# ginaslogo2medGlobal Ingredient Archival System 2017 Meeting

USP Headquarters 12601 Twinbrook Parkway Rockville MD 20852

October 11 8:30 am – 5:00 pm

USP and NCATS are excited to host the 2017 GInAS Meeting. The meeting will coincide with the release of the Global Substance Registration System (G-SRS) Version 2.0, a freely-distributable substance registration system. The system provides access to a substantial amount of substance information curated by both NCATS and FDA scientists. We thank the consortium of scientists that have contributed to this project and its vision, including scientists from ANSM (French), BFaRM (Germany), CBG/MEB (Netherlands), EMA, FDA, Health Canada, IPEC, Kew Gardens, PMDA (Japan), Swiss Medic, USP and the WHO Uppsala Monitoring Center.

The meeting is open to the public and free to attend.

**Agenda**

8:30 Welcome

8:35 Data Standards at CBER / CDER Mary Ann Slack (FDA)

9:00 IDMP Overview Vada Perkins (IDMP Lead, Identifica)

9:25 EMA’s SPOR Initiative Isabel Chicharo (EMA)

10:00 ISO 11238 Version 2.0 Larry Callahan (FDA)

10:35 Defining Advanced Therapies Marcel Hoefnagel (CBG/MEB)

11:00 Integrated Regulatory Information Management-based on Data Standards in LDC Jude Nwokike (USP)

11:30 VigiBase and Global ADR reporting and signal detection.

Malin Jakobsson (WHO UMC)

12:00 USP Adulterants Database Anton Bzhelyansky (USP)

12:20 Lunch (Provided by Chickasaw Nation Industries)

1:00 Inactive Ingredients in FDA-G-SRS Frank Switzer (FDA)

1:30 USAN and USP Dictionary Andrzej Wilk (USP)

2:00 G-SRS 2.0 and Beyond Tyler Peryea (NCATS)

2:15 Excel tools for the G-SRS Mitch Miller (Scientific Thinking)

2:25 Unified Sketcher for Small Molecules and Macromolecules

Jinbo Lee (Scilligence)

2:50 Standardizing Laboratory Data Vinny Antonucci (Allotrope)

3:30 Coding of suspect products in FDA AERS adverse event reports

Sonja Brajovic (FDA)

4:15 Daily Med and RX-Norm Tammy Powell (NLM)

4:45 Pubchem Evan Bolton (NLM)

5:15 Linking Quality-Pharmacology-Toxicology-and Clinical Medicine to Substances

Tyler Peryea (NCATS)

**ginas** welcomes participation and sponsorship by regulatory agencies and other public health organizations throughout the world. It aims to be a global resource that will benefit public health by facilitating the transfer of regulatory information and providing industry and other interested stakeholders with a uniform process for depositing substance-related information.

Please contact us at: [ginas@mail.nih.gov](mailto:ginas@mail.nih.gov)

**GSRS Workshop**

*October 12th, 2017*

*Location: NCATS @ 9800 Medical Center Drive, Rockville MD 20850*

*9:00am - 12:00pm : Board room 3rd floor, Building B*

*12:00pm - 5:00pm : 3rd floor, Building B, Room 203A*

*Target audience:*

*The main target audience for this workshop is developers and technical experts who wish to better understand GSRS, better understand how to use it, and better understand how to develop software using or extending GSRS. However, we are flexible to accommodate some more general topics of discussion.*

*Format:*

*This workshop is meant to be an open exploration of the GSRS software, how it can be used, and how it can be supported. While there are a few set-in-stone topics of exploration and discussion, we will decide as a group which topics are explored in more depth, based on the interests and needs of those attending. Please see* ***Open Topics*** for the tentative list of topics which can be selected to explore. Other suggestions are welcome either before or during the workshop. The last section of the meeting is for open office hours, where available NCATS staff will be available to answer questions and walkthrough what is desired.

*Parking:*

*Parking is available at 9800.*

*Arrival Considerations:*

*Arriving at 9800, please see your way to the main entrance by the circle. You can enter the atrium, but to be let into the building you will need an NCATS escort. From 8:45 to 9:30 we will check the front lobby every 10 minutes for new arriving guests.*

*If you arrive some other time, you can call this number to ask to be let in:*

*315-775-8953*

Tentative Agenda

9:00 am -- Coffee, preparations, and basic setup

9:30 am -- Overview of goals, discussion of which topics will be covered in depth.

10:00 am -- Installation walkthrough

11:00 am -- Basic Web UI walkthrough

11:30 am -- Basic API walkthrough

12:00 pm -- Break for lunch (NCATS will lead any interested group to a restaurant across the street from 9800)

1:00 pm -- Excel Powertools Overview

2:00 pm -- Overview topic 1

2:30 pm -- In-depth topic 2

3:30 pm -- Office Hours

4:30 pm -- Office Hours

5:00 pm -- Meeting wrap-up

**Suggested Open Topics:**

1. Registering / updating substances from web interface
2. Contributing to / extending GSRS proper
   1. Developing custom facets
   2. Developing custom exports
   3. Extending existing models / connecting other data
3. Developing custom consumers of API
   1. Simple Web-page
   2. Google sheets
4. HowTo: Exchange substance messages
5. Excel PowerTools Basics
   1. Resolving basics
   2. Basics of running scripts
6. Excel PowerTools Developers
   1. Basics of developing new resolvers
   2. Basics of developing new scripts
7. Using git to contribute to project

**Global Ingredient Archival System**

***A Critical Regulatory Tool for a Globalized Economy***

**Background**

The growing impact of globalization presents tremendous challenges and opportunities for national regulatory agencies, the pharmaceutical industry, and global health as a whole. Emerging diseases and the health impacts of catastrophic events respect no national boundaries, nor does the increasing volume of substandard, contaminated, and counterfeit products that overburdens national regulators. Ingredients for pharmaceutical products are typically sourced on a global basis and it is very rare that all ingredients for a single product are produced within one jurisdiction. To regulate the global supply chain efficiently and to better respond to and prepare for catastrophic events it is essential to have a global information system for pharmaceutical ingredients.

**Project Description and Goals**

The Global Ingredient Archival System (**ginas**) represents a major opportunity for international regulatory efforts to tackle these challenges. This cutting-edge tool will make it possible to create a global standard for defining substances and a common identifier to identify ingredients in medicinal products. This will enable the global health community to share and use information to significantly improve health care delivery, the proper use of medications, and the management of risks involved in their use.

The project’s main goal is to provide a consistent definition of substances globally, and a common identifier for all the substances used in marketed medicinal products as well as active substances under clinical investigation. It is envisioned that a consortium of regulators from different national and international agencies would operate and maintain the programme in a secure and trusted manner. The system could play a vital role in facilitating a global approach to pharmacovigilance; identifying and tracking substandard products and ingredients; alleviating drug shortages; enhancing clinical development; and coordinating and streamlining regulatory actions worldwide.

The ISO 11238 health informatics standard is one of five international standards that were created to harmonize the description and specification of medicinal products and their component substances. Along with ISO 11615, ISO 11616, ISO 11239, and ISO 11240, it provides an international standard for identifying medical products (IDMP), to facilitate medical product regulation, communication between agencies, and their interaction with product sponsors.

ISO 11238 specifically addresses the identification and exchange of regulated information on substances. Working closely with that standard’s authors and regulatory authorities from various countries, the National Center for Advancing Translational Sciences (NCATS) at the National Institutes of Health (NIH) has developed an information system to register and store substance-related information and provide identifiers. This will ensure a robust substance registration system that supports the additional needs of national and regional authorities and is consistent with the ISO 11238 standard. The system will support all substance types described in the 11238 standard and provide multiple language capability for the naming of substances and controlled terminology used within the system.

**G-SRS Software**

The Global Substance Registration System (G-SRS) software stores, retrieves, and distributes substance-related information described in the ISO 11238 standard. Its purpose is to unambiguously and consistently identify all substances which may be present in regulated products or substances produced metabolically from these substances or interacting with these substances in biological systems. It is a freely distributable, maximally self-contained system to register substances and store a wide variety of structured information on the identification, analysis, use, manufacture, pharmacology, and toxicology of medical product substances that are of interest to health product regulators, product sponsors, and health researchers.

FDA uses this software to efficiently, effectively and reliably define substances and maintain unique identifiers for substances in drugs, biologics, foods and devices in a consistent manner with the ISO 11238 standard. To accomplish this, each substance entered into the system is assigned a strong, non-proprietary identifier known as a Unique Ingredient Identifier (UNII) that is permanently associated with the defined substance. G-SRS provides UNIIs freely for general use and specifically for electronic ingredient listing activities. This data is available to users and systems via a web client and REST and JAVA APIs. The scope of regulated products covered by G-SRS includes:

* Drugs: Both active and inactive ingredients used in drug products, including those for veterinary purposes.
* Biologics: Both active and inactive ingredients used in biologics, such as blood products, therapeutic products, vaccines, cellular and gene therapy products, allergenic products and tissues.
* Devices: Components of devices including, for example, silicon for implants and chemical reagents for glucose test kits.
* Cosmetics: Components of cosmetic products, such as flavors, fragrances, colorants, vitamins, plant and animal derived ingredients and polymers.
* Foods: Specific foods or components of food, regardless of whether the food is in conventional food form or a dietary supplement, such as vitamins, minerals, herbs or other nutritional substances.

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