DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

National Institutes of Health
National Center for Advancing
Translational Sciences

Fourth GInAS workshop February 2-4 2015, Rockville Maryland

FDA and NIH will host a workshop on February 2-4, 2015 to advance work on an international framework for the standardized registration of ingredients in medical products used throughout the world.

FDA has been working closely with other international regulators to develop standards for exchanging information on regulated medical products and ingredients (the IDMP ISO 11238 standard), to better ensure the safety and availability of medicines globally. In parallel, researchers at the NIH have developed software implementing the proposed standard and are providing this as a practical tool for stakeholders and researchers.

The software and embedded data entitled , the Global Ingredient Archival System, abbreviated as GINAS (pronounced jEE-nas), was written by software developers at the NIH's National Center for Advancing Translational Sciences (NCATS) in close coordination with FDA staff, and staff from the Dutch Regulatory Agency (CBG-MEB), the European Medicines Agency, the European Pharmacopoeia (EDQM), the German Regulatory Agency (BfArM), Health Canada, the Japanese Regulatory Agency (PMDA), Kew Gardens, the Swiss Regulatory Agency (Swissmedic), the United States Pharmacopeia (USP), the WHO Uppsala Monitoring Center (WHO-UMC) and many subject matter experts from industry through a series of workshops and meetings. FDA is currently transitioning its own substance registration system to this new software, to support the initiative's goals and will discuss this at the workshop.

FDA and NIH are hosting the workshop on GInAS and the implementation of the ISO 11238 standard at an NCATS facility, located at 9800 Medical Center Drive, in Rockville, Maryland, from February 2-4, 2015. The workshop will provide detailed guidance on the installation, maintenance and update procedures for the software as well as provide information on the best practices of registering ingredients using the GInAS software. FDA will also discuss its efforts in transitioning to the new software. An updated version of the GInAS software along with data from the public domain will be provided at the workshop.

The workshop is open to all interested parties, who are directed to contact Noel Southall southalln@mail.nih.gov or Larry Callahan Lawrence.callahan@fda.hhs.gov for further information and to register for the workshop. There is no charge for the workshop but space may be limited and remote access will also be provided.

Best Regards,

Larry Callahan and Noel Southall,

GInAS Project group