June 2016

Northern California

President's Message

Dear NorCal SOT Regional Chapter Members,

As we begin the new 2016-17 season, we would like to take a moment to reflect on the previous year, celebrate our successes and, welcome new chapter and board members. The NorCal SOT chapter is one of the most active chapters and the 2015-16 year has not wavered from that tradition. We have had a large variety of activities, including our fall and spring local symposia, numerous student outreach events, and professional development groups. Importantly, we would like to thank all our members for continued interest in and contribution to our scientific community here in Northern California.

Our symposia aim for broad interest topics with cutting-edge scientific presentations. Both symposia were well attended by students, members, and sponsors. At the Fall Symposium, we focused on reproductive and developmental toxicity testing in the morning session and honored George Alexeeff's Legacy with an afternoon session on public health and risk assessment at Cal/EPA. In the Spring Symposium, our speakers highlighted advances in genetic and epigenetic toxicity testing and large molecule therapeutics, with an emphasis on antibody-drug conjugates. In addition, NorCal SOT graduate student and postdoctoral fellow award recipients presented their current research. Graduate student award recipient Kyla Walter presented her developmental toxicity research studying the impact of thyroid alterations in a zebrafish model. Postdoctoral award recipient Kimberly Keil presented her mechanistic research on DNA methylation effects on dendritic arboration. In addition, undergraduate travel awards were expanded to 3 students this year based on the merit of their applications: Joey Chiang (UC-Berkeley), Emily Hamilton (UCSF), and Kevin Zhang (UC- Berkeley). During the symposia, we also continued our lunch with an expert, poster, and sponsor sessions.

One of the unique opportunities for our chapter is Jeff Tepper's preclinical safety dinner series at Chalet Ticino in Foster City. This year we were fortunate to have three such events, where several dozen scientists gather to socialize and share ideas around a topic. In September, Kathila Rajapaksa, Senior Scientist at Genentech, led a discussion centered on biological and pharmacologic impacts of monoclonal antibodies modifications.

Officers

President
Eric Harstad

Vice President
Toufan Parman

Vice President-Elect
Doris Zane

Secretary
Howard Stock

Treasurer
Julie Rider

Past President
Pamela Lein

Councilors
Joanne Birkebak
Lolita Boyd

Postdoctoral Representative
Sunnie Zhu

Student Representative
Ray Zhang

K-12 Committee
Toufan Parman
Doris Zane

Preclinical Drug Safety Group
Jeff Tepper

Newsletter Editor & Website Liaison
Howard Stock

Award Contact
Joanne Birkebak

In December, Bob Parker, Director of DART at Envigo, discussed reproductive and juvenile toxicity testing strategies. Most recently, David Jacobson-Kram, former Associate Director of Pharm/Tox and chair of eCAC at FDA, shared his regulatory and scientific expertise on genetic and carcinogenetic toxicity testing. As we begin to plan for the Fall Symposium and future preclinical safety dinners, please reach out to any board member if you would like to share a topic, speaker idea, or sponsor the event.

We continue to provide various mentoring opportunities for students and postdoctoral fellows. Doris Zane and Toufan Parman have continued their K-12 efforts at the engaging Discovery Day event at Cal State East Bay and kicked off a NorCal SOT mentoring program with San Mateo High School's Technology Laboratory. And Ray Shang and Sunnie Zhu led a NorCal career mentoring event at UC-Berkeley where undergraduate and graduate students and postdoctoral fellows can engage professionals for career information and networking. We'd like to especially thank Ray for once again organizing an amazing reception at the SOT meeting in New Orleans.

With this newsletter, it is time to thank our outgoing board and welcome new members. First, Pamela Lein has been on the board for four tireless years and contributed greatly to ensuring leadership of our group and balance across academic and industry groups. I'd like to personally thank Pam for her guidance as president as I now assume her role as past president. Toufan Parman and Doris Zane will no doubt lead the NorCal SOT chapter with their diligence and clear goal achievements over the next year as president and vice president. Kathryn Page was elected as the vice president-elect this year although she is not new to NorCal SOT as she previously served on the board as the postdoctoral representative. We welcome Rod Prell as the new councilor and thank Lolita Boyd for her years supporting NorCal. Lastly, we wish Sunnie and Ray all the best of luck as their careers grow beyond their student and postdoc roles. Ray's multitude of efforts for NorCal SOT over the years to our receptions and student mentoring events have been monumental and key to success every time. Ray, we can't thank you enough for the impact and legacy you leave behind. We look forward to a bright career! And as we introduce Alicia and Sam, our new postdoctoral and student representatives, we again are blessed to welcome similar talent and commitment to the success of our organization. Similarly, we extend a warm welcome to all members who have recently joined NorCal SOT.

In closing my last message as outgoing president, I look forward to continuing these traditions with new members and enjoying a vibrant, active regional chapter. Please do read on for greater detail on these activities, people, and several job postings. And of course, reach out when you have an idea or would like to get more involved.

Cheers

Eric Harstad
Outgoing President, NorCal SOT

New NorCal SOT Members

Each year the NorCal SOT recognizes a graduate student and postdoctoral researcher for their contribution to toxicology. To be considered for the awards, applicants submit an abstract of a poster they are presenting at the SOT Annual Meeting and a letter of recommendation from their advisor. Judging is based on scientific merit, relevance to the field of toxicology, and quality of the abstract. The recipients will be presenting their award winning work at the NorCal SOT Spring Symposium. In addition, NorCal also provides an undergraduate student travel award that recognizes a student who demonstrates a strong interest in toxicology and is attending the SOT Annual Meeting. In the spirit of encouraging the next generation of toxicologists, NorCal chose to provide three undergraduate student awards. There were a large number of well qualified applicants this year making the selection process difficult. After careful consideration, the following applicants were chosen for the NorCal SOT achievement and travel awards.

Graduate Student Achievement Award
Kyla Walter (University of California, Davis)
Abstract: “Identification of Molecular, Cellular and Behavioral Endpoints Associated with Developmental Hyperthyroidism and Hypothyroidism in Larval Zebrafish”

Postdoctoral Achievement Award
Kimberly Keil (University of California, Davis)
Abstract: “DNA Methylation as a Mediator of Hexachloropiphenyl (PCB95) Induced Dendritic Arborization”

Undergraduate Student Travel Award
Joey Chiang (University of California, Berkeley)
Emily Hamilton (University of California, San Francisco)
Kevin Zhang (University of California, Berkeley)

A big **THANK YOU** to the Past Presidents - Jeff Tepper, Linval DePass and George Clemens - for serving as our Judges.

New NorCal SOT Members

Lisa	Miller	UC Davis	Lisa	Miller	UC Davis
Michelle	Kossack	UC Davis	Michelle	Kossack	UC Davis
Justin	Tsui	Cal EPA	Justin	Tsui	Cal EPA
Sarah	Daniels	UC Berkeley	Sarah	Daniels	UC Berkeley

Michelle	Guignet	UC Davis	Michelle	Guignet	UC Davis
Alejandro	Castaneda	UC Davis	Alejandro	Castaneda	UC Davis
Kyla	Walter	UC Davis	Kyla	Walter	UC Davis
Vasundhra	Bahl	UC Riverside	Joel	Bercu	Gilead Sciences Inc
Claire	Neilan	Gilead Sciences Inc	Kim	Truong	UC Davis
Deborah	Cole	Aragen Bioscience	Ly	Kawaguchi	Allergan Inc
Joe	Flynn	7th Wave Labs	Warren	Casey	NIH
Alan	Loch	BASi	Tina	Levine	Electric Power Research Institute
Thomas	Monticello	Amgen Inc	Yichen	Lin	Safety and Health Technology Center
Lindsey	Schwenk	SNBL USA, Ltd.	Suren	Bandara	UC Davis
Tod	Harper	Amgen Inc	Joey	Chiang	UC Berkeley
Vipin	Tyagi	University College of Medical Sciences and GTB Hospital (University of Delhi)	Keri	Hayakawa	UC Davis
Alicia	Taylor	UC Berkeley	Kevin	Zhang	UC Berkeley
Earl	Morrison	Organovo	Emily	Hamilton	UCSF
Marie	Piazza	Millipore Sigma (BioReliance/EMD Millipore)	Amy	Sharma	Amgen, Inc.
Douglas	Crowder	Comparative Biosciences	Leah	Wehmas	EPA
April	Lake	Gilead Sciences Inc	Lauren	Mihalcik	Amgen Inc
Laura	Leung	Circuit Therapeutics	Mausumee	Guha	
Ravi	Persaud	Apple Inc	Mikhail	Baklashov	Comparative Biosciences
Otto	Raabe	UC Davis	Mike	Conley	Leadscope, Inc.
Samantha	Feng	UC Davis	Darren	Craig	Envigo
Kyla	Walter	UC Davis	Richard	Egolf	MicroConstants
Leonard	Levin	Electric Power Research Institute	Glenn	Myatt	Leadscope, Inc.
Rachel	Novick	Cardno ChemRisk	Noel	Premkumar	Eurofins Pharma

					Bioanalytics Services US Inc
Sunjay	Sethi	UC Davis	John	Welch	Ricerca Biosciences
Teresa	Reyes	Genencor DuPont	Misrach	Mitiku	DC3 Therapeutics
Michelle	Kossack	UC Davis	Jonathan	Wray	DC3 Therapeutics,

A Review of the 2015 Fall NorCal SOT Symposium

On October 22, 2015, NorCal SOT hosted the 2015 Fall Symposium South San Francisco Conference Center. We welcomed greeted 120 registered attendees from regional business, government, and academia. Our featured speakers and their topics are listed below:

- **Identifying toxicity in the adult reproductive system: important considerations for interpreting male and female specific endpoints:** Dianne Creasy,PhD, DipRCPath (Tox), FRCPath, Dianne Creasy Consulting LLC.
- **Current State and Future of Reproductive and Developmental Toxicity Testing:** Alan M. Hoberman, PhD, DABT, Fellow ATS, Executive Director of Global Developmental, Reproductive and Juvenile Toxicology, Charles River Laboratories
- **Juvenile Animal Studies to Support Pediatric Drug Development: How, why, what?** LaRonda L. Morford, PhD, Senior Research Advisor, Toxicology, Eli Lilly
- **CalEnviroScreen: A Tool for Evaluating California Communities:** John Faust, PhD, Chief of the Community Assessment and Research, OEHHA
- **Approaches to Including Sensitive Subpopulations in Risk Assessment:** Melanie A. Marty, PhD, Acting Deputy Director for Scientific Affairs, OEHHA
- **California's Public Health Goal for Perchlorate in Drinking Water:** Elaine Khan, PhD, Chief of the Water Toxicology Section, OEHHA

The presentations were all excellent examples of cutting edge science across many areas of our toxicology discipline and updates on new regulatory issues. Each was well received based on lively Q&A and subsequent speaker engagement. Over the lunch hour, we had a strong turnout of mentors and mentees for our popular "Lunch with an Expert" event with conversations continuing after the meeting. Thank you all for your time and contributions to yet another successful NorCal symposium!

Above all, we would like to appreciate and thank our Sponsors for making this event a success:

- Gold Sponsor: Envigo

- Silver Sponsors: WIL Research, MPI Research, SNBL, Seventh Wave Laboratories, Covance
- Bronze Sponsors: Charles River, BioReliance, BASi, ITR Laboratories, Organovo, Comparative Biosciences, Gilead, NSF International, SRI International, Ricerca, Amgen, CitToxLAB Research Inc., Cyprotex, Wuxi AppTech
- Friend: EPL

Newly Elected NorCal SOT Board Members for 2016-2017

It is with great pleasure that we announce the 2016-2017 NorCal SOT regional chapter executive committee. Thanks to all of those members who sought positions and to those that voted. Although all of the races were tight, here are the results:

Kathryn Page, (The Clorox Company) – Vice President-Elect (4 yr term)
Alicia Taylor, UC Berkeley – Postdoctoral Representative (2 yr term)
Samantha Faber, UC Davis – Graduate Student Representative (2 yr term)
Rod Prell, Genentech – Councilor (2 yr term)

The continuing members rounding out the executive committee are:

Toufan Parman, SRI International – President (2 yr remaining)
Doris Zane, Intarcia Therapeutics– Vice President (3 yr remaining)
Julie Rider, Edison Pharmaceuticals – Treasurer (1 yr remaining)
Joanne Birkebak, Gilead – Councilor (1 yr remaining)
Howard Stock, Charles River Laboratories – Secretary (1 yr remaining)
Eric Harstad, Genentech – Past President (1 year remaining)

Preclinical Drug Safety Group

By Jeff Tepper, PhD, DABT, Past President

A NorCal preclinical drug safety group meeting was held on 2/18 at the Chalet Ticino in Foster City. We were honored to have dinner with Dr. Jacobson-Kram, who served as the Associate Director of Pharmacology and Toxicology in FDA's Office of New Drugs and chair of the eCAC. Dr. Jacobson-Kram has retired from the FDA and is currently a drug development consultant, so he was free to answer a wide range of questions regarding his time at the FDA. The evening's discussion focused on hot topics in *in vitro* gene toxicity testing and the use of transgenic mice in carcinogenicity studies; however, topics of all kinds came up during the discussion. As always the food was great and the networking, and information provided by Dr. Jacobson-Kram were excellent. NorCal would like to thank BioReliance who arranged Dr. Jacobson-Kram visit and sponsored the meeting.

K-12 Event Report

By Doris Zane, PhD, DABT, VP Elect and Toufan Parman, PhD, DABT (VP)

K-8: On October 24, 2015, NorCal SOT hosted activities at the Science Festival 2015 - Discovery Day at Cal State East Bay. Several hundred students (K-12) participated in the Science Festival. Approximately 50+ activities were available at the Science Festival (including Chemistry Magic Show, Observe the Sun and Moon with a Telescope, Mathematics Puzzles, Creepy Critter Spooktacular, Computer Science for Fun, Potpourri of Physics, Health Screenings, and a Robot Zoo), with demonstrations, experiments, hands-on-activities, exhibits, lectures and much more. Special thanks to Andrew Campbell for helping to coordinate this event.

K-12 Education Outreach Event at the Science Festival 2015 - Discovery Day at Cal State East Bay.

High-School Exploration and Presentation: This October NorCal SOT started a mentoring program with San Mateo High School's (SMH) Technology Laboratory. Lily Qian (a Senior SMH student) is currently being mentored by Mr. Ed Riccio (SRI International) and Dr. Toufan Parman to conduct a basic research at this high school's technology laboratory. Lily's project is to determine the mutagenic potential of the Chinese herbal medicine Rhizoma Phragmitis in plant, liquid extract, and granule forms using the Ames test. The plan is to have this student present a poster at the next year's SOT. We hope that next year we can expand this program to more than one student but we cannot do this without the help of our member volunteers. If you are interested in mentoring a high school student and would like to help them put together a fun project that can be presented at SOT please contact Toufan (toufan.parman@sri.com).

Postdoc/Student Corner

By Sunnie Zhu, PhD, Postdoctoral Rep. and Ray Zhang, Graduate Student Rep.

News, events, and updates from your NorCal SOT student and postdoc representatives.

Past Events

On Thursday, November 19, 2015, NorCal SOT hosted a career mentoring event at The Berkeley Faculty Club on the UC Berkeley campus. The event was a conscious effort to bring more career events to Bay Area universities in order to facilitate access for the student and postdoc populations as well as working professionals in the region. Participants enjoyed good food and wine while mentors offered perspectives on their

careers and the important decisions that brought them to where they are now. Mentors represented companies such as Genentech, Clorox, Gilead, as well as CalEPA-OEHHA. We would like to thank everyone who drove out to Berkeley for our event, especially the mentors, as it is their continued support that makes NorCal SOT career events worthwhile and successful.

We would also like to thank the more than 140 people who came out to Pat O's on the River in New Orleans for the NorCal SOT Annual Reception! Guests enjoyed Hurricanes and a variety of Cajun-style foods, socialized and networked, and enjoyed the beautiful view of the Mississippi River and waterfront from the balcony. We are glad the event was a success and everyone had such a great time.

Our New Representatives

The votes are in, and NorCal SOT will be bringing in a set of new postdoc and student representatives for 2016-17! Without further ado, please help us welcome Alicia Taylor (UC Berkeley) as our new postdoc representative and Samantha Faber (UC Davis) as our new graduate student representative. They are both extremely excited and more than capable of bringing fresh new ideas to foster interactions and participation between the student and postdoc members of NorCal SOT. We are very excited to have Alicia and Samantha and look forward to the career, outreach, and social events that they will put on over the next year. Take time to congratulate them at the upcoming Fall Symposium and let them know if you have any interesting event ideas!

Job Announcements

Scientist/Senior Scientist Development Toxicology, Safety Assessment
Requisition #00445611 (www.gene.com)

Description

The Department of Safety Assessment at Genentech provides scientific leadership and plays an active role in the process of drug development from the discovery period through marketed products. We are seeking a Scientist/Senior Scientist in Development Toxicology to support drug development. This role will involve working in a collaborative team environment as part of the comprehensive safety assessment of Genentech therapeutics by providing toxicology representation to small and large molecule programs.

Responsibilities:
The successful candidate for Scientist/Senior Scientist will provide scientific leadership and play an active role in the process of drug development from discovery through marketed products. Working in a collaborative team environment, the Scientist/Senior Scientist leads the safety assessment of Genentech therapeutics by creating a best-evidence synthesis of existing knowledge and comprehensive investigations of toxicologic activity, strategic planning, and designing/implementing/supervising toxicology studies in support of program advancement.

The responsibilities for Scientist/Senior Scientist include:

- Interdisciplinary project team membership, scientific leadership in the design and implementation of safety assessment strategies to support program advancement and decision-making
- Designing and supervising in vitro and in vivo toxicology studies, working closely with Study Monitors, Pathologists and Pharmacokinetics's to deliver high quality GLP and non-GLP study reports, authoring and reviewing regulatory documents, and representing Genentech in meetings with regulatory authorities
- Leading hypothesis-driven investigation into mechanisms of toxicity, proactive management of potential safety liabilities and communication of impact to teams and governance committees.
- Additional responsibilities include leading or supporting inter- and intra-departmental initiatives.

Qualifications:

- A PhD and post-doctorate or equivalent experience in toxicology or a relevant field along with a minimum of 4 (Scientist) or 8 years (Senior Scientist) relevant experience in the pharmaceutical/biotechnology/CRO industry related to toxicology.
- Extensive experience in drug development and interaction with global regulatory authorities.
- Board certification in toxicology is highly desirable.
- The successful candidate must also demonstrate strong decision-making, complex problem solving, critical data analysis and interpretation, excellent written and verbal communication skills; and the ability to build productive cross-functional collaborations both within and external to Genentech

Associate Scientist/Scientist Development Toxicology, Safety Assessment
Requisition #3231382223 (www.gene.com)

Description
The Department of Safety Assessment at Genentech provides scientific leadership and plays an active role in the process of drug development from the discovery period through marketed products. We are seeking an Associate Scientist/Scientist in Development Toxicology to support drug development. This role will involve working in a collaborative team environment as part of the comprehensive safety assessment of Genentech therapeutics by providing toxicology representation to small and large molecule programs.

Responsibilities:
The successful candidate for Associate Scientist/Scientist will provide scientific leadership and play an active role in the process of drug development from discovery through marketed products. Working in a collaborative team environment, the Associate Scientist/Scientist leads the safety assessment of Genentech therapeutics by creating a best-evidence synthesis of existing knowledge and comprehensive investigations of toxicologic activity, strategic planning, and designing/implementing/supervising toxicology studies in support of program advancement.

The responsibilities for Scientist/Senior Scientist include:
- Interdisciplinary project team membership, scientific leadership in the design and implementation of safety assessment strategies to support program advancement and decision-making
- Designing and supervising in vitro and in vivo toxicology studies, working closely with Study Monitors, Pathologists and Pharmacokinetics's to deliver high quality GLP and non-GLP study reports, authoring and reviewing regulatory documents, and representing Genentech in meetings with regulatory authorities
- Leading hypothesis-driven investigation into mechanisms of toxicity, proactive management of potential safety liabilities and communication of impact to teams and governance committees.
- Represent Safety Assessment on interdisciplinary research and development teams and contribute to scientific and strategic decision making in order to bring next generation therapeutics to patients.
- Additional responsibilities include leading or supporting inter- and intra-departmental initiatives.

Qualifications:
- A PhD and post-doctorate or equivalent experience in toxicology or a relevant field. Relevant experience in the pharmaceutical/biotechnology/CRO industry related to toxicology (2-5 years) is strongly preferred, but outstanding candidates without industry experience may be considered.
- Experience in ocular toxicology or the development of ophthalmology products strongly preferred.
- The successful candidate must also demonstrate strong decision-making, complex problem solving, critical data analysis and interpretation, excellent written and verbal

communication skills; and the ability to build productive cross-functional collaborations both within and external to Genentech

Veterinary Clinical Pathologist
Requisition #00445243 (www.gene.com)

Description
We are seeking an experienced Veterinary Clinical Pathologist to join the Genentech Development Sciences Safety Assessment Department. The successful candidate will provide scientific leadership in the Clinical Pathology Core Laboratory and play an active role in the process of drug development from early-stage research through marketed products. You will have the opportunity and responsibility for the strategic growth of laboratory capabilities, to ensure production of best quality clinical pathology data from both internal and partner laboratories. Working in a team environment, you will also participate across projects in the design, implementation and data analysis of both investigative and regulatory studies, driving the comprehensive, highly integrated safety profiling of Genentech drug candidates. Responsibilities include cross-functional leadership, interdisciplinary project team participation and leadership, design and conduct of investigative and mechanistic studies, representation of Genentech in meetings with regulatory authorities, functional area mentorship, and participation in safety, biomarker and diagnostic development programs.

Requirements:
- Extensive practical and theoretical expertise in understanding the pathological basis of disease and drug development practices
- Experience in the management of a clinical pathology laboratory in a collaborative and cooperative environment.
- Ability in providing scientific guidance and feedback to non-DVM Scientists and laboratory staff
- Evidence of scientific productivity and critical thinking skills with application to drug development.
- Excellent verbal and written communication skills.

Education:
- DVM or equivalent, Board certified by the American College of Veterinary Pathologists or European College of Veterinary Clinical Pathology (ECVCP) in Clinical Pathology.
- PhD (or, equivalent) preferred but significant investigative and industry experience in clinical pathology, toxicology or a related discipline also considered.

Veterinary Anatomic Pathologist
Requisition #00445871 (www.gene.com)

Description

We are seeking an experienced Veterinary Anatomic Pathologist to join the Genentech Development Sciences Safety Assessment Department. The successful candidate will provide expert pathology support, scientific leadership and play an active role in the process of drug development from early-stage research through marketed products. Working in a team environment, you will participate across projects in the design, implementation and data analysis of both investigative and regulatory studies, driving the comprehensive, highly integrated safety profiling of Genentech drug candidates. Responsibilities will include active cross-functional collaboration, interdisciplinary project team participation and leadership, design and conduct of investigative and mechanistic studies, representation of Genentech in meetings with regulatory authorities, functional area mentorship and the opportunity to participate in cross-industry consortia and professional society initiatives.

Requirements:

- Extensive practical and theoretical expertise in understanding the pathological basis of disease and drug development practices
- Demonstrated capability in collaboration, scientific guidance and feedback to non-DVM Scientists and laboratory staff.
- Evidence of scientific productivity and critical thinking skills with application to drug development.
- Excellent verbal and written communication skills.
- Position level dependent on experience and body of work

Education:

- DVM or equivalent, Board certified by the American College of Veterinary Pathologists or European College of Veterinary Pathology (ECVP).
- PhD (or, equivalent) preferred but significant investigative and industry experience in clinical pathology, toxicology or a related discipline also considered.

Senior Manager/Associate Director, Safety Assessment Study Operations
Requisition #3230036458 (www.gene.com)

Description
General Responsibilities:
The Senior Manager/Associate Director of Safety Assessment Study Operations will be responsible for ensuring all non-clinical studies are executed effectively. He/She will provide strategic operational guidance for on all non-clinical studies for programs across the drug development continuum. Additionally, He/She will be responsible for building and maintaining robust collaborations within Safety Assessment, and across the Development organization. He/She will work with internal and external resources to ensure that non-clinical studies are conducted according to high standards that which meet rigorous regulatory and GLP guidelines. In anticipation of growth, the Sr Mgr/AD will be responsible for maintaining a vision as well as building and developing the Study Operations group. The successful candidate will be accountable for developing and

sustaining scalable business processes in non-clinical study execution to ensure efficiencies. Additional responsibilities include: directing the Study Operations Management team and; delivering ensuring completeness and consistent delivery of multiple studies and programs on budget and within previously defined timelines; ensuring that project/personnel resources are staffed/allocated appropriately to meet program goals and timelines; ensuring the development of robust operational infrastructure such as implementation of new technologies, processes and training programs to that create greater synergy and consistency across multiple programs; mentoring and developing direct reports.

Specific Responsibilities:
Responsible for the functional management of Nonclinical Study Monitoring and for ensuring successful study implementation, conduct and reporting of studies executed at Contract Research Organizations (CROs). Ensure that operational procedures are efficient, in compliance with the study protocol, regulatory standards, and aligned with departmental goals. Provide leadership to develop Study Operations as a Center of Excellence. Prioritize and assign projects to staff in alignment with corporate objectives. Work with cross-functional team members and CROs to resolve study related issues. Identify and evaluate CROs for Good Laboratory Practice (GLP, 21 CFR Parts 58) and non-GLP studies supporting projects that range from research to full development. Serve as a liaison between CROs and Genentech by establishing collaborative relationships. Support activities that ensure career growth and development for self and direct reports.

Education:
BS or BA in biology, life sciences or equivalent

Experience:
At least 10 years experience in the biotechnology or pharmaceutical industry. Previous experience with toxicology, pharmacokinetics and/or metabolism studies. A track record of successful direction of multiple early development programs and expertise in managing complex non-clinical studies. Proven ability to manage, motivate and inspire a diverse group of staff to produce exceptional results. Proven ability to positively and strategically influence employees at all levels and an accomplished record of leading cross-functional teams in a highly matrixed organization. Direct experience within a biotechnology/pharmaceutical company, in taking a product through the early development drug development process to IND and approval. Experience accomplishing results in a project-oriented environment including setting timelines, developing milestones and producing time bound deliverables. Demonstrated ability to work within a GLP environment. Demonstrated ability to effectively implement process improvement initiatives. Strong communication, presentation and interpersonal skills and the ability to form strong cohesive partnerships. Excellent judgment and analytical skills. Demonstrated ability to diagnose issues, manage conflict and provide alternative solutions.