



**San Francisco/  
Bay Area  
Chapter**

ENGINEERING  
PHARMACEUTICAL  
INNOVATION

**“Trends in Drug Development”**  
**Thursday, September 18, 2008**

At South San Francisco Conference Center  
255 South Airport Blvd., South San Francisco, CA 94080  
(650) 877-8787  
<http://www.ssfconf.com/>

*Free parking for all attendees*

**SCHEDULE:**

11:00 – 11:30 am	Registration
11:30 - 12:30 pm	Lunch
12:30 - 4:00 pm	Presentations

**COST:** ISPE Members..... \$65  
Non-Members..... \$90

**Presenters:**

This year's Half Day Seminar will feature a panel of speakers addressing a variety of interesting trends in the development of biopharmaceutical and pharmaceutical drug products including follow on biologics (also known as biosimilars) and offshoring aspects of drug production.

**Biosimilars: New drugs or just simple copies of original drugs?**

Rudolf Grimm, Ph.D., Agilent Technologies, Santa Clara, CA, USA

**Will the US Lose Its Lead in Biotech Manufacturing?**

Peter Watler, PhD, Chief Technology Officer, JM Hyde Consulting, Inc.

**UCSF Institute for Regeneration Medicine**

David Bendet, AIA, LEED™ AP, Project Manager, UC San Francisco

# Synopsis

## **Biosimilars: New drugs or just simple copies of original drugs?**

Rudolf Grimm, Ph.D., Agilent Technologies, Santa Clara, CA, USA

In recent years the public and economical pressure is continuously increasing to develop so-called biogeneric or biosimilar drugs in order to reduce overall health care costs as well as making important biopharmaceutical drugs such as rEPO, RHGH, RGCSF and others available to a broader community around the world, especially in third world countries.

So far the development of biosimilars is still in a grey zone due to a lack of guidelines, especially in North-America. This, as well as the pressure of originators, is the major cause for only a few biosimilar products being on the market so far.

The speaker who led the biotech laboratories of Hexal Biotech (now part of Novartis) in Germany before he joined Agilent Technologies will share his experience and knowledge about the strategy and successful development of the biosimilar version of EPO Alpha which was approved by EMEA in June 2007. The entire development project from start to approval took about 8 years with costs of roughly 50 Mio. Euro.

## **Will the US Lose Its Lead in Biotech Manufacturing?**

Peter Watler, PhD, Chief Technology Officer, JM Hyde Consulting, Inc.

Having just reached its 25th anniversary, the \$50 billion biopharmaceutical manufacturing industry in the U.S. has approached a critical juncture in its lifecycle. While most U.S. biopharmaceutical companies manufacture their products in the USA, lower corporate taxes and labor costs are incentivizing firms to build facilities off shore. After years of heavy government regulation and risk-averse operating strategies, biopharmaceutical manufacturers are encumbered with inefficient and costly production systems. These issues must be addressed and Cost-of-Goods must be driven down if companies are to maintain market share and operating margins.

Adding to the complexity are rising production yields, which coupled with increased product competition, are driving down the output requirements of these billion dollar factories. Add to this the emerging field of personalized medicine, which could radically change the conventional approach to mass market medicines. These factors may result in smaller, specialized and highly efficient biopharmaceutical manufacturing facilities.

In the next few years we will see answers to the questions – what will the plant of the future look like, how big will it be and where will it be.

## **UCSF Institute for Regeneration Medicine**

David Bendet, AIA, LEED™ AP, Project Manager, UC San Francisco

Regenerating injured tissues and organs might sound like science fiction. But as we gain a greater understanding of how stem cells in our body change from their undifferentiated states to become specialized tissues, UCSF's Institute for Regeneration Medicine is at the threshold of developing cell-based approaches and therapies for various diseases that result from tissue injury or degeneration.

The UCSF Institute for Regeneration Medicine (IRM) combines the talents of molecular biologists, developmental and cell biologists, neurobiologists, immunologists and cancer researchers. Their efforts, organized around research areas, are aimed at gaining a better understanding of how defined types of tissues develop, and are directed toward cell-based approaches to the treatment of disease. These insights will shape and direct potential therapies, which will be tested and refined in UCSF-based clinical trials.

The IRM's organization is designed to foster collaborations derived from work on different organs and tissue systems. Accordingly, the laboratories and research efforts are organized along a series of pipelines, each focusing on a particular tissue or organ system, and including basic research as well as translational research directed toward clinical applications. A basic researcher and a clinician direct each pipeline.

Seven different pipelines, based on extensive research and clinical strength, have been developed:

- \* Hematopoiesis
- \* Musculoskeletal
- \* Neural
- \* Cardiovascular
- \* Pancreas/Diabetes and Liver
- \* Epithelial
- \* Reproductive

## **ABOUT THE PRESENTERS:**

**Dr Rudolf Grimm** is Worldwide Proteomics and Metabolomics Market Development Manager for Agilent Technologies Inc. Rudi Grimm received his Ph.D. in Biology at the University of Munich. After completing a post-doc at the University of Freiburg/Germany and the Riken Institute in Tokyo/Japan, he joined Hewlett-Packard as a Senior Life Science Application Chemist in 1991. In 1998 he left the company and became the Head of Protein Chemistry at the Munich-based proteomics company Toplab. In June 1999 he joined Hexal Pharma to establish the biotech laboratories for the development of generic recombinant protein drugs. In September 2002 he rejoined Agilent Technologies. Since May 2006 he has been working at the Agilent Technologies headquarters in Santa Clara/California. He is author of more than 110 scientific publications.

**Peter K. Watler, PhD** is Principal Consultant and Chief Technology Officer with JM Hyde Consulting Inc. He has 20 years of GMP biopharmaceutical process experience with a focus on process design & scale-up, facility start-up, and validation. He was previously Vice President, Manufacturing at VaxGen and spent 12 years at Amgen, leading process development, manufacturing support and pilot plant operations. Dr Walter holds a Bachelor's and a Master's degree in Chemical Engineering from the University of Toronto and a PhD in Chemical Engineering from Yamaguchi University, Japan.

**David Bendet, AIA, LEED™ AP** is a Project Manager for UC San Francisco Capital Programs and Facilities Management. He is on the ISPE San Francisco Bay Area Chapter's Board of Directors currently serving as Chair of the Commuter Conference Committee. He has a Bachelor's Degree from the University of Colorado at Boulder, and a Master's Degree from the University of California at Berkeley.

Previously he was a Senior Associate for Hellmuth, Obata + Kassabaum in San Francisco. As a practice leader of HOK's Science + Technology Group, David's expertise includes the planning and implementation of Quality Control/Quality Assurance guidelines for architectural design and project delivery.



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**REGISTRATION FORM**  
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Name badges and receipts will be given at the event.**

If paying by check, fax your registration first, then mail your check **by September 11** or bring your check with you to the meeting. Checks should be made payable to: **ISPE SAN FRANCISCO/BAY AREA CHAPTER**, 5319 University Dr., Suite 641, Irvine, CA 92612 • Federal Tax ID #68-0282494 • Tel: 949-387-9046 • Email: [ksyre@cox.net](mailto:ksyre@cox.net)

**COST:** \_\_\_\_\_ **ISPE Members..... \$65**                      \_\_\_\_\_ **Non-Members..... \$90**

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# DIRECTIONS

South San Francisco Conference Center  
255 South Airport Blvd.  
South San Francisco, CA 94080  
(650) 877-8787  
<http://www.ssfconf.com/>

Getting to The South San Francisco Conference Center  
Conveniently located on the San Francisco Peninsula just north of the San Francisco International Airport at the Highway 101 South Airport Boulevard exit.

Located 20 minutes away from both downtown San Francisco and Silicon Valley, The South San Francisco Conference Center is visible from and located just east of Highway 101.

## **Arrival By Air**

San Francisco International Airport (SFO) is the closest airport. South San Francisco Conference Center is close to the airport. However, a rental car or taxi is recommended as it is not walking distance from the airport.

## **Other Area Airports**

San Jose International (SJC)  
Oakland International (OAK)

## **Bay Area Driving Directions**

### ***From the South (San Jose)***

Take Highway 101 north to the South Airport Boulevard exit (which is two miles north of the San Francisco International Airport). At the first stop light, drive straight across the intersection and directly into the parking lot. The South San Francisco Conference Center is on the left.

### ***From the North (San Francisco)***

Take Highway 101 South to the South Airport Boulevard exit in South San Francisco. Stay to the right and turn east under the freeway overpass. Make a right, at the Hungry Hunter Restaurant, onto South Airport Boulevard. The South San Francisco Conference Center is located on the left.

### ***From Marin County, 19th Avenue, Daly City***

Take the Golden Gate Bridge to 19th Avenue and continue on to Highway 280 South. From Highway 280, take Highway 380 East to Highway 101 North (San Francisco). From Highway 101 North exit at South Airport Boulevard. At the first stop light, drive straight across the intersection into the parking lot. The South San Francisco Conference Center is located on the left. Note: There is a South Airport Boulevard exit off Highway 380. Do not take this exit. Please take the South Airport Boulevard exit off of Highway 101 North.