The IAF Initiative for Accredited Certification to ISO 13485 – Medical Devices

Vision Statement

“To provide opportunities to develop national medical device regulations while maintaining access to safe and effective healthcare technologies”.
ISO 13485 – What is Being Done to Achieve Global Acceptance of the Harmonized Standard for Medical Devices Manufacturing

Presentation by Grant Ramaley
ISO 13485 WG Convener
ISO 13485

Medical Device Regulations are harmonized with or rely on ISO 13485

ISO 13485 for compliance under 93/42/EEC Annex II
European Union

FDA

ISO 13485 Referred to by SOR/98-282
Health Canada

ISO 13485 Referred to by Legislative Instruments F2008L04337
TGA

Ministerial Ordinance No. 169 “harmonized” with 13485:2003
MHLW
ISO 13485

Each regulatory body allows third party auditors/inspectors
Each regulatory body accredits auditors/inspectors independently
Regulatory bodies in more countries are contemplating ISO 13485-based Quality Management Systems for regulatory purposes.

REGULATORY COMPLIANCE IS NOT AN OPTION

Accepts ISO 13485 for compliance with 93/42/EEC Annex II
European Council

FDA

Refers to by SOR/98-282
Health Canada

Refers to by Legislative Instruments F2008L04337
TGA

Ministerial Ordinance No. 169 “harmonized” with 13485:2003
MHLW
Medical device trade and healthcare are dependent on one another. As other countries create their own national ISO 13485 accreditation system, many healthcare products will cease to become available.

Of 192 countries worldwide, 150 countries do not have effective medical device regulations.

What would happen if ALL countries developed their own ISO 13485 QMS accreditation scheme?!
The Cost of One Inspection?

ISO 13485
Average cost per year is **$13,000** for a company with 50 employees.

If all 14 remaining APEC members *nationalize* 13485 accreditation...

GRAND TOTAL **$28,000**

**Remainding APEC Members Considering GHTF and ISO 13485**

- **$3000**
- **$3000**
- **$3000**
- **$3000**
- **$3000**

**Est. For Small Business**
What will the rest of the world do?

One Inspection For 150 Countries $13,000

OR

150 Inspections For One Manufacturer $455,000!
5.4 billion people live in 150 countries that do not have developed medical device regulations.

Most countries would lose access to many healthcare technologies under a national accreditation system.
Smaller countries heavily depend on foreign made medical devices to serve national public health needs.

**Tasman Market**
- Australia & New Zealand
- 2% of world market

2100 suppliers
- 38,000 different devices
- 400,000 to 600,000 catalogue items

More than 85% of devices are imported
Less than 10% of devices could be classified as high-risk
Most of Medical Device Manufacturers are Small

“Medical device manufacturing and development facilities were generally small in size as more than half (57 percent) had fewer than 25 employees and 37 percent had from 25 to 49 employees”.

<table>
<thead>
<tr>
<th>Number of Employees</th>
<th>Number of Facilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 to 24</td>
<td>634</td>
</tr>
<tr>
<td>25 to 49</td>
<td>408</td>
</tr>
<tr>
<td>50 to 150</td>
<td>45</td>
</tr>
<tr>
<td>More than 150</td>
<td>8</td>
</tr>
<tr>
<td>Not Classified</td>
<td>6</td>
</tr>
</tbody>
</table>

95% have fewer than 50 employees
Smaller manufacture do not profit significantly from most foreign countries.

Sales To TASMAN from Small Medical Device Manufacturer

- TASMAN 1%
- The Rest of The World 99%
### Profile of Small and Medium Size Manufacturers

<table>
<thead>
<tr>
<th>Country</th>
<th>Sales as % of Total Sales</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAYMAN ISLANDS</td>
<td>0.0193%</td>
</tr>
<tr>
<td>HUNGARY</td>
<td>0.0206%</td>
</tr>
<tr>
<td>DENMARK</td>
<td>0.0269%</td>
</tr>
<tr>
<td>BELGIUM</td>
<td>0.0276%</td>
</tr>
<tr>
<td>TRINIDAD AND TOBAGO</td>
<td>0.0287%</td>
</tr>
<tr>
<td>SAUDI ARABIA</td>
<td>0.0292%</td>
</tr>
<tr>
<td>PARAGUAY</td>
<td>0.0303%</td>
</tr>
<tr>
<td>P.R. CHINA</td>
<td>0.0325%</td>
</tr>
<tr>
<td>GUAM</td>
<td>0.0339%</td>
</tr>
<tr>
<td>VIRGIN ISLANDS, BRITISH</td>
<td>0.0340%</td>
</tr>
<tr>
<td>AMERICAN SAMOA</td>
<td>0.0344%</td>
</tr>
<tr>
<td>KENYA</td>
<td>0.0347%</td>
</tr>
<tr>
<td>VENEZUELA</td>
<td>0.0365%</td>
</tr>
<tr>
<td>RUSSIA</td>
<td>0.0370%</td>
</tr>
<tr>
<td>EL SALVADOR</td>
<td>0.0393%</td>
</tr>
<tr>
<td>LITHUANIA</td>
<td>0.0421%</td>
</tr>
<tr>
<td>NICARAGUA</td>
<td>0.0444%</td>
</tr>
<tr>
<td>MOROCCO</td>
<td>0.0471%</td>
</tr>
<tr>
<td>EGYPT</td>
<td>0.0499%</td>
</tr>
<tr>
<td>UNITED ARAB EMIRATES</td>
<td>0.0543%</td>
</tr>
</tbody>
</table>

**Brazil Audit**
- BGMP inspection
- Cost $20,000

**Canada Audit**
- CMDCAS audit
- Cost $13,000

**86 Countries**
- Provide for less than 1% of total sales.

**60 Countries**
- Purchased less than $10,000 in product

Most countries buy less than 1% of what a medical device manufacturers will sell. Small and medium size manufactures will sell only $100 to $10,000 worth of product to most of these countries.
Profile of Small and Medium Size Manufacturers

$1,000 in product
Can treat more than 250 patients per year

Smaller manufacturers make innovative medical devices

Aribex NOMAD® Pro handheld x-ray system has been selected as a finalist in the 2012 Medical Design Excellence Awards competition
As economic levels in isolated communities rise, the amount of sugar and other fermentable carbohydrates in the diet increases and this is often associated with a marked increase in dental caries. World Health Organization.
“Dental caries (tooth decay) is the single most common chronic childhood disease – 5 times more common than asthma and 7 times more common than hay fever”. ORAL HEALTH IN AMERICA: A REPORT OF THE SURGEON GENERAL
$1,000 in product
Can treat more than 250 patients per year

Smaller manufacturers make innovative medical devices
Aribex NOMAD® Pro handheld x-ray system has been selected as a finalist in the 2012 Medical Design Excellence Awards competition
Most medical device manufacturers are small and cannot justify paying for many ISO 13485 based QMS accreditations.

As medical device manufacturers cannot afford to comply, many healthcare products will cease to legally exist in many countries.

What must happen?

“Accredited once, accepted everywhere”

5.4 Billion People at Risk!!
International Accreditation

What is it?

Accreditation Body organizations perform Accreditation activities using international Accreditation standards.
(IAF) Documents for ISO 13485

Informative Guidance Handbook

Explains:

- Why the program was created
- How it can improve healthcare locally and worldwide
- How the system fits in with other regulations for Medical Devices
- How the IAF Mandatory Documents are used.
- How to recognize IAF accredited certificates for ISO 13485.
(IAF) Documents for ISO 13485

ISO 13485 No Changes

ISO 17021 IAF MD9:2011

ISO 17011 IAF MD8:2011

National Regulation requires IAF Accredited ISO 13485 Certificate

Regulatory Recognition

Accreditation Bodies (AB)

Conformity Assessment Bodies (CAB)

Medical Device Manufacturers

SG-4 Guidance Integrated into MD9

GHTF

IAF

Integrated into MD9
(IAF) Documents for ISO 13485

ISO 17021
IAF MD9:2011

ISO 17011
IAF MD8:2011

Accreditation Bodies (AB)

Conformity Assessment Bodies (CAB)
Table 1.5 – STERILIZATION METHODS FOR MEDICAL DEVICES

<table>
<thead>
<tr>
<th>Main Technical Areas</th>
<th>Technical Areas</th>
<th>Product Categories</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sterilization Method for Medical Devices</td>
<td>Ethylene oxide gas sterilization (EOG)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Moist heat</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Aseptic processing</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Radiation sterilization (e.g. gamma, x-ray, electron beam)</td>
<td></td>
</tr>
</tbody>
</table>

MD 7.9.5

The accreditation certificate shall indicate the scope of accreditation which should clearly specify the Technical Areas as defined in Annex 1 – Scope of Accreditation. To include within the scope of accreditation, devices that are sterile or intended for end-user sterilization, the certification body shall be competent according to sterilization process detailed in Table 1.5 of Annex 1.

7.10 Appeals

No additional requirements for ISO 13485.
(IAF) Documents for ISO 13485

ISO 17011
IAF MD8:2011

ISO 17021
IAF MD9:2011

Accreditation Bodies (AB)

Conformity Assessment Bodies (CAB)

Enforcement By IAF Accreditation Assessors
### Annex D
(Normative)

#### Table D.1
Relationship between effective number of personnel and audit duration (Initial Audit only)

<table>
<thead>
<tr>
<th>Effective Number of Personnel</th>
<th>Audit Duration Stage 1 + Stage 2 (days)</th>
<th>Effective Number of Personnel</th>
<th>Audit Duration Stage 1 + Stage 2 (days)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-5</td>
<td>3</td>
<td>626-875</td>
<td>15</td>
</tr>
<tr>
<td>6-10</td>
<td>4</td>
<td>876-1175</td>
<td>16</td>
</tr>
<tr>
<td>11-15</td>
<td>4.5</td>
<td>1176-1550</td>
<td>17</td>
</tr>
<tr>
<td>16-25</td>
<td>5</td>
<td>1551-2025</td>
<td>18</td>
</tr>
<tr>
<td>26-45</td>
<td>6</td>
<td>2026-2675</td>
<td>19</td>
</tr>
<tr>
<td>46-65</td>
<td>7</td>
<td>2676-3450</td>
<td>20</td>
</tr>
<tr>
<td>66-85</td>
<td>8</td>
<td>3451-4350</td>
<td>21</td>
</tr>
<tr>
<td>86-125</td>
<td>10</td>
<td>4351-5450</td>
<td>22</td>
</tr>
<tr>
<td>126-175</td>
<td>11</td>
<td>5451-6800</td>
<td>23</td>
</tr>
<tr>
<td>176-275</td>
<td>12</td>
<td>6801-8500</td>
<td>24</td>
</tr>
<tr>
<td>276-425</td>
<td>13</td>
<td>8501-10700</td>
<td>25</td>
</tr>
<tr>
<td>426-625</td>
<td>14</td>
<td>&gt;10700</td>
<td>Follow progression above</td>
</tr>
</tbody>
</table>

Factors used to determine the audit time
4.5 Openness

MD.4.5.1
In order to increase the confidence from interested parties and specifically regulators that accept or take into consideration ISO 13485 accredited certification for the purpose of their recognitions, it is expected that CBs establish appropriate agreements with their clients to release audit report information to regulators that recognize ISO 13485.
The defibrillator battery did not charge, and the patient was unable to be revived.

Record of Serious Adverse Event.

Utilizes native speaking auditors to assess quality system procedures, records and customer complaints.

The maximum flow rate must not exceed 100 mL per minute.

إن البطارية لم تشحن، وعندما يحاولون أن يعيدوا الحياة إلى المريض لاحظوا أنهم لم يستطيعوا.

I Utilizes native speaking auditors to assess quality system procedures, records and customer complaints.

I The maximum flow rate must not exceed 100 mL per minute.
For each class of In-Vitro Diagnostic (IVD) there are restrictions on type of certificates that may be used to demonstrate that a manufacturer has the appropriate manufacturing processes to make the IVD (Manufacturer’s Evidence).

ISO 13485 Certification body accredited by signatory of IAF MLA
IAF ACCREDITED CONFORMITY ASSESSMENT SYSTEM

CONTRIBUTIONS TO HEALTHCARE PROTECTION

FAKE CERTIFICATE UNCOVERED BY IAF MEMBERS

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration
CE and CMDCAS audits improved ("side effect")

Where ISO 13485 audits are combined with CE and CMDCAS audits, the regulatory audits have improved

How??

Eliminating overuse of ISO 9001 auditors for ISO 13485
CABs more inclined to use auditor technical expertise

Uncovering root causes of medical device problems
Provides enforceable arrangements to allow participating regulators access to audit reports.

Provides Medical Device Manufacturers with one ISO 13485 audit that is cost effective since it is “accepted everywhere”.

Provides healthcare systems with access to a global supply medical devices, which have been properly screened.
In keeping with safe and effective medical technologies, while providing opportunities to develop national medical device regulations.  

IAF Working Group Vision Statement

“"To provide opportunities to develop national medical device regulations while maintaining access to safe and effective healthcare technologies"."