Dear BTSS members –

The Executive Committee is looking forward to seeing everyone at the upcoming SOT Annual Meeting. We have many great events planned, including our Specialty Section reception that will take place on Monday, March 14, at 6:00 pm at Hilton Riverside Grand Salon 3. Please join us as we will have an exciting guest speaker—Dr Bethany Kraft from the Ocean Conservancy—who will give a talk on the Deepwater Horizon oil spill and its impact on the Gulf. In addition, we will be offering a New Orleans signature cocktail (and a free drink ticket) for all attendees.

We would also like to welcome our newly elected BTSS Executive Council members:

Vice President-Elect: Jorg Blumel
Secretary/Treasurer: Amy Sharma
Councilor: Jacintha Shenton
Postdoctoral Rep: Prathap Kumar S. Mahalingaiah

We will also host 2 additional mentoring events at the Annual Meeting (see below) in support of our goal to increase student/postdoctoral involvement in BTSS activities. We look forward to seeing new faces and increasing awareness of toxicology in the biotechnology industry.

See you in New Orleans!
2015-2016 BTSS team

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Upcoming Biotech Meetings of High Interest

CDERLearn – FDA offered Training and Continuing Education Courses
http://www.fda.gov/Training/ForHealthProfessionals/default.htm?
source=govdelivery&utm_medium=email&utm_source=govdelivery

Center for Drug Evaluation and Research (CDER’s) primary mission is to make certain that safe and effective drugs are available to the American people. There is, however, a strategic initiative to inform and educate people about the safe use of medicine, the drug regulatory process and many other important issues. Online training is one way to share FDA expertise with many more people than face-to-face classroom sessions would allow. Listed below are a few courses offered by CDER.

FDA’s Role in Public Health: Drug Efficacy, Safety, Quality, and Beyond
FDA Overview of Biosimilar Products
CDER Small Business and Industry Education Series
Case Studies in FDA’s Drug Regulatory Processes
Risk Assessment and Communication
The FDA Process for Approving Generic Drugs

BioSafe/DruSafe Emerging Technologies Workshop: Real-Life Experiences with Microphysiological and Organoid (3D) Systems”

Date & Time: March 31 2016, 8-12pm,
Location: USFDA, Silver Spring, MD
https://iqconsortium.org/events/biosafe-drusafe-emerging-technologies-real-life-experiences-w-microphysiological-organoid-systems

Summary
This workshop will provide an exchange of the ‘real-world’ experience of the evaluation and use of ‘organ-on-a-chip” and organoid (3D) platforms from pharmaceutical industry. This will include discussion of the drivers for their evaluation, qualification/validation approaches, application for screening or investigation of toxicology, DMPK and pharmacology questions, and the experiences gained regarding advantages, disadvantages, challenges, and limitations. The topics will include an overall perspective, update on the collaboration between NCATS and the IQ Consortium; hepatotoxicity cross platform evaluation of small molecules and ADCs; drug disposition modeling; development of a thrombosis model; application to cardiac safety; and evaluation of GI models. The session is meant to be interactive and will end with a panel discussion.

Cancer Vaccines: Targeting Cancer Genes for Immunotherapy (X1) joint with the meeting on Antibodies as Drugs (X2)

Date & Time: March 6—10, 2016
Location: Fairmont Chateau Whistler, Whistler, British Columbia, Canada
http://www.keystonesymposia.org/16X1

Summary
Monoclonal antibodies have had a pronounced impact in medicine and biology, with a broad array of approved agents that are used for the diagnosis, treatment and characterization of cancers, immunological disorders, and infectious diseases. Because of their exquisite target specificities, together with their favorable pharmacologic properties, antibodies are destined to have even increased clinical impact, particularly in diseases that are understood at the molecular level. This Keystone Symposia meeting will focus attention on many of the key advances in antibody-based technologies as well as on where the field is heading. Some of the critical topics to be covered in-
Upcoming Biotech Meetings of High Interest

- Antibody structure and function
- Engineered antibodies and antibody-like molecules for improved efficacy
- Antibody pharmacologic properties and biologic distribution
- Antibody-based therapies for cancer and infectious diseases
- Targeting costimulatory pathways and immunological checkpoints
- Antibodies as carriers of drugs, cytokines, radioisotopes and imaging agents
- Antibody mimetics
- Clinical advancements and challenges

This meeting has become an established forum that attracts both new investigators and leaders in the field, coming from academia, industry and research institutes around the globe. The goals of the meeting will be to address the critical issues facing the broad field of antibody-based therapeutics, provide an overview of recent advances and bring together interdisciplinary groups for the generation of new ideas and promising areas of investigation.

Protein Engineering Summit Boston: Preventing Toxicity in Immunotherapy

Date & Time: April 25-26, 2016
Location: Seaport World Trade Center, Boston
http://www.pegsummit.com/immunotherapy/

Summary

When dosed with an immunotherapy, adaptive and innate immune systems are activated, better allowing them to recognize disease cells in the body. However, the immune system also becomes more sensitive to self, potentially causing cytokine storm, macrophage activation syndrome, or autoimmunity. Predicting and preventing toxic effects in immunotherapies remains one of the biggest roadblocks in making these treatments a reality. The Inaugural Preventing Toxicity in Immunotherapy will examine effective preclinical models, biomarkers, and dosing considerations. The usefulness of preclinical models will also be debated with regards to humanized models vs. standard mouse models and cross reactivity. Finally, potential toxicity issues in combination therapies will be addressed. Overall, this event will enable researchers to continue moving forward rapidly, but safely.

2016 NewYorkBio Annual Conference

Date & Time: May 11-12, 2016
Location: 10 on the Park @ Time Warner Center
http://www.newyorkbio.org/site_page.cfm?pk_association_webpage_menu=2131&pk_association_webpage=7087

Summary

The NewYorkBIO Annual Conference is one of the largest life science business conferences, in the US, drawing hundreds of attendees from across the Northeast and far beyond. Because our mission is to support New York's industry-wide success, we present a broad and deep view of the state's massive life science opportunity. Each year the NewYorkBIO Annual Conference provides a forum where emerging companies, established players, academic investigators, institutional investors, industry analysts, and senior biotechnology executives have the opportunity to shape the future of New York's biotechnology industry. The conference features issue-oriented keynote and plenary sessions, educational sessions focused on hot therapeutic areas and key business issues, company presentations, one-on-one meetings, and great networking opportunities.
The Gordon Research Conference on Drug Safety

Date & Time: June 26—July 1 2016  
Location: Stonehill College, Easton, MA


Summary: The Drug Safety Gordon Research Conference is a leading venue for discussing contemporary approaches to drug safety assessment and to translate innovation in the lab to clinical drug safety research. Building on the momentum of a very successful inaugural meeting, for the 2016 Conference, experts and thought leaders from academia, industry and regulatory agencies will discuss the latest development and application of innovative methodologies for pharmaceutical risk assessment. The meeting sessions are organized to parallel the flow of knowledge in drug discovery and development beginning with computational models and systems biological approaches to drug safety assessment, through microphysiological systems and on to the pivotal transition to clinical development before addressing post marketing concerns. The conference will also feature a session on drug safety of biologics, a timely and important topic for which classical drug safety tools often don't suffice. For the first time, a Gordon Research Seminar on Drug Safety will be held in conjunction with the conference and will provide young researchers and early-career scientists the opportunity to present and discuss their current research with their peers. Networking and the free exchange of ideas is an important part to the success of the conference. Participants will have the opportunity to present their cutting-edge work in poster format during session breaks in a relaxed setting that stimulates open dialogues which often carry on into the social activities during the afternoon sessions and at the bar at the end of the day. A committee will select some posters for short oral presentations that will be featured during late-breaking sessions, allowing those participants to share their work with leading experts in their field and to receive feedback from an audience of experts.
Maximize Grad School and Break Into Your First Industrial Job: Tips from A Recent Graduate

Vijay P. Kale M.V.Sc., Ph.D., D.A.B.T.
Principal Research Scientist, Battelle Memorial Institute, Columbus, Ohio

A PhD is at least a 5-year long commitment! Rigorous study and tests make first two years quite stressful. Once you come out of this furnace, you enter into the years of dreams. I call the 3rd and 4th years as dream years because this is the time when students imagine themselves as scientists who are all set to solve the world’s most pressing problems. These years are full of excitement, energy, and curiosity. You may spend most of your day in the laboratory conducting experiments. The terms like weekend, vacation, and holidays may become alien to you. During these two years you will have a thrilling ride on a roller-coaster of excitement and frustrations and you will get most of your research work done during these two years. During the 5th year of a PhD program, once you start hearing discussions about your graduation, you will start wondering, ‘what do I do after my PhD?’ And you will start exploring various opportunities. You will struggle to devote some time to explore the opportunities from important lab work (actual bench work, publications, and thesis writing). And of course you are so close to solving a problem that you will need (be forced/tempted) to spend more time on those “key experiments”!

So the question is, how can I find time to plan for my next step? What is the right time to start thinking about my post-PhD career? How can I maximize my PhD time?

Here are some of tips which can help you to navigate through graduate life and plan your career.

Start Early: Start thinking about your career the day you enter grad school. Remember, grad school is not your final destination. It is a key stepping stone of your career. So start planning your grad days in line with your career. Everyone does not necessarily know where they want to go after their PhD. The more are unclear your career goals, the more effort you need to put into to get the path clear.

By starting early you will get enough time to acquire different tools which can make the job search easy when the time comes. Don’t attempt to dig the well when you are thirsty!

Develop Technical Skills: By the end of your PhD you are supposed to be ready to launch yourself as a scientist. You are going to use those technical skills and academic knowledge irrespective of the field of your career. This is your foundation, at least early in your career. Learn technical skills as much as you can. Start taking interest in learning the techniques not only from your lab mates but from your friends, collaborators and other available resources.

Either technical skills or soft skills will take priority to make you successful depending on the field and stage of your career. If you aim for academia as your next career step, technical skills will be your foundation and soft skills will leverage them. But to be successful (in basic sciences as a scientist, an
Tips from A Recent Graduate...

Executive in industry/CRO or as a regulator and policy maker in government, one needs to have some key soft skills. These soft skills are worth investing time. This investment will pay you back throughout your career – starting from landing the first job through late in your career.

Hone Your Communication Skills: A employer looks for a candidate who has verbal and written communication skills. These skills are going to be key to your successful career. Take all the opportunities to explain your research to people around you. It is said that you are a good communicator if you can explain your research to your granny and can even converse proficiently with scientists in your field of research. You should be able to explain your research for any length of time between 2 minutes to 1 hour. Be ready to give an elevator pitch. Take every opportunity to present your work at your school events and at national/international scientific meetings. Volunteer to write manuscripts, reviews, book chapters, grant proposals etc. This will prepare you to write effective protocols, proposals, technical reports, regulatory documents etc in your industrial job.

Learn Oral Presentation Skills: Your presentation skills are of the utmost importance. If you are unable to convince your audience, years of your work becomes insignificant. On the contrary if audience leaves the auditorium with a clear message, you are successful! During your onsite interview, you will be asked to present your research. You should be able to get your research across a wide range of audiences; from an administrative assistant, technicians to senior scientists in the company. Only mantra to succeed in the presentation is practice! practice!! and practice!!! As mentioned above, take every opportunity to present your research. Learn to prepare an effective Power Point presentation and present convincingly. There are many great online resources like http://www.nature.com/scitable/topicpage/effective-oral-presentations-13906743 and The Craft of Scientific Presentations (http://sharif.edu/~namvar/index_files/Scientific-Presentation.pdf). It’s worth investing time for this life-long asset of your skill set.

Be a Problem Solver: Industry seeks out solvers! Being a PhD graduate it is expected from you that an ideal candidate will have skills to solve scientific problems. Grad school is a great place to develop those skills. Take complete hold of your project. Before asking advisor for help, try your best to solve the problem by using your own resources. This habit will help develop you as a problem solver.

Acquire An Ability to Handle Multiple Projects: Whether you are in a pharmaceutical industry, CRO or a Government organization, you are required to handle multiple projects. That’s the nature of your job. You can develop this skill during grad school. Along with your lead project, volunteer to work on few other projects and learn to manage them effectively.

Learn to Play in Teams: This is a world of team work. No matter in what field you will work, you will have to work in a team. Period! The days of working individually are gone. There is not a single field in science, at least to my knowledge, where team work is not required. Team work always results in synergy. In team work 1+1 does not equal...
Tips from A Recent Graduate...

2. It can be 3, 11 or 1000, depending on the harmony in the team. Team work is working interdependently (it is different from being independent). Only independent people can be good interdependent players. To develop team work attitude **delegate some of your work to your colleagues**, if possible. **Volunteer yourself** to do some work for your colleagues or other projects in the lab. Develop some small projects with your neighboring lab. This will develop an attitude of trusting in people, working out differences and focus on the project, and develop a sense of time commitment. This will also teach you the art of work delegation and leverage.

**Strive To Be A Leader:** Leaders can make or break the organizations. Companies look for future leaders in the candidates. They do not necessarily expect you to be a great leader at this stage of your career, but they will look for your potential to be a great leader. Learn skills of leadership early in your career. And these skills are not learned overnight. It requires proactiveness and time investment. Fortunately, there are many platforms to develop and exercise these skills. SOT is one of such great platforms. Get involved in **Graduate Student Leadership Committee (GSLC)** as early as possible in grad school. Another good platform is **Graduate Student Association (GSA)** at your university. Get involved in GSA either as a volunteer or an executive committee member. Don’t hesitate to take responsibilities. **ToastMasters** is another excellent, cost-effective resource ([https://www.toastmasters.org/](https://www.toastmasters.org/)). At ToastMasters you will get a chance to develop your communication and leadership skills through its well formulated program.

**Develop A Strong Network:** A major gateway to a job is your network! This is the prime source for your job hunt. You will be surprised to see how your contacts are instrumental in getting a job for you. It’s not only the quantity but the strength in your each connection matters. So create some strong connections. A question often question asked is, how to network? **Scientific meetings** are great resource to meet people in the field of your interest. Work on your **LinkedIn profile**. If you don’t have time to work on your LinkedIn profile, don’t create one now. But if once you create the one, have a complete professional profile. Recruiters and hiring managers search for candidate on LinkedIn. If your profile is incomplete, you will lose the opportunity. If they find your profile interesting, they may contact you when they have a suitable opportunity for you or even when you are ready to graduate. You may expect to receive LinkedIn messages from recruiters for the opportunity. Make sure you respond to those messages in a timely manner.

**Select Your Mentor In Early Phase:** Mentors are the people who have already travelled the path and reached the goal where you want to reach. You can have as many mentors as you need/want. Select the mentors who are at different stages of their career. I would prefer to have mix of **mentors in their early career, mid-career and senior position on my board of mentors**. They will have different perspectives on your questions. Also you can have mentors from industry, CRO or government if you are not sure where you want to go. They will help you to understand their field and guide you accordingly. Mentors are also a great
source in job hunting. Some mentors can introduce you to their network and recommend you. But that depends on quality of the relationship you have with your mentor. Developing mentor-mentee relation is a long term process. So start early! SOT has numerous mentoring events organized by Graduate Student Leadership Committee (GSLC) and Specialty Sections during annual SOT meeting and round the year through webinars. Make sure you attend them. You may find your mentor there.

Maximize The Benefits Of SOT: This bullet requires a separate discussion. However, I will try to summarize here. SOT is a student-friendly organization. SOT graduate student membership dues are only $20! You have an opportunity to be involved in SOT activities throughout the year (please refer https://www.toxicology.org/groups/gs/graduates.asp for volunteering opportunities). SOT offers leadership opportunities in GSLC and in various specialty sections. Plan to attend annual SOT meeting each year. SOT meeting registration fees for graduate student is quite affordable. SOT also has numerous awards for graduate students (http://www.toxicology.org/application/af/awards_details.aspx?criteria=14). This is an opportunity to receive recognition for your years of efforts among your fraternity. Even if your lab does not support travel to SOT meeting, it is definitely worth using your piggy bank for SOT meeting. The SOT meeting is great place to meet your mentors in person and network with other colleagues. SOT members are very helpful. Just you need to approach them.

The SOT job bank works! If you are planning to graduate, apply through the SOT job bank and get interviewed at the SOT meeting. It’s a direct interaction with the hiring managers. If you have a good network, you will be surprised to see that the hiring manager is in your direct or indirect network! If you plan well, you can take appointment of industry people before SOT to meet and chat with them. People may not have much time. So you will need to explain your research succinctly to them. At this time you will appreciate the worth of time you spent to develop this skill over the years. You can also visit industry booths at SOT and explore job opportunities with them.

Know Thyself: Last but not the least! Know yourself. When you are interviewed in person, you will be evaluated on several measurement scales. The most important will be, do you know yourself? How people feel about you? And that feeling will decide whether you will get that job or not. A good feeling is transmitted by you when you are clear about your goals and what you want. It’s important to know your strengths. Everyone has some special strengths. Identify and reinforce those strengths even more. The books like StrengthsFinder 2.0™ may help understand those strengths and how you can synergize with the strengths of other people. You are unique because of your unique strengths. Hence it is important to showcase those strengths during the interview. It is also important to know weaknesses. But unless those weaknesses are not major hurdle to your core development, do not invest lot of efforts in correcting them. Manage them! Compensate those weaknesses by strengthening your unique strengths!

In nutshell, successful launching in a desired job requires meticulous planning of 5 years of graduate life! Have lots of patience! Be optimistic. Eve-
Zika virus is a flavivirus closely related to dengue, West Nile, and yellow fever viruses. Zika virus spreads to humans through mosquito bites. The spread of the virus through blood transfusion and sexual contact have been reported in isolated cases. While it has mostly been restricted to parts of Africa and Asia, Zika virus has spread to the pacific islands and most recently the Americas. As of Feb 24th, 127 travel-associated cases have been reported in the United States, per the Centers for Disease Control and Prevention (CDC). Cases are expected to be on the rise.

Symptoms are usually mild and include severe rash, joint pain and conjunctivitis that last up to a week. Most alarming is the link to an increase in the birth of babies with abnormally small heads and in cases of Guillain-Barre syndrome. There are currently no vaccines. The only prevention is through avoiding mosquitos and preventing sexual transmission by using protection.

CDC has developed a test that can confirm Zika within the first week of illness. Efforts are underway to provide more rapid testing using cutting-edge genomic methods and improve mosquito control. The Department of Health and Human Services at CDC is doing important work related to Zika virus to speed the development of tests, treatments and vaccines. Prevention at this point...


BTSS Sponsored Symposia & Workshop

Continuing education:

Next-Generation Sequencing in Toxicogenomics

Sunday, March 13, 8:15 AM–12:00 Noon
AM07 | CE ADVANCED | MORNING COURSE
Molecular Toxicology: Mechanistic Insights and Hazard Assessment Recent Advances in Safety Assessment

Chairperson(s): Weida Tong, National Center for Toxicological Research, US FDA, Jefferson, AR; and Jos Kleinjans, Maastricht University, Maastricht, The Netherlands.

Endorser(s): Biotechnology Specialty Section Molecular and Systems Biology Specialty Section Regulatory and Safety Evaluation Specialty Section

Unique Approaches to Safety Assessment of Gene, Cell, and Nucleic Acid-Based Therapies

Sunday, March 13, 1:15 PM–5:00 PM
PM12 | CE BASIC | AFTERNOON COURSE
Recent Advances in Safety Assessment

Chairperson(s): Timothy MacLachlan, Novartis, Cambridge, MA; and Joy Cavagnaro, AccessBio, Boyce, VA.

Endorser(s): Biotechnology Specialty Section Regulatory and Safety Evaluation Specialty Section

Workshops:

Developmental Immunotoxicology—Are We Adequately Evaluating Safety?

Thursday, March 17, 9:30 AM to 12:15 PM
Developmental Toxicity: Mechanisms and Evaluation

Chairperson(s): Laine Peyton Myers, US FDA, Silver Spring, MD; and Gary R. Burleson, Burleson Research Technologies, Inc., Morrisville, NC.

Endorser(s): Biotechnology Specialty Section Drug Discovery Toxicology Specialty Section Immunotoxicology Specialty Section

Roundtables:

Combination Toxicology: Are We Testing the Right Things?

Wednesday, March 16, 12:30 PM to 1:50 PM

Chairperson(s): Leigh Ann Burns Naas, Gilead Sciences Inc., Foster City, CA; and Helen Haggerty, Bristol-Myers Squibb Company, New Brunswick, NJ.

Endorser(s): Biotechnology Specialty Section Immunotoxicology Specialty Section Regulatory and Safety Evaluation Specialty Section
BTSS Organized Mentoring Sessions at SOT 2016

The BTSS is very happy to organize the mentoring sessions for this year's SOT 2016. We have two events lined up for you all during the annual meeting.

Lunch and Learn event—

Venue: Convention Center Room 236
Monday (03/14/2016) , 12.15-1.45pm.
(Lunch will be provided)

If you are deciding your career path and need experts from the field to clarify some of your questions, this event will be a great opportunity. We have a panel of highly qualified experts from the field of Toxicology and Biotechnology for this year, who will be leading this event. Feel free to participate and expand your network.

Yes, lunch is provided for all the attendees !!

Coffee with Mentor— You will be paired with a mentor upon request

This is a casual session between the mentor and mentees, which will happen over coffee. Mentee will be matched with a mentor from their corresponding career field of interest. This session will be conducted during the 55th SOT Annual Meeting at a suitable time and location in accordance to the convenience of the mentor and their respective mentees. The idea of this casual informal mentoring session is to enable network development, which is very much essential for a career path and job search.

BTSS FINANCIALS

Net Assets at the end of February 2016: $20,217