



IDMP implementation and ISO

Christian Hay, Convener TC 215,
WG 6 «pharmacy and medicines
business»



12 September 2013



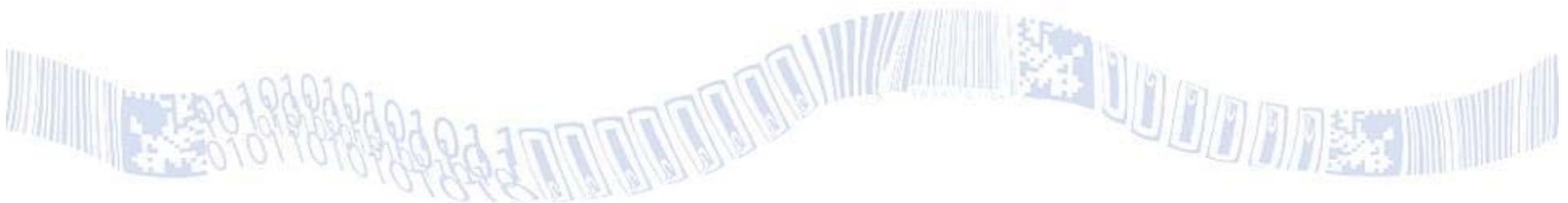
- 9:40-10:00
- The presentation of Dr. Christian Hay should be handling the aspect that the development of the ISO Standard(s) is in line with both the scientific and telematics development of the implementation and relationships development in GInAS. So when changes in GInAS has to made for IT-, Pharmacovigilance -, relationship or scientific development reasons are needed, they are in compliance with ISO –IDMP standard or future development of the (substance) ISO IDMP standard. Developments in GInAS may make changes necessary in the Standard, as for now changes in the standard has consequences for implementation in GInAS. Therefore, in my opinion, there is a need that ISO is involved in the governance of GInAS.



agenda

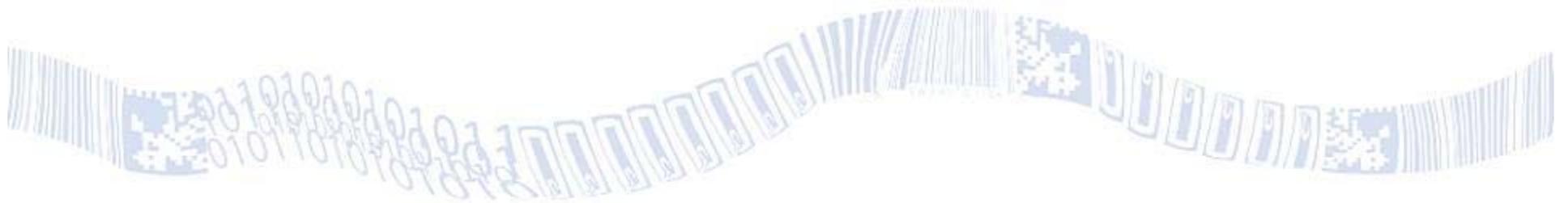


- Who am I?
- Why IDMP @ ISO ? (role of ISO regarding stds required by stakeholders)
- Market need/requirement → updates, adjustments
- Market need / requirement → implementation is 11238 (and others) sufficient for implementation?
- ISO document for supporting implementation





Who am I ?





Christian Hay



- Master in Laws, University of Geneva
- Married, 2 children
- Board Swiss Medical Informatics Association
- Past-chair IHE Suisse
- Convenor ISO TC 215 Pharmacy Group
- With GS1 since 1991





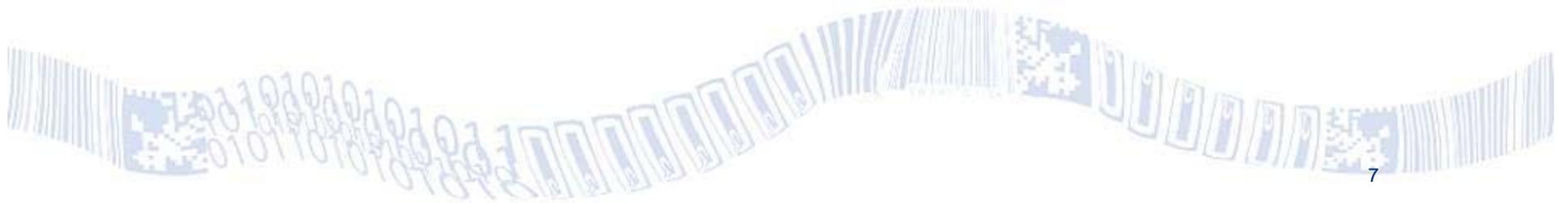
GS1 – an international standard organisation



Not-for-profit
111 Member Organisations
Over one million members
(from SME to global companies)
Member driven
150 countries served; 20 different domains
2,500 people helping us
Close relationship with ISO, UN, WHO, etc.



WHY IDMP & ISO ?



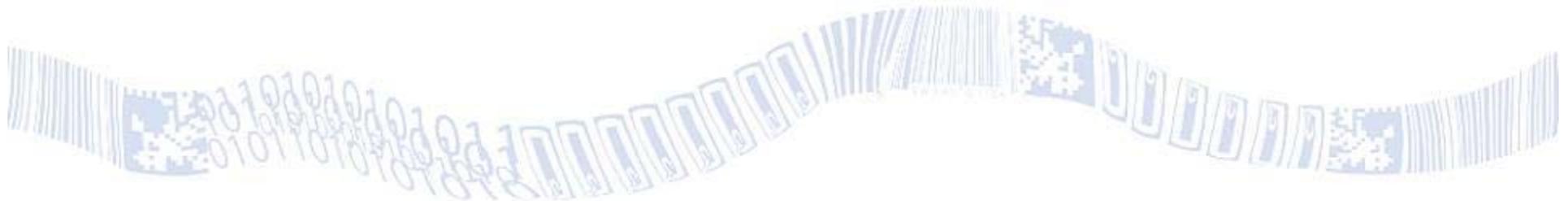


Why ISO?

Some possible answers:



- ISO has a defined, recognised, process for the development of international standards
- ISO involves a very large experts community in the standard development / assessment
 - Not only National Mirror Bodies, but a number of Liaison organisations
- ISO standards are recognised in the international community for their value as reference (e.g. requirement of ISO standards is not a technical barrier to free trade)

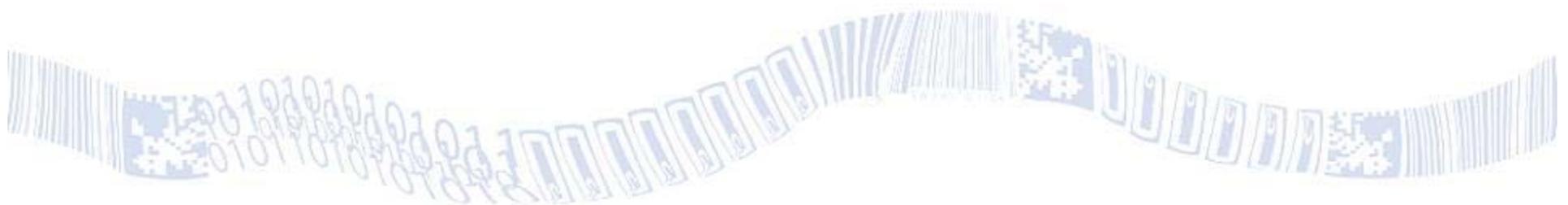




When does ISO deliver standards?



- Standard development can only occur when there is a market need
- Market need has to be formulated and submitted to the international ISO experts community
- New work item's approval must be justified by each National Mirror Body.
- When a majority of National Mirror Bodies approves a new work item, then the standard development can start
 - NU₂ (Need / Usfulness / Usability)





**Market need/requirement
→ updates, adjustments**





Characteristics of standards and market needs



- *Per se*, a standard is a static document
 - subject to review regarding their continuing utility, on a maximum five year cycle
- Some standards require frequent updates
 - Example: DICOM, where the ISO standard is updated at a lower frequency than DICOM itself
- Newer standards require frequent updates
 - Example: BRIDG – several updates a year
 - Discussion with CDISC and ISO has been initiated a suitable solution

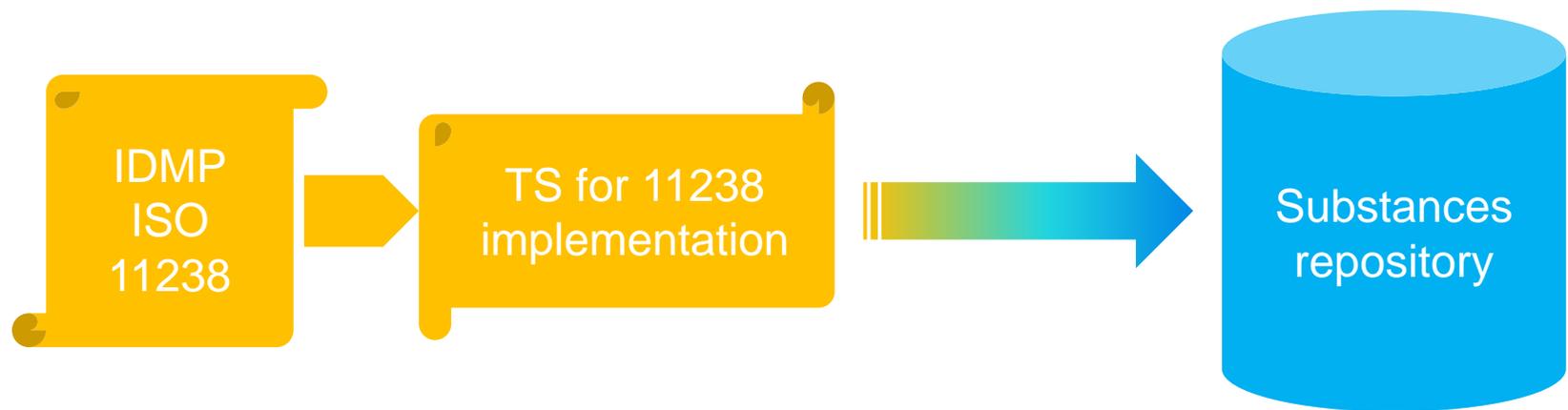




Standards and frequent updates



A possible illustration of the solution





**Market need / requirement
→ implementation**





Implementation of IDMP



- Users across the world need transparent information about IDMP maintenance
 - Agenda for the next ISO meeting (Sydney) includes this point, and the meeting should deliver a ready-to-ballot document
- Users from regulatory and MAH recognise the need for «implementation guides» for IDMP
 - Agenda for the next ISO meeting (Sydney) includes a discussion point «IDMP implementation», with no pre-defined deliverable as a target.





ISO document for supporting implementation

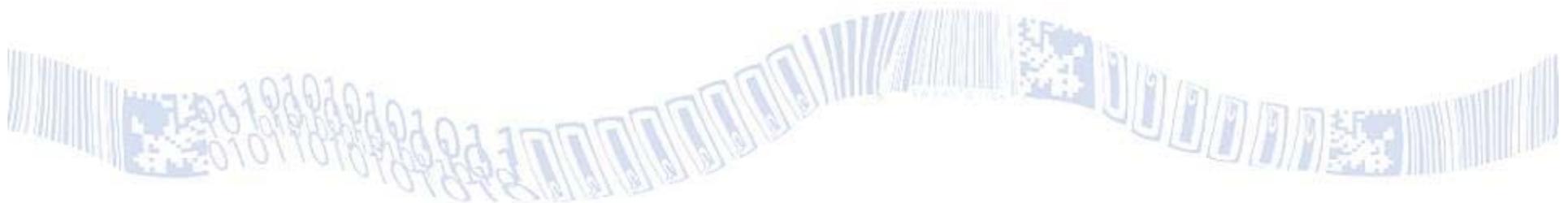




How to support implementation?

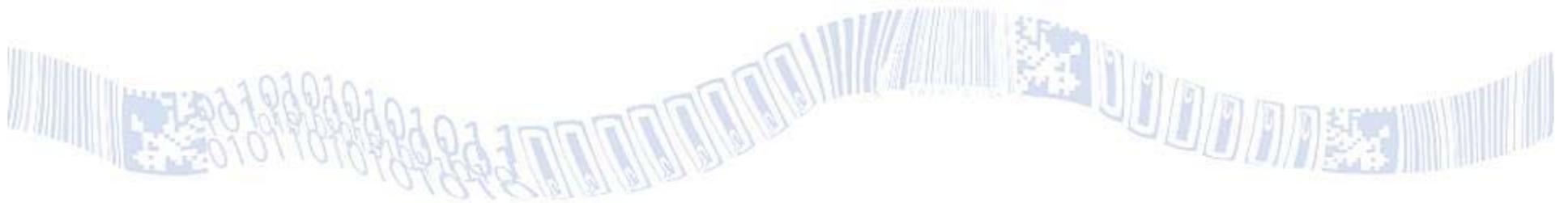


- Does the users community require more high-level information to be introduced into IDMP?
- What should be the appropriate document for that purpose?
- If an ISO document, a «Guide» should be appropriate
 - Although TC 215 has not produced any Guide until now.





Take away





What do you expect from ISO? What does ISO expect from you?



- You and ISO:
 - Standard available for IDMP implementation
 - Standard that includes a frequent update process
 - ISO to contribute to IDMP's success
- ISO and you:
 - You dedicate experts for standard development
 - You document the «how» and the «why» about the frequent update process – so that the best solution can be made available





Contact



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