

GI_nAS SUMMER MEETING

LOCATION
CBG-MEB MEDICINES EVALUATION BOARD,
GRAADT VAN ROGGENWEG 500,
3531 AH UTRECHT,
THE NETHERLANDS

IF THE NUMBER OF PARTICIPANTS EXCEEDS THE CAPACITY OF THE MEETING ROOM, ONE OR MORE DAYS MIGHT CHANGE LOCATION TO ANOTHER VENUE IN CENTRAL UTRECHT

THURSDAY 12 SEPTEMBER 2013

GOVERNANCE AND MAINTENANCE OF GI_nAS

08:15 Registration with coffee

09:00 Opening by Drs. Aginus A.W, Kalis, Head CBG-MEB

09:10 Session 1

ISO perspective on IDMP Terminology Maintenance

Speaker: Dr. Christian Hay, Sr. Consultant Healthcare, GSI, and Convener of ISO TC215, WG6 (Pharmacy and medicines business)

Use of GI_nAS in Pharmacovigilance science

Speakers: Drs. Anja van Haren, CBG-MEB and Drs. Naomi Jesserun, Netherlands Pharmacovigilance Center Lareb.

10:00 Coffee Break

10:20 Session 2

Overview of GI_nAS Architecture

Speaker: Dr. Noel Southall, National Institutes of Health, National Center for Advancing Translational Sciences (NIH/NCATS).

Scope and structure of GI_nAS in the context of Access and User rights and Versioning of Substances

Speakers: Thomas Balzer, BfArM – Drs. Herman Diederik, Substance Department, CBG-MEB.

11.40 Session 3

Possibilities for European Pharmacopeia for Scientific Cooperation in GI nAS

Speaker: Dr. Christopher Jarvis, European Directorate for the Quality of Medicines & HealthCare.

Focus on Substance Class: Structural Diverse Substances; Herbals

Speaker: Dr. Burt H. Kroes, CBG-MEB, alternate Herbal Medicinal Products Committee and Chair Quality Working Group HMPC and Ing. Ciska G. Matai, Substance department, CBG-MEB.

12:30 Sandwich Lunch

13:30 Session 4

Demonstration of the GI nAS data base: Case study Peptides.

Speakers: Tyler Peryea, Trung Nguyen and Noel Southall, PhD., National Institutes of Health, National Center for Advancing Translational Sciences (NIH/NCATS)
Drs. H. Diederik, Ing. Ciska G. Matai, Substance Department, CBG-MEB.

14:00 Need for Maintenance and Governance structure of GI nAS with respect to the Implementation of ISO 11238 Substance Standard

Speakers: (presentation delivered via TC/Video conf):
Captain Director Vada Perkins, US Public Health Service, FDA, CBER Business Operation Lead and Dr. Mary Ann Slack, FDA, CDER Data Standards Lead.

15:15 Coffee Break

15:45 Session 5: Round Table Discussion

GI nAS Operational Structure, Governance and Maintenance

Chair: Dr. Andrew P. Marr, Managing Director, Marr Consultancy.

16:30 Closure of the day and drinks

FRIDAY 13 SEPTEMBER 2013

SYMPOSIUM AND DEMONSTRATION OF GI_nAS

- 08:15** **Registration with coffee**
- 09:00** **Opening by Drs. Stan van Belkum, Deputy Director CBG-MEB**
- 09:10** **Session 1: Introduction and background of the GI_nAS project**
- Overview of the GI_nAS project, implementation of the ISO 11238 Standard**
Speaker: Dr. Lawrence Callahan, PhD, FDA Substance Registration System.
- Functional design, nomenclature, case study**
Speaker: Drs. Herman Diederik, Ing. Ciska G. Matai Substance Department, CBG-MEB
- 10:15** **Coffee Break**
- 10:35** **Session 2: GI_nAS in detail**
- GI_nAS Data Model**
Speaker: Thomas Balzer, BfArM
- 11:00** **Session 3: Stakeholder perspectives**
- Application and use of the data base for Swissmedic**
Speaker: Dr. Philipp Weyermann, Swissmedic.
- Focus on biologicals, EPO's**
Speaker: Dr. Marcel H.N. Hoefnagel, Department of Pharmacological, Toxicological and Biotechnological Assessment, CBG-MEB
- Pharmaceutical and Software Industries Perspective**
Speaker: Dr. Andrew P. Marr, Managing Director, Marr Consultancy, IRISS Forum IDMP Topic Group Lead.
- IT Perspective: hosting the database in Canada**
Speaker (presentation delivered via TC/Video conf): Dr. Vikesh Srivastava, Associate Director, Business informatics, Health Canada
- 12:20** **Session 4: Open floor for questions and discussion**
Facilitators: Drs. Stan van Belkum, Deputy Director, CBG – MEB
Dr. Lawrence Callahan, PhD, FDA Substance Registration System
Dr. Klaus Menges, BfArM, Product Information Management
- 12:40** **Sandwich Lunch**
- 13:30** **Session 5: GI_nAS Architecture**
- Overview of GI_nAS Architecture, Scope and Development, Live Case study of Ritonavir**
Speaker : Dr. Noel Southall, National Institutes of Health, National Center for Advancing Translational Sciences (NIH/NCATS)
- 14:15** **Focus on biologicals**
Speaker (presentation delivered via TC/Video conf):
Tina Morris, PhD., Vice President Biologics and Biotechnology, USP

14:45 Coffee Break

15:15 Session 6: Demonstration of GInAS

Demonstration of the GInAS data base: Structure search, Case studies, e.g. Brentuximab Vedotin, Relationships

Speakers: Tyler Peryea, Trung Nguyen and Noel Southall, PhD., National Institutes of Health, National Center for Advancing Translational Sciences (NIH/NCATS).

Dr. Lawrence Callahan and Dr. Frank Switzer, FDA, Substance Registration System.

Thomas Balzer, BfArM.

Drs. Herman Diederik and Ing. Ciska G. Matai, Substance Department, CBG-MEB.

16:30 Closure of the day and drinks