Outgoing President’s Message

Mitch Cohen

It really is hard to believe that a year has already gone by and that my term as head of this truly great Specialty Section is coming to an end. Not sure if my inability to sit here and recall all that has gone by is due to fact that there was just so much to recall or simply a case of plain old mental burn-down. Either way, in my last message to you, I’ll have a swing at recalling our SS triumphs and mention a few seeds planted for the future.

First, I want to thank everyone who took the time to nominate a paper for Best Publication of the Year or encouraged students and post-docs (PDs) to apply for Best Presentations Awards for the Charlotte SOT meeting. While we were kind of wobbly consistency-wise with those awards over the past few years, the response this year was stellar and all applicants of top-notch quality. Many Awards Committee members commented to me on how hard the selection process was this year. Congratulations to all nominees and of course, the awardees!!

Second, our Section’s ongoing and growing interactions with the Japanese Society of Immunotoxicology has been acknowledged - and lauded - by SOT National in several different forums. Along those lines, based on the theme of their upcoming annual meeting in Kobe, the JSIT Board requested that Drs. Rod Dietert and Ken Hastings be this year’s representative presenters from our SS. I’m happy to say that plans are already underway to select one or more of IMTOX members to speak at the JSIT 2008 meeting in Tokyo. On our end, having finally worked out several major logistical kinks, we are in the process of helping to bring the first JSIT-designated member to one of our national meetings (in Seattle 2008) where they too will have the honor of speaking in a scientific session.

Apart from the JSIT, I have been continuously trying to establish similar links/collaborations/exchanges with our colleagues in South Korea. If any member can help our SS to reach out to other Immunotox societies and/or organizations in Asia, Africa, Australia, India, and/or Latin America, please contact me so that we can start those processes promptly.

Third, the idea about creating a mechanism by which we might be able to bring a grad student/PD from Europe to an annual meeting has gained a lot of

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Incoming president’s message ........................................ page 2
Committee reports ....................................................... page 4
Committee Lists - 2007-2008 ........................................ page 8
Photos from SOT 2007 ................................................... page 9

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The Immunotoxicology Specialty Section Newsletter is published 3 times/year (May, August and November). If you would like to share a book review, meeting report, interesting web site or any other item of interest with members of the Specialty Section, please send it to us by the middle of the month preceding the planned publication date. All comments on, or suggestions for, the newsletter are welcome.

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Typesetting provided by L. Peyton Myers, Ph.D.
strength. Similarly, there has also been increasing interest in creating more opportunities (travel $$$, etc.) for students from USA and/or Canada to attend the meeting. So long as our finances remain strong and our SS continues to receive the support of National SOT (moral and, more importantly, financial), both of these goals are likely to be achieved in Steve Pruett’s term.

Fourth and last, there are many challenges that our SS will be facing in the coming year(s), and Steve, Jeanine, and Jean are already working on them. The one I feel is most likely to be the biggest issue is the Study Section problem that is really starting to affect many of our members. I know that Steve is on this already and I hope the problem gets the recognition (by SOT National and NIH) and, more importantly, resolution that it merits - quickly. Another topic is the ability of our SS to raise funds beyond those we get for membership and attendance at annual meetings. Several ideas are floating about on this topic. Hopefully, our SS will be able to lock into one or two mechanisms and then raise substantial funds to allow us to pursue a lot of new goals (that cost many bucks), including the increased support for student/PD travels to meetings, the international exchange programs, and the new Pool of Lecturers program.

In closing, it really was an honor and privilege to have been Immunotoxicology SS President. As was noted in the outgoing statement of the SS President last year (and that of the year before and the one before that), our SS is comprised of a terrific group of scientists, and more importantly, group of people.

Steve – you have the reins now. Lead on.

P.S. Thanks to all of you who expressed your sympathies in Charlotte. Your comments helped quite a lot and made it possible for me to persevere during a most surreal week.

Incoming President’s Message

Submitted by Steve Pruett

As I prepare to become President of the Immunotoxicology Specialty Section, I would like express my thanks to Mitch Cohen for teaching me along the way and for his excellent work as President for 06-07. Mostly, my intention is simply to continue on the course established by Mitch and those before him. One of my goals is to maintain and even improve our membership numbers. This really depends on each of our members encouraging others at their institution to join. Another important link in this effort is maintaining accurate membership records. Those maintained by SOT tend to fluctuate wildly from year to year depending on the percentage of members who pay their dues on time. We have been able to keep our numbers relatively constant by contacting people who were members last year and reminding them that we value their membership (and reminding them to pay up). George DeGeorge has been at the center of this effort. He has maintained outstanding and up to date membership records in his role as
Chair of the Membership Committee, and I am pleased that he has agreed to continue to serve in this important role.

Interesting scientific programs have also contributed much to the viability of this Specialty Section. Mitch was particularly interested in encouraging “new” investigators to submit proposals for symposia, roundtables, etc. This effort was successful this year, and I would like to continue it. Most of us “old timers” really enjoy hearing from young investigators and learning from the scientific programs they assemble. Please see the Program Committee’s section later in this Newsletter for information on deadlines and how to submit a proposal, do not be deterred simply because you have never submitted one before. Our Program Committee will help you polish the proposal during the review process. Jeanine Bussiere and the Program Committee for 06-07, did an excellent job of encouraging submissions and helping those who proposed programs modify them to increase their chances of acceptance by the SOT Program Committee.

If there is one issue outside the Specialty Section on which I would like to focus in the upcoming year, it is the problem that immunotoxicologists are having with review of their grant applications by NIH Study Sections. I have appointed an ad hoc committee, which includes Norb Kaminski, Mike McCabe, Deborah Keil, Prakash Nagarkatti, Judy Zelikoff, Paige Lawrence, and myself. The goal of this group will be to gather data on this issue and present it in a compelling manner to the SOT Task Force. Mike McCabe has already obtained some very interesting numbers that objectively illustrate the problems that immunotoxicology investigators are having. Dr. Pat Mastin also sent me some numbers he has compiled at NIEHS, which indicate a similarly dismal situation. Hopefully, we can help the Task Force make a more convincing case with regard to the need for additional reviewers with immunotoxicology experience or (even better) a new study section for immunotoxicology, developmental toxicology, cardiovascular toxicology, and mechanisms of toxicity.

This is becoming an increasingly urgent matter, as the number of academic immunotoxicologists is already quite small, and there is a real threat that some will be unable to continue work in this area quite soon. This comes at a particularly interesting time, with the approval of the ICH S8 Guidelines (International Committee on Harmonization Immunotoxicology Guidelines), which will implement immunotoxicology testing for drugs under development in Europe, Japan, and the US. Thus, basic research in immunotoxicology is declining just as Guidelines for immunotoxicology testing (which have substantial economic and health implications) will be implemented. One problem with this approach is illustrated by the history of basic research and regulatory practices for carcinogenicity. In evaluation of carcinogens, mechanistic information has allowed much more informed and accurate risk assessment based on the mechanism of action of the compounds. This is not possible for immunotoxicants, because we know the mechanisms of action of so few of them. Unless immunotoxicology grants begin to be reviewed by qualified persons who are genuinely interested in such issues, the necessary mechanistic data will not be forthcoming any time soon.

I hope our colleagues in government and industry positions will not be impatient with this focus of attention, but those of you who have spoken to me about it recognize that this issue could eventually affect all sectors, if fewer Ph.D. and post-doctoral trainees in immunotoxicology will be available in future years. If you have particular information to share (e.g., anecdotes about grant reviews you have experienced), ideas for changes, or other matters related to this topic, please contact one of the members of this ad hoc committee. Hopefully, there will be something to report on this front in the next newsletter.

On a very related but perhaps more positive note, I hope the specialty section (perhaps through this ad hoc committee) can provide concrete suggestions to investigators in immunotoxicology that will increase chances for funding in the current environment. For example, combining the new NIEHS focus on toxicants as modifiers of disease processes and the interest of current study sections on basic mechanisms of immunity and inflammation, applications that use immunotoxicants to
reveal new information about disease processes or mechanisms of immunity or inflammation may be more favorably reviewed than applications that directly address mechanisms of immunotoxicity. Hopefully the ad hoc committee can develop some specific recommendations to share with our members in this regard.

I would also like to continue the efforts begun by Mitch to increase interaction and communication between the Immunotoxicology Specialty Section and its counterpart in Japan. The practice of supporting travel for a member of the Japanese organization to the SOT meeting is one way to accomplish this, and I plan to continue this practice.

When I attended my first SOT meeting (no I will not admit how long ago that might have been), I was immediately impressed that regulators, regulated, and academicians could meet in a collegial atmosphere and focus on presenting and discussing high quality scientific work. This is especially evident in our specialty section, and I am looking forward to working with you in 2007-2008 to ensure that this worthwhile tradition continues.

Awards Committee Report

Submitted by Greg Ladics

I wanted to thank our specialty section for all of the student, post doc, and paper of the year award nominees that were submitted to our committee this year. We received 13 student award nominees (compared to none last year), 4 post doc award nominees, and 5 nominees for paper of the year. Outstanding!- you really made the committee work this year. Due to the large pool of nominees, the committee decided to give a 1st, 2nd, and 3rd Place award for students and a 1st and 2nd Place award for Post-Docs. Let's try for even more nominees next year! The winners of each award category are as follows:

Post-Doc Awards

1st place - Dr. Venkatesh Hedge—University of South Carolina. Delta-9-tetraydrocannabinol-Induced Dramatic Infiltration of Neutrophils in Mice is Mast-Cell Dependent

2nd place - Dr. Lewis Shi - University of Wisconsin. Aryl Hydrocarbon Receptor (AhR) Is Required for Innate Immunity to Listeriosis

Vos Award Career Achievement in Immunotoxicology

Dr. Nancy Kerkvliet
Oregon State University

Paper of the Year

Camacho IA, Singh N, Hegde VL, Nagarkatti M, Nagarkatti PS. Treatment of mice with 2,3,7,8-tetrachlorodibenzo-p-dioxin leads to aryl hydrocarbon receptor-dependent nuclear translocation of NFkB and expression of Fas ligand in thymic stromal cells and consequent apoptosis in T cells. J Immunol. 2005 Jul 1;175(1):90-103.

Student Awards

1st Place - Lauren Tarantino - NYU School of Medicine. Mouse Models of Beryllium-induced Sensitization and Granulomatous Lung Disease

2nd Place - Alice Ng - NYU School of Medicine. Gender Susceptibility is a Factor Influencing Offspring Tumor Risk and Response to Prenatal Cigarette Smoke Exposure: A Role for Testosterone

3rd Place - Ava Rhule - University of Montana. Panax Notoginseng Attenuates Dendritic Cell Function Through Inhibition of NFkB Activation

Young Investigator Award

Dr. Jean Pfau
University of Montana
Serving on committees is a great way to make new contacts and to learn about hot topics in immunotox. Student participation for these committees has been low in the past so let’s make an active effort to give ourselves a good name.

Want to broaden your network? Have your advisor nominate you to become the next student representative of the ISS. Sheung Ng’s term will run out next year and we are actively looking for a new student representative. All your advisor has to do is send a letter of recommendation to the ISS president that includes verification that he or she can fund your travel to SOT for the next two years. Your term would run from March 2008-March 2010 and you would serve as the student voice on the ISS. Think about it. You can’t expand your professional network by hiding in the lab. If you have any questions about student representation in the ISS or how the ISS can best serve you as a student of immunotox, please do not hesitate to contact me at sanderson4@cdc.gov or Sheung at ng@env.med.nyu.edu.

I’m working on compiling an email contact list for all of the ISS students/post-docs. I think this is a great way to increase awareness of upcoming events and will give us on opportunity to voice our opinions and concerns (at least to each other). Hopefully this will increase interaction and participation of the students. If I leave out anyone or anyone has upgraded their student/post-doc status please let me know so I can keep the list current. I’m currently searching for a meeting place for the mixer in Seattle. If anyone is familiar with the area and has suggestions or recommendations for where the mixer could be please let me know. Also, any other thought on how to increase student/post-doc participation at the mixers would be appreciated.

I would like to begin by thanking Jamie Dewitt for her service as the post-doc representative for the last two years. I think I can speak for everyone in commending Jamie on a job well done. We hope all of you had a productive and enjoyable time in Charlotte. If you missed the ISS student/post-doc mixer at Ri-Ra’s Irish pub, we will have a similar opportunity to socialize with one another and with the leadership of the ISS at the meeting in Seattle. Please watch for information about our meeting place in upcoming communications from the ISS as the national meeting approaches. We hope more of you attend future mixers, it is a great way to get to know the other students/post-docs in ISS.

Greetings fellow students and post-docs! My name is Stacey Anderson and I am your new ISS post-doc rep. My term will run for the next two years until 2009. I obtained by Ph.D. in cellular and molecular biology from West Virginia University and I am currently located at CDC/NIOSH in Morgantown, WV in the Allergy and Clinical Immunology Branch of the Health Effects Laboratory Division. I am in the third year of my post-doc and working in Dr. Albert Munson’s laboratory. My research focuses on the investigation of the immunotoxic effects of occupational hazards. I have been a member of the ISS for the last two years and welcome the opportunity to enhance my involvement in ISS through this post-doc ISS representative position.

I would also like to remind all student members that ISS committees are open to students. Committees include the Awards, Communications, Membership, Program, and Regulatory Committees. Descriptions of these committees are available on the ISS website. Please let me know if anyone is interested in donating some time. I will also be sending out an email about this shortly.

If you have any questions about student representation in the ISS or how the ISS can best serve you as a student of immunotox, please do not hesitate to contact me at sanderson4@cdc.gov or Sheung at ng@env.med.nyu.edu.

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Program Committee Update

Submitted by Jeanine Bussiere

This year we had a great response from the committee and members of the specialty section for program proposals for the 2008 meeting in Seattle. Proposals were submitted for two roundtable sessions and six symposiums. The Immunotoxicology Specialty Section is endorsing both roundtable (RT) proposals and three symposium (S) proposals. Two additional symposium needed further review and one was held for 2009 for further development.

In addition, the Immunotoxicology Specialty Section has been approached to co-sponsor a symposium with the Risk Assessment Specialty Section on Risk Assessment for Biotherapeutics. There were no submissions for CE courses which are always very successful. The two CE courses sponsored by the Immunotoxicology Specialty Section at the 2007 meeting were very well attended; some of the best for this year.

The SOT Program Committee will meet in late May to decide which proposals will be included on the 2008 program. To find out which proposals were accepted by SOT, check the Immunotoxicology Specialty Section web page or the next issue of the Newsletter.

My many thanks to the people who served on this year’s Program Committee: Dori Germolec, Ian Kimber, Greg Ladics, Tony Arulanandam, Mike Woolhiser, Petia Simeonova, Jamie DeWitt, Girish Ramdas Chaudhari, Allen Silverstone, M. Firoze Khan, Lynne LeSauteur, Robert Caldwell, Kathy Sarlo, Steve Pruett, and Mitch Cohen. Everyone put significant effort into evaluating program proposals, and several committee members submitted proposals.

The new chair of the Program Committee is Jean Regal (jregal@d.umn.edu); her term began on May 1st. Please help Jean and the members of the committee out by thinking now about program ideas for the 2009 meeting in Baltimore. Unlike some of the other specialty sections, we depend on our members for program suggestions, rather than generating program ideas in a committee. If you have an idea for a session, as a potential presenter or as a topic that you would like to have presented, please contact Jean. If you need a bit of advice, or have never put together a proposal and are not sure where to start, members of the Program Committee will be happy to help. For 2008, the program committee is: Keiko Nohara, Jean Regal.

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<thead>
<tr>
<th>Status</th>
<th>Title</th>
<th>Chair/Co-Chair</th>
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<tbody>
<tr>
<td><strong>RT - Endorsed</strong></td>
<td>Immunotoxicity Testing: Should elevated antibody responses be interpreted as an indicator of immunotoxicological hazard?</td>
<td>Bob Luebke, Michael Holsapple</td>
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<td><strong>RT - Endorsed</strong></td>
<td>Application of the ICH S8 Immunotoxicology Testing Guideline in drug development</td>
<td>Pramila Singh, Tom Kawabata</td>
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<tr>
<td><strong>S - Endorsed</strong></td>
<td>The Allergic March: The role of chemicals in the increasing prevalence of allergy and asthma</td>
<td>Ian Kimber, Ben Nemery</td>
</tr>
<tr>
<td><strong>S - Endorsed</strong></td>
<td>Natural Killer cells as targets of drugs, toxicants and biologicals</td>
<td>Raj Krishnaraj, Steve Pruett</td>
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<tr>
<td><strong>S - Endorsed</strong></td>
<td>Ligation of peroxisome proliferator activated receptor alpha: Impacts on the immune system</td>
<td>Jamie DeWitt, Bob Luebke</td>
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<tr>
<td><strong>S - Review</strong></td>
<td>Linking hormone-like xenobiotics in the environment to immune dysfunction</td>
<td>Charles Rice, Fujio Kayama</td>
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<tr>
<td><strong>S - Review</strong></td>
<td>Mechanisms of pseudoallergic/infusion reactions and predictive testing approaches</td>
<td>Tom Kawabata, Rob Caldwell</td>
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<tr>
<td><strong>S - Hold for 2009</strong></td>
<td>Protein adducts of xenobiotics in organ toxicity and autoimmunity</td>
<td>M. Firoze Khan, Lance Pohl, Jack Uetrecht</td>
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Biotechnology-derived proteins are being used increasingly as therapeutic agents for cancer, immune disorders and other diseases. It is well known that these proteins have the potential to produce antibody in humans receiving the drug. This is of increasing concern to companies developing and manufacturing these compounds, as well as to the regulatory agencies responsible for assuring safety in humans.

Under the auspices of the European Medicines Agency (EMEA), the Committee for Medicinal Products for Human Use (CHMP) has issued a draft document entitled "Guideline on Immunogenicity Assessment of Biotechnology-Derived Therapeutic Proteins". This document was adopted by the CHMP for release for consultation in January of 2007 and is now available for review and comment. This document reviews the risk factors for developing an immune response against a therapeutic protein, discusses the predictivity of both nonclinical animal models and in vitro/ex vivo tests to predict a potential response, and highlights the factors that affect clinical safety of protein therapeutics.

The deadline for public comments is July 31, 2007.


Submitted by Peter Thomas

We have had an outstanding response for the Education Committee's newly-developed Speakers Bureau. Over 20 immunotoxicologists have responded who are willing to give a class lecture at a nearby - or not so nearby - university in their specific field of interest. Those that have already volunteered their time are listed below. However, it is not too late to add your name to this worthy venture. You can see from the list that the current pool of lecturers come not just from academia but include immunotoxicologists from industry and government. In the not too distant future, I will be sending out a follow-up questionnaire to the lecturers regarding your specialty, geographic preference for teaching, timetable and whether or not travel funds are needed. With classes beginning again in September, I hope this list of speakers will prove a valuable asset for our SS. Indeed, Mitchell and I expect to be inviting a few people to our Environmental Immunotoxicology class come the Spring semester. However, don't be surprised if I call some of you about my Organ System Toxicology course this fall.

Once I have the database complete with all necessary information, I will let everyone know and you can begin your requests. In the meantime if you want to volunteer or have any questions please feel free to contact me. Thanks

Submitted by Judy Zelikoff
2007-2008 Regulatory Committee
Peter Thomas (Chair)
Chidozie Amuzie
Tony Arulanandam
Rod Dietert
Robert M. Gogal, Jr.
Ken Hastings
Robert W Lange
Ji-Eun Lee
Susan Makris
Peyton Myers
Courtney Sulentic
Jeffrey Tepper
Haizhou Zhang

2007-2008 Awards Committee
Rod Dietert (Chair)
Danuta Herzyk (Co-Chair)
Yong Joo Chung
George DeGeorge
Jamie DeWitt
Michelle Horner
Vic Johnson
Mitzi Nagarkatti
Margie Peden-Adams
Tina Satterwhite
Lewis Shi
Courtney Sulentic
Sabine Teske

2007-2008 Immunotoxicology Pool of Lecturers
Judy Zelikoff (Organizer)
Leigh Ann Burns-Naas
Mitch Cohen
Rod Dietert
Ken Draper
Deborah Finco-Kent
Kathleen Gilbert
Ken Hastings
Robert House
Norb Kaminski
Ian Kimber
Nancy Kerkvliet
Raj Krishnaraj
David Lawrence
Mike McCabe
Mitzi Nagarkatti
Prakash Nagarkatti
Margie Peden-Adams
Joseph Piccotti
Helen Ratajczak
Jean Regal
Maryjane Selgrade

2007-2008 Education Committee
Judy Zelikoff (Chair)
David Lawrence
Lin L. Mantell
Yanli Ouyang
MaryJane Selgrade
Haizhou Zhang

2007-2008 Communications Committee
Susan McKarns (Chair)
Jamie DeWitt
Kathleen Gilbert
Cynthia Graham
Nancy Kerkvliet
Margie Peden-Adams
Sabine Teske

2007-2008 Membership Committee
George DeGeorge (Chair)
Venkatesh Hegde
Cherie Pucheu-Haston
Marsha Ward

Please contact Chair if you still want to join a specific committee.
Dr. Jamie DeWitt
Post-Doc Representative

Dr. Greg Ladics presenting certificate to Alice (Sheung) Ng, Second Place Winner, Student Award

Dr. Steve Pruett presenting plaque to Brenda House for her outstanding work on the ISS Newsletter in years past

Lauren Tarantino
First Place Winner, Student Award

Dr. Venkatesh Hedge, First Place Winner, Post-Doc Award

Dr Lewis Shi, Second Place Winner, Post-Doc Award

Dr. Mitzi Nagarkatti and Dr. Greg Ladics

Immunotoxicology Specialty Section
Reception Gathering
Charlotte Convention Center
March 27, 2007
Drs. Susan McKarns, Barbara Kaplan, Courtney Sulentic, Nancy Kerkvliet, and Dave Shepherd celebrating Nancy’s award.

Dr. Nancy Kerkvliet, receiving the Vos Award for Career Achievement from Dr. Judy Zelikoff

Dr. Jerry Heindel

Students and Post-Docs mingling at the ISS Student Post-Doc Mixer

Drs. Dave Shepherd and Steve Pruett

Alice (Sheung) Ng discussing student issues at the ISS business meeting.

Dr. Robert House
In order to enhance its long-standing commitment to the promotion of immunotoxicology, the nonprofit association “Summerschool in Immunotoxicology” is pleased to announce that it will present an Annual PhD Award starting from 2007, in recognition of outstanding student candidates for their contribution to the field of immunotoxicology.

In addition to the 1,000 € prize, the 2007 recipient will be the guest (including registration, accommodation and travel expenses) of the 16th Summerschool in Immunotoxicology to be held in October in Lyon (France), and will be invited to give a 15-min oral presentation summarizing his (her) most significant results.

Any student having obtained a PhD degree (or recognized equivalent) during the 12 months prior to the application deadline for original work strictly in the area of immunotoxicology is eligible. However, the submitted PhD thesis should be either in English or French, unless an English or French summary is provided together with the applicant’s original papers strictly derived from his or her PhD work.

Applications, including the candidate’s CV and PhD thesis in final form should be submitted to the Summerschool President Prof. Jacques Descotes:

E-mail: jacques-georges.descotes@chu-lyon.fr

Post mail : Centre Antipoison, 162 av. Lacassagne, 69424 Lyon cedex 03, France.

The next deadline for application is 1st June 2007.
 Provisional program

NONCLINICAL SAFETY EVALUATION OF BIOPHARMACEUTICALS

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
       Part 1- A case of non-prediction? Ch. Horwath (Archemix, USA)
       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. Speaker to be confirmed
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
11:45  Risk assessment with case studies:
       Preclinical case studies. L. Plitnick (Merck, USA), Curtis 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 (Utrecht University, the Netherlands), 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)

<table>
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<tr>
<th>Time</th>
<th>Session</th>
<th>Speaker/Details</th>
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<tr>
<td>9:00</td>
<td>General principles and unique (molecule /class-specific) approaches in biopharmaceutical development [ICH S6].</td>
<td>J-W Van der Laan</td>
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<tr>
<td>9:45</td>
<td>Chronic toxicology studies for biopharmaceuticals. Speaker to be confirmed</td>
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<td>10:30</td>
<td>Coffee break</td>
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<td>11:00</td>
<td>Carcinogenicity: the need for in vitro and in vivo studies. M. Oliecswis (Novo-Nordisk, Denmark)</td>
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<td>11:45</td>
<td>Alternatives for safety assessment of biopharmaceuticals (surrogates, transgenics). Speaker to be confirmed</td>
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<td>12:30</td>
<td>Lunch</td>
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<td>13:00</td>
<td>Lunch</td>
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<td>13:30</td>
<td>Use of non-human primates in reproduction toxicology. Speaker to be confirmed</td>
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<td>14:15</td>
<td>Safety pharmacology. Speaker to be confirmed</td>
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<td>15:00</td>
<td>Risk assessment of monoclonal antibodies. Speaker to be confirmed</td>
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<td>15:45</td>
<td>Coffee break</td>
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<tr>
<td>16:15</td>
<td>Roundtable on ICH S6: where does it work and where it does not. J-W. Van der Laan, S. Spanhaak</td>
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<td>17:45</td>
<td>Concluding remarks. J-W. Van der Laan, J. Descotes</td>
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**DRAFT**

**GUIDELINE ON IMMUNOGENICITY ASSESSMENT OF BIOTECHNOLOGY-DERIVED THERAPEUTIC PROTEINS**

http://www.emea.europa.eu

London, 24 January 2007


The Committee for Medicinal Products for Human Use (CHMP)

The end of consultation (Deadline for comments) is 31 July 2007.

Comments should be provided electronically in word format using the template (see below) to: BMWP.secretariat@emea.europa.eu.

NOTICE TO ALL STUDENTS AND GRADUATE STUDENT PROGRAMS

The Dose-Response Specialty Group (DRSG) of the Society for Risk Analysis is pleased to offer a merit award to a student conducting graduate research in dose-response assessment. The research may be on any topic broadly related to dose-response assessment, including but not limited to: laboratory investigation, methods development, comparative analyses, novel applications, studies on strengthening the role of dose-response assessment in risk assessment, uncertainty analysis, harmonization, dosimetry, genetics, and molecular biology. In addition to the peer recognition of your scientific accomplishment, the award includes a registration fee waiver to the SRA Annual Meeting, an engraved plaque, and a $500 honorarium. The DRSG award winner will present his/her results and receive his/her award at the annual meeting, absent an extraordinary circumstance preventing this.

The award is merit based and competitive. The Executive Committee of the Dose-Response Specialty Group will rely on the following criteria to evaluate submissions:

1. Relevance of the topic to dose-response in the broadest sense
2. Originality of the research
3. Significance of the conclusions toward advancement of a principle, line of research, or the field as a whole
4. Breadth of the inquiry and degree of complexity of procedures and analyses
5. Quality of the extended abstract (clarity, logic, organization)
6. Submission to, publication in, or publishable in a peer reviewed journal

All abstracts must be submitted for presentation at the 2007 SRA Annual Meeting December 9-12, 2007 in San Antonio, TX, following normal SRA guidelines for abstract submission (www.sra.org/events_2007_meeting.php) for meeting dates, guidelines and deadlines). Examples of previous year’s winners’ abstracts can be found on our website www.sra.org/drsg/drsgawar.htm

Questions concerning the DRSG award procedures should be addressed to:

Paul I. Feder, Ph.D.
Vice-Chair, DRSG
Battelle
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E-mail: feder@battelle.org
Information, Registration, Poster Session Sign-Up:

The registration deadline was May 20.
However, you may still register.
Please e-mail Tom Kawabata at thomas.t.kawabata@pfizer.com and he will arrange registration with the GRC.

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Mitochondrial Toxicity
Novel Molecular Targets and Implications for Toxicity Testing
Adverse Drug Reactions with Biological Therapeutics: Mechanisms and Testing Approaches
Nanotechnology Applications in the Development of Therapeutics
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Functional Genomic Approaches to Adverse Drug Reactions
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Here is a sampling of articles that have appeared in recent issues:
New Developments in the Assessment of Developmental Immunotoxicology, Rodney R. Dietert
Preclinical Immunogenicity Testing for Recombinant Therapeutic Proteins, Holly W. Smith and Daniel Wierta
Altered Spleenocyte Function in Aged C57BL/6 Mice Prenatally Exposed to Diethylstilbestrol, Julian B. Feneaux, Robert M. Gogal, David Lindsay, Carrie Hardy, Daniel L. Ward, Geoffrey Saunders, and S. Ansar Ahmed
The Relationship Between Noncoplanar PCB-Induced Immunotoxicity and Hepatic CYP1A2 Induction in a Fish Model, Jessica E. Duffy and Judith T. Zelikoff

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**Position Summary:** This is middle level Toxicologist position to evaluate the safety of MEDI’s biologics and vaccines candidates. The position requires experience in designing, planning, conducting, monitoring, and reporting of non-clinical safety studies. Previous vaccine and monoclonal therapeutic product development experience at a pharmaceutical or biotechnology company is preferred. Specific experience in multiple vaccine constructs (e.g., protein, adjuvants, adenovirus, LVS, etc.), routes of administration (IM, ID, SC, and IN) and species (rabbit, ferret, rodent, and large animal) as well as experience with various study designs (toxicology, biodistribution, neurovirulence, enhanced disease models, etc.) is highly desirable. Familiarity with GLP regulations and regulatory guidelines for the testing of biopharmaceutical and vaccine products. Experience with compilation of toxicology information into various regulatory submission documents. Excellent communication skills. Background in cell biology, immunology, and experimental disease models preferred. Major Duties and Responsibilities (including supervising others):

Responsibilities include the design and conduct of nonclinical safety studies (toxicology, pharmacokinetics, distribution, elimination, exploratory toxicology). Acts as Study Director, Study Monitor and/or Principal Investigator for nonclinical safety studies conducted in-house and at contract facilities. Analyzes data and writes protocols and reports. Supervises associate scientists. Serves as the toxicology representative on multi-disciplinary product development teams and updates project teams on pharmacology and toxicology issues.

**Education:** Ph.D. in Toxicology or Biomedical Sciences
**Board certification Experience:** 5 to 10 years post-Ph.D. experience, including 3 years in a biotechnology company
**Special Skills/Abilities:** Hands on and project management related experience in preclinical safety of biologics and vaccines
**Job Complexity:** Medium; Supervision: High level of independence

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**Fax:** 301.398.8244  
**ManetzS@MedImmune.com**

For more information, refer to the MedImmune website ([www.medimmune.com](http://www.medimmune.com)).
Sr. Scientist/Principal Scientist - Immunotox (R4/R5)

Working within the Immunotoxicology Center of Emphasis of Drug Safety Research and Development, you will be focused on supporting assay development and sample testing for non-clinical and clinical studies in 3 major areas: (1) immunogenicity of biologicals, (2) hypersensitivity testing of low MW compounds, and (3) immunomodulation testing. Your responsibilities will include the development and validation of in vitro and in vivo methods to evaluate immunomodulation and predict and investigate hypersensitivity reactions with low MW and biologicals; supporting the development and validation of immunoassays and cell-based assays for immunogenicity testing of biologicals; investigating new technologies that can be applied to immunotoxicity testing; presenting findings to internal teams and at national meetings; and publishing findings in peer reviewed journals. You will also be responsible for overseeing assay development, sample analysis and report preparation at contract research organizations (CROs); supervising and mentoring lab scientists in the conduct of studies; and preparing annual performance evaluations.

The qualified candidate will have a Ph.D. in toxicology, pharmacology or immunology, or related biological disciplines; at least 2 years of post-doctoral training in immunotoxicology or immunology; experience with the development and validation of in vitro and in vivo methods to assess immune function; demonstrated excellence and productivity though publication in peer reviewed journals; and experience with supervising/mentoring laboratory staff, GLP, project management and/or CRO interactions. Good communication skills, attention to detail, trouble shooting skills and ability to work collaboratively are required.

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The qualified candidate will have a Ph.D. in toxicology, pharmacology or immunology, or related biological disciplines; post-doctoral training in immunotoxicology or immunology; at least 10 years of experience working in the area of immunotoxicology with greater than 5 years of experience at a pharmaceutical / biotechnology company; supervisory experience with the development and validation of in vitro and in vivo methods to assess immune function; experience in working with regulatory agencies in dealing with immunotoxicology issues; and demonstrated excellence and productivity through publication in peer reviewed journals. Excellent communication skills, attention to detail, trouble shooting skills and ability to work collaboratively are required.

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Sudheer AR, Muthukumaran S, Devipriya N and Menon VP. Ellagic acid, a natural polyphenol protects rat peripheral blood lymphocytes against nicotine-induced cellular and DNA damage in vitro: With the comparison of N –acetylcysteine. Toxicology 230:11-21, 2006.


**General Immunotoxicology**


Bhat SH, Azmi AS and Hadi SM. Prooxidant DNA breakage induced by caffeic acid in human peripheral lymphocytes: Involvement of endogenous copper and a putative mechanism for anticancer properties. TAAP 218:249-255, 2007.


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