



The U.S. Pharmacopeial Convention (USP) and the National Center for Advancing Translational Sciences at the National Institutes of Health (NIH/NCATS) are hosting a two-day meeting on GInAS on Wednesday, June 11 and Thursday, June 12, 2014 at USP Headquarters in Rockville, Maryland. This meeting will address both scientific and information technology aspects of defining, registering and linking essential information related to substances in medicinal products.

GInAS (Global Ingredient Archival System) is a newly developed substance registration tool based on the ISO IDMP 11238 Substance Standard (EN ISO 11238:2012), Health Informatics, Identification of Medicinal Products (IDMP) standard: 'Data elements and structures for unique identification and exchange of regulated information on substances'. In the GInAS Project Group, FDA, CBG-MEB, BfArM, Swissmedic, HealthCanada and collaborating expert scientists have made significant progress thus far in developing a system and data model to implement the ISO IDMP 11238 Substance Standard that could be used by regulators throughout the world to register substances and critical information related to substances. This database will also provide all stakeholders with global ISO IDMP-Identifiers for substances used in medicinal products (for further information see enclosed documents).

On behalf of the GInAS Project Group, NCATS welcomes you to attend either one or both days, depending on your interest and availability.

Discussion will focus on GInAS support for challenging classes of substances including polymers, herbal substances, and cell therapies. Presentations by stakeholders will provide regulatory and practical perspectives on the description and use of substance information. Case studies, demonstrations of the GInAS system, and a status update on deployment of the GInAS at FDA will also be presented.

The meeting will conclude with discussion of the ISO IDMP implementation process, planning for further deployments of the GInAS, use of GInAS for generating global substance identifiers, and defining a roadmap for the further development of the GInAS project.

Please inform us at your earliest convenience on which day(s) we may welcome you.

The meeting location for both days will be the United States Pharmacopeia Headquarters, 12601 Twinbrook Parkway, Rockville, Maryland, USA. If you are not able to attend the meeting in person, but wish to join via remote facilities please indicate this in your answer so that we can make the necessary arrangements. A list of the invited participants and the provisional program are enclosed. The final program will be sent to you in May.

The GInAS project group sincerely hopes that you will join us at the summer meeting.

Best Regards,

Noel Southall,

GInAS Project group