owards a Global Vision on Medical Softwar

troduction and International Comparative Overvie

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AHWP TC Training Workshop – Parallel session 2
Chinese Taipei
November 03, 2012

Summary

1. What is DITTA?
2. DITTA vision on medical software
3. An international comparison of regulations f medical software
4. What DITTA is doing on medical software?
5. Our workshop today…

TTA is the Global Diagnostic Imaging, Healthcare IT, and Radiation Thera
ade Association

TTA is a global trade association representing medical imaging, radiation th
ealthcare IT, electromedical and radiopharmaceutical Industry.

TTA was officially incorporated in 2012 as a non-profit trade association in
nited States after more than 12 years of existence.

TTA's membership currently includes COCIR (Europe), JIRA (Japan), MEDEC
anada), MITA (United States), THAIMED (Thailand), CAMDI (China) and IME
ussia).

More on *http://globalditta.org*

COCIR

MITA
MEDICAL IMAGING
& TECHNOLOGY ALLIANCE
A DIVISION OF NEMA

JIRA

MEDEC
CANADA'S MEDICAL TECHNOLOGY COMPANIES
LES SOCIÉTÉS CANADIENNES DE TECHNOLOGIES MÉDICALES

THAIMED

What does DITTA do?

TTA Member Goals:

- Detect disease early
- Improve the quality of care
- Reduce the likelihood of medical errors
- Lower the long-term cost of health care

TTA Activities:

- Communicate, cooperate and coordinate between associations
- Identify topics and trends with global industry impact
- Develop and submit joint industry positions
- Promote ethical conduct and practices
- Leverage the benefits of international standards
- Build and improve public awareness and relevance of industry products in healthcare and its benefits for patien and users
- Advocate for efficient and appropriat regulation that promotes innovation
- Enhance the global competitiveness member companies
- Identify unnecessary regulatory burdens
- Promote and pro-actively provide solutions to harmonize regulatory frameworks as much as possible (approved once, accepted everywher
- Expand market access for member companies
- Streamline clearance processes

2. BHTA vision on medical software

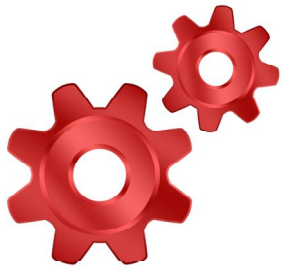
ferences across the globe challenging for manufactu

ernational harmonization is urgently needed...

- In the best interest of patient safety,
- To resolve different interpretations among differen ountries,
- Where possible, to reduce regulatory uncertainty a emove trade barriers,
- To resolve unfair competition at tender level

"Registered once, accepted everywhere"

Europe

	Stand Alone Software with medical purpose		
	communicates	stores	communicates, stores + changes or creates
 Human entered information			
 Medical device sent information			

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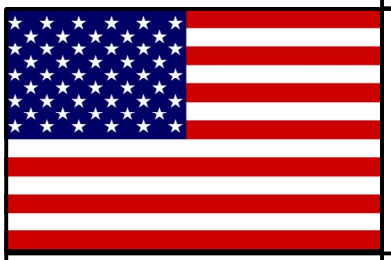
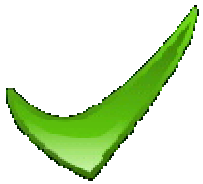
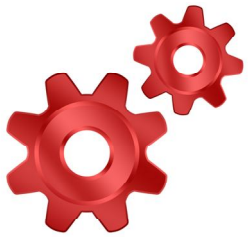
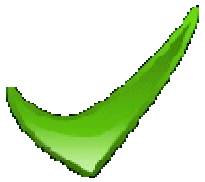
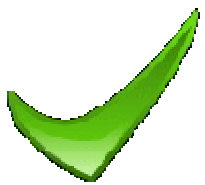
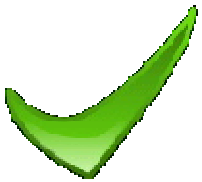
egulated

ends

USA

	Stand Alone Software with medical purpose		
	communicates	stores	communicates, stores + changes or creates
 Human enters information			 MMH, drug dose calc
 Medical device sends information	 MDDS, LMD	 MDDS, LMB, NNF	 LLZ

ted

gulated

ends

Blood bank software (MMH, 864.9175)

Medical Device Data Syster (MDDS, 880.6310)

Calculator/data device processing module for clinic use, e.g. LIS (862.2100)

Drug dose calculator (868.1

Digital image storage device PACS, opthalmic image sto devices (NNF), some RIS (LMB, 892.2010)

Medical image communicati device, e.g. MIMS (LMD, 892.2020)

Image processing system, e PACS (LLZ 892.2050)

Harmonisation still not there….

	Stand Alone Software with medical purpose		
	communicates	stores	communicates, stores + changes or creates
man enters nformation	✗	✗	✓
dical device s information	✓	✓	✓

	Stand Alone Software with medical purpose		
	communicates	stores	communicates, stores + changes or creates
Human enters information	✗	✗	i
Medical device sends information	✗	i	✓

	Stand Alone Software with medical purpose		
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n entered rmation	✗	✗	i
al device formation	✗	✗	i

ROW	Stand Alone Software with medical purpose		
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Medical device sends information	✗	✗	i

Countries know
regulate stand
software with m
purposes:

1.Australia
2.Brazil,
3.Canada,
4.China, EU,
5.Morocco,
6.Japan,
7.Taiwan
8.Singapore

✓ regulated

✗ not regulate

i It depends

TTA submitted a New Work Item Proposal on medical software to IMDRF
b. 2012
To achieve global regulatory convergence on medical software
To determine common key criteria to qualify whether software is a medica
device or not

TTA set up a dedicated Task Force on medical software
To develop DITTA position and strategy with respect to IMDRF NWIP on m
software
To develop concrete proposals that support a pragmatic implementation c
relevant regulations for medical devices with respect to software in genera
in particular for standalone software
To contribute to the development on harmonized Guidelines on qualificati
and classification of stand alone software as medical device
To monitor trends in regions (USA, Canada, Japan, China, etc.)

sessions and six presentations covering major geographies and main t

ssion 1 on the Regulatory Framework in Key Countries

rope: Lauren Selles – DG SANCO, European Commission
SA and Canada – John Abbott, MITA (replaced with Peter Linders)
pan - Susumu Takahashi, JIRA

ssion 2 on Standards to Support Regulations

IEC and ISO – Peter Linders, COCIR Standardisation Focus Group Deputy C
NELEC TC 62 Chair
Notified Bodies – VDE Testing & Certification Institute, Head of Medical De
sting
Industry – Maurizio Andreano, COCIR Member

his workshop will give you **an opportunity** to learn more about regulatio
pplicable to software used in medical practice in several geographies: c
oing discussions on regulatory framework especially in Europe, Canada, U
nd Japan?

Ve hope this workshop will also enhance a **collaborative partnersh**
etween regulators and regulated industry by strengthening our **mutual tru**
nd structural collaboration

ITTA is committed to strengthening its cooperation with AHWP and othe
takeholders in the interest of patient safety and better patient access to
dvanced health IT technologies.

Thank you!

and have a good and fruitful workshop!