OPENING KEYNOTE ADDRESS: History of Specific Immunotherapy (SIT) and Allergen Standardization
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CLOSING KEYNOTE ADDRESS:
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FEATURED TOPICS

1. Legal Aspects of the Regulation of Allergen Products
   • Legal Status and Regulation of Allergen Products in the US
   • Regulation of Allergen Products in Europe (including NPPs)
   • Current Status and Regulation of Allergen Products in Different Countries

2. Standardization and Characterization of Allergen Products
   • Update on the FDA/CBER Allergen Standardization Program
   • Validation of Major Allergen References and ELISAs – Current State of the BSP 090 Project
   • Molecular and Functional Characterization of Natural Allergen Extracts
   • Standardization of Major Allergen Measurements and Implications for Assessments of Biologic Potency
   • The Potential of Mass Spectrometry as Novel Tool in Standardization of Natural Allergen Extracts

WHO SHOULD ATTEND
Professionals, researchers, academia, regulatory affairs, contract research organizations, and clinicians focused in standardization, diagnosis and clinical immunology for allergen products.

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EAACI – European Academy of Allergy and Clinical Immunology
NIAID – National Institute of Allergy and Infectious Diseases

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Drug Information Association, Inc.
800 Enterprise Road, Suite 200
Horsham, PA 19044, USA

Regional Offices
Basel, Switzerland  Tokyo, Japan  Mumbai, India  Beijing, China
3. Methods in Product and Study Design of Effective Allergen Products for Therapy

- Quality by Design
- Primary Endpoints, Validation, Clinical Efficacy of Specific Immunotherapy (SIT) Trials
- Specific Aspects of SIT Trials in Children
- Efficacy Testing of Allergen Mixtures
- Surrogates and Biomarkers for Determining Efficacy
- Multiplex IgE Testing as Tool to Define Study Populations
- Pollen Count Variation Within and Among Regions of North America
- Environmental Exposure Chamber in SIT Clinical Trials
- Statistical Analysis for Demonstrating Efficacy in SIT Trials

4. Standardization and Characterization of Modified and Recombinant Allergen Products

- Physicochemical Characterization of Allergoids and Adsorbed Allergoids
- Physicochemical Characterization of Recombinant Allergens and Hypoallergenic variants
- Antibody-based Techniques for Characterization of Allergoids and for Stability Studies of Alum Adsorbed Drug Product

5. Immunological Mechanisms of Allergy Immunotherapy

- An Overview of Proposed Mechanisms of SIT
- Mechanisms of Immunotherapy Specific to the Sublingual or Oral Route
- Oral Immunotherapy for Food Allergy
- Th2 heterogeneity: Do specific Th2 Subpopulations Alternatively Drive Allergy vs. Tolerance
- Use of Trichuris suis ova (TSO) Therapy for the Treatment of Allergy

6. Immunotherapy with Purified Allergen Components

- Current Status of Subcutaneous and Sublingual Immunotherapy with Recombinant Allergens
- Recombinant Allergens for SIT of Mite Allergy
- Recombinant Allergens for SIT of Cat Allergy
- Novel Approaches of Immunotherapy for Food Allergy
- Targeting Antibody Receptors as an Approach Towards Immunotherapy

7. Extrinsic Adjuvants in the Use of Allergen Immunotherapy

- Aluminum Hydroxide: Mechanism of Action and Safety Assessment
- Toll Like Receptor Ligands as Adjuvants
- Adjuvants and Vector Systems for the Sublingual Route

8. Immunomodulatory Properties of Allergens

- Inherent Adjuvant Biological Properties of Natural Allergens
- Inherent Adjuvant Structural Properties of Natural Allergens

9. State-of-the-Art Immunotherapy in Different Allergic Diseases

- Sublingual Route (SLIT)—Overview of American Experience
- SLIT for Allergic Rhinitis in the United States
- The Role of Subcutaneous Immunotherapy (SCIT) and SLIT in Rhinoconjunctivities across Europe
- SIT for the Treatment of Atopic Dermatitis
- SIT for the Treatment of Asthma
DiA is a financially independent nonprofit, global, multidisciplinary association that provides a neutral forum for sharing information that optimizes the development and lifecycle management of biopharmaceutical and related products.

13th International Paul-Ehrlich-Seminar
Allergen Products for Diagnosis and Therapy: Regulation and Science
Event #11018 • September 14-17, 2011
Hyatt Regency Washington on Capitol Hill, Washington, DC, USA

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Registration Fee — All Attendees
Registration fee includes refreshment breaks, luncheons, reception, dinner*, and will be accepted by mail, fax, or online.

Fee (includes dinner for all registered attendees) US $750
Companion Dinner Fee* TBD

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