



Development of a Freely Distributable Data System for the Registration of Substances and Related Information Based on ISO 11238



Goals of Meeting

- Establish the Need for a Freely Distributable Substance Registration System
- Review and Refine the 11238 Substance Model
- Gather Requirements for the Development of the State of the Art Substance Registration System
- Decide what Data needs to be linked to Substances
- Take advantage of Data Already in Existence
- Promote a Global Substance Registration System



Need For Freely Distributable Substance Registration System

- Currently no single substance registration system that cover the breadth of substances in Medicinal Products
- Substance Can be Very Complex 11238 is complex
 - 500 to 1000 fields
- All Regulatory Agencies are in need of a Substance Registration System
 - Economic Advantages
 - Quality Advantages
- Advantage to companies
 - Facilitate Submissions



Need For Freely Distributable Substance Registration System

- Facilitate Collaboration
- Share responsibility
- Promote Drug Safety
- Consolidate Data and Expand Content
- Track Clinical and Quality Data
- Improve Safety and Usage of Medication