International Accreditation Forum

Medical Devices Working Group for ISO 13485

Medical Device Conformity Assessment System

ISO 13485 – What is Being Done to Achieve Global Acceptance of the Harmonized Standard for Medical Devices Manufacturing

Steve McRoberts, CSci CPhys MInstP

Underwriters Laboratories

How the *Harmonized* Quality Management System is becoming the biggest barrier to medical device trade and threatens world health

ISO 13485

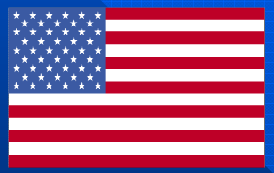
Medical Device Regulations are *harmonized* with or rely on ISO **13485** .

GHTF

Global Harmonization Task Force
Working Towards Harmonization in Medical Device Regulation

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

European Council



21 CFR Part 820 "harmonized" with ISO 13485:1996

FDA

Referred to by SOR/98-282

Health Canada

Referred to by Legislative Instruments F2008L04337

TGA

Ministerial Ordinance No. 169 "harmonized" with 13485:2003

MHLW

How the *Harmonized* Quality Management System is becoming the biggest barrier to medical device trade and threatens world health

ISO 13485

Each regulatory body allows third party auditors/inspectors

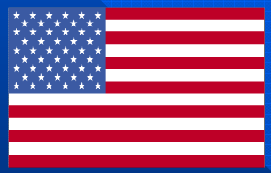
Each regulatory body accredits auditors/inspectors independently

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



21 CFR Part 820 "harmonized" with ISO 13485:1996

FDA

13485 *Referred to by SOR/98-282*

Health Canada

13485 *Referred to by* Legislative Instruments F2008L04337

TGA

Ministerial Ordinance No. 169 "harmonized" with 13485:2003

MHLW

How the *Harmonized* Quality Management System is becoming the biggest barrier to medical device trade and threatens world health

Medical device trade and healthcare are dependent on one another.

As other countries create their own national ISO 13485 accreditation, many healthcare products will cease to become available.

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

What would happen if ALL countries developed their own ISO 13485 QMS accreditation scheme?!

The Cost of One Inspection?

ISO 13485

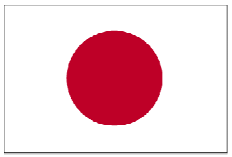
Annual Inspection Cost is $5,000 to $8000 per year for a company with less than 50 employees.

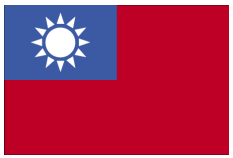
Est. FOR SMALL BUSINESS

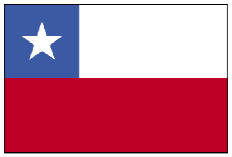
ISO 13485 $5000


+ $3000


+ $3000


+ $3000


+ $3000


+ $3000

GRAND TOTAL
$20,000

REMAINING APEC MEMBERS CONSIDERING GHTF and ISO 13485


$3000


$3000


$3000

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

$62,000


$3000

What will the rest of the world do?

One Inspection For 150 Countries $8000

OR

Per Year!

150 Inspections For One Company *$450,000*

Why "*Nationalizing*" The ISO 13485 Inspection Is Bad

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 if they adopted a *national ISO 13485 based* accreditation system into a new medical device regulation.

What *could* happen

ISO 13485

80% of 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.

5.4 Billion People at Risk!!

What *must* happen?

MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT
IAF

"Accepted once, accepted everywhere"

Smaller countries heavily depend on foreign made medical devices to serve national public health needs.

Example

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

International Accreditation Forum (IAF) ISO 13485 Working Group

IAF Documents

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.

International Accreditation Forum (IAF) ISO 13485 Working Group

MD8 MD9 Documents

Mandatory Documents

Accreditation Body Requirements

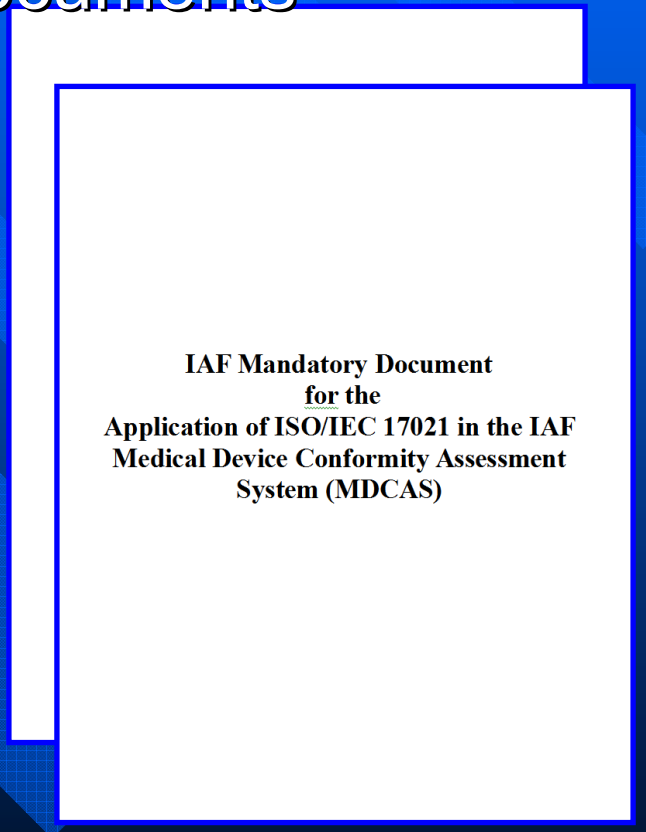
MD8 Based on ISO/IEC 17011

Input from Regulatory Authorities

Conformity Assessment Body (CAB)

MD9 Based on ISO/IEC 17021

including: Input from GHTF



International Accreditation Forum (IAF) ISO 13485 Working Group

The New ISO 13485 IAF ACCREDITED

CONFORMITY ASSESSMENT SYSTEM

MAJOR CONTRIBUTIONS TO HEALTHCARE

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

除細動器のバッテリーが充電できず、患者を蘇生させることができなかった。

مدخلات التصميم
المواصفات الفنية
لايجوز ان يتعدى معدل الجريان عن ١٠٠ مللتر لكل دقيقة

International Accreditation Forum (IAF) ISO 13485 Working Group

ISO 13485 IAF CONFORMITY ASSESSMENT SYSTEM
MAJOR CONTRIBUTIONS TO HEALTHCARE

- Provides enforceable arrangements to allow participating regulators access to audit reports.

- Provides Medical Device Manufacturers with one ISO 13485 audit that *can* be *"accepted everywhere".*

- Provides healthcare systems with access to a global supply medical devices, which have been properly screened.

For More Information Contact

Steve McRoberts:

Steve.a.mcroberts@ul.com

IAF Medical Devices Working Group Vision Statement

"在保持采用安全和有效的医疗保健技术的同时,提供各种机会以支持国家医疗器械法规的发展".