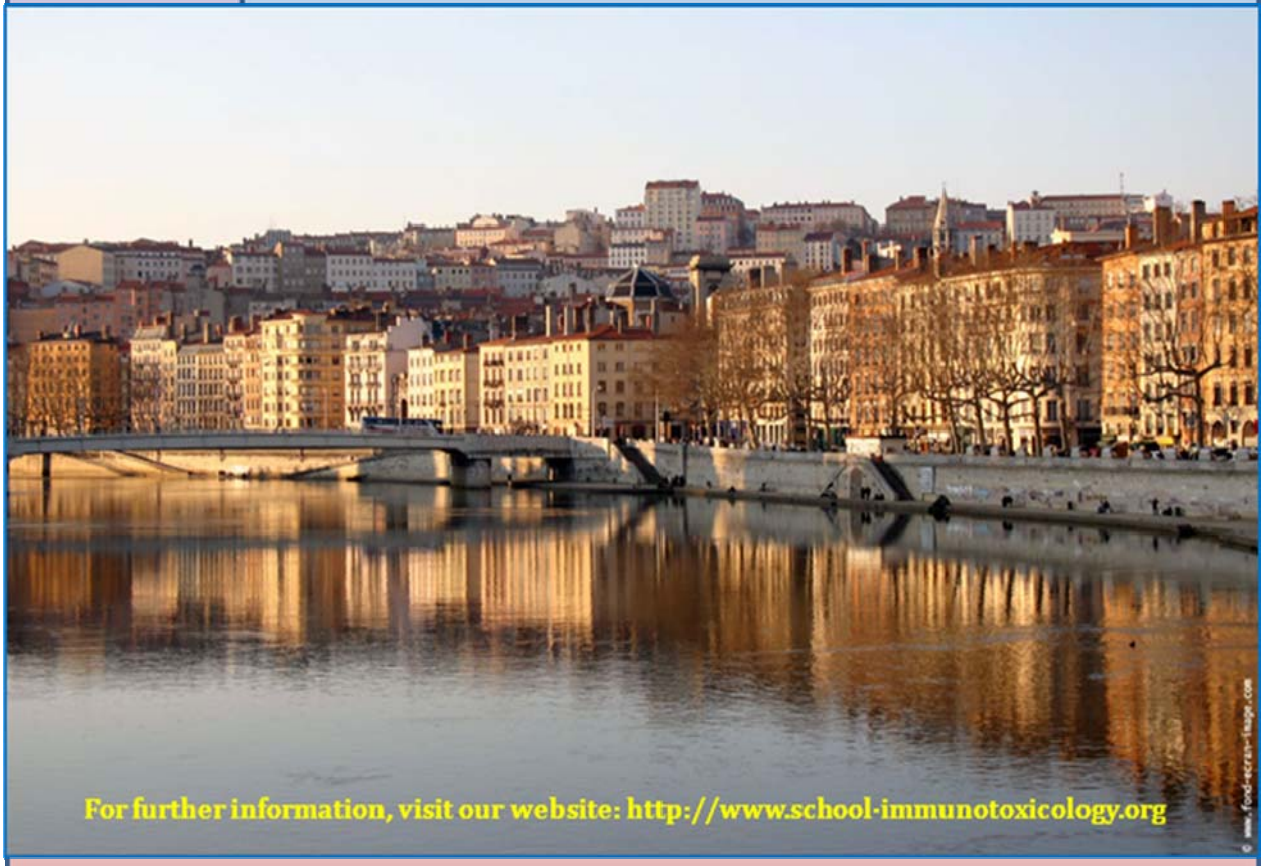
NONCLINICAL SAFETY EVALUATION OF BIOPHARMACEUTICALS

JOINT MEETING:

16th Summerschool in Immunotoxicology
HESI- ITC Immunogenicity Round Table
ICH S6 European Discussion Meeting

Sofitel Hotel, Lyon (France) , 1-3 October 2007



MDS Pharma Services

Centre Antipoison

Summerschool in Immunotoxicology

H E S I

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16TH SUMMERSCHOOL IN IMMUNOTOXICOLOGY

HESI-ITC IMMUNOGENICITY ROUNDTABLE

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Program (22 May 2007)

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Monday 1 October

Chairperson: *J. Descotes (Lyon Poison Center, France)*

10:00	*Start of registration and welcome coffee*
12:00	*Opening lunch*
13:15	*Welcome to participants*
13:30	TGN1412: lessons to be learnt
13:30	Part 1- A case of non-prediction ? *Ch. Horwath (Archemix, USA)*
13:45	Part 2- ABPI/BIA recommendations regarding the MABEL approach. *J. Sims (AstraZeneca, UK)*
14:00	Part 3- Regulatory consequences guideline on high-risk medicinal products. *Ch. Schneider (Paul Erlich Institute, Germany)*
14:15	General discussion
14:45	Biopharmaceuticals: current developments and perspectives. *H. Schellekens (Utrecht University, the Netherlands)*
15:30	*Coffee break*
16:00	Adverse effects of biopharmaceuticals: from immunopharmacology to the clinic. *J. Descotes*
16:45	Summerschool in Immunotoxicology Annual PhD Award
17:30	*Social event*
20:00	*Dinner*

Tuesday 2 October

Chairpersons: *E. Evans (Scherring-Plough, USA) & B. Molinier (Sanofi-Aventis, France)*

9:00	Purpose of immunogenicity evaluation in preclinical vs clinical studies. *J. Bussiere (Amgen, USA)*
9:30	Overview of immunogenicity assays and regulatory aspects. *R. Thorpe (National Institute for Biological Standards and Control, UK)*
10:00	Practical application of immunogenicity assays. *D. Finco-Kent (Pfizer, USA)*
10:30	*Coffee break*
11:00	Risk assessment with case studies: Preclinical case studies. *L. Plitnick (Merck, USA), C. Maier (GSK, USA)* Clinical case studies. *T. Kawabata (Pfizer, USA), H. Haggerty (Bristol-Myers Squibb, USA)*
12:30	*Lunch*
13:45	HESI-ITC Immunogenicity roundtable: risk assessment and application of the EMEA guideline on the immunogenicity of therapeutic proteins. *P. Chamberlain (MDS Pharma, France), H. Schellekens, Ch. Schneider, and all the speakers of the day*
15:45	Coffee Break
16:15	Social Event and Gala Dinner

Wednesday 3 October

Chairpersons: *J-W. van der Laan (RIVM, The Netherlands) & S. Spanhaak (Johnson & Johnson, Belgium)*

9:00	General principles and unique (molecule /class-specific) approaches in biopharmaceutical development [ICHS6]. *J-W Van der Laan*
9:45	Chronic toxicology studies for biopharmaceuticals. *R. Ponce (Zymogenetics, USA)*
10:30	*Coffee break*
11:00	Carcinogenicity: the need for in vitro and in vivo studies. *M. Oliecsiwis (Novo-Nordisk, Denmark)*
11:45	Alternatives for safety assessment of biopharmaceuticals (surrogates, transgenics). *B. Silva Lima (University of Lisbon, Portugal)*
12:30	*Lunch*
13:30	Use of non-human primates in reproduction toxicology. *M. Niehaus (Covance, Germany)*
14:15	Safety pharmacology. *S. Chivers (??, USA).*
15:00	Risk assessment of monoclonal antibodies: a regulatory perspective. *T. Maurer (SwissMedic, Switzerland)*
15:45	*Coffee break*
16:15	Roundtable on ICH S6: where does it work and where it does not. *J-W. Van der Laan, S. Spanhaak*
17:45	Concluding remarks. *J-W. Van der Laan, J. Descotes*