

# Standards for medical devices

How ISO/IEC standards  
contribute to the regulation of  
medical devices

# Topics

- Regulatory recognition of ISO and IEC standards
- Developing standards, who is involved
- Challenges
- Example ISO 14155
- Conclusion

# Regulatory recognition

- Compliance with standards is voluntary
  - EU: directives make references to harmonized standards
  - USA has a system of recognition of approved ISO and IEC standards

# Regulatory recognition

- Level of recognition of standards by the different geographic areas varies.
- For industry, working with worldwide accepted standards means a significant improvement in efficiency.

# ISO and IEC standards supporting regulations

- ISO standards represent a more focused level of detail in addition to the regulations either
  - Product specific
  - System specific i.e. quality systems, clinical investigations

# ISO and IEC standards supporting regulations

- ISO standards are usually developed by a combined effort of pre-dominantly industry experts in collaboration with regulatory authorities.

# ISO and IEC standards supporting regulations

- Through ISO and IEC standards, industry experts can have a clear contribution to the regulations
  - Translate regulatory requirements into practical field application
  - Or identify/clarify grey areas and be more specific when needed

# ISO and IEC standards supporting regulations

- Through ISO approval process, a common acceptance can be reached...
- as much as possible!

# Challenges

- Developing standards takes time
- Not always in line with the regulations either by contents or time-wise.
- Different opinions may exist

# Challenges

- Difficult to be specific and in line with all regulatory systems (especially with system standards)
  - Too vague, not sufficient support is provided
  - Too detailed may lead to non-acceptance by certain countries.

# Challenges

- The devil is in the detail!
  - Even with a lot of detail, different interpretations may still exist
  - Different interpretations may lead to compliance problems

## Example: ISO 14155

- Current harmonized ISO 14155 part 1: general requirements for clinical investigations with medical devices
- ISO 14155 part 2: clinical investigation plan
- Both issued in 2003

# ISO 14155

- Industry needs the ISO 14155:
  - Clinical investigations are costly
  - Repetition due to non-acceptance (not only due to ISO 14155) of foreign data is expensive
  - ISO 14155 currently not accepted by USA nor Japan

# ISO 14155

- ISO currently does not provide sufficiently detailed support and lacks content concerning several critical items of a clinical investigation.
- Further work was initiated in 2004 and officially a work item was created in 2007.

# ISO 14155

- Two opinions exist:
  - Wait for longer feedback on the use of the standard or
  - Continue to work on known deficiencies while current version is in place.

# ISO 14155

- Participants in WG
  - Mainly from Europe
  - Mainly from industry
  - Only few Competent authorities
    - USA
    - Japan
    - Denmark
    - France

# ISO 14155

- Insufficient opportunity for input from expert before DIS lead recently to a negative vote on the revision of the document (Jan 2009)

# ISO 14155

- Urgent need for the revision:
  - EU with the revision of clinical evaluation requirements of the MDD (implementation in march 2010)
  - USA current national requirements
  - Japan with specific view on safety and terminology requirements

# ISO 14155

- ISO 14155 has a strong chance for consensus over the course of the next 12 months.
- Many aspects are involved, not only medical device regulatory systems but ethics on the conduct of clinical investigation and data protection.

# ISO 14155

- Total of 1'200 comments have been received, about 20-25% are duplicates and about 2% are true technical comments
- Editing committee is active, expected to finalize all comments by June 10<sup>th</sup> 2009

# ISO 14155

- **Examples:**

,This is not a standard but a guidance document. It is not written in regulatory format with Requirements against which compliance can be assessed.'

,Definitions are not aligned with MedDev 2.12-1 rev5, which leads to confusion.'

,It would be helpful to include a definition of clinical investigation insurance.'

# ISO 14155

- **Examples:**

,Our negative vote is due to current clause 4.2 which is not in line with Directive 93/42 and its revision 2007/47. Currently, the wording of clause 5 of the working draft of 29 January 2008 “Clinical investigations” from GHTF/Study group 5 should be the more adequate basis’

# ISO 14155

- Still some critical items directly related to the regulatory system exist
  - i.e. fundamental decision on justification for conduct of a clinical investigation
  - Aligning the terminology of safety to comply with the Japanese system

# ISO 14155

- Finding consensus is not only a matter of principle but also using a fine line of terminology and wording
- Danger is to provide too much detail and not have a consistent interpretation. We do not want to write a textbook.

# ISO 14155

- Many experts are largely influenced by the existing guidance from the pharmaceutical world (ICH 6)
- The specificities of the medical device area makes it difficult to apply ICH

# ISO 14155

- Delays in producing the revised version of the ISO 14155 may lead to creation additional parallel guidance documents by the competent authorities in Europe.

# ISO 14155

- Strong relationship with GHTF group 5 is needed to
  - Avoid too much overlap
  - Avoid inconsistency
  - Avoid missing items in both documents

# Conclusion

- I(nternational)SO
- Better acceptance is needed at national levels

# Conclusion

- Safety of devices should be of identical concern worldwide... so
- Is it justified to stay vague, leaving room for different interpretations, in an international standard due to national differences?

Thank you