出國案件 C10101103

參與第二段階段「台歐醫療器材優良製造規範 GMP 稽核報告交換技術合作方案」討論會議

「台歐醫療器材優良製造規範 GMP 稽核報告交換技術合作方案」

服務機關：行政院衛生署食品藥物管理局 醫療器材及化粧品組
姓名職稱：劉麗玲 組長、呂理福 簡任技正、陳志宏 薦任技正

派赴國家：比利時、英國

出國期間：101 年 3 月 10 日~101 年 3 月 18 日

報告日期：101 年 5 月 31 日

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壹、 摘要

本次出國係參與第二階段『台歐醫療器材優良製造規範 GMP 稽核報告交換技術合作方案』討論會議，於 101 年 3 月 10 日啓程，經曼谷直飛荷蘭阿姆斯特丹，再轉往首站比利時布魯塞爾，於 3 月 12 日赴歐盟總部，爭取我國醫療器材廠優良製造規範稽核報告能獲得歐盟相關機構之承認，以減少重複稽核，隨後於 3 月 13 日轉往英國倫敦，此行赴英主要目的有二：(1) 3 月 15 日拜會英國衛生部門，磋商有關我國醫療器材廠 GMP 在進入歐盟地區的英國，有關 ISO13485 的驗證簡化事宜，並瞭解英國醫療器材邊境管理的執行方式與成效；(2) 3 月 16 日參加第二階段「台歐醫療器材優良製造規範/GMP 稽核報告交換技術合作方案」討論會議及瞭解合約簽署相關議題意見交換:；並利用 3 月 14 日行程空檔期間，安排當日上午參觀英商史耐輝股份有限公司(Smith & Nephew Orthopaedics Ltd)，有關骨科醫療器材之研發、設計及製造現場；下午則轉往英國倫敦市區訪問 UKAS, United Kingdom Accreditation Service， 探詢 UKAS 之認證及驗證作業，以就近了解英國 MHRA 與認證單位間的互動模式。

此行的最大特點在行前準備縝密，並將執行『台歐醫療器材優良製造規範 GMP 稽核報告交換技術合作方案』有關磋商單位做了縱向深度的規劃與安排，以便溝通協商與實地參觀訪問等實際議題作爲日後政策執行與推展的依據與參考。

貳、 目的

衛生署為推動與國際調和，分別於民國八十八年、九十年與美國、歐盟簽訂醫療器材換文協定(Exchange of Letter, 以下簡稱 EOL)，推動雙邊法規技術交流與查廠結果相互承認事宜，由於我國醫療器材優良製造規範與歐盟所採認的標準不相符合，尚無法順利達成相互承認之推展，為積極爭取我國醫療器材優良製造規範稽核報告受他國家所承認，須要主動積極與歐盟的換文協定的實質效果。

然而自台歐 TCP 推動六年以來，雖有效協助歐盟業者以簡化方式取得我國醫療器材優良製造規範認可登錄，但歐方採認我方報告之目標尚未達成。此外自民國九十四年正式公告實施以來，歐盟方面的十二家代施查核機構之中，已有六家經過改組、併購或更換名稱等變更，與衛生署後續又與瑞士簽訂換文協議，在此同時歐盟會員國自 16 國擴大到 26 國，其他代施查核機構如德國 DEKRA、 LRQA、TUV NORD、挪威 DNV、捷克 SZU、瑞士 SQS 先後表達加入台歐 TCP 意願，至於我國方面衛生署代施查核機構之一塑膠工業研究發展中心亦尚未加入台歐 TCP，實有必要推動第二代台歐 TCP。

且自過去與歐盟的換文協定以來，隨著時間與空間變化、歐盟法規政策變動、以及實質技術之推展，台歐雙方有必要就第二階段「台歐醫療器材優良製造規範/GMP 稽核報告交換技術合作方案」(即第二代台歐 TCP)做部分重點修正，修訂內容如下：採納歐盟於 2011 年 6 月所公佈更嚴格的代施查核機構管理標準 (Code of Conduct for Notified Bodies under Directives 90 / 385 / EEC and 93 / 42 / EEC)、明文規定歐盟代施查核機構採認我方稽核報告之時間表，必要時淘汰績效不彰或未能履約之歐盟代施查核機構，未來可適時受理符合第二代台歐 TCP 規定之其他優良代施查核機構加入。

醫粧組鑑於國內醫療器材製造業者希望透過台歐 TCP 策略，爭取我國醫療器材優良製造規範稽核報告受到歐盟相關機構之承認，以減少重複稽核，及早取得歐盟 CE 驗證，以利國產醫療器材產品進入歐盟國家級市場之順暢。並促成台歐兩國的醫療器材代施查核機構間進一步簽署「台歐醫療器材優良製造規範/GMP 稽核報告交換技術合作方案」(以下簡稱台歐 TCP)，使台歐醫療器材優良製造規範稽核報告能夠朝相互承認之實質平等互惠原則發展。

參、 行程

食品藥物管理局醫粧組赴歐洲參加第二階段「台歐醫療器材優良製造規範/GMP 稽核報告交換技術合作方案」討論會議及出訪歐盟衛生主管機關 SANCO 及英國 MHRA，排定行程如下：

3 月 10 日　[交通時間] 晚間自桃園機場出發，經泰國曼谷轉往荷蘭阿姆斯特丹。

3 月 11 日　[交通時間] 下午自荷蘭阿姆斯特丹轉機至比利時布魯塞爾。

3 月 12 日　在比利時布魯塞爾歐盟衛生主管機關 SANCO 總部 (European CommissionDirectorate General for Health and Consumer Affairs, DG SANCO)，與英國衛生主管機關 MHRA 官員(Tore Johansen 及 Sandor Beukes 等人)會面。[見第 7 頁]

3 月 13 日　[交通時間] 自比利時布魯塞爾搭機前往英國倫敦。

3 月 14 日　[參觀] 上午至英國骨科醫療器材廠 - 英商史耐輝股份有限公司(Smith & Nephew Orthopaedics Ltd)，參觀骨科醫療器材研發、設計及製造現場，並實地了解醫療器材廠之品質管理系統。[見第 40 頁]

[訪問] 下午至英國倫敦訪問 UKAS， 探詢 UKAS 之認證及驗證作業，如何在 IAF, International Accreditation Forum 架構下，其公正、獨立、透明之認證機制獲得國際間的相互採認，並聽取業務簡報及進行討論。[見第 43 頁]

3 月 15 日　赴英國衛生部(Medicines and Healthcare products Regulatory Agency, MHRA,

UK)，與衛生主管機關 MHRA 官員(Tore Johansen 及 Sandor Beukes 等人)會面。[見第 51 頁]

3 月 16 日　在 British Standards Institution (BSI)總部會議室，了解 Training Workshop on TCP II European Notified Body Partners，以及參加第二階段「台歐醫療器材優良製造規範/GMP 稽核報告交換技術合作方案」討論會議及合約簽署。[見第 57 頁]

3 月 17 日　[交通時間] 上午自英國倫敦赴荷蘭阿姆斯特丹搭機返台。

3 月 18 日　[交通時間] 上午經泰國曼谷返抵桃園機場。

行程一

3 月 12 日　在比利時布魯塞爾歐盟衛生主管機關 SANCO 總部(European Commission Directorate General for Health and Consumer Affairs, DG SANCO)，與英國衛生主管機關 MHRA 官員(Tore Johansen 及 Sandor Beukes 等人)會面。

台歐醫療器材優良製造規範 GMP/ISO13485 稽核報告交換技術合作

Meeting on the EU-Chinese Taipei Exchange of Letters Implementation Review

會議日期/Date： Monday, 12th March 2012

會議時間/Time： 14:00 ~ 16:00

會議地點/Venue：Rue De Mot 24, 1040 Brussels (DM24, 2/67), Belgium

與會人士/Participants:

歐盟方面/European Commission:

Laurent SELLES, DG SANCO

Manfred KOHLER, DG SANCO

Miranda, DG SANCO

歐洲驗證單位/EU Notified Bodies:

Gert BOS, BSI,

Guido LIGHART, DEKRA

Corinne DELORME, LNE

Georg BAUER, TUV SUD

Wilma HARTUNG, TUV Rheinland

Steve McRoberts, UL(UK)

台灣/**Taiwan:**

劉麗玲組長/食品藥物管理局 **Li-Ling LIU, Taiwan Food and Drug Administration**

阮娟娟組長/駐歐盟兼駐比利時代表處衛生組 **Chuan-Chuan YUAN, Taipei Representative Office in EU and Belgium**

呂理福簡任技正/食品藥物管理局 **Li-Fu LU, Taiwan Food and Drug Administration**

陳志宏薦任技正/食品藥物管理局 **Jih-Horn CHEN (Stanley), Taiwan Food and Drug Administration**

許志明依等商務秘書/駐歐盟兼駐比利時代表處經濟組 **Chin-Ming HSU, Taipei Representative Office in EU and Belgium**

李子偉主任/工研院量測中心 **Albert T. W. Li (Albert), ITRI**

陳遠明資深工程師/工研院量測中心 **Christopher Chan, ITRI**

會議附件/**Attachment:**

歐盟方面/ **DG SANCO**

Meeting on the exchange of letters between EC and ROC Taiwan, 12 March 2012

Table ZB.1 – Relationship between Annex II of Directive 93/42/EEC and the clauses of EN ISO 13485 & ZB.3 Relationship with Annex V of Directive 93/42/EEC

台灣方面/**TFDA, Taiwan**

Briefing Notes on EU-Chinese Taipei Exchange of Letters Implementation Review

重要結論/**Summary**：

1. **It is agreed that the EOL has benefited many European manufacturers in reduction of preparation to access the Chinese Taipei market, but not the other way round. Upon agreeing this unbalance of the EOL, we should still move forward and with future improvement on that aspect.**

   - 歐方認同：台歐換文提供歐洲醫療器材製造商縮短產品進入台灣的時程，但台方並未蒙受相對等的待遇，基於此換文不平衡的認同，歐方仍應努力並進一步改善此種不平衡現象。

2. **Although it may not be the best of time to update the EOL, the possibility of proposed revision to the EOL by TFDA should still be investigated.**

   - 雖然此時並非更新換文的最佳時刻，**tFDA** 所提的可能換文版本仍應該加以研究。

3. **In the mean time and to move forward, it is agreed that the exchange of auditing information is always beneficial. Taiwanese manufacturers are encouraged to provide TFDA GMP audit reports to TCP EU Notified Bodies for review. EU Notified Bodies should perform conformity assessment in accordance to Europe Directives.**

   - 在此向前推展的同時，歐方認同交換稽核報告訊息對雙方是有利的，鼓勵台灣的醫療器材製造廠商將經由 **tFDA** 核可的醫療器材優良製造規範 **GMP/ISO13485** 稽核報告，提供歐方 **TCP** 方案之驗證單位**(Notified Bodies)**，作爲歐方依據歐盟相關指令執行符合性評估時的評估參考。

4. **It is encouraged better collaboration and partnership among EU Notified Bodies and TFDA Authorized Auditing Organizations under the TCP partnership.**

   - 在 **TCP** 合作方案下，鼓勵歐盟驗證單位與 **tFDA** 間的驗證稽核作業合作與夥伴關係。

5. **As moving forward DG SANCO suggested Taiwan's Authorized Auditing Organization should look into register in Europe as Notified Body.**

   - 站在 **DG SANCO** 立場寄望未來 **tFDA** 的驗證稽核作業也能夠加入在歐洲註冊爲驗證

稽核作業單位。

6. **It is agreed that the UDI is a global direction, and with Mr. Selles's invitation, Taiwan would look into the participation and supporting IMDRF in the work of UDI Workgroup.**

- 在全球使用醫療器材的安全及功效朝向 **UDI, Unique device identifier** 趨勢，台灣將與歐盟主席 **Mr. Selles** 共同在國際醫療器材法規聯盟**(IMDRF, The International Medical Device Regulators' Forum)**致力於建構 **UDI** 的法規國際化推展。

全體與會人員會後在比利時布魯塞爾歐盟 SANCO 前合影

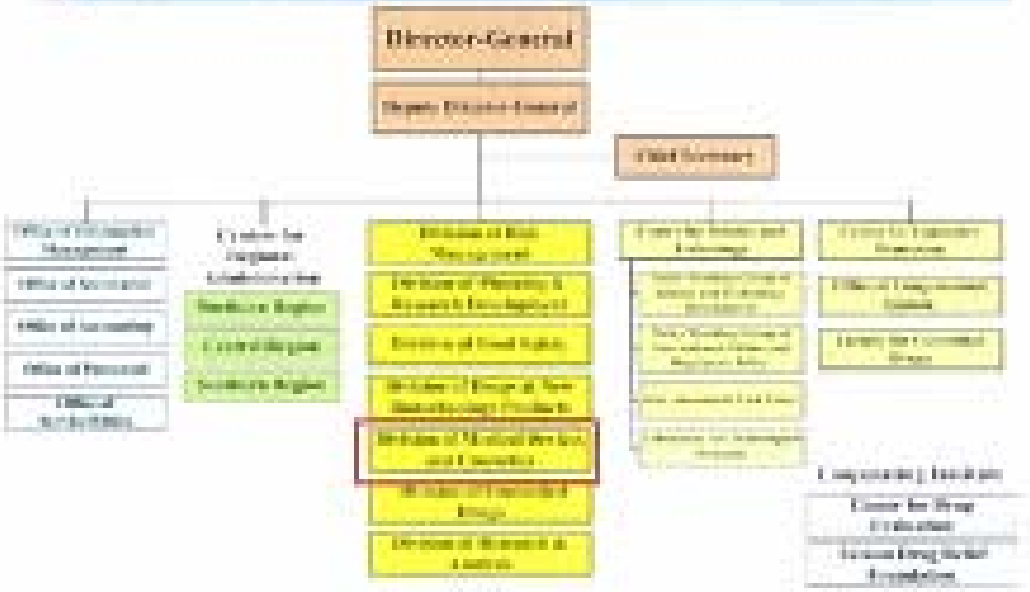
Implementation of Medical Devices GMP In Taiwan

Taiwan Food and Drug Administration
Director
Division of Medical Devices and Cosmetics
Li-Ling Liu, M.S., R.Ph.

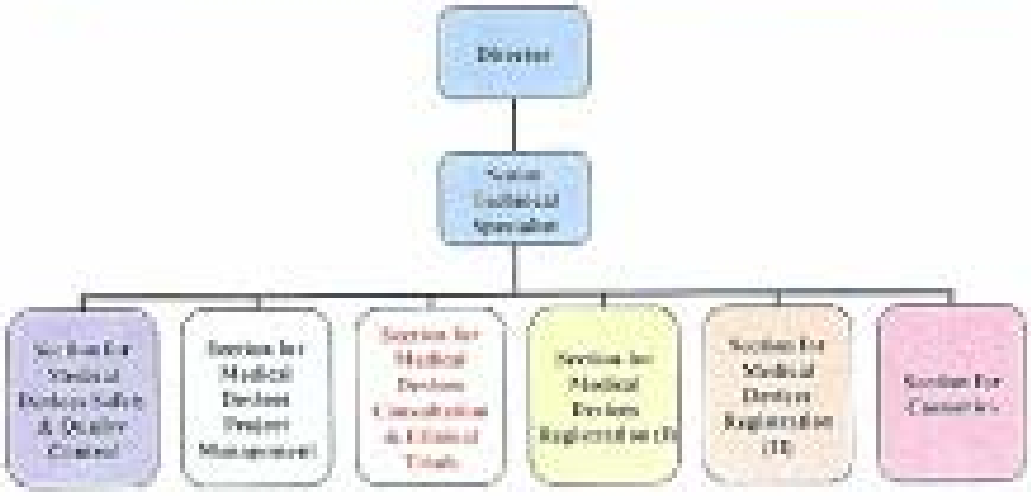
Food and Drug Administration, Taiwan (TFDA)

- TFDA was inaugurated on Jan. 1, 2010
- TFDA supersedes the following 4 bureaus of Department of Health
  - Bureau of Food Safety
  - Bureau of Pharmaceutical Affairs
  - Bureau of Food and Drug Analysis
  - Bureau of Controlled Drugs

TFDA Organization Chart



Organization Diagram of Division of Medical Devices and Cosmetics

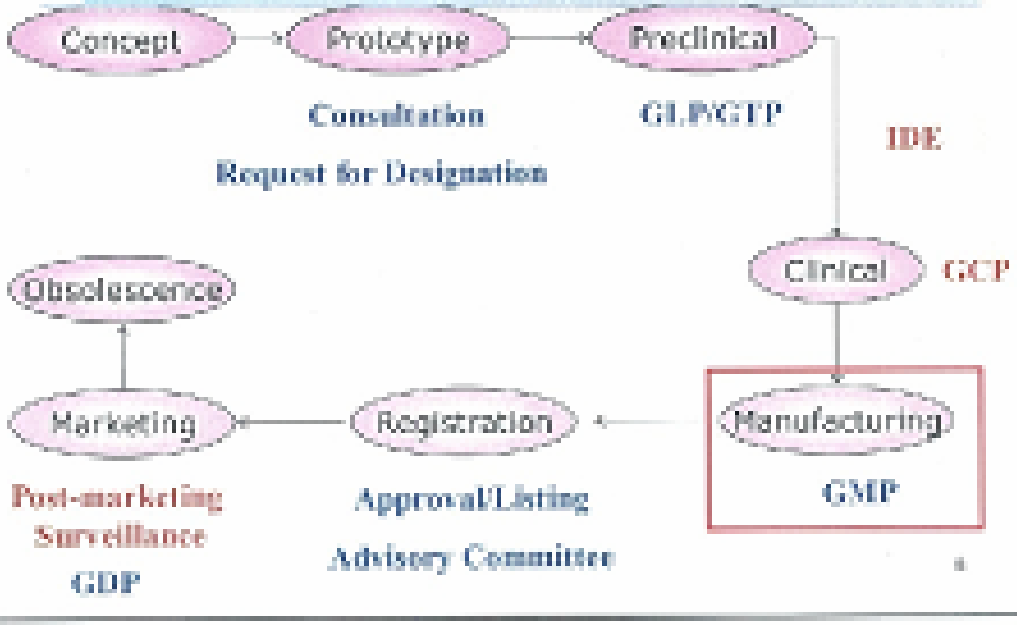


Management Goal and Framework for Medical Device and Cosmetics

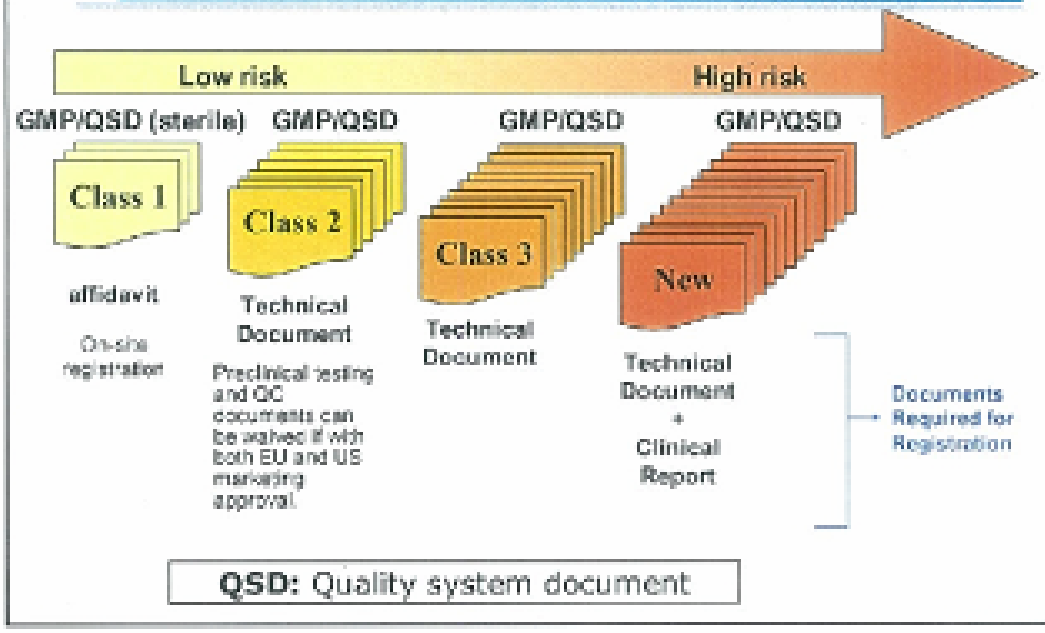
Main goals of Management

1. To assure safety for consumer
2. To facilitate the innovation of medical device industry
3. To consolidate the law and regulation
4. To strengthen international cooperation

Medical Devices Life Cycle and Clinical investigation policy

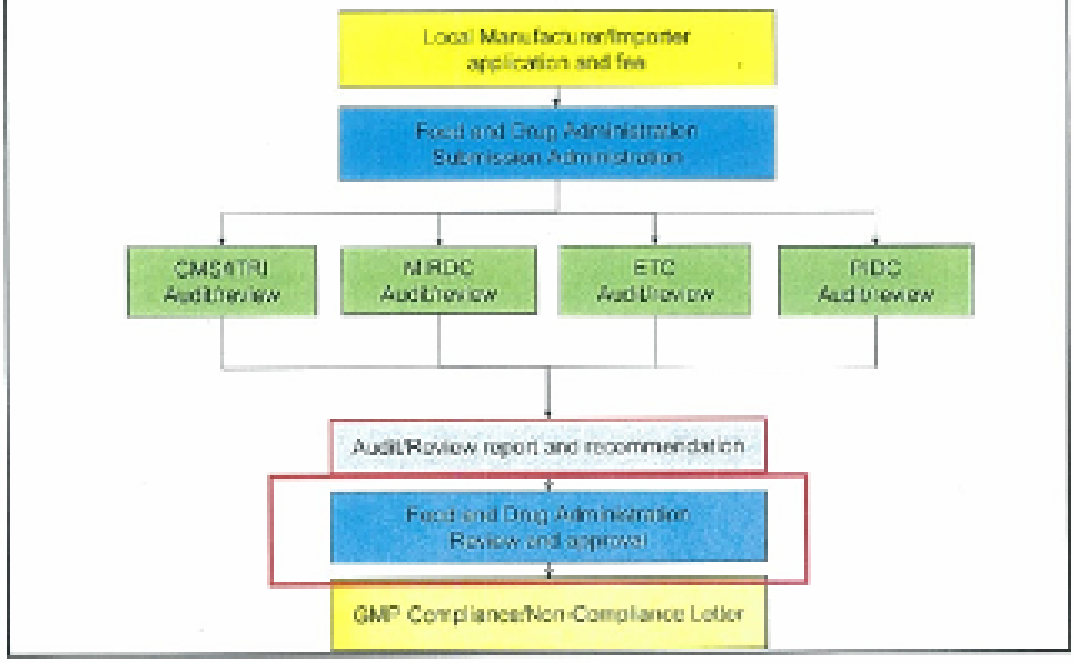


Risk Based Regulation



QSD: Quality system document

The Inspection Process of Medical Device GMP in Taiwan



Inspection Mode

- **Domestic manufacturers: site inspection**
- **Imported manufacturers: QSD review**
  - Full quality system document
  - Simplified mode of European Union technical cooperation program

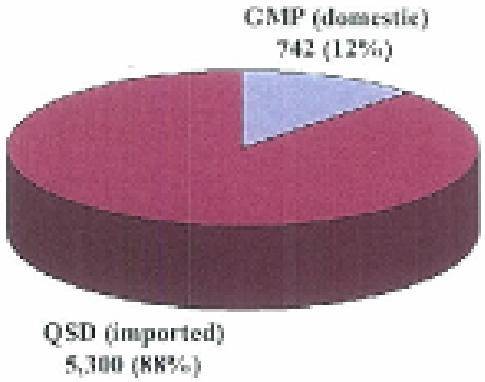
9

Implementation of Medical Device GMP

- **Program initiated in 1997**
- **Effective on February 10, 1999**
- **Third parties** (DOH designated GMP auditing organizations, DAO) **inspection**
  - Metal Industries Research & Development Center (MIRDC)
  - Industrial Technology Research Institute (ITRI)
  - Electronics Testing Center (ETC)
  - Plastics Industry Development Center (PIDC)
- **Monitoring by TFDA**
  - Third party complies with ISO/IEC Guide 62 → ISO 17021
  - Consensus meetings with the third party (4 times/ year)
  - Site inspection with the third party (irregularly)

10

Statistics of GMP/QSD by Domestic and Imported Manufacturers



Updated 2010.07.13

11

Medical Devices Manufactured from EU

- **Manufacturers numbers : *675***

  (Update to 2012/02/16)

- **Medical Devices license numbers : *8,120***

  (Update to 2011/04/01)

12

The Status of Implementation of the EU-Taiwan Exchange of Letters

Governing Laws and standards of GMP Regulations

- Governing Laws
  - TW based on **Pharmaceutical Affairs Act**
    - Article 57 (GMP Standards / certificate)

      - When manufacturing of medicaments meets the regulations of the central competent health authority, the pharmaceutical dealers may pay application fees to apply for **certificate** issued by the central competent health authority.
    - Article 71 (Method of Inspection)
    - Article 92 (Penalty Provisions)

Governing Laws and Standards of GMP Regulations among TW / EU / UK

- Complying Standards
  - TW
    - ISO13485: 2003
  - EU
    - ISO13485: 2003
  - UK
    - ISO13485: 2003

EU NB – Taiwan DOH DAO Cooperation

- **Technical Cooperation Program between EU NB and DOH designated GMP auditing organizations (CMS/ITRI, MIRDC, ETC) since 2002.**
- **Acceptance of ISO 13485 audit report to eliminate duplicate inspection**
  - **2004-TUVPS, NSAI, G-MED, MDC, BSI PS, TUV Rheinland.**
  - **2006-KEMA, SGS UK, AMTAC, MEDCERT, DGM, UL UK.**
  - **Audit report can be used as part of the QSD requirement.**

The Application Process of Medical Device QSD between EU/Taiwan

Benefits

- More than 1,600 application cases from European manufacturers apply abbreviated Quality System Documentation (QSD) submission through this Programme with audit information provided by EU Notified Body Partners since the implementation of the Programme.
- *However, the manufacturers in BOTH Europe and Taiwan have not been able to benefit further from the initiative in reduction of duplicate audits, as the current implementation has a leaning and that ISO 13485 audit reports issued by TFDA is not accepted by EU!*

EU-Taiwan Exchange of Letters in 2001

Para. 6, page2 :

- Manufacturers established in the European Community exporting to the Chinese Taipei can under this co-operation allow *Notified Bodies to present the appropriate audit reports to the competent authorities in Chinese Taipei as part of the documentation regarding access to the Chinese Taipei market.*

In 2012…
Proposal to Amend EOL

- Under this co-operation, manufacturers established in the European Community exporting to Chinese Taipei can allow *Notified bodies to present the appropriate audit reports & GMP certificate to the competent authorities in Chinese Taipei, and manufacturers established in Chinese Taipei exporting to the European Community can allow Chinese Taipei authorized Third Parties to present the appropriate audit reports to the Notified Bodies, as part of the documentation regarding access to the market.*

歐盟方面/ DG SANCO

EN ISO 13485 Table ZB.1 Relationship between Annex II (full quality assurance system) of Directive 93/42/EEC (2007/47) and the clauses of EN ISO 13485

Paragraph of Directive 93/42/EEC, Annex II	Text of 93/42//EEC	Clause(s) of EN ISO 13485	Comments/Qualifying remarks
3.1 first sentence	*3.1. The manufacturer must lodge an application for assessment of his quality system with a notified body.*		Not covered
3.1 second paragraph 1st indent	*- the name and address of the manufacturer and any additional manufacturing site covered by the quality system,*		Not covered
3.1 second paragraph 2nd indent	*- all the relevant information on the product or product category covered by the procedure,*	4.1, 4.2	Not covered
3.1 second paragraph 3rd indent	*- a written declaration that no application has been lodged with any other notified body for the same product-related quality system,*		Not Covered
3.1 second paragraph 4th indent	*- the documentation on the quality system,*	4.1, 4.2	Partial coverage: The documentation required in 4.2 of the standard does not cover entirely the quality system documentation detailed in 3.2 of Annex II unless the explicit legal requirements are

			incorporated into the quality system documentation. See also coverage of 3.2 below.
3.1 second paragraph 5th indent	- *an undertaking by the manufacturer to fulfill the obligations imposed by the quality system approved,*	4.1, 5.1, 5.4, 5.5, 5.6	Covered
3.1 second paragraph 6th indent	- *an undertaking by the manufacturer to keep the approved quality system adequate and efficacious,*	4.1, 5.1, 5.4, 5.5, 5.6	Covered
3.1 second sentence 7th indent	*an undertaking by the manufacturer to institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase, including the provisions referred to in Annex X, and to implement appropriate means to apply any necessary corrective action. This undertaking must include an obligation for the manufacturer to notify the competent authorities of the following incidents immediately on learning of them: (i) any malfunction or deterioration in the characteristics and/or performance of a device, as well as any*		Not covered

	inadequacy in the instructions for use which might lead to or might have led to the death of a patient or user or to a serious deterioration in his state of health; *(ii) any technical or medical reason connected with the characteristics or performance of a device leading for the reasons referred to in subparagraph (i) to systematic recall of devices of the same type by the manufacturer.*		
3.2 first paragraph first sentence	*3.2. Application of the quality system must ensure that the products conform to the provisions of this Directive which apply to them at every stage, from design to final inspection.*		Not covered. The application of EN ISO 13485 does not by itself assure the fulfilment of all regulatory requirements of Directive 93/42/EEC. The legal requirements must be examined, applied and verified one by one and the solutions adopted must become part of the quality system in the meaning of the Directive.
3.2 first paragraph second sentence	*All the elements, requirements and provisions adopted by the manufacturer for his quality system must be documented in a systematic and orderly manner in the form of written policies and procedures such as*	4.1, 4.2	Covered

	quality programmes, quality plans, quality manuals and quality records.		
3.2 second paragraph	*It shall include in particular the corresponding documentation, data and records arising from the procedures referred to in point (c).*		Not covered
3.2 third paragraph (a)	*It shall include in particular an adequate description of:* *(a) the manufacturer's quality objectives;*	4.2.1, 5.1, 5.3, 5.4.1	Covered
3.2 third paragraph (b)	*(b) the organization of the business and in particular:*	4.2.2, 5.1.1	Covered
3.2 third paragraph (b) 1st indent	*- the organizational structures, the responsibilities of the managerial staff and their organizational authority where quality of design and manufacture of the products is concerned,*	4.2.2, 5.1, 5.5.1, 5.5.2	Covered
3.2 third paragraph (b) 2nd indent	*- the methods of monitoring the efficient operation of the quality system and in particular its ability to achieve the desired quality of design and of product, including control of products which fail to conform;*	4.1, 5.6, 7.1, 8.2.2, 8.3, 8.4, 8.5.2, 8.5.3	Covered provided that the methods and criteria chosen by the manufacturer ensure that the requirements of the Directive are fulfilled
3.2 third paragraph (b) 3rd indent	*where the design, manufacture and/or final inspection and testing of*	4.1, 4.2, 7.4, 8.5.1	Covered provided that control processes are documented in accordance

	the products, or elements thereof, is carried out by a third party, the methods of monitoring the efficient operation of the quality system and in particular the type and extent of control applied to the third party;'		with 4.2.1.
3.2 third paragraph (c)	*the procedures for monitoring and verifying the design of the products, including the corresponding documentation, and in particular*	7.1, 7.2, 7.3	Covered
3.2 third paragraph (c) 1st indent	— *a general description of the product, including any variants planned, and its intended use(s),*		Not covered
3.2 third paragraph (c) 2nd indent	the design specifications, including the standards which will be applied and the results of the risk analysis, and also a description of the solutions adopted to fulfil the essential requirements which apply to the products if the standards referred to in Article 5 are not applied in full,	7.1, 7.2, 7.3.2, 7.3.3, 7.3.6	Covered provided that there is a description of the standard that will be applied.
3.2 third paragraph (c) 3rd indent	*the techniques used to control and verify the design and the processes and systematic measures which will be used when the products are being designed,*	7.3.1, 7.3.5, 7.3.6, 7.3.7	

3.2 third paragraph (c) 4th indent	*if the device is to be connected to other device(s) in order to operate as intended, proof must be provided that it conforms to the essential requirements when connected to any such device (s) having the characteristics specified by the manufacturer,*	7.3.2, 7.3.3, 7.3.5, 7.3.6	
3.2 third paragraph (c) 5th indent	*a statement indicating whether or not the device incorporates, as an integral part, a substance or a human blood derivative referred to in section 7.4 of Annex I and the data on the tests conducted in this connection required to assess the safety, quality and usefulness of that substance or human blood derivative, taking account of the intended purpose of the device,*		Not covered
3.2 third paragraph (c) 6th indent	*a statement indicating whether or not the device is manufactured utilising tissues of animal origin as referred to in Commission Directive 2003/32/EC (*),*		Not covered
3.2 third paragraph (c) 7th indent	*the solutions adopted as referred to in Annex I, Chapter I, Section 2,*		Not covered
3.2 third paragraph (c)	*the pre-clinical*		Not covered

8th indent	*evaluation,*		
3.2 third paragraph (c) 9th indent	*the clinical evaluation referred to in Annex X,*		Not covered
3.2 third paragraph (c) 10th indent	*the draft label and, where appropriate, instructions for use.*		Not covered
3.2 third paragraph (d) 1st indent, sterilization	*- the processes and procedures which will be used, particularly as regards sterilization, purchasing and the relevant documents,*	6.4, 7.5.1, 7.5.2	Covered
3.2 third paragraph (d) 1st indent, purchasing	*- the processes and procedures which will be used, particularly as regards sterilization, purchasing and the relevant documents,*	7.4	Covered
3.2 third paragraph (d) 1st indent, relevant documents	*- the processes and procedures which will be used, particularly as regards sterilization, purchasing and the relevant documents,*	4.2, 7.1	Covered
3.2 third paragraph (d) 2nd indent	*- the product identification procedures drawn up and kept up to date from drawings, specifications or other relevant documents at every stage of manufacture;*	4.2, 7.5.3	Covered
3.2 third paragraph (e)	*(e) the appropriate tests and trials which will be carried out before, during and after manufacture, the frequency with which they will take place, and the test equipment used;*	4.2, 7.1, 7.5.3.2.1, 7.6, 8.2.4	Covered provided that the frequency at which tests are carried out is documented and that test results can be traced to the test equipment used.

	it must be possible to trace back the calibration of the test equipment adequately.		

EN ISO 13485 Table ZB.3 Relationship between Annex V (production quality assurance) of Directive 93/42/EEC and the clauses of EN ISO 13485

Paragraph of Directive 93/42/EEC, Annex V		Clause(s) of EN ISO 13485	Comments/Qualifying remarks
3.1	*3. Quality system* *3.1. The manufacturer must lodge an application for assessment of his quality system with a notified body.*		Not covered
3.1 second paragraph 1st indent	*The application must include:* *- the name and address of the manufacturer,*		Not covered
3.1 second paragraph 2nd indent	*- all the relevant information on the product or product category covered by the procedure,*		Not covered
3.1 second paragraph 3rd indent	*- a written declaration that no application has been lodged with any other notified body for the same products,*		Not Covered
3.1 second paragraph 4th indent	*- the documentation on the quality system,*	4.1, 4.2	Partial coverage: The documentation required in 4.2 of the standard does not

			cover entirely the quality system documentation meant in 3.2 of Annex V unless the explicit legal requirements are incorporated into the quality system documentation. See also coverage of 3.2 below.
3.1 second paragraph 5th indent	*- an undertaking to fulfil the obligations imposed by the quality system is approved,*	4.1, 5.1, 5.4, 5.5, 5.6	Covered
3.1 second paragraph 6th indent	*- an undertaking to maintain the practicability and effectiveness of the approved quality system,*	4.1, 5.1, 5.4, 5.5, 5.6	Covered
3.1 second sentence 7th indent	*- where appropriate, the technical documentation on the types approved and a copy of the EC type-examination certificates,* *an undertaking by the manufacturer to institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase, including the provisions referred to*		Not covered

	in *Annex X, and to implement appropriate means to apply any necessary corrective action. This undertaking must include an obligation for the manufacturer to notify the competent authorities of the following incidents immediately on learning of them;*		
3.1 second paragraph 8th indent 3.1 second paragraph 8th indent (i) 3.1 second paragraph 8th indent (ii)	*- an undertaking by the manufacturer to institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means to apply any necessary corrective action. This undertaking must include an obligation for the manufacturer to notify the competent authorities of the following incidents immediately on learning of them:* *(i) any malfunction or deterioration in the characteristics and/or performance of a*		Not covered

	device, as well as any inadequacy in the labelling or the instructions for use which might lead to or might have led to the death of a patient or user or to a serious deterioration in his state of health; *(ii) any technical or medical reason connected with the characteristics or performance of a device for the reasons referred to in subparagraph (i) above leading to a systematic recall of devices of the same type by the manufacturer*		
3.2 first paragraph	*3.2. Application of the quality system must ensure that the products conform to the type described in the EC type-examination certificate.* *All the elements, requirements and provisions adopted by the manufacturer for his quality system must be documented in a systematic and orderly*		Not covered. The application of EN ISO 13485 does not by itself assure the fulfilment of all regulatory requirements of Directive 93/42/EEC. The legal requirements must be examined, applied and verified one by one and the solutions adopted must become part of the quality system in the meaning of the Directive.

	manner in the form of written policy statements and procedures. This quality system documentation must permit uniform interpretation of the quality policy and procedures such as quality programmes, plans, manuals and records.		
3.2 second paragraph	*It must include in particular an adequate description of:*	4.1, 4.2	covered
3.2 third paragraph (a)	*(a) the manufacturer's quality objectives;*	4.2.1, 5.1, 5.3, 5.4.1	Covered
3.2 third paragraph (b)	*(b) the organization of the business and in particular:*	4.2.2	Covered
3.2 third paragraph (b) 1st indent	*- the organizational structures, the responsibilities of the managerial staff and their organizational authority where manufacture of the products is concerned,*	5.1, 5.5.1, 5.5.2	Covered
3.2 third paragraph (b) 2nd indent	*- the methods of monitoring the efficient operation of the quality system and in particular its ability to achieve the desired quality of product, including control of products which fail to conform;*	4.1, 5.6, 7.1, 8.2.2, 8.3, 8.5.2	Covered provided that the methods and criteria chosen by the manufacturer ensure that the requirements of the directive are fulfilled.

3.2 third paragraph (b) 3rd indent	*where the manufacture and/or final inspection and testing of the products, or elements thereof, are carried out by a third party, the methods of monitoring the efficient operation of the quality system and in particular the type and extent of control applied to the third party;*	4.1, 4.2.1, 7.4, 8.5.1	Covered provided that control processes are documented in accordance with 4.2.1..
3.2 third paragraph (c) 1st indent, sterilization	*(c) the inspection and quality assurance techniques at the manufacturing stage and in particular:* *- the processes and procedures which will be used, particularly as regards sterilization, purchasing and the relevant documents,*	6.4, 7.5.1, 7.5.2	Covered provided that the explicit requirements of the Directive are incorporated into the quality system documentation
3.2 third paragraph (c) 1st indent, purchasing	*(c) the inspection and quality assurance techniques at the manufacturing stage and in particular:* *- the processes and procedures which will be used, particularly as regards sterilization, purchasing and the*	7.4	Covered

	relevant documents,		
3.2 third paragraph (c) 1st indent, relevant documents	*(c) the inspection and quality assurance techniques at the manufacturing stage and in particular:* *- the processes and procedures which will be used, particularly as regards sterilization, purchasing and the relevant documents,*	4.2, 7.1	Covered
3.2 third paragraph (c) 2nd indent	*- the product identification procedures drawn up and kept up to date from drawings, specifications or other relevant documents at every stage of manufacture;*	4.2, 7.5.3	Covered
3.2 third paragraph (d)	*(d) the appropriate tests and trials to be carried out before, during and after manufacture, the frequency with which they will take place, and the test equipment used; it must be possible adequately to trace back the calibration of the test equipment.*	4.2, 7.1, 7.5.3.2.1, 7.6, 8.2.4	Covered provided that the frequency at which tests are carried out is documented and that test results can be traced to the test equipment used.

台灣方面/TFDA, Taiwan

Briefing Notes on EU-Taiwan Technical Cooperation Programme Implementation Review

Aim:

The purpose of the present document is to provide the background and supporting information to facilitate the current discussion and reviewing the status of implementation of the EU-Taiwan Exchange of Letters Regarding the Mutual Exchange on Medical Device. And to move forward and build on the past success, thereby reaching a common ground for mutual acceptance of ISO 13485 Audit reports issued by TFDA (Designated Auditing Organizations) and EU Notified Bodies as part of (quality system) requirements of conformity assessment procedure for medical devices.

Background:

The current version, as it is non-expiratory, of the EU-Taiwan Exchange of Letters (EOL) on Medical Devices, was signed by Mr. Mogens Peter Carl, Director General, DG Trade European Commission and Mr. Steve R.L. Chen, Vice Minister, MOEA, ROC, on the 21st of October, 2001.

With effect from the EOL, "The co-operation between the Chinese Taipei and European Community will include in particular the following activities and areas" (Paragraph 6, page 2):

EU-Taiwan Exchange of Letter	TCP between EU NBs and TFDA DAOs
1. Manufacturers established in the European Community exporting to the Chinese Taipei can under this co-operation allow Notified Bodies to present the appropriate audit reports to the competent authorities in Chinese Taipei as part of the documentation regarding access to the Chinese Taipei	3. Prorgamme Summaries: Each party shall provide through the manufacturer the information regarding the audit report, and conclusion of the audit to the other party for determining the compliance to ISO 13485/GMP of the manufacturers utilizing this

market.	Programme (page 7)
2. Notified Bodies can, in conformity with the MEDDEV 2.10.2 rev. 1 – relating to subcontracting of quality systems for regulatory purposes, subcontract specific tasks to third parties established in Chinese Taipei.	3. Prorgamme Summaries The technical cooperation specified in this programme is based upon delegation. DOH Designated Auditing Organizations may delegate their foreign audits to particular EU Notified Body Partners. Participative EU Notified Body Partners may delegate their audits to auditors of DOH Designated Auditing Organizations. Each party reserves the right to join the delegated audit (joint audit).

Implementation of the EU-Taiwan Exchange of Letters on Medical Devices:

Between 2002~2005, the Technical Cooperation Programme (TCP) on the Exchange of Medical Device GMP and ISO 13485 Audit Reports between Designated Medical Device GMP Auditing Organizations of DOH, ROC and EU AIMD/MDD/IVDD Notified Body Partners (TCP) was established. Audits performed shall be in line with GHTF SG4 Guidance documents.

In 2004 and 2006, a total of 12 EU Notified Bodies were accepted by DOH as TCP prgoramme partners, which are: NSAI, mdc, TÜV Rheinland PS, G-MED, TÜV PS, BSI PS, KEMA, AMTAC, SGS, MEDCERT, DGM, and UL (UK).

In Taiwan, the three TCP participating DAO are, CMS/ITRI, MIRDC and ETC, with PIDC joining the programme at TCP II. To assure the standard of the audit, review meeting by TFDA and the four DAOs are held quarterly each year, and TFDA officers will join the audit from time to time as audit observer.

	Number of Quality System Documentation application		Number of GMP Auditors	Number of EU Notified Body Recognized Auditors

	handled in the past 10 years			
CMS/ITRI	564		9	3 (MDC+BSI)(2*(SGS+BSI))
MIRDC	528		7	2 (SGS+BSI)(SGS+TUV SUD)
ETC	571		4	1 (SGS)
Total	1663		20	6

The current capacity for implementation of TCP programme in Taiwan

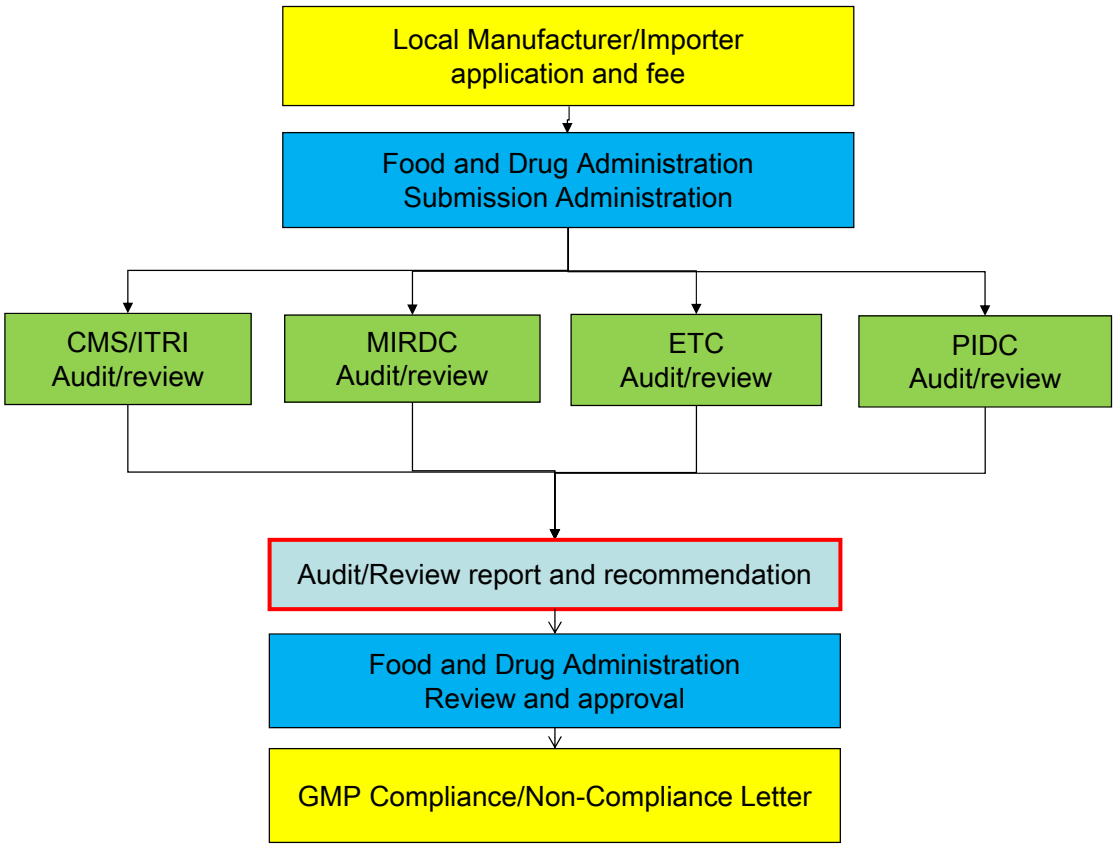
More than 1,600 European manufacturers apply abbreviated Quality System Documentation (QSD) submission through this Programme with audit information provided by EU Notified Body Partners since the implementation of the Programme.

However, the manufacturers in BOTH Europe and Taiwan have not been able to benefit further from the initiative in reduction of duplicate audits, as the current implementation has a leaning and that ISO 13485 audit reports issued by TFDA is not accepted by EU.

Issues:

The EOL and TCP programme have been very successful and benefit a lot of establishment and the General Public in reduction of regulatory administration cost without sacrificing the safety as well as accessibility of medical device. Ten years on, especially in view of recent medical device incident, it may be time, not only to review the implementation of the EOL and TCP program, but also to update and upgrade the EOL and TCP program, so as to inline with the International Medical Device Regulatory Harmonization direction, and reaching a common ground to mutual acceptance of ISO 13485 Audit reports issued by Taiwan TFDA and EU Notified Bodies as part of requirements of conformity assessment procedure for medical devices through Empower EU-Taiwan TCP Notified Bodies to accept TFDA DAOs ISO13485 audit reports.

Appendix: The Inspection Process of Medical Device GMP in Taiwan



The four Designated Auditing Organization of TFDA:

CMS/ITRI – Center of Measurement Standard, Industrial Technology Research Institute

MIRDC: Metal Industries Research & Development Centre

ETC: Electronics Testing Center, Taiwan

PIDC: Plastics Industry Development Center

行程二

3 月 14 日　[參觀] 英國骨科醫療器材廠 - 英商史耐輝股份有限公司(Smith & Nephew Orthopaedics Ltd)，參觀骨科醫療器材研發、設計及製造現場，並實地了解醫療器材廠之品質管理系統

參觀英商史耐輝股份有限公司(Smith & Nephew Orthopaedics Ltd)

訪問日期/Date： Monday, 14th March 2012

訪問時間/Time： 09:30 ~ 12:00

訪問地點/Venue：Aurora Spa Park, Harrison way, Leamington Spa Warwick, CV31 3HL, UK

與會人士/Participants:

受訪單位/ **Smith & Nephew Orthopaedics Ltd:**

Tim Band, Global Director, Advanced Bearing System

Dave Telling, Quality & Regulatory Director, Advanced Bearing System

Bill Aubrey, Regulatory Specialist, Advanced Bearing System

Amir Kamali, Research Manager, Implant Development Centre

Chenxi Li, Senior Materials Scientist, Implant Development Centre

台灣/**Taiwan:**

劉麗玲組長/食品藥物管理局 **Li-Ling LIU, Taiwan Food and Drug Administration**

阮娟娟組長/駐歐盟兼駐比利時代表處衛生組 **Chuan-Chuan YUAN, Taipei Representative Office in EU and Belgium**

呂理福簡任技正/食品藥物管理局 **Li-Fu LU, Taiwan Food and Drug Administration**

陳志宏薦任技正/食品藥物管理局 Jih-Horn CHEN (Stanley), Taiwan Food and Drug Administration

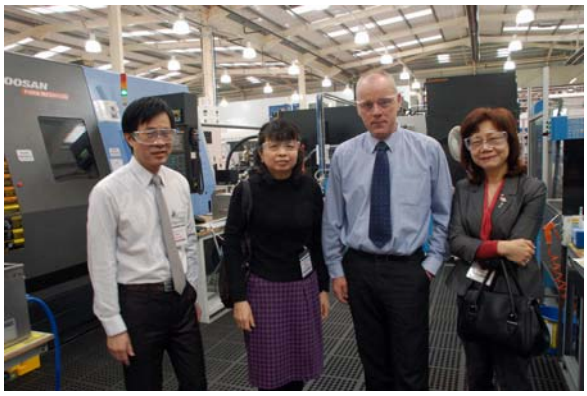
訪問緣起:

此次參觀英商史耐輝股份有限公司(Smith & Nephew Orthopaedics Ltd)係位於英國倫敦約 90 英哩的 Leamington Spa Warwick，主要係藉由實際的參觀國際知名骨科醫療器材製造廠，增加對製造廠的管理風貌及相關品質管理系統了解，作爲未來政策規劃時的參考。

當天的參觀由該廠之 Advanced Bearing System 的全球營運總裁 Tim Band 主持，先了解該廠的簡介及工廠的配置輪廓，隨後帶領參訪人員蒞廠參觀：(1) 骨科專業醫師訓練實驗室，該實驗室提供全球各大醫院使用人 - 骨科器材專業醫師的使用訓練，並在過程中讓各受訓的專業醫師熟悉正確的臨床專業使用知能及其財的功效及安全風險，藉以提升位病人植入相關骨科器材之正確專業知識與技術。(2) 骨科股骨頭球型圓滑面拋光及精準圓面的品質檢測技術，以降低植入股骨頭的摩擦係數，使病人植入後的骨關節活動滑順減少摩擦延長人工植入物的使用時間。(3) 利用電腦及現場排程配置，以利分段批次加工的品質系統管理。(4) 材料失效鑑定實驗室運用材料數值分析輔助材料失效的成因判定，以利骨科材料異常失效的原因判定，作爲設計製造之品質確保依據。

與 Smith & Nephew Orthopaedics Ltd 招待人員合影

劉組長(右)與 S&N 全球營運總裁(左)



呂簡技(左一)劉組長(左二)及阮組長(右)

工廠參觀隨影一

工廠參觀隨影二

行程三

3 月 14 日　[訪問] 訪問位於英國倫敦 UKAS， 探詢 UKAS 之認證及驗證作業，如何在 IAF, International Accreditation Forum 架構下，其公正、獨立、透明之認證機制獲得國際間的相互採認，並聽取業務簡報及進行討論。

訪問英國國家指定認證單位 Ukas, United Kingdom Accreditation Service

訪問日期/Date： Monday, 14th March 2012

訪問時間/Time： 14:30 ~ 16:30

訪問地點/Venue：21-47 High Street, Feltham, Middlesex, TW13 4UN, London, UK

與會人士/Participants:

受訪單位/ **Ukas:**

Lorraine Turner, Director of Technical Division

台灣/Taiwan:

劉麗玲組長/食品藥物管理局 Li-Ling LIU, Taiwan Food and Drug Administration

阮娟娟組長/駐歐盟兼駐比利時代表處衛生組 Chuan-Chuan YUAN, Taipei Representative Office in EU and Belgium

呂理福簡任技正/食品藥物管理局 Li-Fu LU, Taiwan Food and Drug Administration

陳志宏薦任技正/食品藥物管理局 Jih-Horn CHEN (Stanley), Taiwan Food and Drug Administration

訪問緣起:

台灣有關醫療器材廠優良製造規範 GMP 之技術性查核，係委託四家非營利財團法人(工研院量測中心、電子檢驗中心、金屬工業發展研究中心及塑膠工業發展研究中心)執行，亦即

透過四家代施機構執行醫療器材廠優良製造規範之現場查核，將所製作的現場稽核報告送交本局核發核准或不准的認可登錄函，此程序與歐盟國家之驗證單位(Certified bodies)所執行的醫療器材品質管理系統稽核動作相當。因此，爲方便及維持在歐盟區域間不同國家之不同驗證單位所執行之驗證品質一致，任何驗證單位之驗證動作均必須由認證單位(Accreditation bodies 如 Ukas)，根據歐盟指令(European directives)及相關標準與指導書(European Norms and Guidance)進行稽核後，方由各國依據歐盟法規認定其所執行技術稽核報告，作爲法規性之 CE 標誌(CE marking)符合性驗證依據，Ukas, United Kingdom Accreditation Service 便是英國衛生主管單位指定之國家認證機構，與醫療器材相關的法規性之 CE 標誌之符合性驗證單位，均經由 Ukas 依據歐盟法規認證後方得執行驗證動作與核發符合性驗證證書，此次訪問 Ukas 的目的有三大重點:

1. 觀摩 UKAS 如何以符合國際規範之公正、獨立、透明認證機制建立及維持英國認證制度；
2. 瞭解 UKAS 認證機制，如何在技術層次評核驗證單位[Notified body 如 BSI] ，並提供政府權責單位[Competent authority 如 MHRA]採認獲得國際公允的 Certificate；
3. 探詢 UKAS 之認證及驗證作業，如何在 IAF, International Accreditation Forum 架構下，其公正、獨立、透明之認證機制獲得國際間的相互採認。

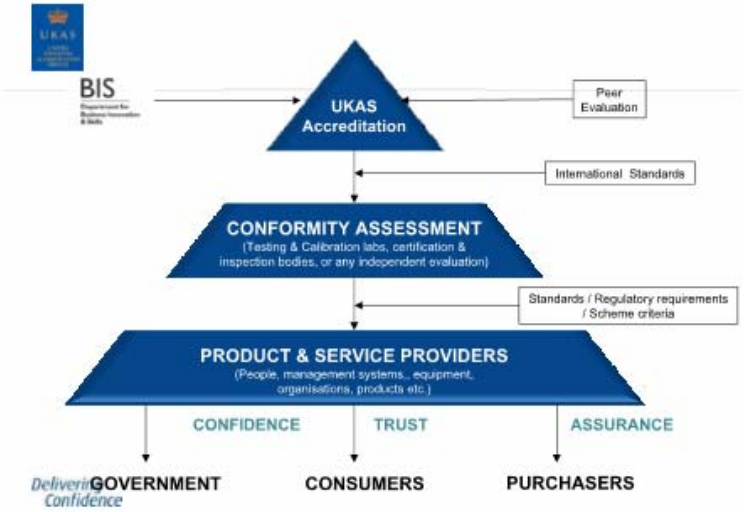
參訪人員在 Ukas 總部會議室合影

UKAS Accreditation

14 March

Taiwan FDA Visit

Delivering Confidence



UKAS status

- New EU Legislative Framework – Regulation EC 765/2008
- UKAS appointed as national accreditation body by The Accreditation Regulations 2009
- UKAS operates under Memorandum of Understanding with Department for Business, Innovation & Skills (BIS) on behalf of HMG
- UKAS established as a self-funding private company limited by guarantee (non-profit distributing)

Delivering Confidence

UKAS' scope of operation

Delivering Confidence

UKAS customer base

Delivering Confidence

UKAS Key facts

- 190 full time staff (70% technical)
- Pool of 300 technical assessors (contract)
- Operating in the public interest
- 16 'Members'

Delivering Confidence

UKAS Members

Government

Customers

Business

Professional and other Interests

Delivering Confidence

Growth into new areas


Radiology


Green Deal


Point of Care Testing


Police Forensic Labs


Legionella Risk Assessments


Competent Persons


Nuclear New Build


Scene of Crime

Delivering Confidence

Accreditation Standards

- Certification Bodies
  - EN 45011:1998/ISO Guide 65:1996
  - ISO/IEC 17021:2011
  - ISO 17024:2003
- Inspection Bodies
  - ISO 17020:1998

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Accreditation Standards

- Laboratories
  - ISO 17025:2005
  - ISO 15189:2007
- PT Providers
  - ISO/IEC 17043
- Reference Material Producers:
  - ISO Guide 34/ISO 17025

Delivering Confidence

Notified Bodies

UKAS assesses on behalf of UK competent authorities for the appointment of Notified Bodies

- Criteria
  - EU Directive
  - UK Regulations
  - Guidelines
  - Relevant EN 45000/ISO17000 series standard

Delivering Confidence

UKAS Assessment Process

Delivering Confidence

UKAS Process

- Receipt of applications (including relevant documents)
- Contract review (UKAS/app.)
- Document review
- Pre-assessment visit
  - feedback to applicant
  - further information from applicant

Delivering Confidence

UKAS Process

- Assessment
  - Confirmation of scope
  - Appointment of team
  - Visit(s) to organisation
  - Witnessing of work
- Report

Delivering Confidence

UKAS Process

- Recommendation
- Grant
- Surveillance annually
- Reassessment every 4 years
- Extensions to scope

Delivering Confidence

International Activities

Delivering Confidence

New Legislative Framework

- Regulation (EC) 765/2008 of 9 July 2008
- Provides legal framework for accreditation across EU
  - Single accreditation body
  - Non-competition
  - Strong links with Government
  - Strong co-ordination through EA
- UKAS appointed as the UK's NAB via The Accreditation Regulations 2009 (Statutory Instrument: 2009/3155)

Delivering Confidence

The Network(s)

- European co-operation for Accreditation (EA) (Calibration, Testing, Certification (QMS, EMS, Product, Personnel), Inspection)
- International Laboratory Accreditation Co-operation (ILAC) (Calibration, Testing, Inspection)
- International Accreditation Forum (IAF) (Certification, Inspection)

Delivering Confidence

International Programme

- Provides the means for the UK to participate in accreditation as it is currently organised internationally
- Programme covers UKAS participation and influence in international accreditation meetings
- The MoU between BIS and UKAS provides that BIS will consider requests from UKAS for financial assistance on a project specific basis in respect of UKAS' international activities

Delivering Confidence

Activities in EA

- Chair of EA – Graham Talbot
- EA Executive
- EA Laboratory, Certification and Inspection Committees
- EA Multilateral Agreement Committee (MAC)
- Supply Peer Evaluators incl. Team Leaders
- Participation in EEEPT, EALC ILC Working Groups, Healthcare WG

Delivering Confidence

2011 - 2014 UKAS International Programme

- Total planned time in 2011-2014 programme:
  - 708 working days per annum
  - About 25 staff members involved
- Total cost of main programme: £646,480 per annum (including time, and travel & subsistence costs)
- Support from BIS: £402,000 agreed for 2011/12

Delivering Confidence

Programme Review

- Quarterly reports to BIS
- Quarterly invoicing (up to agreed BIS contribution)
- Activity reports to BIS and UKAS Policy Advisory Council (PAC)
- Review of programme priorities by PAC

Delivering Confidence

行程四

3 月 15 日　赴英國衛生部(Medicines and Healthcare products Regulatory Agency, MHRA, UK)，與衛生主管機關 MHRA 官員(Tore Johansen 及 Sandor Beukes 等人)會面

磋商英國驗證單位接受台灣 ISO13485 稽核報告乙事

Meeting on UK Notified Body to Accept ISO 13485 Audit Reports issued by tFDA Authorized Auditing Organizations between MHRA and TFDA

會議日期/Date：　Thursday, 15th March 2012

會議時間/Time：　14:30 ~ 16:00

會議地點/Venue：R-Y 514, MHRA, Victoria, London

與會人士/Participants:

英國/UK:

Sandor Beukers, MHRA

Sarah Speedie, MHRA

Tore Johnson, MHRA

英國驗證單位代表/UK Notified Bodies:

Gert BOS, BSI

John Hewlett, BSI

Bryan Johnson, SGS

Chris Jepson, SGS

Steve McRoberts, UL(UK)

台灣/Taiwan:

劉麗玲組長/食品藥物管理局 Li-Ling LIU, Taiwan Food and Drug Administration

阮娟娟組長/駐歐盟兼駐比利時代表處衛生組 Chuan-Chuan YUAN, Taipei Representative Office in EU and Belgium

呂理福簡任技正/食品藥物管理局 Li-Fu LU, Taiwan Food and Drug Administration

陳志宏薦任技正/食品藥物管理局 Jih-Horn CHEN (Stanley), Taiwan Food and Drug Administration

李子偉主任/工研院量測中心 Albert T. W. Li (Albert), ITRI

陳遠明資深工程師/工研院量測中心 Christopher Chan, ITRI

會議附件/Attachment:

台灣方面/tFDA, Taiwan

- Background Notes for Meeting between MHRA, UK and TFDA, Chinese Taipei

重要結論/Summary：

1. Under the current status, the sharing of information regarding individual qualify assessors among UK Notified Bodies are acceptable, while UK Notified Body subcontracting quality system auditing to another auditing organization would not be acceptable by MHRA.
   - 依目前狀況，英國方面接受合格的個別評核員所提供的稽核報告，但不允許驗證單位將品質系統委由其他驗證單位執行稽核作業。

2. As part of confidence building exercise, TFDA invites delegates of UK Notified Bodies to observe GMP auditing conducted by TFDA Authorized Auditing Organization, whom are not yet qualified by UK Notified Bodies.
   - 在雙方進行建立信心過程，台灣方面邀請英國驗證單位代表，觀察 tFDA 尚未取得英國驗證單位認證之醫療器材 GMP 稽核作業的執行情況。

3. Taiwanese manufacturers are encouraged to provide TFDA GMP audit reports to TCP Notified Bodies for review. TCP Notified Bodies should perform conformity assessment in accordance to Europe Directives. TCP Notified Bodies may reduce the scope and frequency of inspection for the Taiwan manufacturers.
   - 英國方面鼓勵台灣醫療器材製造廠商提供經過 tFDA 認可登錄的稽核報告作爲 TCP 合

作方案下之驗證單位根據歐盟指令之稽核參考，透過此合作將縮減台灣醫療器材製造廠商之稽核範圍與頻率。

4. On assessing the amount of reduction of audit manday and/or audit duration, and thereby reduction in auditing cost, the following factors may be taken into account, e.g.:
   A. risk of device
   B. length of time since the last audit
   C. size of company
   - 在減少與縮短稽核過程之人天與/或稽核時間，以下諸因素將可以減少稽核成本，如醫療器材風險、離上次稽核時間間隔、以及廠商之規模。

5. TFDA may consider adjusting GMP audit frequency to be comparable with EU' MDD/IVDD.
   - 台灣方面可以考慮調整現行醫療器材廠 GMP 之稽核頻率，以便與歐盟醫療器材指令(MDD, Medical Device Directive)/體外診斷試劑指令(IVDD, In-vitro Device Directive)之規範相當。

6. Regarding the Exchange of Letter on information exchange related to medicine, MHRA agreed to prepare a confidential agreement for review by TFDA. The contact persons for MHRA and TFDA are Mr. Sandor Beukers and Ms. Li-Ling Liu respectively.
   - 關於台英涉及醫療訊息保密交換的換文，英方同意準備一份機密協定提供 tFDA 評估，英國 MHRA 及台灣食品藥物管理局的聯絡人分別爲 Mr. Sandor Beukers 與劉麗玲組長。

會議附件/Attachment:

Background Notes for Meeting between MHRA, UK and TFDA, Chinese Taipei

Aim:

The purpose of the present document is to provide background and supporting information to facilitate the current discussion for reaching a common ground for UK Notified Body to accept ISO 13485 audit reports issued by Taiwan Food and Drug Administration of the Department of Health (FDA/DOH or TFDA) Authorized Auditing Organization as part of the quality system requirements of conformity assessment procedure under MDD/IVDD.

Background:

The current version of the "EU-Chinese Taipei Exchanges of Letters regarding the mutual exchange of information on medical devices" (EOL) was signed on 3 December 2001 by Mr. Mogens Peter Carl, Director-General of DG Trade of the European Commission, and Mr. Steve R.L. Chen, Vice Minister of the Ministry of Economic Affairs of Chinese Taipei.

With effect from the EOL:

- *Manufacturers established in the European Community exporting to the Chinese Taipei can under this co-operation allow Notified Bodies to present the appropriate audit reports to the competent authorities in Chinese Taipei as part of the documentation regarding access to the Chinese Taipei market.*

- *Appropriate information concerning the designation and monitoring of Notified Bodies will be made available for clarification to the Chinese Taipei authorities by the competent authorities of the EC Member States, upon duly justified request.*

Between 2002 and 2005, the "Technical Cooperation Programme on the Exchange of Medical Device GMP and ISO 13485 Audit Reports between Designated Medical Device GMP Auditing Organizations of DOH, ROC and EU AIMD/MDD/IVDD Notified Body Partners" (known as the TCP) was established based on the EOL. Within TCP, audits performed shall be in line with ISO 13485 requirement and GHTF SG4 guidance documents.

In 2004 and 2006, a total of 12 EU Notified Bodies were accepted by DOH as TCP partners. They are: NSAI, mdc, TÜV Rheinland PS, G-MED, TÜV PS, BSI PS, KEMA, AMTAC, SGS, MEDCERT, DGM, and UL(UK). In addition to being Notified Bodies for MDD, IVDD and AIMD,

these 12 Notified Bodies were selected for their representativeness of EU members' state composition and market impact, experience & recognition in global regulatory auditing, and quality system & integrity.

In Taiwan, all regulatory audits (including unscheduled audits) for Class I (sterile), II and III medical devices manufactured for the Taiwan market are performed by DOH authorized auditing organizations, which include CMS/ITRI, MIRDC, ETC and PIDC. Audits are performed in accordance to international harmonized medical device quality system standard and guidelines. These authorized auditing organizations are all statutory established not-for-profit organizations and are regulated by government agency. Authorized auditing organizations need to have established a quality system in accordance with GHTF SG4 guidance and ISO 17021. All GMP auditors are trained with ISO 13485 auditing requirement and fulfill GHTF SG4 personnel requirement. To ensure the standard of the audit, all audits are monitored and their results reviewed by TFDA. Authorized auditing organizations are audited by TFDA in accordance with Pharmaceuticals Affairs Act and ISO 17021 regularly. As experience shows, all GMP registered manufacturers are shown to be able to ISO 13485 certified by either TCP or other Notified Bodies successfully.

To further implement the activities described in the EOL, the Chinese Taipei government allowed an abbreviated review mechanism for the EU manufacturers through TCP, with audit information provided by EU Notified Body Partners to be reviewed by authorized auditing organizations and final decision approved by TFDA. To date more than 1,600 application cases from European manufacturers have benefited from this aspect of EOL initiative.

TCP has moved forward with a pilot programme between BSI, SGS and authorized auditing organizations to establish confidence of the auditing reports sharing since 2011. This includes auditor qualification, joint audit and observed audit, which demonstrates competence of authorized auditing organizations, with positive indication that required further expansion.

However, manufacturers in both Europe and Taiwan could have been benefited further from the EOL with reduction of duplicate audits, but the current operation of EOL has never been reviewed since signing, and that ISO 13485 audit reports issued by authorized auditing organizations are not accepted in EU.

Discussion:

The initiatives in EOL has some success, and benefited many European establishments and the general public by reducing regulatory administrative cost without sacrificing the safety and accessibility of medical devices. The current meeting seeking for a common ground to mutual acceptance of ISO 13485 audit reports issued by UK Notified Bodies and Chinese Taipei authorized auditing organizations as part of the requirements of conformity assessment procedure for medical

devices, will require the empowerment of UK TCP participating Notified Bodies to accept ISO 13485 audit reports of authorized auditing organizations and thereby return the EU market with better assured safe and regulated medical device.

Prepared by Industrial Technology Research Institute,

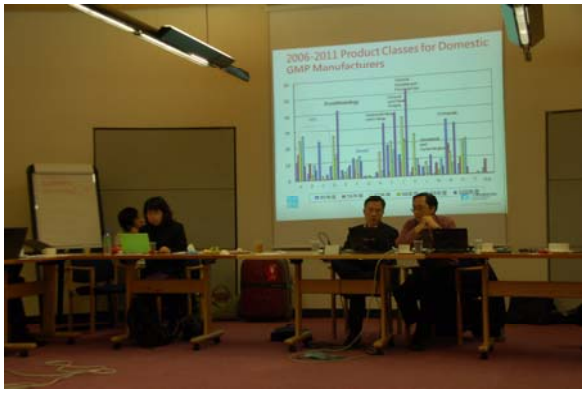
行程五

3 月 16 日　在 British Standards Institution (BSI)總部會議室，了解 Training Workshop on TCP II European Notified Body Partners，以及參加第二階段「台歐醫療器材優良製造規範/GMP 稽核報告交換技術合作方案」討論會議及合約簽署

Training Workshop on TCP II European Notified Body Partners (2011.3.16)

該次會議係本局醫療器材 GMP/QSD 代施查核單位「財團法人工業技術研究院量測技術發展中心」，向參與台歐 TCP 的 12 家歐盟 Notified Bodies 代表介紹有關我國醫療器材法規管理的制度，以及對醫療器材 GMP 的申請與查廠作法，並介紹及討論第二代 TCP 的執行方法，藉此讓歐盟 notified bodies 了解國內法規管理加深未來合作及互信；會中也與各代施查核機構代表逐條檢討第二代 TCP 的合約條文內容。

本次會議由劉麗玲組長帶領本組同仁呂理福簡任技正及陳志宏薦任技正列席參與，會中劉組長向與會相關歐盟 Notified Bodies 代表表示：(1) 台歐換文提供歐洲醫療器材製造商縮短產品進入台灣的時程，但台方並未蒙受相對等的待遇，基於此換文不平衡的認同，歐方仍應努力並進一步改善此種不平衡現象；(2) 在 2012.03.12 在歐盟總部召開之「台歐醫療器材優良製造規範 GMP/ISO13485 稽核報告交換技術合作」：歐方認同交換稽核報告訊息對雙方是有利的，鼓勵台灣的醫療器材製造廠商將經由 tFDA 核可的醫療器材優良製造規範 GMP/ISO13485 稽核報告，提供歐方 TCP 方案之驗證單位(Notified Bodies)，作爲歐方依據歐盟相關指令執行符合性評估時的評估參考，並鼓勵歐盟驗證單位與 tFDA 間的驗證稽核作業合作與夥伴關係；(3)歡迎相關歐盟 Notified Bodies 蒞臺觀摩或稽核目前 tFDA 之四家醫療器材 GMP/QSD 代施查核單位，而我方必要時也將對等進行對歐盟 Notified Bodies 之稽核，以利加速台歐雙方在 ISO134855 之查核議題能夠快速建立對等互惠相互認證之信心。



當日會議簡報現場實況，劉組長聽取並向與會相關歐盟 Notified Bodies 代表表達：本局對過去台歐換文後的不平衡現象不滿意，更期望雙方共同努力，以加速台歐雙方在 ISO134855 之查核議題能夠快速建立對等互惠相互認證之信心，俾便台歐雙方在 ISO134855 之查核議題早日達成平衡與互惠雙贏的目標。

說明及研討會議程：

Training Workshop on Technical Cooperation Programme between EU AIMD/MDD/IVDD Notify Body Partners and R.O.C. DOH Designated Auditing Organizations rev. 2.0 2012

March 16, 2012

BSI – Corporate Headquarters

Room G1, 389 Chiswick High Road, London, W4 4AL, United Kingdom

Time		Subjects
Morning Session	8:30	Registration
	8:45	Welcome & Roll Call
	9:00	Opening Address
	9:15	R.O.C. Medical Device Regulation and GMP Requirements
	10:00	Progress of Technical Cooperation Programme between EU AIMD/MDD/IVD Notified Body Partners and R.O.C. DOH Designated Medical Device GMP Auditing Organizations
	11:00	Break
	11:20	Medical Device GMP Inspection: On-site Audit for Domestic and Overseas Manufacturers
Lunch	12:00	Lunch
Afternoon Section	13:00	Medical Device GMP Inspection: QSD Review for Overseas Manufacturers
	14:00	Break
	14:20	Process for EU and Taiwan Manufacturers to Utilize TCP II
	15:00	Discussion on the continuous improvement of TCP II
	16.00	Close

肆、 心得

本次行程最大的特色在於行前準備縝密，舉行多次行前討論會議，包括台歐第二代 TCP 方案都作深入討論，因此成果豐碩。

一、 與歐盟達成共識、其代施查合機構(Notified Body) 得依我國稽查報告，評估減少或減免受查核單位之範圍及頻率，減少重複查廠，並減輕廠商負擔。

九十四年第一代 TCP 方案已實施多年，但我國廠商產品輸入歐洲時，歐盟代施查合機構都以全項模式執行稽查作業，並未減少或減免查核頻率及範圍，主要歸因於但施查核機構式政府委辦單位，又歐盟係多個國家聯合之單位，之間協合性困難度大。本次拜訪比利時歐盟衛生主管機關 DG SANGO 獲得共識。他們認知台歐簽訂 EOL 後，歐方確實已獲實質效益，對台灣並不均等，限於歐盟係多國組成之單位， 他們同意重新研此項議題。他們也同意鼓勵台灣廠商提供台灣地區之稽查報告給歐盟國家之代施查核機構，該代施查核機構得依稽查報告內容減少或減免受查核單位之範圍及頻率，減少重複查廠，並減輕廠商負擔。本行已獲實質效益。

二、 拜訪英國衛生單位簽訂「台英藥物保密協定」

本次行程亦前往英國拜訪英國衛生單位，經過雙方之熱烈討論，達成共識，同意簽訂「台英藥物保密協定」，雙方於本協定下可以互相交換該等技術文件資料，以確保重大公衛利益。在重大公衛利益下互相交流技術文件，包括有 1.安全監視資料 2.產品回收訊息 3.產品上市申請案及變更案及 4.查核報告等四項資訊交換，目前草案已經雙方認可，已在辦理行政程序簽核中。另，查美國與英國也有簽訂類似協定，英美之保密協定僅簽訂有三項資訊交換，台英藥物保密協定較台美藥物保密協定多「查核報告」資訊之交換。

三、 參觀英商史耐輝股份有限公司(Smith & Nephew Orthopaedics Ltd)

英商史耐輝股份有限公司係國際知名的骨科專業器材的設計及製造廠，生產的人工植入物如股骨關節、膝關節、及骨釘骨板等產品，此次實地參觀該廠的現地

作業概況，從實務面瞭解醫療器材廠 ISO13485 的作業建構與作業程序，整體醫療器材之設計、製造、品質控制、產品上市、技術支援、上市後回饋與監視的作業程序,以及如何回應使用人需求與當地衛生主管機關對於功效及安全之法規要求等事務，比較印象深刻的是：

(一) 英商史耐輝股份有限公司爲了讓植入人工植體到病患身上，能夠維持既有明訂功效與安全品質確保，建立專業醫師使用該公司各式產品操作及使用專業技術之模擬養成培訓中心，提供新進醫療專業使用人的技術養成，對於人工植入物的功效及安全，提供正面的技術宣導與產品最終植入的品質確保；

(二) 建立上市後產品使用面的消息回饋之測試及分析實驗室，隨時從實際市場面取得產品負面品質資訊，利用科學的產品力學及材質分析，以便支持以上市產品不良反應的發現、判定及改進依據，可以積極回應品質問題，並可以更積極改善產品品質。

四、 訪問英國國家指定認證單位 Ukas, United Kingdom Accreditation Service

Ukas 係英國國家指定認證單位，台灣在操作醫療器材相關的技術標準銜接作爲法規的認定作業上，此一系統尚未建立，其重要性在於任何宣稱『測試合格』或是宣稱『符合標準』者，其究竟在何種技術作業架構與規範下，其操作的技術專業資源能力是否勝任合格、其採認作業程序是否具普世之公正性、人力技術是否合乎現況技術水準要求、在評定與判別過程是否合乎整合性與一致性等，這是任何宣稱『測試合格』或是宣稱『符合標準』的等同性，跨越不同的地域、法規政治框架、標準體系、認證與驗證單位、乃至於必要的再現性要求所必須滿足的先決條件，Ukas 係在 IAF, International Accreditation Forum 國際組織架構下的一個執行認證的鑑別驗證單位成員，在英國取得 Ukas 認證則其所驗證的 Certificate 便能夠跨越地域，得到其他等同於 IAF 架構下取得 Certificate 相對等的合可認同，可以減少技術上同質或等同 Certificate 的重複驗證，有助於國際間技術性產品如醫療器材產品的流通，其結果有助於類似相互認證的驗證結果。

五、 磋商英國驗證單位接受台灣 ISO13485 稽核報告乙事

此行在英國 MHRA 係整體策略上以英國作爲處理 ISO13485 之第二代技術合作相互承認的試金石，承襲著 3 月 12 日在比利時布魯塞爾歐盟總部，所討論「台歐醫療器材優良製造規範 GMP/ISO13485 稽核報告交換技術合作」的原則，此次與 MHRA 磋商有關「英國驗證單位接受台灣 ISO13485 稽核報告」乙事，就英國 MHRA 的立場上，已是將 3 月 12 日在比利時布魯塞爾歐盟總部的結論在此付諸實施，整體談判磋商較有利於我方，因此，英國方面鼓勵台灣醫療器材製造廠商提供經過 tFDA 認可登錄的稽核報告作爲 TCP 合作方案下之驗證單位根據歐盟指令之稽核參考，透過此合作將縮減台灣醫療器材製造廠商之稽核範圍與頻率。在減少與縮短稽核過程之人天與/或稽核時間，以下諸因素將可以減少稽核成本，如醫療器材風險、離上次稽核時間間隔、以及廠商之規模。台灣方面可以考慮調整現行醫療器材廠 GMP 之稽核頻率，以便與歐盟醫療器材指令(MDD, Medical Device Directive)/體外診斷試劑指令(IVDD, In-vitro Device Directive)之規範相當。

六、 Training Workshop on TCP II European Notified Body Partners

基本上，這是由工業技術研究院醫療器材認證實驗室，代表我方四個現行代施查核單位來英國，爲歐盟地區所有執行 ISO13485 醫療器材驗證單位所舉辦的一場說明會，主要提供歐盟驗證單位瞭解我方四個現行代施查核單位，在台灣執行醫療器材廠 GMP 查核作業如何執行 ISO13485:2003 年版的技術細節，讓歐盟驗證單位從我方實際執行的技術現況，進而對我方經過食品藥物管理局核可的療器材廠 GMP 優良製造規範查核作業建立彼此的互信，以便在執行第二代 TCP 的作業有更積極的正面進展，此外並向歐盟驗證單位直接面對面溝通有關 TCP II 的新機制。

伍、 建議事項

一、 擬訂我國醫療器材 GMP 稽查制度說帖，爭取國際認同

我國對於醫療器材製造工廠之管理制度，與美國制度較相似，以製造廠之品質系統爲主軸，展開稽查作業。而於歐洲上市之產品，歐盟組織以取得 CE 認證方式爲之，取得 CE Mark 同時必須執行工廠稽查作業。因此，歐盟國家於執行工廠 GMP 作業稽查時，同時亦查核產品之技術性文件資料。我國之產品技術性文件資料則於產品辦理查驗登記時爲之。瞭解以上之異同，我們應該積極擬訂說帖說明，歐美與國制度上之異同，爭取國際認同，如此才較容易獲得共識，取得協議。

二、 提升代施機構稽查能與量

我國醫療器材製造工廠之稽查作業係委託第三機構爲之，英國對於其代施機構之資格認定係要求取得國際認證機構之認證。我國雖然對於代施機構有基本資格及能力認定，但較於歐盟之管理模式，較不具說服力。因此我們也可以參考英國之模式，引進台灣地區之國際認證組織(例如 TAF)之資源，幫忙我國之代施查核機構取得國際能力認證，如此，與其他國家談互相認證時才能在一個有共識及信任的環境中完成。

三、 建立歐盟代施機構減少或減免稽查我國國產醫療器材工廠查核範圍及頻率之資料，持續監督後續效益

此行最重要之效益之一即取歐盟組織認同，歐盟組織下之各國家得依台灣廠商提供台灣地區之稽查報告給歐盟國家之代施查核機構，該代施查核機構得依稽查報告內容減少或減免受查核單位之範圍及頻率，減少重複查廠，並減輕廠商負擔。雖已有共識，但其後續效亦值得持續關注。

建議可透國內各公協會協助，幫忙建立歐盟各國家之代施查核機構稽查我國工廠之情形，評估後續效益，解以瞭解該共識落實之程度，若有必要，以可解由該項資料與歐盟國家執行再一次之協議談判。

四、 行前準備應該縝密

本次行前以作過多次討論及演繹，因此多能掌握談判內容及重點，獲得實質效益，建議以後參加各種國內外活動時，都應落實行前準備工作，如此，才能有實質效益產生。

陸、 附件

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