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EXECUTIVE COMMITTEE

Sumit Sen, Ph.D.

President

U.S. FDA

(949) 608-2927

E-Mail: Sumit.Sen@fda.hhs.gov

Yan-Bo Yang, Ph.D.

B. Braun Medical

Past-President

(949) 660-2405

E-Mail: yan-bo.yang@bbraun.com

Gina Zhang, Ph.D.

Medtronic Diabetes

Treasurer

(818) 576-5490

E-Mail: gina.zhang@medtronic.com

Richard E. Sullivan, Ph.D.

BioScreen Testing Services

Secretary

(310) 214-0043

E-Mail: Rsullivan@bioscreen.com

Members-at-Large

Esther Gamallo-Herrera

U.S. FDA

(949) 608-2923

E-Mail: esther.gamallo-herrera@fda.hhs.gov

Assad Kazeminy, Ph.D.

Irvine Pharmaceutical Services

(949) 951-4425

E-Mail:

Assad.Kazeminy@IrvinePharma.com

Tiffany Tran,

B. Braun Medical,

(949) 660-2414

E-Mail: tiffany.tran@bbraun.com

M. L. Jane Weitzel,

Watson Pharmaceuticals,

(951) 493-4134

E-Mail: mljweitzel@watsonpharm.com

Message from the President AOAC - Pacific Southwest Southern California Section

Sumit Sen, Ph.D.

As the year 2008 winds down, I have been reflecting on the achievements of the AOAC Southern California Section (SCS). It has indeed been a very productive year for us. On April 24th and 25th, 2008, AOAC SCS jointly organized with the USP Western Compendial Discussion Group (WCDG) two-day meeting as part of our ongoing Seminar Series "Critical Regulatory and Compliance Issues with the US FDA in the 21st Century". This two-day conference based on Impurities / Extractables & Leachables in Pharmaceuticals & Medical Devices was a resounding success which included presentation topics, namely, "Impurities and the USP Flexible Monograph", "Systematic Approach to Evaluation of Extractables & Leachables in Support of Container & Closure used in Pharmaceutical Product", "Impurities in Parenteral Drug Product: Strategies for Development and Case Studies", "Current Drug Issues: FDA's Office of Regulatory Affairs", "Evolution of Extractable / Leachable Regulatory Requirements", "Investigation and Characterization of Semi-Permeable Container-Closure Related Leachables", and "Accelerated Solvent Extraction (ASE) Instrumentation and Methods for Medical Devices and Plastics". Distinguished speakers from the US FDA, from the Pharmaceutical Industry, and from the Instrument Manufacturers presented at this meeting which was very well attended. I want take this opportunity to sincerely thank all the speakers for taking the time out of their busy schedules to make their thought-provoking presentations and making well-informed comments during the open forum session. I also want to genuinely thank the attendees for showing up for this meeting and making it such a big success. I want to

convey my sincere thanks to the meeting sponsors too for their support. I would also like to thank the entire Executive Committee of AOAC SCS and WCDG for their tireless efforts in organizing this conference.

Our next meeting was a "Discussion Day" on Dietary Supplements in conjunction with WCDG. The focus of this conference was to provide a platform for representatives from independent & in-house testing labs and the dietary supplements manufacturers, FDA officials, and participants from academia who are involved in the dietary supplement analysis to discuss the analytical challenges faced in meeting the new GMP regulations with emphasis on issues specific to the testing labs. We were very fortunate to have knowledgeable speakers from the US FDA, from the Dietary Supplements Industry & Testing Labs, and from Consultant Firms. Presentation topics included "How Good Lab Management System helps to address Critical Dietary Supplements Industry Issues", "Analysis of Dietary Supplements for Toxic Heavy Metals - Some Challenges and Solutions", "How Other Industries have Addressed the Challenges Dietary Supplement Industries are Facing", "Challenges Of A Lab Supporting The Dietary Supplement Industry And The Actions They Are Taking To Address These Issues", and "Industry Concerns and Challenges to cGMP Compliance". Once again, I would like to sincerely thank all the speakers, the participants, and the sponsors for making this meeting a grand success. We had an extremely lively open forum session where critical issues were discussed and attendees from the regulatory industry, the regulated dietary supplements industry, and academia participated and shared their views & experiences.

We are wrapping up our activities in 2008 by organizing another WCDG - AOAC SCS Meeting to be held on December 4 & 5, 2008, at the FDA@Irvine facility. We put a lot of effort in bringing to you highly



experienced and knowledgeable speakers for this two-day meeting as part of our ongoing Seminar Series "Critical Regulatory and Compliance Issues with the US FDA in the 21st Century". The general theme of this conference is ASSIST FIRMS IN UNDERSTANDING HOW TO PREPARE BETTER SUBMISSION PACKAGES TO FDA FOR THEIR PRODUCTS, HOW TO PREPARE BETTER FOR UPCOMING FDA INSPECTION, AND HOW TO RESPOND BETTER TO DEFICIENCIES OR WARNING LETTERS. A genuine note of thanks goes out to the speakers for accepting to present at this meeting. I sincerely urge all of you to attend this meeting and take advantage of this rare opportunity of hearing from experts from US FDA, Industry, and established Consultancy Firms across the country. Thank you for your continued interest and your support for our meetings and hope to see you on Dec 4th & 5th.

Sincere Regards!

Agenda

Critical Regulatory and Compliance Issues with the US FDA in the 21st Century

DAY 1 - Thursday, Dec 4, 2008

7:00 A.M. Registration/Continental Breakfast

8:30 A.M. Welcome Remarks

William Martin, Ph.D., *Laboratory Director*, PRL-SW, US FDA

Alonza Cruse, M.S., *Director*, Los Angeles District, US FDA

Sumit Sen, Ph.D., *Chemist & Foreign Inspection Cadre Member*, US FDA PRL-SW, AOAC SCS Meeting Host

Assad Kazeminy, *President*, Irvine Pharmaceutical Services, Irvine, CA, US WCDG

9:00 A.M. USP <467> Residual Solvents, USP Glycerin, and other USP Hot Topics

Speaker: Larry Ouderkirk., *Director*, Compendial Operations Staff, Standards and Technology Team, CDER/OPS-IO, US FDA, Silver Spring, MD

9:40 A.M. Elements of Effective FDA-483 Response Letters: What Works (and What Doesn't)

Speaker: David L. Chesney, *Vice-President*, Strategic Compliance Services, PAREXEL Consulting, Lowell, MA

10:20 A.M. Refreshment Break

10:40 A.M. Implementation of the Residual Solvents Requirement: Industry Update

Speaker: Susan Schniepp, *President*, Schniepp and Associates, LLC, Bosborough, MA

11:20 A.M. Lessons to Be Learned from Recent Scandals, FDA Cannot Do Everything

Speaker: Steven S. Kuwahara, Ph.D., *Principal Consultant*, GXP BioTechnology LLC, Sunnyvale, CA

12:00 P.M. Sponsor Presentations

12:30 P.M. Lunch (Provided)

1:30 P.M. Panel Discussion Session

Moderator: Sumit Sen, Ph.D.

Participants: Larry Ouderkirk, David Chesney, Sue Schniepp, and Steve Kuwahara

3:00 P.M. Adjourn

DAY 2 - Friday, Dec 5, 2008

7:00 A.M. Registration/Continental Breakfast

8:30 A.M. How FDA Views Individual Responsibility: The Lesser Known Aspect of an FDA Inspection

Speaker: David L. Chesney, *Vice-President*, Strategic Compliance Services, PAREXEL Consulting, Lowell, MA

9:10 A.M. Winning Inspections

Speaker: Laurel S. Hacche, Ph.D., *Director*, Worldwide Quality Assurance, Allergan, Inc., Irvine, CA

9:50 A.M. Refreshment Break

10:10 A.M. FDA Lessons Learned from a CEO's Perspective

Speaker: Patrick Walsh, *Biotechnology Industry Executive, Managing Director*, Portola Group, Laguna Beach, CA

10:50 A.M. Key Compliance Concerns Surrounding Quality Systems for the Pharmaceutical and Biotech Industry

Speaker: Donald Harrigan, *Senior QA/RA Associate*, Jeff Yuan & Associates, Orange, CA

11:30 A.M. Sponsor Presentations

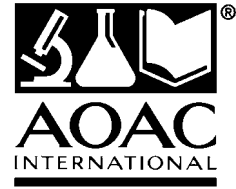
12:00 P.M. Lunch (Provided)

1:00 P.M. Panel Discussion Session

Moderator: Sumit Sen, Ph.D.

Participants: David Chesney, Laurel Hacche, Patrick Walsh, and Donald Harrigan

2:30 P.M. Adjourn



Please note:

Pre-registration is REQUIRED. NO REGISTRATIONS will be taken at the event. FDA Security requires at least 24 hours notice. Registration fees paid by mail with a postmark on or before November 28 are: (payable by cash or check only) **Current students** - \$20 for 2 days, \$10 for one day, [first 5 students to register receive free registration]; **FDA employees** - free; **AOAC members** - \$250 for 2 days, \$150 for one day; **Non-members** -\$300 for 2 days and \$200 for one day.

Make checks payable to AOAC-Southern California Section. Yearly dues of \$20 for AOAC local section membership can also be paid at this time.

Address Information for Meeting Registration

The e-mail address for the Southern California Section Treasurer, Dr. Gina Zhang, is gina.zhang@medtronic.com Please send your reservation for the December 2008 AOAC Meeting and address all further treasury business to Gina at this address. You can also mail your reservation to Dr. Gina Zhang, AOAC Southern California Section Treasurer, 4397 Park Monte Nord, Calabasas, CA 91302.

General Directions to the FDA

From the north, take the 405 freeway to Tollroad CA- 73 heading south. Exit at Jamboree. Turn left on Jamboree, then right onto Fairchild. From the south, take the 405 or 5 north to CA-73. Exit at Bison, turning left onto Bison. Turn right on MacArthur continuing on to Fairchild and turn right. Turn right into FDA entrance at the guard house. Identify yourself to the guard as a participant in the AOAC Meeting. You

will need to pass through security once inside the building. As at the airport, knives, scissors etc can be confiscated.

Sponsors

The AOAC SCS would like to thank the following company whose generous support for this meeting is gratefully appreciated:

B. Braun Medical Inc.

Abstracts of Presentations

USP <467> Residual Solvents, USP Glycerin, and other USP Hot Topics

Larry Ouderkirk

This presentation will focus on the latest developments on FDA's implementation of USP <467> *Residual Solvents*, including comments received to the CDER draft guidance for industry "Residual Solvents in Drug Products Marketed in the United States." Recent revisions to the tests and limits for diethylene glycol in the USP *Glycerin* monograph will also be discussed, as well as other USP topics of vital interest to industry and FDA.

Winning Inspections

Laurel S. Hacche, Ph.D.

This presentation shall include a review of key points to consider when conducting an inspection of a pharmaceutical manufacturing facility. Inspection preparation, scheduling, agenda selection and determination of audit type will be discussed. A review of points to consider in relation to audit conduct will be provided including: the opening meeting, the plant tour, review

of documentation, and audit close out. Finally, expectations for audit responses and verification of corrective action closure will be communicated.

Biographies of Speakers

Larry A. Ouderkirk has worked in the FDA for over three decades. Mr. Ouderkirk began his FDA career as an analytical microbiologist in the FDA National Center for Antibiotics Analysis in Washington, DC. From 1982-1997, he worked as a biopharmaceutics reviewer in the Office of Generic Drugs (OGD) and developed a specialty in the review of dissolution studies, serving also on the USP-FDA Joint Committee on Bioequivalence.

In late 1997, Mr. Ouderkirk accepted a position in the CDER Compendial Operations Staff (COS). The COS is a main communications link between CDER and USP. In 2004, Mr. Ouderkirk assumed the Directorship of the COS. Currently, he serves as CDER's representative to many USP working groups, co-chairs the OPS Compendial Task Group, and coordinates many activities linking CDER with USP and other standards-setting organizations.

Mr. David L Chesney, Vice President, Strategic Compliance Services for PAREXEL Consulting, works with PAREXEL clients in the pharmaceutical, biologics and medical device industries worldwide. He also directs PAREXEL Consulting's Strategic Compliance Services group. Prior to joining PAREXEL Consulting, he served 23 years with the FDA. Between 1972 and 1988 Mr. Chesney advanced from Investigator to Supervisory Investigator and Director,



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Investigations Branch, working in the Boston, Seattle and Philadelphia District Offices. In 1991, he was appointed the District Director, San Francisco District Office, where he served until joining PAREXEL (then known as KMI) in 1995.

His expertise includes GMP, GCP, GLP, QSR and MDR compliance consulting and auditing. Mr. Chesney is highly experienced in the FDA enforcement process and specializes in helping clients avoid or mitigate enforcement sanctions such as Warning Letters, Consent Decrees and other similar situations. He has extensive experience providing adjunct services to client legal counsel, including FDA communication strategies, conduct of internal investigations, due diligence assessments and other privileged matters. He has directed PAREXEL services in several enforcement matters for which PAREXEL is named as an FDA-mandated Expert Consultant.

Mr. Chesney frequently conducts briefing and training sessions for managers and executives in compliance topics and FDA inspection readiness. He is an experienced public speaker and has published articles in several industry publications. Mr. Chesney received his BA in Biology from California State University, Northridge. He subsequently completed postgraduate study in biology there and at California State University, San Diego, and recently received a Certificate in Health Care Compliance from Seton Hall University School of Law. He is an active member of the Parenteral Drug Association, the Food and Drug Law Institute, and the Regulatory Affairs Professionals Society.

Susan J. Schniepp has over 28 years of experience in quality assurance for both the food and pharmaceutical industries. She has a degree in microbiology from Northern Illinois University and began

her career in 1980 as a food microbiologist working for Quaker Oats and M&M/Mars, where she first used the USP. Since 1984 she has worked in the pharmaceutical industry as a quality professional for Searle Pharmaceuticals, Abbott Laboratories and Hospira, respectively. In 2007 she formed her own consulting firm specializing in Training, Quality Systems, Technical Writing and Standards Interpretations. During her career in industry she had responsibilities for complaints, labeling, validation, documentation and other quality systems with a primary focus on establishing communications with compendial authorities.

Currently, Sue is Chair of USP's Monograph Development – Psychiatric and Psychoactives Expert Committee for the 2005-2010 revision cycle and served on the Council of Experts Executive Committee from 2005-2007. In addition to her USP activities, Sue has been involved with the Generic Pharmaceutical Association and founded both the Midwest and Western Compendial Discussion Groups. Sue is also active in Parenteral Drug Association (PDA) where she has presented at a number of PDA Meetings and participated on a number of Committees including the Joint Regulatory Conference Steering Committee, RAQC, Program Advisory Board, Technical Books Advisory Board, and The Membership Committee. Sue is author of a number of articles and was the Recipient of PDA's 2007 Distinguished Author Award for her book titled *Understanding the United States Pharmacopeia and the National Formulary: Demystifying the Standards-Setting Process*. In 2008 she received the PDA Distinguished Service Award. In November 2007, Sue was the first woman appointed to the Editorial Advisory Board for *Pharmaceutical Technology Magazine*.

Originally from Hawaii, **Steven S. Kuwahara, Ph.D.**, holds degrees in Biochemistry from Cornell and the University of Wisconsin. Starting as an Assistant Professor of Chemistry, he began his industrial career in the Division of Biologic Products at the Michigan Department of Public Health (now BioPort Corp.), where he became the head of Quality Control. Here he developed expertise in the testing of blood derivatives, viral and bacterial vaccines. He moved to the Hyland division of Baxter Biotech where he was in charge of assay development and quality control. He later became responsible for quality systems for a biological device. After a short period with a contract testing laboratory and another blood fractionator, he became the director of quality control with a gene and cell therapy company. In recent years he has worked as the director of assay validations for a large contract testing laboratory and as a GMP consultant to a start-up cell therapy company. His last position was as the Director of Quality Control and Assay Development with a virtual company. He is currently the head of his company, GXP BioTehnology LLC.

Dr. Kuwahara is an experienced analytical biochemist who has applied his academic knowledge to quality control in the pharmaceutical industry. He work has also dealt with all aspects of GMP and GLP in relation to biopharmaceuticals. He has worked with small molecules, proteins, cells, gene therapy vectors and nutritional supplements..

Dr. Kuwahara has written several papers and book chapters and serves on the editorial advisory boards of BioPharm, BioQuality, and the Journal of GXP Compliance. He and a colleague have recently published translations of the Chinese GMPs and the Inspection Checklist for the Chinese GMP Certificates. He has held certifications as a CQA, CQT, and CQE from the American Society of Quality and was certified (RAC) by the



Regulatory Affairs Professionals Society.

Laurel S. Hacche, Ph.D., is a Director of Worldwide Quality Assurance for Allergan, Inc. She currently has QA oversight for the corporate CAPA system, annual product reviews, government agency communication records, third party manufacturers, the global stability program, complaint management, and R&D technology transfer. In addition to the above activities, she serves as the lead corporate QA liaison for FDA and alternate regulatory agencies. Dr. Hacche has been with Allergan, Inc. for 19 years. Her career with Allergan, Inc. began in 1989 when she was first employed as a chemist to develop and validate test methods for products under development.

Prior to Dr. Hacche's employment at Allergan, Inc., she served as a Postdoctoral Researcher in the Dept. of Biological Chemistry at the California College of Medicine at U.C. Irvine. She has held an Associate Faculty position at the Math, Science, and Engineering Department at Saddleback College and served as an Assistant Professor at the Joint Science Department for The Claremont Colleges. Dr. Hacche holds a Ph.D. in Physical Polymer Chemistry from U.C. Irvine and an A.B. in Chemistry from Occidental College.

Patrick Walsh joined Portola Group in 2008 as Managing Director and will also lead the growth and expansion of Portola's Southern California business opportunities. The Portola group works on behalf of business owners and entrepreneurs, functioning as the clients "Personal CEO" in support of their strategic business needs. The Portola Groups portfolio of companies serves as financial architects for wealth

management by providing business leadership alongside financial expertise in a straightforward advisory role.

Pat brings an extensive global business and management background in the pharmaceutical industry. He is an experienced CEO with documented accomplishments in leading high achieving management teams, private equity and public market fundraising, and managing high growth business opportunities. He has extensive management experience in running successful ventures, has managed corporations with over 2,000 employees on a global scale, and has worked with many successful entrepreneurs over the course of his 28 years of management experience. His background includes expertise in biotechnology contract manufacturing, business development, and managing pharmaceutical manufacturing and R&D facilities on a global scale.

Prior to Portola, Pat's most recent venture involved leading the successful asset sale of Kadmus Pharmaceutical's to Organon BioSciences in 2007. The transaction was valued at over \$125 million and Kadmus was at an "A" round valuation at the time of the sale. Pat was the company's President and CEO and was a member of the board of directors. His previous work experience includes serving for 4 years as CEO of a venture-backed company and over 4 years as President and COO of Gensia Sicor, a publicly traded specialty pharmaceutical company that eventually sold to Teva Pharma for \$3.4 billion. Prior to Gensia Sicor, Pat spent 10 years at Fujisawa USA leading the U.S. and international pharmaceutical businesses.

Pat has served as a board of director for numerous public and private healthcare companies over the course of his career. He currently serves as a Director for three biotechnology companies, including the role as Non-Executive Chairman of the Board, and is a member of the UC-Irvine Chief Executive Roundtable organization.

Donald Harrigan's Areas of Expertise includes Regulatory Affairs – NDA, ANDA, 505(b) (2) and 510K development, and Quality Systems - Aseptic Processing, Auditing, FDA Regulation, Laboratory, Medical Devices, Pharmaceuticals, Quality Assurance, Training and Validation. His work experience spans over several years including his position as Senior QA/RA Associate with Jeff Yuen and Associates, Inc., in Orange, CA, from 2005 to present. He worked as a Consultant in Dabur Oncology in New Delhi, India, from 2004 to 2005, where he provided full time support and coordination from a R&D, Quality and Regulatory perspective to assist Dabur in the entry to the US Pharmaceutical market, was a Member of the Management Committee for the strategic alliance Dabur formed with Hospira (Abbott Laboratories), was responsible for providing direction and oversight for upgrading Dabur's aseptic manufacturing facility located at Borden, UK to assure it meets or exceeds FDA cGMP requirements, he developed and implemented a risk analysis program based on FDA Quality Systems program to evaluate the existing level of compliance at the Borden manufacturing facility, he developed programs to support the development of approximately 15 ANDA's over the next two years and assure the program support both US and European filings, he developed strategy based on pre-clinical studies to support filling of a nano-particle drug delivery system used for various drugs as a 505(b) (2) "paper NDA" application, he provided regulatory support for the pre-clinical and clinical design for two novel oncolytics, and he coordinated patent strategy development for the ANDA products including the development of strategy for two Paragraph IV patent challenges. He also worked for Lachman Consultants, Inc. in Westbury, NY, from 2001 to 2004, where he provided high level regulatory and quality consulting including interim direction of Quality Operations for a major generic pharmaceutical company, he provided

strategic oversight of the remediation and certification process for response to a consent decree for a major pharmaceutical company reporting directly to the company CEO, he coordinated for the past three years, the drug development process for a novel oncolytic including pre-clinical and clinical design for a small biotechnology company. The drug is now entering phase one trials as an orphan drug with FDA granting the product an expedited review. In this firm he also provided expertise in auditing and assessing biological facilities including fermentation and cell culture, and he earned extensive experience in auditing and review API manufacturing facilities. In addition, Donald Harrigan was a Self Employed Consultant in Chicago, IL, from 2000 to 2001, worked for Jordan Pharmaceuticals, Inc., in Elk Grove Village, IL, as Vice President of Scientific Affairs, from 1998 to 2000. He also worked for Gensia Laboratories, Ltd./Kendall McGaw Pharmaceuticals, in Irvine, CA, as the Director, Regulatory Affairs/Compliance, from 1987-1997, and he worked for Invenex (Division of Life Technologies) / LyphoMed, Inc., in Grand Island, NY, as the Director, Regulatory Compliance from 1983 to 1987. From 1977 to 1983, he worked at the Deaconess Hospital, in Buffalo, NY as a Pharmacist, where he developed a clinical pharmacokinetic dosing service and worked as a clinical consultant and managed daily activities within the pharmacy. Donald Harrigan received his MS degree in Chemical Engineering from the State University of New York, Buffalo, New York, in 1986, his BS Pharmaceutics degree from the State University of New York, Buffalo, New York, in 1983, and his BS Pharmacy degree from the State University of New York, Buffalo, New York, in 1976.