DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

National Institutes of Health
National Center for Advancing
Translational Sciences

Program of the 2014 GInAS Project Summer Meeting

United States Pharmacopeia Headquarters
12601 Twinbrook Parkway
Rockville, Maryland

Wednesday, June 11

8:30 am – 8:45 am Introduction and Welcome by USP
8:45 am – 9:15 am What is GinAS, what can it be, how will it be sustained, how will it be governed. Ajit Jadhav (NCATS)/Larry Callahan (FDA)/Noel Southall (NCATS)
9:15 am – 10:00 am European perspective on herbal substance specification. Burt Kroes (CBG-MEB)/Ciska Matai (CBG-MEB)/Thomas Balzer (BfArM Germany)
10:00 am – 10:15 am Break
10:15 am – 10:45 am Development of a unified vocabulary for plant parts. Elizabeth Dauncey (Kew Gardens)
10:45 am – 11:15 am Herbals in the FDA/SRS system, GinAS and other systems. Frank Switzer (FDA)
11:15 am – 11:45 am Herbal discussion, Industry perspective. Maged Sharaf (American Herbal Product Assoc.)
11:45 am – 12:15 pm Current state of GInAS, Overview of System and Data Migration. Noel Southall/Tyler Peryea
12:15 pm – 1:00 pm Working lunch, GinAS system and tool demonstration. Tyler Peryea (NCATS)
1:00 pm – 1:45 pm Requirements for polymer registration by regulators. Herman Diederik/Ciska Matai (CBG-MEB)
1:45 pm – 2:30 pm Industry perspective on polymer specifications/registration. Katherine Ulman (Dow Corning)
2:30 pm – 3:00 pm Polymers in the Pharmacopeia Monographs. Catherine Sheehan (USP)
3:00 pm – 3:30 pm Polymers in FDA/SRS and GinAS. Larry Callahan (FDA)/Tyler Peryea (NCATS)
3:30 pm – 4:00 pm Polymer discussion
4:00 pm – 4:15 pm Break
4:15 pm – 5:30 pm GinAS, Governance Models, ISO IDMP Implementation at FDA, Europe. Vada Perkins (FDA), Mary Ann Slack (FDA), Ilaria Del Seppia (EMA)

Thursday, June 12

8:45am – 9:15am Welcome, Summary of previous day's discussion. Herman Diederik/Larry Callahan/Noel Southall
9:15am – 10:00 am Perspectives on cell therapies and other unique substance classes. Marcel Hoefnagel/Herman Diederik (CBG-MEB)
10:00 am – 10:45 am Pharmacopeial perspectives: cell therapies & complex biological material. Fouad Atouf (USP)
10:45 am – 11:00 am Break
11:00 am – 11:45 am Complex biologics in the FDA/SRS, GinAS and discussion. Larry Callahan (FDA)
11:45 am – 12:15 pm Open FDA Making FDA data available to the public. Taha Kass- Hout (FDA)
12:15 pm – 1:00 pm Working lunch/GInAS demonstration of local deployment/general questions. Trung Nguyen/Tyler Peryea(NCATS)
1:00 pm – 1:30 pm Transparency at the FDA, Legal Perspective. Dan Sigelman (FDA)
1:30 pm – 2:00 pm USP and Drug Quality in Africa/Asia Role of GinAS. Patrick Lukulay (USP)
2:00 pm – 2:30 pm Pill Box and Drug Dictionaries. David Hale/Mike Hazard (National Library of Medicine)
2:30 pm – 3:00 pm Linking Clinical Trials to Substances. Paul Houston (CDISC)
3:00 pm – 3:15 pm Linking Pharmacology Data to Substances. Noel Southall (NCATS)
3:15 pm – 4:00 pm CMC Data, Need and Requirements for a Global Spectral Library. Steve Wolfgang (FDA)/Carl Sciacchitano (FDA)
4:00 pm – 4:30 pm Making Industry Data Available in GInAS An IPEC perspective. David Schonecker (IPEC)
4:30 pm – 5:30 pm GInAS collaboration, development and deployment roadmap, role of regulatory authorities, pharmacopeias, NGOs, NCATS/NIH, Industry, next steps. Ciska Matai, Elizabeth Dauncey, Fouad Atouf, Frank Switzer, Herman Diederik, Larry Callahan, Noel Southall, Philipp Weyermann (Swiss Medic) , Thomas Balzer.