# GSRS
FDA Global Substance Registration System

Global access to **library of unique substances**

**Freely distributable** to industry, academia other regulators predominantly **open source**
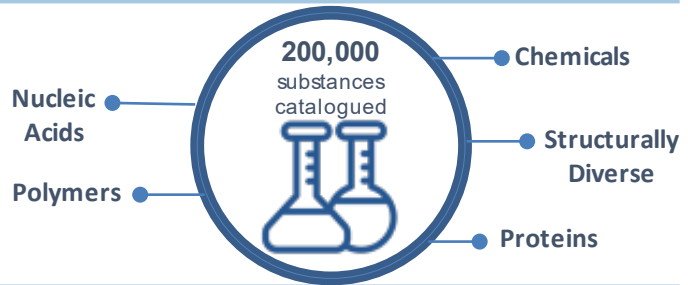
Implements the **ISO 11238 standard** (Identification of Medicinal Products)

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

**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 (UNIIs)
- Knowledgebase of substance information that helps consumers, clinicians, and researchers know what substances are in commercial products

**200,000** substances catalogued

Nucleic Acids

Polymers

Chemicals

Structurally Diverse

Proteins

## 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*

*For Software and Public Data Downloads*
**gsrs.ncats.nih.gov**