Drug Information Association

November 16-18, 1998
Hotel Le Méridien, NICE
France

1st International Workshop on:

Statistical Methodology in Non-Clinical R&D

Programme Chairperson

Dr. Merete JØRGENSEN
Novo Nordisk A/S, Denmark

Faculty

Dr. Bruno BOULANGER
Eli Lilly, Belgium

Prof. Ludwig HOTHORN
University of Hannover, Germany

Dr. Tomas MORSING
Astra Hässle, Sweden

Dr. Jørgen SELDRUP
Quintiles, France

Workshop Objectives

The goal of the Workshop is to bring Statisticians from Pharmaceutical Industry, Academia and Regulatory Agencies together to provide an *Open Forum* to discuss:

- Important issues of current interest to statisticians involved in Non-clinical R & D.
- Appropriate statistical methods for the area and to be described in Non-clinical guidelines and related safety and quality ICH documents.

The various Sessions will allow sufficient time for fruitful discussions and sharing experiences between Speakers and Participants.

Key Topics

Statistical Issues within:

- Stability Testing
- Validation of Analytical Procedures & Impurities
- Quality of Biotechnological Products: Viral Safety, Analysis & Deviation
- Specifications for New Drug Substances
- Safety / Toxicology / Toxicokinetics
- Discovery

For further Information,or more details, please contact:

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Sunday, November 15, 1998

18:00-20:00 **Pre-Registration**
18:30-19:30 **Speakers Reception**

Monday, November 16, 1998

08:00 Registration

09:00 Welcome & Introduction

SESSION I
VALIDATION OF ANALYTICAL PROCEDURES & IMPURITIES
Session Chairperson:
Dr. Tomas MORSING
Astra Hässle, Sweden

Statistical Aspects of Validation of Analytical Methods
Dr. Aage Vølund, Novo Nordisk, Denmark

Ruggedness/Robustness Testing in Method Validation
Yvan van der Heyden, Free University of Brussels, Belgium

The Conceptual Idea of LOD from a Statistical Point of View
Claes Ekman, Astra Hässle AB, Sweden

10:30 **COFFEE-BREAK**

11:00 **SESSION 1 (Cont'd)**

Statistical Issues in the Validation of Analytic Dilution Assays
Wendell Smith, Eli Lilly, USA

Inference on the Relative Standard Deviation
Per Broberg, Astra Draco, Sweden

Robustness Analysis: General Overview of Application to HPLC Method Validation
Yves L. Grize, AICOS Technologies, Switzerland

PANEL DISCUSSION

2:30-14:00 **LUNCHEON**

14:00 **SESSION 2**
DISCOVERY
Session Chairperson:
Dr. Bruno BOULANGER
Eli Lilly, Belgium

Some Thoughts on Assay Validation and Quality Control in High Throughput Screening
Bert Gunter, Merck Research Labs, USA

Predicting Biological Activities Using Molecular Descriptors
Kerry Bemis, Lilly, USA

Technology Transfer of Analytical Methods: An Equivalence Approach
Mike Dymond, Astra Pharmaceuticals, UK

5:30-16:00 **COFFEE-BREAK**

16:00 **SESSION 3**
QUALITY OF BIOTECHNOLOGICAL PRODUCTS, VIRAL SAFETY, ANALYSIS & DEVIATION
Session Chairperson:
Dr. Merete JØRGENSEN
Novo Nordisk A/S, Denmark

Statistical Issues in Viral Validation Studies
Jochen Mueller-Cohrs, Behringwerke AG, Germany

Viral Safety
A Regulatory View

Validation of Assays Used to Characterize Vaccines
Timothy Schofield, Merck Research Laboratories, USA

17:30 **Close of Monday Sessions**

7:30-18:30 **WORKSHOP RECEPTION**

Tuesday, November 17, 1998

09:00 **Workshop re-starts**

SESSION 4
STABILITY TESTING
Session Chairperson
Dr. Merete JØRGENSEN
Novo Nordisk A/S, Denmark

On the Problem of Pooling in Complex Stability Studies
Phil Woodward, Pfizer Central Research, UK

Analysis of Stability Study Data: A Practical Interpretation of the ICH/CPMP Guideline
Olof Bengtsson, Astra Hässle AB, Sweden

10:30 **COFFEE-BREAK**

11:00 **Session 4 (Cont'd)**

Statistical Analysis of Stability Data - Case Studies with Special Emphasis on General Concepts and Principles and with Special Reference to ICH (and other) Guidelines
Gert Nielsen, Novo Nordisk A/S, Denmark

A US Regulatory View

PANEL DISCUSSION

12:30 **LUNCHEON**

14:00 **SESSION V**
DESIGN IN TOXICOLOGY, SAFETY & TOXICOKINETICS
Session Chairperson:
Professor Ludwig HOTHORN
University of Hannover, Germany

Consistency in Statistical Analysis of Standardized Toxicological Studies
Helle Andersen, Novo Nordisk, Denmark

Sample Size Determination in Non-Clinical Experiments-How Should we Do It?
Corinne Thomas-Haimez, Servier, France

Trends in Toxicology Data
Dennis Lendrem, TTL Training & Consulting, UK

15:30-16:00 **COFFEE-BREAK**

SESSION V (Cont'd)

Conduct of Pre-Clinical Oncogenicity Assays - What is wrong with the European Guideline
Peter Ceuppens, Zeneca Pharmaceuticals, UK

A Regulatory View

PANEL DISCUSSION

17:30 **Close of Tuesday Sessions**

19:30 **OPTIONAL WORKSHOP DINNER**

Wednesday, November 18, 1998

09:00 **Workshop re-starts**

09:00 **SESSION V (Cont'd)**
DESIGN IN TOXICOLOGY, SAFETY & TOXICOKINETICS
Session Chairperson:
Dr. Jørgen SELDRUP
Quintiles, France

Development and Use of Optimal Sampling Designs in Toxicokinetics
François Vandenhende, Eli Lilly, Belgium

Is a Statistical Treatment of Data from Toxicokinetic Studies Worthwhile?
David Young, Sanofi Research, UK

PANEL DISCUSSION

10:30 **COFFEE-BREAK**

11:00 **SESSION V (Cont'd)**

Dual Control Groups: A Power Analysis
Dr. Dennis Lendrem, TTC Training & Consulting, UK

Which Tumour Sites are Detectable in Animal Long-Term Carcinogenecity Studies with Appropriate False-Negative Rate? - A Power Study of Dose-Response Relationships on Proportions
Frank Bretz, University of Hannover, Germany

Estimating the No-Observed Adverse-Effect-Dose in Toxicology Using a Multiple Comparison Procedure on Equivalence
Prof. Ludwig A. Hothorn, University of Hannover, Germany

12:30 **CLOSE OF THE WORKSHOP**

Hotel Information

The DIA has blocked a number of rooms at the :

HOTEL LE MERIDIEN
1, Promenade des Anglais
06046 NICE, France

For this Workshop following special rates are applicable:

Single Room	FRF	800.-
Double Room	FRF	880.-

(Rates are inclusive of Buffet Breakfast, Service & VAT
Local tax of FRF 7.-/person/day is not included)

Attendees must make their own hotel reservation by telephone +33 4 93 82 25 25 or telefax +33 4 93 16 08 90 referring to the DIA Workshop, November 16-18, 1998.

A deposit payment for one night must be made to secure the reservation, either by cheque mailed to the HOTEL LE MERIDIEN, at the above address, or by providing, with signature, the name, number, and expiry date of your credit card.

IMPORTANT: To be assured of accommodation in the HOTEL LE MERIDIEN, registrants are recommended to complete their hotel reservation, by

October 19, 1998

Travel Information

Nice is well served by direct flights from most major European Cities. The Hotel LE MERIDIEN is only 10 minutes by taxi from the Nice Airport and within walking distance of the old town of Nice.

Payment of the Registration Fees

Payment may be made by check in US$, payable to Drug Information Association. You may also arrange payment by bank transfer, of appropriate amount to:

CITIBANK, N.A.
460 Park Avenue
NEW YORK, NY 10022, USA
DIA Account Number: 46820821
Routing Number: 021000089 - ABA # 210

Your name and company name, as well as the Workshop I.D. Code must be included on the transfer document to ensure payment to your account. Payment may also be settled by credit card (see registration form).

Cancellation Policy

Until 10 days in advance, 90% refund
Between 4 to 9 days in advance, 70% refund
3 days in advance, no refund
but registration may be transferred to another person.

Registrants who do not cancel prior to the meeting and do not attend, will be responsible for the full registration fee.
In the event of unforeseen circumstances, DIA reserves the right to alter the venue. If an event is cancelled, DIA is not responsible for airfare, hotel or other costs incurred by registrants.