

# San Francisco/ Bay Area Chapter

ENGINEERING PHARMACEUTICAL INNOVATION

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#### Awarded ISPE's 2009 Platinum Outstanding Award for Excellence and Innovation



ISPE Members Toured UCSF Institute for Regenerative Medicine (IRM)
Facility. See more photos inside the newsletter.

# Past President's Message by Linda Karr of Genentech

s I complete my activities as Chapter President, I want to personally thank all the volunteers who served on the various committees. Over 80 individuals volunteered their time to bring the ISPE programs to you locally. The variety of programs this past year included our usual mix of Commuter Conferences, Dinner Programs, Vendor Night, and Fun Day. In addition, we had multiple Community Outreach events (Elementary School Chocolate Factory programs and Organs-R-Us run) which are unique to the Bay Area Chapter. Also, we added the Oktoberfest and four plant tours including Amgen, Baxter Biosciences, Pyramid Ale House, and the Institute for Regenerative Medicine at UCSF. Every month of the year there is an ISPE activity available to you in the SF Bay Area!

(continued on next page)

# **Past President's Message** by Linda Karr of Genentech (continued)

Three very hard working Members of the SF board of directors are "retiring" after four years of service. Tara Davis and Edda Mihaescu, PhD of Bayer HealthCare and Kristen Dezzani of Alza left their imprint on the Fun Day, Membership, and Young Professional/Student Committees respectively. Because of their leadership and contributions, these programs are well positioned for success going forward.

Congratulations to Novo Construction for winning the annual SF Fun Day golf tournament. We thank all the sponsors who helped make this event possible. There were some unexpected consequences of the new layout of the Chardonnay Club course holes, and the sponsors who were positioned on the Eagle Vines course will receive a reduction in sponsorship renewal cost next year. Meanwhile, the wine tasters enjoyed a very nice day visiting some boutique wineries like Black Cat, Frazier, Ancien and Farella-Parks as well as the return of the lobsterfest lunch.

The dog days of summer are typically a guiet time for ISPE, but there were two great programs held in August. On the 18th, DPR Construction hosted a tour of the Institute of Regenerative Medicine at UCSF in San Francisco. The facility is a unique cantilevered, serpentine structure built using seismic isolators that will allow the building to move 26 inches during an earthquake! Then on August 24th, Life Technologies, formerly Applied Biosystems, hosted a commuter conference on Disposables Technology. BioMarin, Genentech, and Hyde Engineering + Consulting provided case studies of facilities built utilizing single-use technologies. Overviews of our Fall events will be featured in the next newsletter.

All the Chapter volunteer leaders will be carrying on the tradition of excellent programs for the San Francisco Bay Area. Suggestions for topics or speakers are always welcome. The new contact list of SF Chapter Officers and Directors can be found on page 18 of this newsletter. I look forward to continuing my participation in our local Chapter, and I hope to see as many of you as possible at our upcoming programs.

All the best.



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### ISPE San Francisco/Bay Area Chapter

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# RESPONSIBLE BIOPHARMACEUTICAL MANUFACTURING IN THE NEW ECONOMY Thursday, December 2, 2010



**DoubleTree Hotel Berkeley Marina** 200 Marina Blvd., Berkeley, CA 94710

**Networking Reception Presentation** 

5:00 - 6:30 pm 6:30 - 7:00 pm

Tel: (510) 548-7920

#### Presenter:

Dr. Johannes Schweppenhauser, Vice President Technical Operations, Supply Center Berkeley, Bayer Healthcare Pharmaceuticals, Inc.

#### **Driving Directions:**

From San Francisco: Take Highway 101 North to I-80 across the Bay Bridge. Follow I-80 East to Berkeley. Exit University Ave. Drive into left lane and proceed to first stop light at 6th Street. Make a U-turn at 6th Street and proceed on University Ave. (West) to Marina Blvd. Turn right on Marina Blvd., the hotel is on the left side of the street and is hidden from immediate view by trees.

Be sure to look up driving directions from your own starting point.

#### REGISTRATION FOR M

Please link to our processing site for an immediate receipt:

http://event-confirmation.com/ispesf\_meetings.htm

If using this form, please fax to: (949) 266-8461 or (949) 387-9047. Include your credit card information or fax the registration first, then mail your check at least 10 days prior to the event (with original registration form) made payable to ISPE San Francisco/Bay Area Chapter to, 5319 University Dr., Suite 641, Irvine, CA 92612. For questions email Kimberly Syre, Chapter Manager at: ksyre@cox.net or call (888) 275-0189 or (949) 387-9046. Federal Tax ID #68-0282494. Cancellations must be received in writing via fax or email by November 23, 2010 for a refund.

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E-MAIL:	Member Cost: ☐ \$65
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## Summer Ends With A Fun Day by Kim Duncan of Duncan Enterprises Photos by Cynthia Wiggins of IC Engineering

he ISPE San Francisco Chapter hosted the 16th Annual Fun Day networking event featuring a golf tournament and winery tours. The event, held annually in July, was held at the Chardonnay Golf Club in Napa. The event attracted more than 220 golfers and 130 wine participants representing clients and suppliers.

Golfers enjoyed playing at the Chardonnay Golf Club, where the tournament was played on three-9 hole courses (everyone played two of the three tracks). The golf course was awarded four stars by Golf Digest Magazine. The winning foursome of the tournament was the Chuck Flynn, David Salbalvaro, Al Courtney and Jeff Curry team representing Novo Construction with a winning score of 60.

Wine tour participants enjoyed wine tastings and wine maker presentations at the Black Cat, Farella-Parks, Ancien and Frazier wineries in the Southern Napa region. The highlight of the day was an outdoor lobster banquet at Frazier Winery, with sweeping views of the valley.

Sponsors and prizes were awarded at a banquet reception following the golf tournament, which provided an opportunity for golfers and wine tour participants to socialize and network.

Due to the generous support of our event sponsors, we were able to raise a modest profit to finance a new "Member Fund" that will support our Members who do not have the financial means to pay for ISPE events or to fund their annual Membership.

ISPE recognizes and understands that the nature of the economy continues to challenge many of our Members. Some are unemployed yet still want to stay connected to the industry. Others who are employed are experiencing company restrictions on spending for outside meetings and events such as ISPE dinners and tours. The Member Fund supports individuals who have been ISPE Members for three or more years and who want to stay connected to ISPE. We feel strongly that while we are living in extremely tough times, we need to support those who have been faithful to ISPE in the past so that we all can come out of these uncertain economic times stronger and better educated.

Next year's event will be called Business-to-Business (B2B) Networking Day. Please mark your calendar for next year's B2B Day on Thursday, July 28th, 2011!

Hundreds of Fun Day photos, both wine and golf, have been posted online by Cynthia Wiggins-Wyrick, the link to the site is:

http://picasaweb.google.com/111579051276174895884/ISPEFunDay2010PhotosByCynthiaWigginsOflCEngineering?authkey=G v1sRgCLHy4JrR-c3x6QE&feat=email#







# Thank You To This Year's Fun Day Sponsors

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# Fun Day Golf Photos by Cynthia Wiggins-Wyrick of IC Engineering





























# Fun Day Winery Tour Photos by Melody Spradlin and Harvey Steinhaus of Dome Construction and Kimberly Syre, Chapter Manager

























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# Inside Mission Bay by Ed Shea of BNBuilders

he design and construction of projects continues in Mission Bay. UCSF is moving forward with a new project delivery system for the Neurosciences Laboratory and Clinical Research Building 19A at their Mission Bay Campus. Edgemoor/McCarthy Cook LLC will be the developer and has hired Clark Construction / SOM Architects for this design-build effort. Project Management firm LCM was recently hired to assist UCSF's users on the project. Keith Lundquist of LCM is also currently managing the Nektar Therapeutics corporate headquarters project at Block 26 and has previously worked with other Mission Bay tenants such as Five Prime Therapeutics, Celgene Corporation and Pharmion Corporation.

A large attribute to the success of Mission Bay is that there are core groups of individuals within the community who are extremely passionate about the success and growth of the area. One of those individuals is Doug Crawford, PhD of QB3. I recently caught up with Dr. Crawford and although he was extremely busy, he took the time to bring me up to date on what is happening at the bioscience incubator consortium. QB3 and Fibrogen have collaborated and currently house 25 companies at Fibrogen's 409 Illinois address with QB3 hosting an additional five companies at their UCSF campus. The "garage network" is a series of companies who are tackling important bioscience related problems in the fields of health, energy, cancer, biofuels and financing. The "eco-system" of companies are mostly funded through venture capital, grants and angel investors. QB3 allows them to address their common needs and share resources, equipment and access to UCSF's scientific community and seminars.

Dr. Crawford highlighted Green Pacific Biologicals (GPB), a perfect example of the innovation and collaboration that is on-going in Mission Bay. GPB was founded in 2008 by four individuals who had the idea of providing nuclear-genetic engineering technologies for better biofuel production from algae to industry. GPB's solution to excrete oil from algae by a non-toxic mechanism has stirred considerable interest with the big name oil companies. Look for GPB and other QB3-housed companies in the headlines soon.











# **UCSF Institute for Regenerative Medicine (IRM) Facility Tour** By Tareg Barakzoy of ACCO Engineered Systems

Photos by Andy Nelsen of Bay Area Engineers and Harvey Steinhaus of Dome Construction

tour of the newly-constructed IRM building was held for the ISPE SF Chapter in August. The event was sponsored by DPR Construction, ACCO Engineered Systems, Cupertino Electric, and ISEC. Over 70 people attended the Member-only event, which started with a social hour and then followed with the tour of the stem cell research building. The building is a 65,000 ft2, two-story facility with lab space on the first floor and offices on the second floor. The open, split level design is intended to encourage contact, idea-sharing and collaboration. It will house many different research labs doing stem cell research on animal and human development, mechanisms of organ repair, immune rejection, and cancer.

The facility was constructed on a narrow, steep slope wedged between a winding road and the adjacent buildings, which made for a very complex construction project. One of the most critical elements of the project was ensuring maximum earthquake protection. The structure is isolated from seismic activity by a one-of-a-kind uplift restrain device, as well as Friction Pendulum bearings, which can absorb horizontal movement.

Speakers for the event were Michael Toporkoff, Associate Director for Capital Programs at UCSF, and Michael Saks, Project Executive at DPR Construction. They discussed the events that led to the construction and completion of the project. The funding for this project came from California Bond Initiative for Stem Cell Research and from private donors. UCSF intends to attract top scientists in the field to work in this building.











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## Did you know?

Become familiar with all ISPE has to offer with general information and tips that help you "Make the Most of Your Membership!"



<sup>\*</sup> Update your Member Profile to ensure you receive ISPE emails. You may also access these messages at www.ISPE.org

# Disposable Technology Presented to ISPE Members by Patti Larson of DPR Construction

ife Technologies hosted a Commuter Conference in August for ISPE Members. The topic was Disposable Technology and was graciously sponsored by Dome Construction and GL Planning & Design. Below are overviews from the three presentations.

Peter Watler, Ph.D., Principal Consultant and CTO at Hyde Engineering + Consulting provided a case study on "The Implementation of Single-Use Technologies for Bio-processing" which included disposable filters, vessels, connectors, mixers, sampling devices and bulk storage containers in a GMP facility. The use of disposable technologies enabled facility design and construction in only 12 months at a modest cost of \$13 million.



This demonstrates that the use of disposable technology allows for a reduction of both time and cost in the design and construction of pharmaceutical facilities. Reduced up-front capital, shorter equipment lead times, faster construction and rapid start-up all contribute to the savings. In addition, disposable technologies enhance GMP operation by offering excellent control of process stream contaminants such as endotoxins and bioburden.

Peter addressed the practical aspects of implementing disposable technologies

and outlined the challenges associated with implementation, particularly regarding change control, vendor selection and validation. He has found that working with just one carefully selected single source vendor helps in implementation, as does standardizing the bag sizes and fittings for various applications.

A second presentation "Building a Highly Disposable, Multi-Product Facility Concept through Commissioning" was given by Chris Brodeur of BioMarin.

Chris spoke about the 21,800 sq. ft. addition to BioMarin's main commercial manufacturing facility, recently completed by Dome Construction where use of disposable technologies helped to reduce the construction duration and cost of this project. In addition, disposables allowed for a quick start-up of the expansion. Chris said that getting long-term reliable and consistent vendors for the disposable products was important to the success of the operation.

Tim Mathews, Senior Engineer at Genentech presented "The Future State of Biologics Manufacturing." In this presentation, Tim talked about a toolbox of

technologies that may allow for significantly less expensive and more modular facilities of sufficient capacity to match "just in time" production needs. Stating that current Biologics manufacturing production facilities and processes, while robust, are generally built with outdated technologies. Tim discussed several new technologies that have been developed and investigated at Genentech and other companies. Used together, these tools can potentially revolutionize the way manufacturing facilities are built and processes performed. Specifically, he discussed the use of Xcellerex's portable clean room technology, the use of cell culture perfusion for production, sequential multicolumn chromatography and extensive use of in-line dilution of buffer concentrates.

Benefits of the use of disposable components include the reduction of cross contamination and reduced requirements for cleaning and sanitization, which, in turn, significantly reduce water and energy usage. The use of cleaning chemicals is also reduced. Using concentrated buffers diluted with an in-line mixer can add even further cost savings on a project.

Commuter Conferences are by invitation and open to ISPE Members and host facility employees only. If you are an ISPE Member of another Chapter and would like to receive email notices of Commuter Conferences, please email Kimberly Syre at ksyre@cox.net to be added to the invitation list.

Please feel free to provide additional feedback and topic recommendations to the Chapter's Commuter Conference chairperson, Patti Larson at patricial@dprinc.com.





## **ISPE Announces Call for Proposals** Submissions for 2011 and 2012 Due by 1 December 2010

SPE is calling for proposals for content to be included in a variety of the Society's educational activities and resources. By participating, pharmaceutical professionals from around the world have a chance to have a positive impact on their industry.

"Our core purpose is to help prepare our Members to lead global change in the pharmaceutical industry," said ISPE President and CEO Bob Best. "To achieve this goal, we rely on industry professionals to share their knowledge and experiences with our Members through our numerous educational programs. Not only does this enhance these professionals' credentials, but it allows their knowledge and ideas to influence the future of the pharmaceutical industry."

ISPE is now using one single submission form for all topics that may be considered in its Online Learning (webinars, online courses, etc.), Continuing Education, Training, Technical Documents, publications, including Pharmaceutical Engineering magazine, Knowledge Briefs, and E-letters. Submissions are expected to shed light on current, topical issues, and address knowledge gaps within the pharmaceutical science and manufacturing industry.

While content proposals are welcomed at any time, submissions intended to be considered for ISPE's 2011-2012 programming must be received by 1 December 2010. Download the ISPE Proposal Form at www.ISPE.org/CallForProposals. For more information, visit www.ISPE.org and click on Education and Training/Overview. Proposals are welcomed from both individuals and groups.



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# Industry News by Sandra Medlin Sani-tech West

## A resilient biotech industry registers its first profitable year

Ernst & Young has scanned the global biotech industry and found that established biotech hubs not only weathered 2009's scary economic downturn, they achieved a collective profitability for the very first time. But the big accounting firm wasn't ready to call for the champagne just yet.

The yawning gap between the industry's haves versus the have-nots is just as big as ever, small fish in the drug development pond face plenty of challenges obtaining operating cash and anyone trying to make it in biotech today will need to clear a very high bar.

"Biotech companies have long confounded predictions on their ability to survive difficult economic conditions and 2009 was no different," says Glen Giovannetti, Ernst & Young's global biotechnology leader. "Companies will continue to face a challenging funding environment for the foreseeable future. The firms best poised for success are those that can seize the opportunities latent in the near-universal need for increased efficiency--from capital efficiency to new approaches to R&D and creative models for funding and partnering."

**Novartis** has agreed to pay Quark Pharmaceuticals up to \$680 million for the licensing rights to a new therapy for kidney-related diseases. Quark will get \$10 million upfront for an option on QPI-1002, which is currently in Phase II for kidney-related conditions. If Novartis decides to pull the trigger on the option, it will pay out up to \$670 million more in fees and milestones. The drug is being developed for acute kidney disease and delayed graft function in kidney transplantation. The therapy targets the p53 gene, saving cells that could be killed by ischemia and other stress-related conditions.

**Bayer HealthCare** will establish a U.S. Innovation Center in Mission Bay, rotating researchers through the facility and working with UCSF in an attempt to build the German drug maker's product pipeline.

The center at 455 Mission Bay South — across Third Street from the University of California, San Francisco — will house Bayer's hematology research program. But scientists focused on cardiology, oncology, women's health care and diagnostic imaging also will rotate through the center. Bayer did not say how many jobs would be housed in the center or how many might shift from Berkeley or other facilities.

The city's biotech enclave by year end will house facilities for Bayer, one of the world's best-known drug companies, drug powerhouse Merck & Co., Celgene Inc. and home-grown Nektar Therapeutics and FibroGen, in addition to UCSF, the J. David Gladstone Institutes and a handful of smaller biotechs.

Bayer's center could be the backbone of the company's plan to spend 3.5 billion euros (about \$4.4 billion) from 2009 to 2018 on research and development and expanding its infrastructure.

The Mission Bay facility specifically introduces Bayer's idea of a "science hub" for collaborations with academic researchers and small biotech companies. Bayer's involvement, the company hopes, would help those partners translate their discoveries into new therapies.

**Nektar** will move into the structure in the fourth quarter — the same timeframe Bayer has given for opening its labs in Mission Bay.

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## **Industry News** (Continued)

#### Stem cell researchers slammed with funding freeze

The fallout from the startling preliminary injunction against federal support for embryonic stem cell work hit within a matter of hours as the NIH quickly hit the brakes on plans to issue up to \$74 million in fresh R&D funding. And scientists as well as biotech executives around the country were left pondering what work could continue and what would have to wait until the situation was resolved.

The NIH, was left with little choice following a judge's decision to grant a preliminary injunction against federal support for work in the field. \$54 million for renewed grants and up to \$20 million for new work will now be put in limbo until the Justice Department can either get the injunction lifted or Congress can pass new legislation on the issue. Researchers can continue to use the \$131 million in federal funding that has been handed out this year. The judge's decision centered on a little-known provision passed in 1996 prohibiting federal funding on R&D work that involved the destruction of embryos. As the feds didn't directly fund the destruction of embryos required for ESC experimentation, they had long felt that they were acting within the law.

**Genentech** dropped a collaboration with Seattle Genetics on the cancer drug dacetuzumab--or SGN-40. Seattle Genetics says the decision was the result of a product review at Genentech, which now operates under the wing of Roche. Earlier this week, Roche dropped out of partnerships with both Genmab and Actelion. With Roche and Genentech both reviewing pipeline projects in the wake of their multibillion-dollar merger, there are likely some nervous partners out there wondering where the axe will fall next.

BioMarin Pharmaceutical Inc. has announced that it has acquired ZyStor Therapeutics, Inc., a privately-held biotechnology company developing enzyme replacement therapies for the treatment of lysosomal storage disorders. ZyStor's lead product candidate is ZC-701, a novel fusion of insulinlike growth factor 2 and alpha glucosidase in development for Pompe disease. Under the terms of the agreement, BioMarin acquired ZyStor for \$22 million upfront and up to an additional \$93 million if certain development, regulatory and commercial milestones are achieved. There are no royalties owed. The FDA has accepted an investigational new drug application for ZC-701, investigational product has been manufactured and a clinical study is expected to start in Q1 2011. BioMarin has made several other small buyouts like this. Back in the early part of the year the biotech struck a deal to buy Lead Therapeutics for \$18 million. And BioMarin paid \$15 million upfront for Huxley Pharmaceuticals.

Top 5 Biotech Venture Capital Deals, SF Company in lead The first half of 2010 has drawn to a close, so it's time to look back on the biggest biotech venture capital deals so far this year. At the halfway point the leader is Archimedes Pharma, based in San Francisco, CA, has raised \$100 million to support the planned roll-out of PecFent, a fentanyl nasal spray designed to treat breakthrough cancer pain. Overall, the biotech industry has raised \$2.1 billion in 238 deals through the end of June 2010, according to the National Venture Capital Association.

Archimedes Pharma \$100M
Tesaro \$60M
Achaogen \$56M
NGM Biopharmaceuticals \$51M
Neurotherapeutics Pharma \$43M

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## **Industry News** (Continued)

Senators advocate blockbuster remedy for rare drug woes Lawmakers will soon get a chance to start pondering a bill that would dangle some blockbuster cash as an incentive to developers to take on the risk of developing new therapies for rare children's diseases.

The new law would give pharma companies a shot at quicker approvals of blockbusters if they take on new drug programs that tackle rare pediatric diseases. Adding even a few months to a drugmaker's window of market opportunity could add hundreds of millions of dollars to a blockbuster drug's potential revenue. The new bill essentially extends a three-year-old law that provides priority review vouchers to companies which work on treatments for rare tropical diseases. But the bill closes a loophole that gives biopharma companies access to vouchers on drugs that have already been approved. Supporters in Congress say they want to make sure that they're encouraging development of new therapies.

Kids v Cancer, which celebrated the new bill, says that in the past 20 years the FDA has approved only one cancer drug that was expressly developed for the pediatric market. "A priority for Kids v Cancer is to find ways to work with pharmaceutical companies to develop treatments for children with cancer and other rare diseases," said Nancy Goodman, the executive director of Kids v Cancer. "This legislation aligns government and private sector interests and will be a major step forward in addressing the unmet needs of children with devastating illnesses, including life-threatening cancer."

"We are falling woefully and inadequately short in our efforts to cure and treat rare and neglected pediatric diseases and conditions," said Senator Sherrod Brown, who introduced the bill with Sam Brownback and Al Franken.

Gilead Sciences, Inc. and CGI Pharmaceuticals, Inc., a privately-held, development-stage pharmaceutical company focused on small molecule chemistry and kinase biology, announced the signing of a definitive agreement pursuant to which Gilead will acquire CGI. Under the terms of the agreement, Gilead will acquire CGI for up to \$120 million, the majority as an upfront payment and the remaining based on clinical development progress, all of which will be financed through available cash on hand. Gilead anticipates that the deal would close in the third quarter of 2010, subject to satisfaction of certain closing conditions. After closing, CGI will continue operations in Branford as a wholly-owned subsidiary of Gilead.

The source of this information is the ISPE website, confirmed on company websites.

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#### **Welcome New Chapter Members July - October 2010**

Nick Bryant, Automation Engineer, Genentech Kelley Byars, Project Manager, Hathaway Dinwiddie Construction Company Uriel Cadsap, Associate Director, Quality Compliance, Ipsen Raniel Camacho, BAU Service Sales Rep, Siemens Industry, Inc. George Cooney, VP of Technology, S-Matrix Corporation Dorian Cougias, Lead Analyst, University of Delaware James DuPont, New Business Development, Rubber Fab Ahmad Elsayed, BDM, Bayer Frederick Foote, President & CEO, IC Engineering Inc. Tom Fortier, Kling Stubbins Manuel Galaz, Director of Operations, LTE, US Data Management, LLC Gregory Gallegos, Senior Manager, Genentech Alfonso Garcia, NNE Pharmaplan Philippe-Alexandre Gilbert, Senior Scientist, Medimmune Jon Gingrich, Sales Director, Xcellerex Zhengtian Gu, Director, Theravance Jamil Ismael, QA Supervisor, Impax Laboratories Inc Raquel Iverson, Principal QRM Specialist, Genentech David Kirk, Hygienic Market Manager, Pump Solutions Group Christina Lamparski, Account Manager, Honeywell Gilad Langer, Consulting Manager, NNE Pharmaplan Linda Leong, Student, San Jose State University Kevin Lomeli, Engineer, Matrix Technologies Carlos Luna, Senior Business Segment Manager, PG&E David Ma, Student, San Jose State University Gloria Magliari, Senior Project Manager, DGA planning | architecture | interiors Anil Mahavadi, Student, University of California-Berkeley Dermot Mee, Director, Bristol-Myers Squibb David Nelson, Director QA, UnitedBiosource Corporation Lonan Rooney, Process Engineer, CRB Consulting Engineers Nathaniel Ruppert, Engineer 1, Genentech Dimitrios Sagias, Principal Process Engineer, Bayer Andrea SaintPrix Lincon Saki, Asso. Principal Engineer, Southland Industries Anna Shen, Student, University of California, Berkeley Corey Siegel, Process Engineer, Foster Wheeler Biokinetics

Anna Shen, Student, University of California, Berkeley
Corey Siegel, Process Engineer, Foster Wheeler Biokinetics
James Stafford, Senior Engineer, Genentech
David Sterlace, Student, University of California-Berkeley
Julio Taboada, Facility Manager South Campus, Genentech
Adam Washington, Project Engineer, Dome Construction
Thomas Weller, Regional Sales Manager, Sudmo North America

### ISPE San Francisco / Bay Area Chapter Committees

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Chair: Simon Forder, Hyde Engineering + Consulting

Volunteers: Tareq Barakzoy, ACCO Engineered Systems

Kevin Collins, The Collins Group Michael Cooper, Bayer HealthCare Ralf Elsaesser, Dome Construction Leroy Ginn, ACCO Engineered Systems

**Steve Mullen** 

Andy Nelsen, Bay Area Engineers

Brian Vaughn, Banks Integration Group, Inc.

**Commuter Conference Committee** 

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Volunteers: Bruce Anderson, X-nth

Frank Chiu, Life Technologies Rick Ginn, XL Construction

David O'Connell, DCE Consulting, Inc. Harvey Steinhaus, Dome Construction Andrea Zarour, Greater Bay Mechanical, Inc.

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Dave Edgar, Iron Construction

Edda Mihaescu, PhD, Bayer HealthCare LLC Ulrike Ruppelt, Ticular Market Consultants

Glenn Samuels, Alexza

Cynthia Wiggins, IC Engineering

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Volunteers: Sandra Medlin, Sani-Tech West

David O'Connell, DCE Consulting, Inc.

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Volunteers: Nick Armstrong, Genentech

Steve Baker, DST Controls

Fion Cheng, Novartis

**Bill Chestnut, Independent Consultant** 

**Marlene Meza, Novartis** 

Bill VanDerVoort, DST Controls Steve Walker, Consultant

Faculty: Carl Cimino, Pipe Trades Training Center

Jim DeKloe, Solano College

Claire Komives, San Jose State University

Dr. Dorian Liepmann, UC Berkeley Dr. Karen McDonald, UC Davis

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Sue Cost, Foster Wheeler Biokinetics

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Volunteers: Greg Burg, Genentech

John Kelley, Genentech

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**Matt Hanson, Dome Construction** 

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Melody Spradlin, Dome Construction Cynthia Wiggins, IC Engineering

Sokhorn Yim, Genentech

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Mike Britting, Novo Construction Tara Davis, Bayer HealthCare LLC Sandra Medlin, Sani-Tech West

Edda Mihaescu, Bayer

**Bert Rangel, Orcas Project Controls** 

Ed Shea, BNBuilders

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lan Larson, Baxter Bioscience
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Mike Marston, DPR Construction Bob McCollough, Cytokinetics

Gordon Zagar, Cornerstone Integrated

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Mark Hannon, Genentech John Kelley, Genentech Ed Shea, BNBuilders

Council: Sandy Baker, GBSC/Johnson & Johnson

Ruediger Ciesinski, Bayer HealthCare Sean Clemenza, GBSC/Johnson & Johnson

Kaye Cowen, Bayer HealthCare

Al Dadson, XOMA

John Ducote, Bayer HealthCare

Scott Foell, GBSC/Johnson & Johnson

David Harris, Genentech Diane Johnson, Novartis Jeff Lang, Gilead Sciences

**Bob Litwin, XOMA** 

Brian Oppendike, Elan Pharmaceuticals

Mike Ramsay, Cell Genesys Phil Roberts, Exelixis Inc. Chris Stubbs, Genentech

Hank Szeto, BioMarin Pharmaceutical Joe Tarantino, Novartis Pharmaceuticals

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Secretary:

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#### **DIRECTORS**

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#### **Chapter Past Presidents:** 2010 Linda Karr, Genentech Greg Banks, Banks Integration Group 2009 2008 John Kelley, Genentech Rob Lynch, Dome Construction Corp. 2007 2006 Mark Hannon, Genentech Greg Burg, Genentech 2005 2004 Melody Spradlin, Dome Construction 2003-2004 Ed Shea, BNBuilders Jon Sheh, Johnson & Johnson 2002 **Scott Laskey** 2001 Haleh Banisadr-Hughes, TVS, Inc. 2000 Jeff Hargroves, ProPharma Group 1999 Sue Cost, Foster Wheeler Biokinetics 1998 John Sugerik, JTS Enterprises 1997 Dennis Mosher, Bay-Tec Engineering 1996 Ian MacLaren, Southland Industries 1995 Pete McArthur, Amylin Pharmaceuticals 1994

1993



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Jeff Jul, Newsletter Chair
jeff@j2biosystems.com

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ISPE 2010 Calendar

2 December SAVE THE DATE

Responsible Biopharmaceutical Manufacturing

in the New Economy

at Berkeley Doubletree Hotel

ISPE 2011 Calendar

20 January CEO Night

at South San Francisco Conference Center

9 February Commuter Conference

3 March Evening Meeting

7 April Vendor Night

at South San Francisco Conference Center

24 May Commuter Conference

30 June Facility Tour

28 July Business-to-Business (B2B) Networking Day

Formerly Fun Day

30 August Commuter Conference

22 September Evening Meeting

27 October Oktoberfest Social Event

6-9 November ISPE Annual Meeting

Dallas/Ft. Worth (Grapevine) Texas

15 November Commuter Conference

8 December Evening Meeting

All events subject to change due to availability of venue and speakers.

For more details please visit ISPE San Francisco/Bay Area Web site www.ispe.org/sanfrancisco

ISPE's Global Calendar: www.ispe.org

