FDA’s Office of the Chief Scientist, Office of Health Informatics

Global Access | Information Sharing | Regulatory Applications | Open Source

Global access to library of unique substances

Freely distributable to industry, academia other regulators predominantly open source

Implements the ISO 11238 standard (Identification of Medicinal Products)

Links substance to products, regulatory applications, clinical trials and adverse events

GSRS
FDA Global Substance Registration System

Curates substances and creates scientific relationships between substances

What is GSRS?

• ISO 11238 compliant registration module for substances providing global access to information
• Library of Substance Identities with their generated Unique Ingredient Identifiers (UNIs)
• Knowledgebase of substance information that helps consumers, clinicians, and researchers know what substances are in commercial products

What does GSRS currently provide?

• Simplifies a complex and difficult to implement data abstraction and curation process
• Reduces burden on industry, ensures ingredients in products are accurately represented
• Defines ingredients independent of language
• Forms a knowledge base of ingredients and their associated relationships e.g. metabolites, impurities
• Integrates information across domains (applications, clinical trials, pharmacology, products)

What will GSRS provide once globally implemented?

• Mechanism to monitor the global ingredient supply chain
• Single worldwide, authoritative source for quality substance data
• An ability to address shortages, help detect and track substandard ingredients as well as counterfeit ingredients to coordinate inspections
• Enhance global safety and pharmacovigilance

Who is involved in GSRS?

Developed in collaboration with National Institutes of Health (NIH) National Center for Advancing Translational Sciences (NCATS); partners include:

• Regulators
• Sponsors
• Patients
• Researchers

How to get involved with GSRS?

Within FDA Visit gsrs.fda.gov
Contact FDA-SRS@fda.hhs.gov with questions or for more information