




**MONDAY NOV 7  
9:00 AM to 4:30 PM**

<b>SEMINAR ROOM NUMBER 1</b>		<b>SEMINAR ROOM NUMBER 2</b>	
9:00-12:00	<p><b><u>Quality System for Start-up Companies (Development to Early Phase)</u></b></p> <ul style="list-style-type: none"> <li>• Overview, key elements and requirements</li> <li>• Organization</li> <li>• Understanding of the ICH Q11</li> <li>• Development and characterization reports used for later phase, CMC and filing</li> <li>• Regulatory requirements</li> <li>• Good documentation practice for development and early phase</li> <li>• Standard Operating Procedure(SOP)</li> </ul> <p><b><u>Quality System Overview (Phase 3 to Commercial)</u></b></p> <ul style="list-style-type: none"> <li>• Overview, key elements and requirements</li> <li>• Understanding of the ICH Q10 Pharmaceutical Quality System</li> <li>• Roles and Responsibilities of Quality Unit</li> <li>• Review of the regulation sections (ICH Q7, CFR21 and EU) that apply to Quality Unit</li> <li>• Quality Management Review: Purpose, elements, reports, and frequency</li> <li>• Change Control/Change Managements, Product Disposition, Document Control, Production, specifications control, and distribution records.</li> </ul> <p><b>Speakers:</b>  <b>Dr Chunchang Fang, Ph.D., Former FDA</b>                      President, CSPC Dophen Corporation, California, USA  <b>Jamie Jamshidi</b>, Quality &amp; Regulatory Management,                      President and The Bio Science Alliance (BSA), Director of Education and Training</p>	9:00-12:00	<p><b><u>Product Life Cycle, From Discovery to Commercialization</u></b></p> <ul style="list-style-type: none"> <li>• Overview</li> <li>• Drug discovery and development milestones</li> <li>• Pre-clinical study requirements</li> <li>• Clinical studies; phase 1-3</li> <li>• FDA Interactions</li> <li>• The IND Process</li> <li>• Regulations and how they effect the development process</li> <li>• Project management and cross functional teams during the overall process</li> </ul> <p><b>Speaker: Dr Tim Grasel, Ph.D</b>                      Instructor, Biotechnology at Moorpark College, Educational Institution</p> <div align="center">  </div>

**LUNCH BREAK-NET WORKING:  
12:00-1:00**

1:00-3:30	<p><b><u>Implementing a Robust Quality System</u></b>  <b>Speaker:</b> Guest From Industry: TO BE DETERMINED</p> <p><b><u>Vendor and Supplier Qualification Program</u></b></p> <ol style="list-style-type: none"> <li>1. Vendor/Supplier Qualification: Program and monitoring, procedures, components, responsible team, and maintaining a tracking system</li> <li>2. Case Studies</li> </ol> <p><b>Speaker:</b> Guest From Industry; TO BE DETERMINED</p>	1:00-3:30	<p><b><u>Risk Assessment</u></b></p> <ul style="list-style-type: none"> <li>• What is risk assessment</li> <li>• Overview</li> <li>• How to implement an effective procedures and tools</li> <li>• How to predict, quantify and neutralize problems</li> <li>• Discovery, solutions, elimination, success</li> <li>• What are the regulatory requirements</li> </ul> <p><b>Speaker: Zacharias Beckman,</b>                      Senior Technology Executive, RMP/PMP, PGMP, CSQAS, CSCMS</p>
-----------	---	-----------	--

**3:30-4:30: PANEL OPEN QUESTIONS  
ALL SPEAKERS**

**TUESDAY NOV 8**  
**9:00 AM to 4:30 PM**

<b>SEMINAR ROOM NUMBER 1</b> <u>Personal Skill Development</u>		<b>SEMINAR ROOM NUMBER 2</b>	
9:00-11:00	<p><b><u>Avoid Communication Pitfalls That Sabotage Quality &amp; Regulatory Goals</u></b></p> <ul style="list-style-type: none"> <li>• What is communication pitfall?</li> <li>• Reflection &amp; Analysis</li> <li>• The Four Communication Functions</li> <li>• Knowing Which Communication Function to use</li> <li>• Mindfulness in responding to written communication</li> </ul>	9:00-12:00	<p><b><u>Animal Welfare in Biomedical Research</u></b></p> <ul style="list-style-type: none"> <li>• Human care and responsible use of animals in biomedical research through</li> <li>• The animal welfare regulations</li> <li>• Dispel the negative myths about animal research and emphasis the important contributions animals provide for the advancement of human and animal medicine</li> </ul>
11:00-12:00	<p><b>Speaker: Dr. Manijeh Motaghy, PsyD. O.C.,</b> Founder &amp; Senior Consultant, Unite In Vision Consulting.</p>		<p><b>Speaker: Laura Jones,</b> Creative Animal Resource Environments Consultant, President at Sol Del Mar, Inc.</p>


**LUNCH BREAK-NET WORKING**  
**12:00-1:00**

1:00-3:30	<p><b><u>Theory of Mind</u></b></p> <ul style="list-style-type: none"> <li>• The rudimentary explanation of the biological, psychological and emotional development of the brain</li> <li>• Why we do what we do and how we may alter these behavioral pattern.</li> </ul> <p><b><u>Prioritizing your Business Through Focused Awareness</u></b></p> <ul style="list-style-type: none"> <li>• We tend to focus more on our failures than on our successes. You will learn how to highlight your successes as a springboard for making critical decisions in order to efficiently prioritize your business</li> </ul> <p><b>Speaker: Dr Sharr Chardas, Ph.D., C.Ht, M.A., B.A.</b></p>	1:00-4:00	<p><b><u>Auditing Animal facilities</u></b></p> <ul style="list-style-type: none"> <li>• How to select a CRO</li> <li>• What are the key elements to look for during the audit</li> <li>• What are the regulatory and FDA requirement</li> </ul> <p><b><u>Writing an Animal Research Protocol</u></b></p> <ul style="list-style-type: none"> <li>• The detailed process for writing an animal research protocol as specified by the regulations governing the humane care and responsible use of animals in biomedical research</li> <li>• Roles and responsibilities of the Institution, the Institutional Animal Care and Use Committee (IACUC), and the Scientists Design Qualification(DQ)</li> </ul> <p><b>Speaker: Laura Jones,</b> Creative Animal Resource Environments Consultant, President at Sol Del Mar, Inc.</p>
-----------	---	-----------	--




# WEDNESDAY NOV 9

9:00AM to 4:30PM

SEMINAR ROOM NUMBER 1		SEMINAR ROOM NUMBER 2	
9:00-12:00	<p><b><u>US Food and Drug Administration (FDA) Inspections</u></b></p> <ul style="list-style-type: none"><li>• Definition and Principle of Inspections</li><li>• Inspections categories/types</li><li>• FDA "systems" and "risk-based" approaches</li><li>• Preparations plans and activities</li><li>• Elements of an Inspection</li><li>• Meetings</li><li>• Tips: Dos and Don'ts</li><li>• Daily wrap-ups and Inspection outcomes</li><li>• Expected during the Inspection &amp; Post Inspection</li></ul> <p><b>Speakers:</b> <b>Dr Chunchang Fang, Ph.D., Former FDA</b> President, CSPC Dophen Corporation, California, USA</p>	9:00-12:00	<p><b><u>Discussions and Round Tables</u></b></p> 

## LUNCH BREAK-NET WORKING

12:00-1:00

SEMINAR ROOM NUMBER 1		SEMINAR ROOM NUMBER 2	
1:00-4:30	<p><b><u>Current Good Manufacturing Practice (CGMP) Audits. "How to prepare US-FDA (foreign) CGMP inspection"</u></b></p> <ul style="list-style-type: none"><li>• Internal and External Audits</li><li>• Standard Operating Procedures (SOPs)</li><li>• How to set an audit program</li><li>• Checklist, and reports</li><li>• Schedules</li><li>• Confirmations</li><li>• Observations, corrective actions and follow-ups</li></ul> <p><b>Speakers:</b> <b>Dr Chunchang Fang, Ph.D., Former FDA</b> President, CSPC Dophen Corporation, California, USA <b>Jamie Jamshidi, Quality &amp; Regulatory Management,</b> President and The Bio Science Alliance (BSA), Director of Education and Training</p>	1:00-4:30	<p><b><u>Discussions and Round Tables</u></b></p> 



**THURSDAY NOV 10**  
**9:00AM to 12:00PM**

**SEMINAR ROOM NUMBER 1**

9:00-12:00

**Project Management for Quality Organization**

- An overview of project management
- Why project mismanagement - what are the benefits
- Quality organization projects and how manage them
- Set effective procedures and tools
- Select effective team members

**Speaker: Zacharias Beckman,**  
Senior Technology Executive, RMP/PMP, PGMP, CSQAS, CSCMS

**SEMINAR ROOM NUMBER 2**

9:00-12:00

**Contract Facility (CMO/CTO) Management**

- Selecting a Contract Manufacturing Operation Site
- Due diligence, evaluating the Quality systems, evaluating testing and analytical capabilities, manufacturing strategy, audits, on-going monitoring, roles and responsibilities, laboratory controls, and CGMP
- Elements of the Quality Agreement: Write and negotiate Quality Agreements
- Clinical vs. Commercial Requirements
- New Product Introduction/Technology Transfer to CMO sites

**Speaker: Wayne R. Pearl,**  
Technical Expert, Former Amgen Executive/Vice President.

**SEMINAR ROOM NUMBER 3**

9:00-12:00

**What is New in FDA**

- Margaret A. Hamburg, M.D., was confirmed on May 18, 2009 by a unanimous Senate voice vote to become the 21st Commissioner of Food and Drugs. The second woman to be nominated for that demanding position, Dr. Hamburg is exceptionally qualified for her new job by her training and experience as a medical doctor, scientist and public health executive.
- What does her leadership means to industry and FDA?
- What is the FDA New Strategy

**Speaker: Jamie Jamshidi,**  
Quality & Regulatory Management, President and The Bio Science Alliance (BSA), Director of Education and Training

**Thursday, Nov. 10**  
**101 CORRIDOR BIOTECH CELEBRATION EVENT**



**Westlake Hyatt Plaza (4:30PM – 8:00PM)**  
For information: [www.bvsweb.com](http://www.bvsweb.com)

To Register:  
<http://www.bvsweb.com/php/register.php?ShNbr=2215>  
**Exhibition, Keynote Speakers, Networking, and more**





**Zacharias Beckman, Senior Technology Executive, RMP/PMP, PGMP, CSQAS, CSCMS**

Mr. Zacharias J. Beckman has 25 years of experience working with technology-focused clients from the Fortune 500, Government, and private and public sectors, including Xerox®, the Los Angeles Times, the Los Angeles County Sheriff, NASA, and the Department of Defense. Mr. Beckman specializes in Global Project Management and Program Management, successfully addressing the challenges of outsourcing and distributed development for his clients. He is President & CEO of Hyrax International LLC, delivering a comprehensive array of training programs in GPM, Quality Assurance and project management. Hyrax International is your guide to International project management. Today's global businesses need to effectively manage multinational, multicultural teams distributed around the globe. Differences in work ethics, communication, culture, and language present barriers that few companies successfully master. Hyrax International ensures its clients build successful, efficient, multinational teams, keep their vendors on track, and meet the cross-cultural demands of Global business.



**Dr Sharr Chardas, Ph.D., C.Ht, M.A., B.A.**

Dr Chardas has over 30 years of experience in industry working with various organizations and teaching numerous developmental lectures. His career has included such experience as: Foreign Diplomat, Ambassador to the U.S. Government and various Fortune 500 Companies, Key-Note Lecturer, Seminar Leader, Serial Entrepreneur and Global Instructor on topics such as: Governmental & Cultural Training, Psychology, Philosophy of Social Entrepreneurship, Confidence-Building, Biology of Personal Well-Being, Effective Verbal & Non-Verbal Communication Skills, Inter-Personal Relationships, Personal Empowerment, Body Language, Self-Promotion and the Theory of Mind. Dr Chardas has been a global key-note lecturer, seminar leader and instructor, training numerous international audiences, including scientific groups on topics such as: governmental & cultural training, philosophy of social entrepreneurship, confidence-building, biology of personal well-being, effective verbal & non-verbal communication skills, inter-personal relationships, personal empowerment, body language, self-promotion and the theory of mind. He conducts his trainings based on science, and understanding the biology of the brain, how minds works in achieving goals, to become a successful entrepreneur, and build a prosperous company which applies to any industry, specially to start-ups.



**Dr Chunchang Fang, Ph.D., Ex FDA  
President, CSPC Dophen Corporation, California, USA**

Dr Fang has over 22 years of experience in food, and pharmaceutical industries, including generic drugs, OTC drugs, APIs, and Dietary Supplement.

Dr Fang was the Compliance Officer with the Food and Drug Administration (FDA) for seven years. In his position with the FDA, Dr. Fang performed compliance works of imported dietary supplements at San Pedro in Import Operations of the Los Angeles District, conducted inspections of domestic and international of drug firms for API, ANDA (abbreviated new drug application), for verifying CGMP compliance, and recommending regulation actions. Dr. Fang participated in several "Third Party Audit" program, visited private and government laboratories in foreign countries, verified their scientific as well as process capabilities of drug residues testing. He was also worked in CDER conducting research and develop of new analytical methods and lead a group of chemists to perform drug analysis. Dr Fang was instrumental in performing analytical works to check drugs, color additives, pesticides and heavy metals in drugs and food using FAA, FTIR, GC/MSD, GFAAS, HPLC, ICP-MS, UV/Vis. In 2010, Dr Fang was selected as the President of China Shijiazhuang Pharmaceuticals Ltd. Co. (CSPC, parent company). In his position as the President of a Global company, he has been in charge of facilitating IND, NDA, and ANDA applications in the United States. He has managed generic drugs, OTC drugs, APIs, and Dietary Supplement Ingredients sales in the USA. He supports CSPC regulatory compliance activities in China, sources New Chemical Entity drug(s) from the USA for CSPC to develop for the China market and obtains support from the USA for CSPC's biosimilar development works.



**Dr Tim Grasel, Ph.D, Instructor, Biotechnology at Moorpark College, Educational Institution**

Currently teaching courses in the areas of Plant Design and Environmental Monitoring, Quality and Validation, Business and Government Regulations, Cell Culture and Fermentation, and Purification. Director, Technical Services Baxter BioScience, Director, Research Operations, Amgen, Inc. Manufacturing Plant Manager (Bulk and Filling/Packaging), Amgen, Inc., Associate Director, Drug Product Process Development, Amgen, Inc., Specialties: Drug product processes and manufacturing, manufacturing operations and leadership, CMC team leadership, biotechnology education.



**Dr. Michael R. Hamrell, Ph.D, Ex-FDA, President, MORIAH Consultants**

*Dr. Michael R. Hamrell, RAC, FRAPS* is the President of MORIAH Consultants, a Regulatory Affairs and Clinical Research consulting firm located near Los Angeles, CA. Dr. Hamrell has a unique background with over 25 years of experience in regulatory affairs, clinical research and drug development with academia, the FDA, NIH and in the Pharmaceutical industry. He also worked for over 5 years at the FDA and 3 years at the NIH in the Division of AIDS, coordinating the development of drugs, biologics and vaccine products for AIDS, oncology and anti-infectives. Dr. Hamrell has dealt with Regulatory Authorities in over 40 countries and supervised all aspects of product development and approval. Dr. Hamrell spent a number of years doing basic research, first as a Research Fellow at Duke University and later as an Assistant Professor of Pharmacology at the McGill University Cancer Center. He has a Ph.D. degree in Pharmacology from the University of Southern California and a B.S. in Biochemistry from the University of California, Los Angeles. Dr. Hamrell holds an appointment as Adjunct Professor of Molecular Pharmacology and Toxicology at the University of Southern California School of Pharmacy, as Adjunct Associate Professor at the Massachusetts College of Pharmacy & Health Sciences, as an Instructor at the University of North Carolina Wilmington, School of Nursing and as Adjunct Assistant Professor at the George Washington University School of Medicine Clinical Research Program. Dr. Hamrell has received numerous awards for his research, teaching and professional work and is recognized in Who's Who. He has published numerous papers in pharmacology, regulatory affairs, product development, clinical research, computers and information systems. Dr. Hamrell has served on the Editorial Board of Regulatory Affairs FOCUS and Applied Clinical Trials. He currently serves on the Editorial Board of Clinical Trials Advisor and is Editor-in-Chief of the Drug Information Journal and former Editor-in-Chief of the DIA Forum.



**Jamie Jamshidi, The Bio Science Alliance (BSA), Director of Education and Training /Quality & Regulatory Management, President**

Jamie Jamshidi has over 24 years of industry experience, including small molecules and large molecule biologics. She retired from Amgen, Inc., in 2007 after 17 years of service with the company. Some of Jamie's major accomplishments include launching Amgen, Inc.'s first two commercial products, Epogen® and Neupogen®. Jamie was a key team member in the start-up of numerous new Amgen CGMP facilities in the U.S., Puerto Rico and Europe. She helped establish a number of new departments at Amgen, including Contract Manufacturing and Small Molecule Quality Assurance. She was also instrumental in helping Amgen obtain approval of their first small molecule product, Sensipar®. Jamie was the key Amgen Quality Assurance representative at several FDA and other regulatory inspections at contract manufacturing sites. She has extensive knowledge and expertise in the areas of product regulations, Quality Assurance, Manufacturing, Validation, Analytical Labs, Regulatory Submissions, Regulatory Inspections (PAI), Project Management, Managing Contract Manufacturing facilities, Technology Transfer and Team Leadership. In March 2007 Jamie started PQC Consulting, Inc., a consulting firm providing expert technical services, solutions, and training to pharmaceutical and biopharmaceutical companies worldwide. The firm's name converted to Quality and Regulatory Management in 2011. Jamie has a broad understanding of the entire drug development process for both large molecule proteins and small molecules. She has extensive knowledge of U.S. FDA Current Good Manufacturing Practices (CGMP), Current Good Laboratory Practices (CGLP) and Current Good Clinical Practices (CGCP), European and Japanese drug manufacturing regulations, ICH guidelines, and Qualified Person (QP) requirements under EU Directives, and World Health Organization (WHO) regulations. Jamie also has extensive experience in the development and commercialization of pharmaceuticals and biotechnology at all process stages, including Drug Substance (API), Drug Product, Packaging, and Labeling. Jamie has given numerous lectures and talks in the areas of Quality and Regulatory in several colleges, universities and conferences globally. In January 2011 she was selected as the Director of Training and Education for the Bio Science Alliance. She is well known in biopharmaceutical industry for her passion and respect for laws and regulations in ensuring product quality.



**Laura Jones, Creative Animal Resource Environments Consultant, President at Sol Del Mar, Inc.**

Animal Science Specialist with expertise in innovative planning, programming, conceptual design, construction, process improvement. An Animal Scientist who has dedicated a 22 year career to science by providing excellent and humane animal care through leadership and training. Her experiences in Laboratory Animal Science have ranged from early discovery research through pre-clinical drug development. She is a Certified Manager of Animal Resources (CMAR) with a vast range of facility and program knowledge acquired from diverse environments within Amgen, a Fortune 500 Biotech Company, and UCSF, a world renowned University system. Ms. Jones has been a member of a Global Leadership Team where she facilitated the integration of staff and resources through corporate mergers by influencing global harmonization across North America through strategic planning to achieve business and program alignment. She upheld regulatory compliance with Federal, State and local government agencies for 15 years within her organizations which ensured 2 consecutive accreditation renewals with AAALAC International. She has served on an IACUC, Chaired Safety and SOP committees, developed and implemented a Disaster Business Recovery Plan, enforced regulatory compliance and led a Training program for Investigators, Staff and Contractors. In 2008 Ms. Jones founded Sol Del Mar, Inc., a consulting firm dedicated to serving animals and the scientific community by providing animal welfare oversight for the planning, design and process improvement of environmentally enhanced animal facilities. The heart of the company's business is to promote teaching, learning and team work by building alliances with industry leaders for the advancement of science and animal care.



**Dr. Manijeh Motaghy, PsyD. O.C., Founder & Senior Consultant at Mindful Business Institute.**

Dr. Motaghy is a Management Consultant, Professional Trainer, and Speaker. She is the Founder of Mindful Business Institute and the Co-founder of Mindful Valley. She is the author of Leaders & Strategies in COMAND™ Model. A model that shapes healthy wealthy organizations, successful strategies and compassionate leaders. Her approach embodies Organizational Health and Wealth Optimization. Dr. Motaghy's passion for enhancing organizational success through humane practices lead her to study and practice Mindfulness Meditation and developed mindful strategies under the Umbrella of "The Mindful Organization". In order to enhance professional capabilities, Manijeh developed and conducted workshops under the "Cycle of Excellence". She formed Mindful Business Institute with an aim to provide business consulting and training programs that help Optimize Success and Well-being for organizations, teams and individuals.

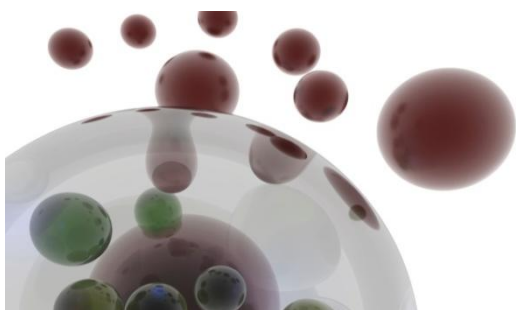


**Wayne R. Pearl, Technical Expert, Former Amgen Executive/Vice President.**

Wayne R. Pearl, a former Vice President at Amgen, Inc., and a veteran of 34 years in protein chemistry and biotechnology, was a key contributor to Amgen's growth and success during its earliest stages, and was directly responsible for managing functions that established Amgen as the world's premier biotechnology company. Wayne's experience in process development, manufacturing, quality, and biotechnology experience has few equals. He was directly responsible for many of Amgen's successes. Wayne is a true biotech pioneer, having helped to start up functions which became key driving forces for Amgen's early success in developing protein therapeutics. In leading many other functions throughout the company, Wyne's efforts helped Amgen to sustain its excellence in both clinical product development and commercial activities. Wayne's career began at the University of Pennsylvania Medical School, working on the isolation and characterization of enzymes from neuroblastoma. He later joined Pittman-Moore, Inc., in developing diagnostic kits, vaccines, and therapeutic products. Wayne has 22-year career at Amgen included the establishment of the Clinical Manufacturing group, the successful startup and management of two drug substance facilities (including production of the blockbuster product Neupogen®), development and leadership of Amgen's international Quality Assurance organization, directing the European logistics center, and vice presidency positions in logistics, manufacturing, and clinical operations.

# BSA Academy Opening November 7<sup>th</sup> through November 10<sup>th</sup>

## REGISTRATION



Please print the following:

LAST NAME \_\_\_\_\_

FIRST NAME \_\_\_\_\_ M.I. \_\_\_\_\_

COMPANY \_\_\_\_\_

ADDRESS \_\_\_\_\_

CITY \_\_\_\_\_ STATE \_\_\_\_\_

ZIP \_\_\_\_\_ PHONE # \_\_\_\_\_

EMAIL \_\_\_\_\_

Class Title	Dates	Time	Cost
			TOTAL

### PAYMENT

Check Enclosed (Payable to BSA)

Half Day = \$185  All Day = \$375  Full conference purchase: \$1000

Government, Health Authority and Academic receive 50% cut-rate

Group sign-up (2 or more) receive 30% reduced registration fees

### REGISTRATION INFORMATION

**Group and Special Discount:** Contact BSA directly to inquire about group discount of 2 or more members from the same company attending. Special discounts are also available for government and academia. Contact BSA at 1-805-479-5169 **Payment Policy:** Payment is due in full at the time of registration.

**Cancellation/Substitution:** Cancellation must be submitted in writing (via mail or fax) up to 10 days prior to start of event and subject to a \$75 processing fee. No refund will be given for cancellation within 10 days of the start of event. Registrant may substitute with any other member of the same company or organization at any time provided that prior written notification is given.

**Terms:** BSA reserves the right to postpone or cancel the event for any reason. Registrant shall be provided full refund in the event BSA cancels the course.

### WAYS TO REGISTER

CALL 805-479-5169 or Fax: 805-418-3101

MAIL registration form and check:  
BSA, 2801 Townsgate Rd #200, Westlake Village, CA 91361

EMAIL registration form: [jamie@biosciencealliance.org](mailto:jamie@biosciencealliance.org)

GO to our website and register: [www.biosciencealliance.org](http://www.biosciencealliance.org)