內容與解決方案，並訂定相關工作的時程表。

2. 劉組長代表 AHWP WG1a 回顧工作小組於去年(101)執行並完成所議定之相關工作，同時展望今年(102)所預定達成的目標，這樣大格局的領導風範受到 LSHTM 代表的認同。

3. 接著，劉組長指示工作小組成員，報告如何深入執行相關工作的細節，並把目前執行的成果展現給 LSHTM 的代表，經過雙方熱烈討論後，也確任未來 1 年的工作執行項目。

4. 經劉組長於會議中積極溝通、協調與爭取，LSHTM 的代表同意提撥 35,000 美金(此經費比去年多 2-3 倍)來協助 AHWP WG1a 執行雙方預定要的達成共識與目標。主要有以下兩大重點:

甲、 研擬並制定一系列的具法規調合之準則或基準來協助開發中國家來有效管理 IVD 醫療器材，尤其是要擬定 IVD 醫療器材的 GCP(Good Clinical Practice)為首要工作。

乙、 依據上述四大目標以及制定法規調合之準則或基準，分別的舉行 IVD 醫療器材國際研討會與相關的訓練課程(含臨床評估及案例介紹)，並邀請 AHWP 會員、開發中國家法規人員、各國法規人員 Stakeholders 及國內產官學界先進代表來共襄參與。

此次會議不但展現了我們政府國際合作的執行力並重視 IVD 醫療器材之臨床評估的發展、國際法規之調和化與世界的趨勢，也透過 LSHTM 代表的反應與誠意證明了劉組長帶領本局醫粧組國際合作是值得肯定，我們會繼續努力。

肆、建議

1. 透過國際合作來分享我國醫療器材法規管理經驗

由於 AHWP WG1a 主要由 TFDA 劉組長來帶領，除了融合亞洲各會員對 IVD 醫療器材法規管理經驗，再加上我國 IVD 醫療器材法規管理經驗，透過國際合作來協助其他國家發展所需的 IVD 醫療器材管理法規。AHWP WG1a 與 LSHTM 合作模式與執行成果就是一個成功的案例。

2. 向國際組織來爭取經費以提升我國醫療器材管理與產業發展之能量

醫療器材管理與產業發展是國際性業務，如果單靠本國市場、現有的產業結構及有限的政府預算是無法來推動的，借著 AHWP WG1a 與 LSHTM 國際合作模式並向國際組織來爭取經費，期可提升我國醫療器材管理之品質與效率外，亦可增進我國醫療器材產業之國際競爭力。

3. 舉辦國際性研討會協助國內醫療器材產業與國際接軌

有了國際組織的經費及各項資源支持，建議可由醫療器材主管機關主辦國際醫療器材法規訓練課程及研討會，邀請各國醫療器材主管機關代表及國際醫療器材大廠專家，說明各國醫療器材法規管理現況，提供國內廠商參與國際會議之機會，同時，國內廠商亦可推廣我國自行研發的醫療器材，以達到相輔相成的雙贏局面。

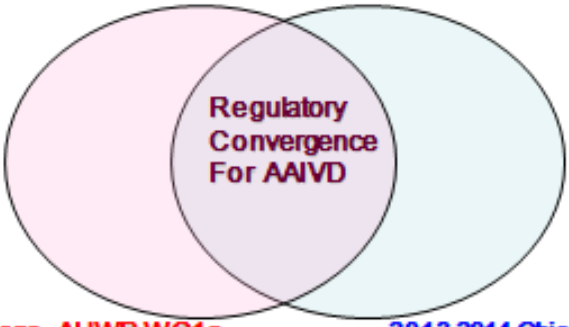
附件 1

Regulatory Convergence for AAIVD Medical Devices

AHWP WG1a-LSHTM Future Collaboration Initiatives

AHWP WG1a IVDD

Moving towards Regulatory Convergence for AAIVD Medical Devices



2012-2014 Missions, AHWP WG1a
(1) To develop AHWP IVD medical devices guidances
(2) To facilitate capacity building and training activities for AHWP member economies and other developing countries

2013-2014 Objectives, LSHTM
(A) A common dossier submission
(B) Reduction in the number of quality system audits
(C) Reduction in the duplication of clinical trials
(D) Post-marketing surveillance

AHWP WG1a-LSHTM Collaboration

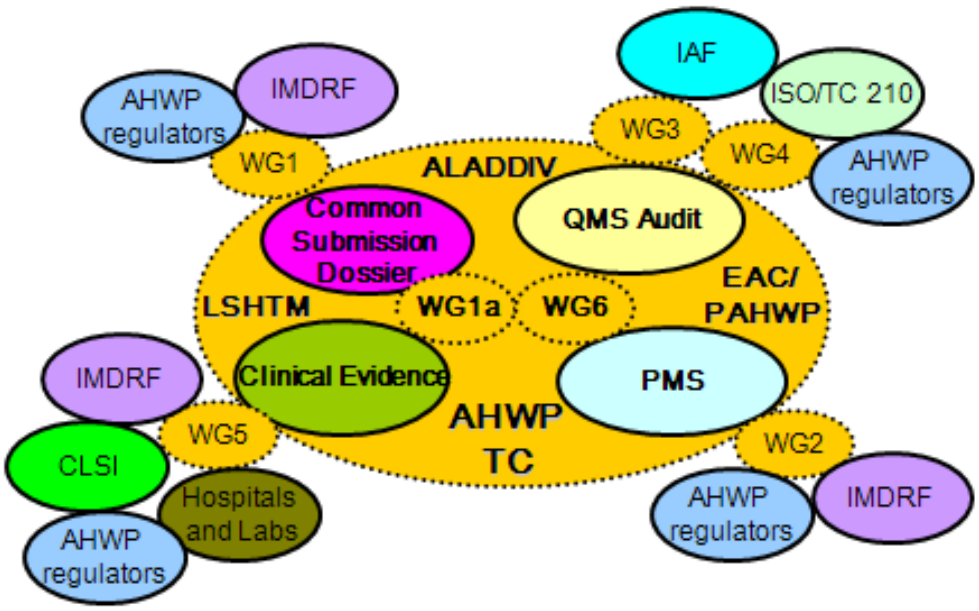
AHWP WG1a progress and plans \ AAIVD Four objectives		(A)	(B)	(C)	(D)
2012 Achievement	(1) Three GHTF Final Documents	✓	✓		
	(2) Recommendations on the use of recognized standards in safety and performance evaluation of IVD medical devices	✓	✓		
	(3) Two international conferences on May and Nov.	✓	✓	✓	
	(4) CSDT-STED comparison done	✓			
2013 KPI[a]	(1) 3 IVD Regulatory Guidances	✓	✓	✓	✓
	(2) Training for AHWP Member Economies (Proposed **IVD Medical Devices Regulations conference** on Sep, 2013)	✓	✓	✓	
	(3) Affordable and Accessible IVD Medical Devices (Proposed "**POC IVD Medical Devices Symposium**" on Sep, 2013)	✓	✓	✓	✓

[a] KPI: Key Performance Index

AHWP WG1a Proposed Documents (Draft)

Doc. No.	Title	Status
AHWP/WG1a/PD001	Strategies for Implementing Regulatory Framework and Affordable Access to IVD Medical Devices	Draft of Proposed Document
AHWP/WG1a/PD002	Essential Principles of Safety and Performance of Medical Devices	Draft of Proposed Document
AHWP/WG1a/PD003	STED for Demonstrating Conformity to the Essential Principles of Safety and Performance of In Vitro Diagnostic Medical Devices	Draft of Proposed Document

Regulatory Convergence Platform for AAIVD Medical Devices



Regulatory Convergence Platform for AAIVD Medical Devices

Objective	Time	Work Items	Remark
1. Common Submission Dossier	Mar-May 2013	Revision of AHWP/WG1a/PD001D - PD003D	.Revision of regulatory guidances (DPD) **.STED-CSDT comparison refined** **.Drafting POC CD4 submission template**
	June-Sep 2013	Public consultation of AHWP/WG1a/PD001D - PD003D	. In-country consultations in EAC and PAHWP .Revision of regulatory guidances (PD) **. IVD Medical Devices Regulations Conference (Sep 2013)** **. POC IVD Medical Devices Symposium (Sep 2013)**
	Jan-Apr 2014	Pilot program of the submission template	Optimization of the submission template
	May-Aug 2014	Adoption of the template	Implementation at GHD, NRAs level

Proposed Topics of IVD Medical Devices Regulations Conference (Funded by TFDA)

- **Proposed time**: Sep 2013
- **Proposed topics:**
  - Regulations updates (US, EU, Japan, China/Korea, Taiwan)
  - Safety and performance evaluation
  - Case studies for the POC IVD device
  - Harmonization and regulatory convergence
- **Expected audience:**
  - AHWP member economics
  - Domestic stakeholders in Taiwan
  - The member economies of **EAC/PAHWP and ALADDIV**

POC IVD Medical Devices Symposium

- To be held in Sep 2013, a side event along with the aforementioned conference
- Proposed topics:
  - **Potential inter-regional collaboration initiatives on GRP, GMP, GCP for IVD medical devices**
  - **POC CD4 test common submission dossier template**
  - **POC CD4 test case study**
    - Product demonstration
    - Bibliography and literature review
    - Current performance characteristics and clinical evidence review
    - Regulatory pathway delineation
- Expected Audience: AHWP, EAC/PAHWP,ALADDIV, IMDRF member economies, standardization bodies, clinical laboratories, hospitals, etc.

Regulatory Convergence Platform for AAIVD Medical Devices

Objective	Time	Work Item	Remark
2. QMS Audit	Mar/Apr 2013	Review on current regulations and recognized standards related to QMS	.Status report and gap analyses **.Identify regulations and related standards**
	May-Nov 2013	Training	**.Facilitate training on:** **.Labeling and traceability** **.IQC and materials control** **.Process validation and suppliers control** **.Handling, protection, storage, packaging** .Liaise to ISO/TC210, AHWP WG3, WG4 **.Proposal to AHWP in alignment with the AHWP conference under AHWP-RAPS MOU**
	Jan 2014	GMP pilot program I	.Plan for GMP pilot program **.Development of inspection protocol and checklists**
	Feb-May 2014	GMP pilot program II	.Launch of the pilot program .Optimization of the GMP

Regulatory Convergence Platform for AAIVD Medical Devices

Objective	Time	Work Item	Remark
3. Clinical Evidence	Mar/Apr 2013	Revision of AHWP/WG1a/PD001D -PD003D	.Revision of regulatory guidances (DPD) .Discuss EP, recognized standards on performance evaluation
	Apr/May 2013	Clinical Evaluation for IVD medical devices I	.Collaborate with IMDRF, AHWP WG5 .Identify regulations and standards for clinical performance evaluation and GCP .Technical consultation on the RFA on clinical trial for IVD
	May-Sep 2013	Clinical Evaluation for IVD medical devices II	.Collaborate with IMDRF, AHWP WG5 .Revision of regulatory guidances (PD) **.IVD Medical Devices Regulations Conference (Sep 2013)** **. POC IVD Medical Devices Symposium (Sep 2013)** **.Technical preview of POC CD4 clinical evaluation information** **.Drafting guidance on GCP and clinical performance evaluation**
	Sep 2013-May 2014	IVD clinical trial pilot program I	Preparation for pilot program .Sites .Databases
	May-Aug 2014	IVD clinical trial pilot program II	.Launch of pilot program .Implementation at GHD, NRAs level

APEC "Best Regulatory Practice" Project

- *"Best Regulatory Practice of Medical Products for Trade Facilitation"*
  - A strategic approach for *Good Review Practice (GRevP)*
- **Co-sponsoring APEC Economies:**
  - Canada, China, Indonesia, Korea, Malaysia, Mexico, Peru, Philippine, Thailand and United States
- **Three key objectives**
  - To *reduce regulatory burden* and *achieve timely market* access of medical products through the adoption of best regulatory practice
  - To *establish mutual confidence* in the assessment reports of regulatory authorities within the APEC region
  - To *provide a platform* for regulatory dialogue

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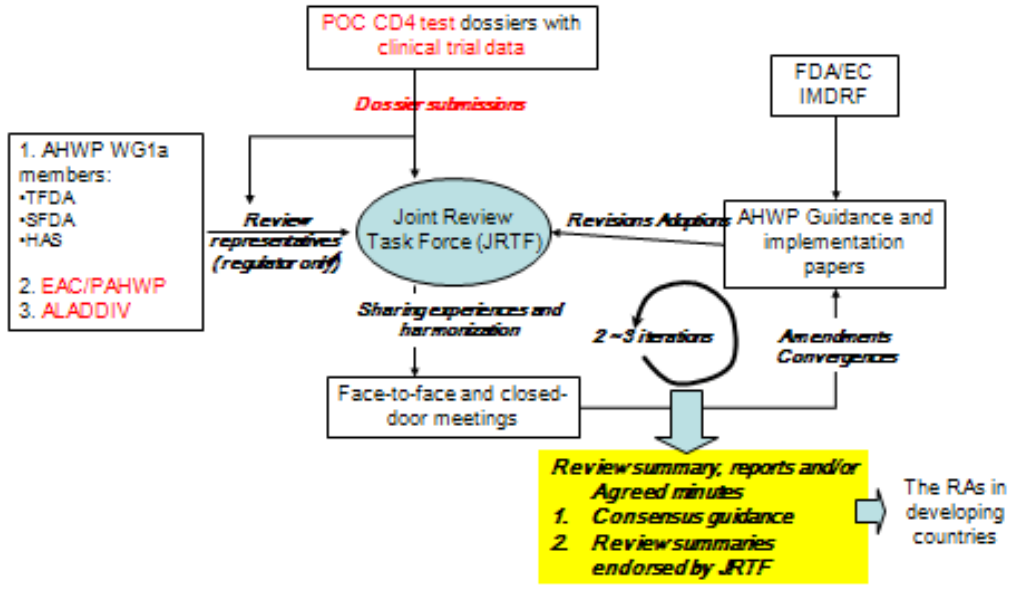
APEC "Best Regulatory Practice" Project

- A **gap analysis survey** characterizing the good review practice (GRevP) of APEC member economies was completed in Nov. 2012.
- A draft roadmap titled "2020 Roadmap for GRevP on Medical Products" was **endorsed (in principle)** by Regulatory Harmonization Steering Committee (RHSC) in Aug. 2012
- Sponsored **four GRevP Workshops** held in Taipei:
  - Kick-off Workshop (Medical Devices) held June 2010
  - Kick-off Workshop (Pharmaceuticals) held Nov. 2010
  - Basic Workshop held Oct. 2011
  - Advanced Workshop held Nov. 2012

Establishing a Consultative Network for Medical Devices Industry and Enhancing the Quality of Medical Devices Clinical Trial System

- Establishing the consulting network for medical device industry
- *Applying "Good Clinical Practices (GCPs)" to enhance the quality of medical device clinical trial*
- *Building training capacity for regulatory seed personnel*
- Advancing regulations of medical device

A Regulatory Model for Affordable and Accessible POC IVD Medical Devices



Regulatory Convergence Platform for AAIVD Medical Devices

Objective	Time	Work Item	Remark
4. PMS	Mar/Apr 2013	Review on current regulations and recognized standards related to PMS	.Status report and gap analyses .**Identify regulations and related standards:** .**ANCAR** .**SADS**
	May 2013	Training	.Collaborate with IMDRF, ISO/TC210, AHWP WG2 .**Delivers training** .Feedbacks to ISO/TC210, AHWP WG2 .**Technical consultation**
	Jun 2013-Feb 2014	POC IVD PMS pilot program I	.Collaborate with IMDRF, ISO/TC210, AHWP WG2 .**Preparation for pilot program**: .Capacity building .Infrastructure .Databases
	Sep 2013-May 2014	POC IVD PMS pilot program II	.Launch of pilot program .Optimization of the PMS system .**Validation**
	Jun-Aug 2014	Implementation of online PMS system	.Feedbacks to ISO/TC210, AHWP WG2 .**Technical consultation** .Official implementation of online PMS system

Collaboration Initiatives

- Drafting POC CD4, Dengue and TB Test common submission dossier
- POC IVD Medical Devices Symposium (Sep 2-6, 2013)
- Drafting guidances on GCP and clinical performance evaluation for IVD medical devices
- Development of inspection protocol and checklists for IVD medical devices QMS audit
- Training on the following:
  - GCP
  - GMP
  - **GSP (pilot in Taiwan)**
  - GRP (Documents will be released at the end of this year)
  - **GVP**
  - **GAP or GIP??**