Key factors of Taiwan Regulation

Medical Devices Product Manager of BSI Taiwan

Hailey Chu 朱惠如
Taiwan Medical Device Regulations

- 藥事法 Pharmaceutical Affairs Act
- 藥事法施行細則 Details of Pharmaceutical Affairs Act
- 醫療器材管理辦法 Regulations for Governing the Management of Medical Device
- 醫療器材查驗登記審查準則 Regulations for Registration of Medical Device
- 藥物製造工廠設廠標準 Standards for Medicament Factory Establishments
- 藥物優良製造準則 Medicament Good Manufacturing Practice
- 藥物製造業者檢查辦法 Pharmaceutical Manufacturer Inspection Measures
- 藥物委託製造及檢驗作業準則 Regulations of Medicament Manufacturer Inspection
- 嚴重藥物不良反應通報辦法 Procedure for Reporting Serious Adverse Reactions of Medicaments
- 藥物安全監視管理辦法 Procedure for Safety Monitoring of Medicaments
- 藥物回收作業實施要點 Guideline for Medicament Recall
- 醫療器材優良安全監視規範 Guidance for Medical Device Good Vigilance Practice
Organization of Taiwan Food and Drug Administration (TFDA)

Center for Drug Evaluation (CDE)
Taiwan Drug Relief Foundation Pharmaceutical Industry
Technology Development Center (PITDC)
Food Industry Research and Development Institute (FIRDI)
Electronics Testing Center (ETC)
Metal Industries Research & Development Centre (MIRDC)
Plastics Industry Development Center (PIDC)
Industrial Technology Research Institute (ITRI)

Division of Medical Devices and Cosmetics
- Medical Devices Security & Quality Control
- Medical Devices Regulations
- New Medical Devices & Clinical Trials
- General Medical Devices
- In Vitro Diagnostic Devices
- Cosmetics
# Frame of Medical Device Registration

<table>
<thead>
<tr>
<th></th>
<th>Class I</th>
<th>Class II</th>
<th>Class III</th>
<th>Novel Product</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Quality management system</strong></td>
<td>GMP / QSD required for sterile / measuring product</td>
<td>GMP / QSD required</td>
<td>GMP / QSD required</td>
<td>GMP / QSD required</td>
</tr>
<tr>
<td><strong>Product registration</strong></td>
<td>Application and registration</td>
<td>Technical file review</td>
<td>Technical file review</td>
<td>Technical file review</td>
</tr>
<tr>
<td><strong>Clinical Report</strong></td>
<td>Not required</td>
<td>Not required</td>
<td>Not required</td>
<td>Literature review or Clinical investigation</td>
</tr>
</tbody>
</table>
Classification of Medical Devices

• **Class I**
  The device is not life-supporting or life-sustaining or for a use which is of substantial importance in preventing impairment of human health, and which does not present the potential for unreasonable risk of illness or injury.

• **Class II**
  The device is purposed or represented to be for use in supporting or sustaining human life.

• **Class III**
  The device is life-supporting or sustaining or for a use which is of substantial importance in preventing impairment of human health. Or, the device may present the potential for unreasonable risk of illness or injury.
## Categories of Medical Devices

<table>
<thead>
<tr>
<th>Category</th>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical chemistry and clinical toxicology devices</td>
<td>226</td>
<td>General hospital and personal use devices</td>
</tr>
<tr>
<td>Hematology and pathology devices</td>
<td>100</td>
<td>Neurological devices</td>
</tr>
<tr>
<td>Immunology and microbiology devices</td>
<td>176</td>
<td>Obstetrical and Gynecological devices</td>
</tr>
<tr>
<td>Anesthesiology devices</td>
<td>131</td>
<td>Ophthalmic devices</td>
</tr>
<tr>
<td>Cardiovascular devices</td>
<td>139</td>
<td>Orthopedic devices</td>
</tr>
<tr>
<td>Dental devices</td>
<td>120</td>
<td>Physical medicine devices</td>
</tr>
<tr>
<td>Ear, Nose, and Throat devices</td>
<td>53</td>
<td>Radiology devices</td>
</tr>
<tr>
<td>Gastroenterology-Urology devices</td>
<td>61</td>
<td>Others recognized by Department of Health</td>
</tr>
<tr>
<td>General and Plastic Surgery devices</td>
<td>75</td>
<td></td>
</tr>
</tbody>
</table>

*Copyright © 2012 BSI. All rights reserved.*
<table>
<thead>
<tr>
<th>序號</th>
<th>分類分級代碼</th>
<th>中文名稱</th>
<th>英文名稱</th>
<th>等級</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>A.0001</td>
<td>藥環利定試驗系統</td>
<td>Phencyclidine test system</td>
<td>2</td>
</tr>
<tr>
<td>2</td>
<td>A.1020</td>
<td>酸性磷酸酶(總量或前列腺的)試驗系統</td>
<td>Acid phosphatase (total or prostatic) test system</td>
<td>2</td>
</tr>
<tr>
<td>3</td>
<td>A.1025</td>
<td>促進上腺皮質荷爾蒙試驗系統</td>
<td>Adrenocorticotropic hormone (ACTH) test system</td>
<td>2</td>
</tr>
<tr>
<td>4</td>
<td>A.1030</td>
<td>肝脂肪轉胺酶試驗系統</td>
<td>Alanine amino transferase (ALT/SGPT) test system</td>
<td>1</td>
</tr>
<tr>
<td>5</td>
<td>A.1035</td>
<td>白蛋白試驗系統</td>
<td>Albumin test system</td>
<td>2</td>
</tr>
<tr>
<td>6</td>
<td>A.1040</td>
<td>鹼醇結合酵素試驗系統</td>
<td>Aldolase test system</td>
<td>1</td>
</tr>
<tr>
<td>7</td>
<td>A.1045</td>
<td>鹼類脂酶試驗系統</td>
<td>Aldosterone test system</td>
<td>2</td>
</tr>
<tr>
<td>8</td>
<td>A.1050</td>
<td>鹼性磷酸酯或同功酶試驗系統</td>
<td>Alkaline phosphatase or isoenzymes test system</td>
<td>2</td>
</tr>
<tr>
<td>9</td>
<td>A.1055</td>
<td>新生兒胺基酸、遊離內酯及臍基內酯篩檢用串聯質譜儀系統</td>
<td>Newborn screening test system for amino acids, free carnitine, and acylcarnitines using tandem mass spectrometry.</td>
<td>2</td>
</tr>
<tr>
<td>10</td>
<td>A.1060</td>
<td>8-胺基乙醣丙酸試驗系統</td>
<td>Delta-aminoleuvulinic acid test system</td>
<td>1</td>
</tr>
</tbody>
</table>
Quality Management Documentation (QSD)

Documents
1. Two completed QSD application forms 輸入醫療器材製造廠符合優良製造規範申請書 2份
2. Quality system documentation of manufacturer 製造廠品質系統文件
3. Company established licence 販賣業藥商許可執照影本
4. Copy of certificate (eg. ISO 13485) 驗證合格登錄證書影本1份
5. Original product approval for registration (Continuing review only) 原認可登錄函正本(後續檢查案件須檢附)

Review Period
- New application: 120 days
- Continuing review: 120 days
- Re-review: 140 days

Application Fee
TWD 20,000
Application Process

1. Application
2. TFDA
3. Authorized party
4. Documents review
5. Technical file review
6. QSD approval
7. Approval of Product
## Technical Cooperation Programme (TCP)

<table>
<thead>
<tr>
<th>Item</th>
<th>Normal</th>
<th>TCP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application form 申請書</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Manufacturer document 原廠說明文件</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>ISO 13485 certificate ISO 13485證書</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Audit report 查廠報告</td>
<td>-</td>
<td>x</td>
</tr>
<tr>
<td>Certificate to Foreign Government 製售證明</td>
<td>-</td>
<td>x</td>
</tr>
<tr>
<td>Layout of factory 全廠配置圖</td>
<td>x</td>
<td>-</td>
</tr>
<tr>
<td>Manufacturing area(s) of each product 各類產品製造作業區域</td>
<td>x</td>
<td>-</td>
</tr>
<tr>
<td>Main equipment 主要設備</td>
<td>x</td>
<td>-</td>
</tr>
<tr>
<td>Manufacturing process 產品製造流程</td>
<td>x</td>
<td>-</td>
</tr>
<tr>
<td>Quality manual 品質手冊</td>
<td>x</td>
<td>-</td>
</tr>
<tr>
<td>List of quality system documents 文件總覽表</td>
<td>x</td>
<td>-</td>
</tr>
<tr>
<td>QMS procedures 品質系統程序文件</td>
<td>x</td>
<td>-</td>
</tr>
<tr>
<td>Original product approval for registration (Continuing review only) 原認可登入函正本 (後續請案適用)</td>
<td>x</td>
<td>-</td>
</tr>
</tbody>
</table>
Application for TCP

QSD Application Form to TFDA

5.2.1 The institutions of factory investigation and verification of European Union (or the counties/areas that have signed the agreement for cooperation) (Please click):
- BSI PS
- G-med
- mdc
- NSAI
- TÜV PS
- TÜV Rheinland PS
- KEMA
- DGM
- AMTAC
- MEDCERT
- SGS(UK)
- UL (UK)
- Other institutions recognized by health administration:

Institution name:

Company Information Form to BSI

Medical Device Related Services:
- CE certification to MDD, AIMD Directive
- Transfer from another Notified Body
- Clinical Strategy Review
- Own Brand Labelling
- EUD택 ISO 13485 Certification (GCC)
- EUD택 ISO 13485 Certification (GCC)
- Australia TGA/EU MRA Fast Track Service (Applicable only to products manufactured in Europe)
- Japan PHL certification
- Saudi Arabia CAB services (Information only)
- ISO 13485 certification (UKAS, SCC or DAAKS)
- ISO 9001 (Quality)
- Safety testing (IEC 60601) and/or EMC
- Medical device or quality system related training
- FDA Accredited Persons (AP) Inspection Programme
- Accelerated Medical Device Registration in Taiwan (Applicable only to EU Manufacturers)
- Hong Kong CAB Product Approval
- Russian Market Access Programme

bsi.

Copyright © 2012 BSI. All rights reserved.
Distribution of Nonconformities in Normal QSD Application

- QMS certificate
- Quality manual
- QMS procedures
- Documents list
- Layout
- Manufacturing area
- Main equipments
- Manufacturing process
- ADR, recall
Distribution of Nonconformities in TCP Application

- QMS certificate
- Certificate to foreign government
- Audit report

Copyright © 2012 BSI. All rights reserved.
Question about QMS Certificate

- The competence of third party to issue ISO 13485 certificate?
- The form of certificate issued by notified body?

Access UKAS website
Access IAF website

Search the name of Notified Body
Search the name of Accreditation Body

Schedule of Accreditation

- 003

ISO 13485:2003 and BS EN ISO 13485:2003 Certification

<table>
<thead>
<tr>
<th>European Co-operation for Accreditation Scope Reference</th>
<th>Extent of Scope</th>
</tr>
</thead>
<tbody>
<tr>
<td>EA 1 - Textiles and Textile Products</td>
<td>Sterile Disposables/Sterile Dressings</td>
</tr>
<tr>
<td>EA 13 - Chemicals, chemical products and films</td>
<td>Medical related adhesives</td>
</tr>
<tr>
<td>EA 14 - Others including Pressure Ulcers, Walking Aids, Wheelchairs, Non-Stereosurgical Healthcare Supplies, Theatre Equipment and Surgical Instruments and Prosthesi Products</td>
<td></td>
</tr>
</tbody>
</table>

BSI Assurance UK Limited
Issue Date: 24 April 2013
Questions about Certificate to Foreign Government

- Different address statement on certificates issued by different third party?
- The wordings “market” or “free to sale” is not on certificate?

美国官方及欧盟会员国之官方或权责机关出具之核准上市证明文件 (发表日期2011-01-12)

欧盟会员国出具之核准上市证明文件，可以CE Mark證書（EC Certificate）代替，但內容必須詳細載明製造廠名稱、地址、產品名稱及型號，且須與所載均相符。又因欧盟權責機關醫療器材管理路徑眾多、相關管理規定可能會有變更，依據原行政院衛生署藥政處與藥物食品檢驗局98年5月6日「醫療器材查驗審查原則討論」會議決議，由欧盟權責機關核發之上市證明或說明函，不管依據哪條指令，只要所載製造廠名稱、地址及產品名稱、型號等相關資料與申請者之製售證明相符，並載明可在歐盟上市（market、free sale或類似的字句）即可接受。反之，若検具之EC certificates未載明可於歐盟上市，則不予接受。

Question about Audit Report

- Is it the latest audit report?
- Audit report is not stated TCP?
- The compliance with number of certificate in audit report and certificate?
- Actions of nonconformities raised in latest audit?
- Acceptance of CAP by auditor / notified body?