# NorCal SOT newsletter

September 2009


## *Letter from the President*

Our chapter has begun 2009 on a successful note, with recognition given to publications by individual Chapter members at the National Meeting in Baltimore, and a well-attended reception (co-hosted by the Pacific Northwest Regional Chapter). I am personally honored to serve as our Chapter President, and must recognize the invaluable contributions to those who were elected and have volunteered to serve as our Officers, including our Past President George Clemens, Vice President Tao Wang, Vice-president elect Karen Steinmetz, Secretary Kent Pinkerton, Treasurer Jeff Tepper, and our Councilors John Wisler and Amy Kim. Special kudos goes to our postdoctoral representative Zhiying Ji and our student representative and web liaison Heather Bolstad. Finally, former student and postdoctoral members Susanne Brander (associate editor of our Newsletter) and Valerie Mitchell (invaluable substitute for me in our office) continue to volunteer their services in an ex officio capacity, proof positive of the interest and energy that the Chapter continues to generate among our membership. It is my personal commitment to continue this success during the next twelve months.

The NorCal Chapter held their Spring Symposium on Target Organ Toxicity with an Emphasis on Hepatotoxicity on April 23, 2009, graciously hosted by Amgen in South San Francisco through the efforts of Councilor (and Amgen Director of Toxicology) John Wisler. The symposium was a huge success, with 133 attendees, including 7 wonderful speakers, 22 generous sponsors (a big thanks to Amgen for hosting the event and providing meals), and 27 students who presented 12 posters. All submitting posters received an award, with first place going to Christopher Carosino of the University of California, Davis.

The NorCal Chapter's Fall Symposium will be hosted by the State of California on October 8, 2009 at the Elihu Harris state office building in Oakland, California. The topics are (1) The Risks and Benefits of Nanoparticles and (2) Biological Equivalents in Predicting Toxic Doses to Humans. All eight of our speakers are confirmed and this promises to be an extremely relevant topic to those examining both the human health impacts of nanotechnology and the relationship between observed toxic effects and human tissue distribution of intentionally (pharmaceuticals) or unintentionally (environmental exposures) administered agents.

On a final note, even in these economically distressed times there continues to be employment opportunities for young toxicologists beginning their careers. My own Office of Human and Ecological Risk is presently offering three positions at the staff level, with at least four more expected in the coming months. I recall (we won't say how many years ago) my experience as a postdoctoral fellow at Temple University looking for employment, and all of us in our chapter are gratified that we can provide help to those who choose toxicology as their career. Hoping for more good news in the future.

Steve

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Tao Wang, Editor
Susanne Brander, Associate Editor


President Steve Dizio

# History of the Northern California Chapter of SOT - a second life

**by Bob Howd**

Our previous NorCal SOT chapter had died in 1997 because of scheduling conflicts among its officers, which made it impossible for them to carry on the required chapter activities.

At the November 2000 ACT meeting in San Diego, I was approached by Steve Harris of the SoCal SOT chapter (and ACT), who urged me to try to get the chapter reorganized. I agreed to give it a shot. Discussions with other SOT members at the annual meeting in 2001 showed considerable interest.

I compiled a list of SOT members in Northern California from the SOT directory and contacted them by email, asking whether they would be interested in restarting a chapter. Several responded affirmatively. Sanjay Chanda volunteered to develop a questionnaire to more formally query interest among SOT members about a local chapter. About 42 people replied with expressions of interest, which led to the scheduling of a first meeting at the Jupiter Brewery on January 31, 2002. Fourteen people attended this meeting. We agreed to reinitialize the chapter, and decided that for purposes of getting started, all those who had shown up for the meeting constituted the chapter membership, and that we could therefore hold an election. The new officers elected were Bob Howd, President; Sanjay Chanda, Secretary; Susan Rice, Vice President; Deborah Novicky, Treasurer; and Councilors Gordon Newell, George Alexeeff, Elizabeth Miesner, and Lin DePass. We then proceeded with further organizational activities.

There was some money left over in a NorCal SOT bank account at that time, and we agreed to spend some of it on a mixer at the 2002 SOT meeting, in order to attract more interest. We joined with the UC Davis alumni group in a joint mixer in Nashville, which worked out magnificently, with 40 or 50 people coming to the mixer. We formally announced to SOT that the NorCal SOT chapter was being revived, and I attended the chapter president's breakfast at the Nashville meeting, learning more details about chapter leadership and working with SOT.

Our first scientific meeting was held in May, 2002. The theme was Chemical and Biological Terrorism: The Role of Risk Assessment. Speakers were Ray Neutra of the California Department of Health Services, Dennis Paustenbach of Exponent, and Karen Folks and Tina Carlsen of Lawrence Livermore National Laboratory. About 40 people showed up for this meeting, and we were off and running!

Since that time, we have held one or two scientific sessions a year, including joint meetings with other local scientific groups, and a social mixer at the annual SOT meeting. The chapter continues to grow!

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## UC Berkeley Practical Toxicology Class Field Trip to the NorCal SOT Spring Symposium

*Michele G. Fromowitz and Sixin S. Lu*
*(UCB PH270C Students)*

On the morning of April 23, the students of the UC Berkeley School of Public Health course, Practical Toxicology (PH270C), with their professor Luoping Zhang, were excited to be on their way to the NorCal Society of Toxicology (SOT) Spring Symposium held at Amgen in South San Francisco. The class consisted of both graduate and undergraduate students from various disciplines including Environmental Health Sciences, Molecular Toxicology, Molecular Cell Biology, and Public Policy. Over the spring semester, the students of PH270C attended a series of lunchtime guest lectures by seasoned Bay Area toxicologists and engaged in discussions that exposed students to the real-life applications of toxicology. The guest lecturers came from government, public health, academia, consulting, chemical and pharmaceutical backgrounds, among them were Linval DePass, a former president of the NorCal SOT and Executive Director of Nonclinical Safety at Durect Corporation in Cupertino, and Susan Rice, another former president of the NorCal SOT and current president of SARA, a toxicology consulting firm. During the facilitated Q&A sessions, the lecturers , many of whom were UC Berkeley alumni themselves, shared their personal and professional experiences from work-life balance to ethics. In this collegial environment, students were encouraged to have critical dialogues and to network with the guest lecturers as well as to explore post-graduation plans and future career paths. The students were happy to extend this experience outside of the classroom by attending the NorCal SOT Spring Symposium.

The NorCal SOT was very gracious in encouraging and supporting the students of PH270C to attend and actively participate in the Spring Symposium. The students presented two posters that represented class debates motivated by discussions with the guest toxicologists and group research. One poster, titled “Green Chemistry vs. Pesticide Management”, was inspired by discussions with Megan Schwartzman, a research scientist at the UC Berkeley Center for Green Chemistry (BCGC) and Center for Occupational and Environmental Health (COEH) and Moire Creek, who oversees the toxicology program at the crop protection firm, Valent USA Corporation. The other poster presented the debate titled “Cancer Treatment vs. Cancer Prevention” and was synthesized from discussions with many of the guest lecturers, including Kathleen Meyer, director of Toxicology at XOMA and Martha Sandy, Chief of the Cancer Toxicology and Epidemiology Unit of Reproductive and Cancer Hazard Assessment Section of Cal/EPA’s Office of Environmental Health Hazard Assessment. Students took advantage of their poster presentations as a means to practice for their class debates. All guest lecturers were invited back to watch the debates and to participate in the post-debate discussion.

For many students, this class was the first opportunity to create a poster and to participate in a professional conference. They especially appreciated the “Lunch with the Experts” segment, in which they were able to reunite with former guest speakers and mingle with other experts in the field. The students also engaged in the meetings’ presentations by asking questions and taking notes. One undergraduate student, Antonio Yip Wlassowsky, expressed sentiments that most of the class could agree on:

***“Not only did going to the NorCal SOT meeting give me a sense of how far reaching the field of toxicology is, but also how multidimensional and diverse toxicology can be. Though a rich experience in itself, being able to meet with and talk to senior toxicologists from different sectors topped it off and is definitely going to get me to keep coming back.”***

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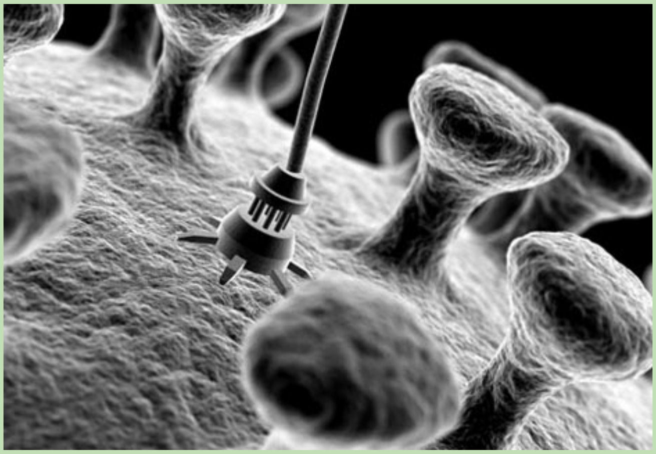

http://www.uml.edu/wuml/podcast/media/nanotechnology-kd-001.jpg

## Research at UC Davis: Series III

by Susanne Brander

The University of California system has recently become a hotbed of activity when it comes to nantotechnology research, specifically in determining the potential for nanoparticle toxicity. The new NSF-supported Center for Environmental Impacts of Nanotechnology (CEIN) offers promising potential for new insights into the possible dangers associated with this emerging technology.

Dr. Kent Pinkerton, a professor at the Center for Health & the Environment at UC Davis and secretary for the NorCal SOT board, has two graduate students currently examining the role of nanoparticles in pulmonary toxicology. Concerns surrounding occupational settings where highly volatile carbon nanotubes can become aerosolized during product manufacturing prompted doctoral candidate Amy Madl to experiment with the removal of metals (such as iron) from these nanotubes to reduce the potential for the generation of reactive oxygen species in pulmonary tissues. She found that reactive metals such as iron can be removed via leaching with acid, without drastically changing the functional properties of the nanotubes. So far, however, removal of the iron does not appear to eliminate issues with toxicity.

Another doctoral candidate in the Pinkerton lab, Laurie Hopkins, has been investigating whether quantum dots can be deposited in the olfactory bulb, which may serve as a portal of entry into the brain, through inhalation. By using quantum dots that are excited at a specific emission spectra, Laurie has tracked the deposition of these particles in the olfactory bulbs of mice. Particles deposited in the olfactory bulb have the potential to be translocated to the brain, and the consequences of this are currently unknown.

While nanoparticles offer great promise in the area of drug development, very little is know about the behavior and long-term consequences of chemicals at the nano-scale. For example, some metal oxides (TiO2) that are relatively harmless in dust are extremely toxic as nanoparticles. And while their use for either drug delivery or pesticide treatment may offer better access to target sites and sustained release, more studies on the saftey of nanotechnology are necessary before large numbers of products are released to the public.

**For more information on CEIN:**

http://www.universityofcalifornia.edu/news/article/18580

http://cein.cnsi.ucla.edu

http://www.cein.ucsb.edu


http://geoffhutchison.net/gallery/main.php?g2_view=core.DownloadItem&g2_itemId=363&g2_serialNumber=2

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**Are you planning to attend the 2010 SOT meeting in Salt Lake city? The Bay Area is a hot spot for biotechnology and pharmaceuticals. For many working in the drug development field, you might find the following Continuing Education and/or scientific programs helpful. Visit www.toxicology.org for more information**

**Deadlines:**

| | |
|---|---|
| **Early bird registration** | **1/22/09** |
| **Housing reservation** | **2/11/2010** |
| **NorCal SOT Yong Investigator Award application** | **12/15/2009** |

## Continuing Education

### AM02—Biologicals: Introduction to Drug Development

Chairpersons: James D. Green, Biogen Idec; and Laura Andrews, Genzyme
Introduction, James D. Green, Biogen Idec
Principles for Development of Monoclonal Antibodies and Related Forms, Randy Soltys, Genentech
Principles for Development of Proteins, Shawn M. Heidel, Eli Lilly & Company
Principles for Development of Novel Biologics: siRNA, Oligonucleotides, Anti-Sense, and Aptamers, Arthur A. Levin
Principles for Development of Vaccines, Cell and Gene Therapies, and Blood Products (CBER-Regulated Products), Timothy MacLachlan, Genzyme

### AM03 Comparative Biology of the Lung

Introduction, Richard Parent, Consultox Ltd., and Daniel Costa, U.S. EPA
Comparative Anatomy of the Mammalian Respiratory System, Kent Pinkerton,University of California, Davis
Interpretation and Limitations in the Assessment of Lung Function in Laboratory Mammals, Jeffrey Tepper, Tepper Nonclinical Consulting
Metabolism and Enzymatic Balance in the Respiratory Tract, Laura Van Winkle,University of California, Davis
Pulmonary Immune Functions Important for Translational Toxicology and Predictive of Risk in Humans, Gary Burleson, Burleson Research Technologies
Concluding Remarks, Daniel Costa, U.S. EPA

### AM07—Reproduction and Regulatory Impact

Chairpersons: Robert E. Chapin, Pfizer, and Jeffrey S. Moffit, Boehringer Ingelheim
Basic Biology and Study Designs, Chad Blystone, NIEHS/NTP
The Regulatory Impact of Reproductive Development: The European Perspective, Aldert Piersma, RIVM
The Regulatory Impact of Reproductive Findings: The U.S. Perspective, Vicki Dellarco, EPA
The Impact of DART Findings on Drug Candidates, Tracey Zoetis, Scilucent

### PM11—ICH Initiatives for Conducting Pharmaceutical Preclinical Safety Studies: New and Revised Guidelines and Challenges

Chairpersons: Tao Wang, Novartis, and David McGuinn, FDA
Introduction, Tao Wang, Novartis
Fundamentals of Nonclinical Drug Development, David McGuinn, FDA
Preclinical Development of Oncology Therapeutics: An Industry Perspective, Daniel Lapadula, Novartis
Use of Genotoxicity and Carcinogenicity Data in U.S. FDA Center for Drug Evaluation and Research, David Jacobson-Kram, FDA
Nonclinical Safety Evaluation of Biotechnology-Derived Pharmaceuticals: FDA Regulatory Perspective on the ICH S6 Guidance and Updates, Anne M. Pilaro, FDA

**Symposia**

- Bile Salt Transport and Liver Injury
- Risk from High-Throughput Data
- Genotoxic Impurities in Drugs and Drug Products: What Is the Right Way to Deal with Impurities in R&D Versus Regulatory Guidance?
- Mechanistic Role of Reactive Intermediate Protein Covalent Binding in Target Organ Toxicity: Past, Present, and Future

**Workshop Sessions**

- Current Thinking and Experiences Related to Developmental and Reproductive Safety Assessment of Biotherapeutics
- Immunotoxicity and Other Safety Considerations in the Development of Therapeutic Vaccines
- Widely Varying Strategies Implemented in Discovery to Reduce the Failure Rate of Clinical Lead Candidates in Development

**Roundtable Sessions**

- Combination Toxicology Studies for Pharmaceutical Agents: Design Considerations and Impact on Clinical Development
- Overview of Current Regulatory Expectations for Oligonucleotide-Based Therapeutics: Case Studies for Different Classes of ONDs

**Informational Sessions: Translational Toxicology**

- Measuring Immune Responses in Monkeys for Drug Development: Opportunities and Challenges for Predicting Human Efficacy and Immunotoxicity

## Travel tips for attending SOT

SOT—Salt Lake City, 2010 Housing is now open. If you plan to attend SOT 2010, make your reservation now in order to take advantage of the favorable rates SOT has procured for various local hotels. Even if you are unsure whether or not you can attend the meeting, you may wish to make a reservation nonetheless, as good rooms are often booked very fast. The deadline for cancelation without penalty is 2/25/09. Under the tight travel budget for many companies, it is always better if you can save some money for your company.

Even if your travel plans do not get approved by your company until the last minute, you can still find inexpensive rates. Here is an interesting true story that we would like to share with our members: three weeks before the 2009 SOT annual meeting in Baltimore, and past the house reservation deadline through SOT, one of our bay area toxicologist booked a room at the SOT headquarter hotel for $75 a night (Hilton) through Priceline. Even he could not believe it!

## Northern California RC NorCal SOT Young Investigators Award

Attention NorCal student and postdoctoral Members! If you are a graduate student or postdoctoral fellow, consider applying for the 2010 NorCal SOT Young Investigator Award. To participate in the NorCal SOT Young Investigator Award competition, membership in NorCal SOT is required (membership is free for students and postdocs). Each award winner will receive a $500 cash award from NorCal SOT Regional Chapter. To be considered, each candidate, whose abstract has been accepted by the SOT for presentation at the 2010 Annual Meeting, must submit: (1) a copy of the abstract, (2) a letter (1 page maximum) discussing the significance and potential impact of the work on toxicology, and (3) a letter of support from your major advisor.

**The deadline for submission of applications will be December 15, 2009**. We encourage all interested graduate students and postdoctoral fellows to consider submitting their abstract for consideration. Full applications should be submitted to Tao Wang at tao.wang@novartis.com.

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# Career Corner

by Amy Kim

I'm often asked by graduate students and post-doctoral fellows how I became interested in toxicology in the biotech/pharmaceutical industry, and my response over the years has become, "By way of a goat roast..." Okay, maybe I've piqued your interest enough to continue reading my particular story and how I try to advise younger professionals in the toxicology discipline on how to keep their options open and use every opportunity to network, even if you happen to be at a goat roast (which was the first time I had ever had goat).

My toxicology career began in the environmental consulting industry primarily conducting site-specific chemical risk assessments for both for-profit and government entities, after earning a Master's of Science in Public Health at the University of North Carolina's School of Public Health in Chapel Hill, NC. My advisor at the time, Dr. James Swenberg, advised me to remain at UNC to pursue my PhD; however, being young and wanting to "earn a living" (and use my salary to support my other passion of playing ultimate frisbee competitively), I left with my Master's and a job thinking that was sufficient. After 4 years of environmental consulting, I returned to UNC as a pre-doctoral student, but in a different lab at the NIEHS. So, my first piece of advice is to listen carefully to your graduate school advisor when making career decisions. Although my personal journey was a bit circuitous, I made the most of my time in the consulting industry by applying what I learned on-the-job to school (second piece of advice). Specifically, I learned how to write well-organized proposals for new jobs, hone my analytical skills conducting numerous human health risk assessments assessing both non-cancer and cancer risk, allocate my time among several projects (i.e., "multi-task"), understand the regulatory implications for each project (EPA vs. FDA), and ultimately, to remember the big picture goal of each project: to protect human health.

While taking courses in the Toxicology Curriculum at UNC, one of my professors gave the class a valuable lesson, unrelated to the subject matter. He asked us what the most important thing we could take away from this course or from the Tox program. Being focused on science, many of the responses were directed at the subject matter at hand, but his answer was, "Communication, communication, communication." Over ten years later, that still rings true. Another piece of advice I like to convey to those getting starting in their careers is that whatever you choose to do, do it whole-heartedly, communicate what you are doing and why you are doing the work: tell the story. Even as a graduate student, one can take full advantage of workshops to improve presentation or communication skills offered by their universities to enable "telling the story" effectively.

As I was approaching the end of my graduate school career at UNC, I began to explore what I'd like to do next. I could have easily returned to a fulfilling career in the environmental field, but I kept my options open. I hadn't seriously considered what role toxicologists had in the pharmaceutical industry, but two things happened that opened my eyes. The director of the Toxicology Curriculum at UNC, Dr. Swenberg, had invited toxicology and pathology colleagues from Pfizer to UNC for a "Career Day" featuring 30 minute presentations describing job responsibilities from each guest speaker. The other event brings me back to the goat roast where I was conversing casually with someone I had just met who informed me that his sister-in-law worked at Merck in Clinical Science and he'd be happy to provide her name to me for an informal telephone conversation.

After my informative discussion with this Merck employee, I became interested in pursuing a career in the pharmaceutical industry. By keeping an open mind and acting on this networking opportunity, I was able to send my CV to an internal source at Merck, who routed my CV appropriately to the hiring manager, as well as applying directly for the job vacancy of toxicologist in Safety Assessment (SA) on Merck's website. After nearly four years at Merck learning how to be a Study Director (GLP and non-GLP studies) and represent SA on interdisciplinary project teams developing small molecules, I ventured out west to learn how to develop large molecules. Along the way, the other skills that I viewed as essential to succeeding as a toxicologist in the biopharmaceutical industry include decision making, collaboration and leadership skills. Although many of these skills were shaped during my professional career, the fundamentals were established early during my days at the bench conducting hypothesis-driven research in a laboratory setting. Ways to develop these skills are based on getting involved: attend seminars and meetings, ask questions, inquire about your fellow students and professors research projects. In other words, don't bury yourself in your lab to complete just your project because you will miss out on all the opportunities to meet wonderful people along the way.

I've been a toxicologist at Genentech for almost 4 years and have helped in Genentech's efforts in the area of small molecule drug development, while getting my feet wet in large molecule development. I still use the principles I learned from my earlier career in the environmental field and apply what I can to my toxicology job in the biotech/pharma industry. I still throw myself whole-heartedly into each project but at the same time maintain an awareness of projects within my department and company, keep abreast of the latest regulatory guidance that may impact my work, maintain a fundamental understanding of some of the newer toxicology tools or technologies that my make my job easier or more efficient, and try to contribute where I can to the scientific societies, including NorCal SOT. Although in drug development, the scale of affected individuals may be smaller, versus human health population as a whole, I believe we toxicologists serve our community by making the world we live in a better place. Maybe a bit cliché, but perhaps I'm a big softie at heart. I would welcome helping any professional starting out in his/her career. Feel free to contact me at kim.amy@gene.com.

# Career Opportunities

"The California Environmental Protection Agency Department of Toxic Substances Control is currently advertising three openings for the Staff Toxicologist position. These positions may be filled at any of our current major regional office locations, including Chatsworth, Cypress, Berkeley, and Sacramento (Cal Center).

Eligibility for these and future openings require first taking an open examination. For those who have already completed this examination, please apply soon.

Both the examination, how to apply, and a listing of the current open positions may be accessed via the following link:

http://www.dtsc.ca.gov/Employment/index cfm#Current_Job_Openings

In DTSC, toxicologists work with teams drawn from more than 1,000 scientists, engineers and specialized support staff statewide to:

Deal with the aftermath of improper hazardous waste management by overseeing site cleanups.

Prevent releases of hazardous waste by seeing that those who generate,handle, transport, store and dispose of wastes do so properly.

Take enforcement actions against those who fail to manage hazardous wastes appropriately.

Explore and promote means of preventing pollution, and encourage reuse and recycling.

Evaluate soil, water and air samples taken at sites, and develop new analytical methods.

Practice other environmental sciences, including toxicology, risk assessment and technology development.

# Amgen, Inc

**Discovery Toxicology**
Senior Scientist - NB50919342
Principal Scientist - NB50919349

Amgen discovers, develops, manufactures and delivers innovative human therapeutics. A biotechnology pioneer since 1980, Amgen was one of the first companies to realize the new science's promise by bringing safe, effective medicines from lab, to manufacturing plant, to patient. Amgen therapeutics have changed the practice of medicine, helping millions of people around the world in the fight against cancer, kidney disease, rheumatoid arthritis, and other serious illnesses. With a deep and broad pipeline of potential new medicines, Amgen remains committed to advancing science to dramatically improve people's lives. To learn more about our pioneering science and our vital medicines, visit www.amgen.com . We are seeking talented individuals to help bring our products to those in need.

Job Summary:
Amgen is seeking Scientists to work in Discovery Toxicology within the Department of Comparative Biology and Safety Sciences (CBSS). Primary responsibilities are to develop in-depth understanding and strategy for management of target liability, and to develop and implement toxicology strategy for lead optimization/ candidate selection. Candidates will also have opportunity to conduct activities related to IND enabling studies and programs. The successful candidate will work in a multi-disciplinary team with chemists, therapeutic area scientists, pharmacokinetic/drug metabolism experts, and pathologists.

Basic Qualifications – Senior Scientist, # NB50919342
Ph.D. in Life Science with a minimum of 3 years post PhD experience or Master's degree in Life Sciences with a minimum of 10 years pharmaceutical/biotechnology company experience or Bachelor's degree in Life Sciences with a minimum of 15 years pharmaceutical/ biotechnology company experience. This position is based in Thousand Oaks, CA.

Basic Qualifications – Principal Scientist, # NB50919349
Ph.D. in Life Sciences with a minimum of 5 years post PhD experience including a minimum of 2 years working in a pharmaceutical or biotechnology/technology industry. This position can be based in Thousand Oaks, CA, San Francisco, CA, or Seattle, WA

**Investigative Toxicology:**
Principal Scientist, Investigative Toxicology, #NB50920409,
Principal Scientist, Molecular Toxicology, #NB50922894

Job Summary – Principal Scientist, Investigative Toxicology, #NB50920409
This role will allow one to develop novel experimental strategies and systems to aid in the drug development process including addressing toxicological problems that arise during drug development, development of prospective systems to improve drug candidate selection, and development and qualification of biomarkers to facilitate monitoring needs for programs. The individual will be responsible for creating novel protocols to address experimental questions, planning activities, including design and execution of experiments, interpret and analysis the results, ensure data quality, provide timely insightful reports, develop and execute strategies for biomarker assay validation, qualification, and application for their use in improving preclinical safety testing and clinical translation. This position is based in Thousand Oaks, CA

Basic Qualifications:
A Ph.D. in Biochemistry, Pharmacology, Toxicology or a Life Science discipline with at least 8 years postdoctoral academic or industry experience in drug development is required. Team lead or hands-on experience with multiple biochemical techniques, assay development, fit-for-purpose validation, and application to toxicological issues, as well as approaches used for biomarker discovery, detection, assay development, validation, and biological qualification are a must.

Job Summary – Principal Scientist, Molecular Toxicology, #NB50922894
Contribute to designing and implementing new strategies for toxicity screening and hazard identification. The successful candidate will have demonstrated leadership in devising and implementing plans for solutions to problems and challenges that arise during the drug development process by using a variety of tools, technologies, and approaches. This position is based in Thousand Oaks, CA

Basic Qualifications:
A PhD in Toxicology, Immunology, or other Life Science with at least 7 years of molecular toxicology analysis and interpretation experience is required.

To apply to these positions, please visit the Amgen career website at www.amgen.com/careers and use reference numbers noted above. You can also submit your resume to Michael Lueddeke at lueddeke@amgen.com

### Position available – Staff Toxicologist (specialist)

### California Department of Public Health

### Occupational Health Branch

The Occupational Health Branch of the California Department of Public Health is currently recruiting for a Staff Toxicologist. The position is full time and is located in Richmond, California. The Staff Toxicologist will provide expert medical and toxicologic consultation as part of the Hazard Evaluation System and Information Service (HESIS).

The Occupational Health Branch is one of the largest State-based programs engaged in the tracking of work-related injuries and diseases, assessment of workplace hazardous exposures, and dissemination of prevention recommendations for employers, employees, health and safety professionals, and health care providers. For the last 30 years HESIS has acted as an "early warning system" for identifying chemical (and other) hazards in California workplaces.

As a member of HESIS, you will:

- Review the toxicologic, epidemiologic, and industrial hygiene literature to identify emerging chemical hazards in California workplaces;
- Provide expert technical consultation to employer and worker organizations, other State programs, health care providers, county health officers, and other health professionals in the prevention of chemically induced occupational illnesses, including the development of occupational health regulations;
- Work with the staff of Cal/OSHA (in the Department of Industrial Relations) and the Office of Environmental Health Hazard Assessment (in the California Environmental Protection Agency) to develop recommendations for health-protective occupational exposure standards; and
- Prepare scientific papers, reports, and other materials for timely and relevant dissemination of important workplace injury and disease prevention recommendations for employers, employees, and health professionals.

We are seeking a PhD-level toxicologist with experience in and/or commitment to occupational public health. Thorough understanding of both qualitative and quantitative risk assessment procedures is required. The candidate will work with a multidisciplinary team and should have excellent writing skills.

**To apply for this position**, complete a State application (available at http://www.cdph.ca.gov/services/jobs/Pages/StateApplication.aspx) and send with a cover letter to Dennis Shusterman, MD, MPH, Occupational Health Branch, 850 Marina Bay Parkway, Building P, Richmond, CA 94804. Inquiries about the position are welcome at (510) 620-5714 or dennis.shusterman@cdph.ca.gov.

**Please note that applicants must be California civil service eligible for the Staff Toxicologist (specialist) in order to be considered.** To apply for eligibility, see http://www.spb.ca.gov/jobs/exams/exam_bulletins.htm; choose "Exams by Title" and select "Staff Toxicologist (specialist)." For more information, contact Inez Tamayo at (510) 620-5749 or inez.tamayo@cdph.ca.gov.

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**Director, Toxicology**

We're changing tomorrow by moving oncology forward. We've developed a pipeline of novel therapeutic fully human monoclonal antibodies (MAbs) to treat solid tumors based on our own proprietary targets. We have discovered and validated a portfolio of clinically relevant targets in 14 different cancer types. Our pipeline includes therapeutic MAbs to multiple cancer indications that are at different stages of clinical and pre-clinical development.

The Director of Toxicology directs and manages toxicology programs for therapeutic MAbs. Prepares non-clinical development plans including necessary studies and their timing. Designs and reviews preparation of protocols for non-clinical toxicology/toxicokinetic studies. Performs site visits and makes site selection decisions. Serves as Toxicologist on Program Development Teams. Reviews, provides comments and approves study reports for toxicology and toxicokinetic non-clinical studies. Prepares and reviews non-clinical toxicology sections in documents (IND, IDB, BD, NDA) and responses to regulatory agencies.

Position Requirements

- Ph.D in toxicology, biochemistry, pharmacology, pharmacokinetics or related sciences; minimum of 10 years of pharmaceutical industry, including 7 years in toxicology and management experience
- Comprehensive knowledge of drug development (non-clinical and clinical)
- Experience with non-clinical CROs
- Knowledge and experience in biopharmaceutics, toxicology, toxicokinetics, ADME and pharmacokinetics with therapeutic antibodies and antibody drug conjugates
- Knowledge of FDA regulations pertaining to non-clinical and clinical drug development.
- Well developed oral and written communication

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