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2016 Division Officers

Chair: Wenzhe Li, Ph.D., DABCC
 Chair-Elect: Judith Finlay, Ph.D.
 Secretary: Stephen Hess
 Treasurer: Peter Harrsch, Ph.D.
 Board Member: YI-Shao Liu, Ph.D.
 Past Chair: Peng Yin, MD, Ph.D.

Division Goals

- To provide a forum for AACC members to meet, identify common interests and concerns, and develop programs that assist them in the workplace. Although the focus of the Division is on issues relevant to industry, or issues from the industry perspective, membership in the Division is open to any member of the association.
- To identify and develop synergies between industry and clinical laboratory members which contribute to the health care system and enhance patient care.

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Message from Division Chair -Wenzhe Li, PhD, DABCC



Welcome, new board members along with all members of the Industry Division! Please encourage your colleagues to join the Industry Division if they have not, and to actively participate if they already are members.

Since its conception, the new board has held meetings as a series of monthly conferences via Go-To-Meeting, typically on a Tuesday night EST 9:00pm - 10:00pm, which is the single time slot that works for us all: Yin Peng and Yi-shao from Asia, Judith and Stephen from California, Peter and I from Philly. The topics touched on membership drives, AACC artery, selecting the winner for the Abstracts, and conducting an effective Monday workshop for 2016 AACC annual meeting in Philadelphia. We would use up the whole hour. We also invited members at large to audit and contribute to our meeting per their requests, thanks to Narayan K and Tom H for their interest and effort.

I would like to share one anecdote for your entertainment and learning. As we attempted to select the receivers for the Industry Division Dunka Award, no one could recall what the award was for. We discussed whether the award should be focused on leaders in commercialization of innovative diagnostic tests. The drafted criteria were: i) To encourage leadership or contribution for commercialization of new tests or methodology; ii) Caters to small companies (<200 employees) and academic intuitions; iii) Open to international nominations and contenders. We were concerned that the award was too small to practically engage a fair assessment by the division.

In the end we understood that the award was for services to Industry Division. In 2015 we initiated the Exhibit Walk. The idea was to help vendors to promote the effectiveness of their exhibits by providing guidance to new visitors for the numerous exhibit booths. Yi-shao took it upon himself to lead and oversee the Exhibit WALK 2015 and it was a great success! We would like to continue it in 2016. Details are being negotiated with AACC HQ. Yi-shao's spirit is inspiring; I nominated him for the Dunka award.

As you can see, though we are experienced industrial professional and leaders, we fumble to get our duties fulfilled. I have recently read the book "The Road Less Traveled" and have taken notes for myself, "Problems are the cutting edge that distinguishes between success and failure. Problems call forth our courage and our wisdom; indeed, they create our courage and our wisdom. It is only because of problems that we grow mentally and spiritually."

--Continued from Page 1, Message from the Division Chair Wenzhe Li --

Enlightenment comes to me as I continue working on the Newsletters, this is the message that I want to pass to you, “In order to solve a worthy problem, one needs to embrace the discomfort long enough to analyze it. It is that willingly tolerance and space in mind that will ultimately lead to the solution.”

---THE END---

Industry Division Awardees

Best Abstract Award

This award is made to the author(s) of an abstract for the AACC national meeting which is deemed to present a significant contribution to the IVD industry in one of the following areas: management, regulatory affairs, or improved patient care through a new or improved medical device. The selection is done through a vote of the Division’s officers and Nominating Committee members.

This year's Abstract Award Goes To:

B-053 Simultaneous detection of zika, chikungunya and dengue viruses in EDTA-plasma samples by RT-qPCR: If their vector is versatile their detection assays also should be

Author: Dr.Gustavo Barra, PhD, Laboratório Sabin, BRASILIA Brazil

Past Awards: \$750

- 2015: John Mills, Mayo Clinic, Rochester, MN
- 2014: Yi-Shao Liu, PhD, Taiwan Semiconductor Manufacturing Co., Taiwan
- 2013: Xiaolei Xie, PhD
- 2012: Mari DeMarco, PhD, Washington University School of Medicine, St. Louis, MI
- 2011: Yu-Jeong Kim, PhD Deajeon, Korea
- 2010: Alison Woodworth, PhD, Vanderbilt University School of Medicine, Nashville, TN
- 2009: Yusheng Zhu, PhD, Medical University of South Carolina, Charleston, SC
- 2008: Yusheng Zhu, PhD, Medical University of South Carolina, Charleston, SC
- 2007: Kenneth Pass, NYS Department of Health, Albany, NY
- 2006: John Ellison, LifeScan, Inc., Milpitas, CA
- 2005: Saeed Jortani, PhD, University of Louisville, KY

Louis J. Dunka, Jr. Award

The Louis J. Dunka, Jr. Memorial Service Award is presented annually by the AACC Industry Division to an individual for outstanding accomplishment that is evidenced by the initiation or support of a single event or continuous effort that has served the AACC Industry Division Membership and/or the IVD industry.

This year's Dunka Award Goes To:

Dr. Yi-Shao Liu, For his outstanding effort and contribution to Exhibit Walk of 2015

Past Awards: \$750

- 2014: David Armbruster, PhD, Abbott, Abbott, IL
- 2011: James Pierson-Perry, PhD, Siemens Healthcare Diagnostics, Glasgow, DE
- 2010: Jacob Levine, Siemens Healthcare Diagnostics, Tarrytown, NY
- 2009: Ronald Laessig, PhD, Wisconsin State Laboratory of Hygiene, Madison, WI
- 2008: Don Powers, PhD, Powers Consulting, Pittsford, NY
- 2007: Richard R. Miller, Dade Behring, Newark, DE
- 2006: Don Powers, PhD, Powers Consulting, Pittsford, NY
- 2005: Mary Lou Gantzer, Dade Behring, Inc., Newark, DE

Industry Division Activities in 2015

- Initiation of Industry Division Feed on AACC Artery
- The AACC Industry Division Activities during 2015 AACC Annual Meeting:

Joint Mixer: Pediatric, Maternal-Fetal Division; Clinical Translational Science; Industry Division; Informatics Division
Time: 7:30 - 9:00pm, Sunday, July 26, 2015 2.

Member Meeting

Time: 1:30 - 3:30pm, Monday, July 27, 2015

Pioneering the Path to Precision Oncology through Next-Generation Sequencing –Gavin J. Gordon, MBA, PhD, Program Leader, Global Oncology Profiling Network, ThermoFisher Scientific

Regulation of Laboratory Developed Tests: What does it mean for the Diagnostics Industry and Next Generation Sequencing? –Brian Du Chateau, PhD, D(ABMLI), VP Business Development, The Binding Site, Inc.

Exhibit Walk (instead of poster walk)

Time: 12:30 - 1:30 pm, Tuesday, July 28

Exhibits visited: Invitae Corporation; Personal Genome Diagnostics; Abbott; IVD Industry Connectivity Consortium and Fraunhofer ICT-IMM.

Division Meeting 2016 & Monday Workshop

This year, our Division's annual business meeting and technical discussion will still be held during the AACC Annual Meeting. With the Elizabeth Holmes lecture, we had moved our meetings around... Now she is moved to late afternoon on Monday, August 1, we are back to the original slot:

Date: Monday Aug 1st

Time: 12:30 -2:30 pm.

Location: Marriott Philadelphia Downtown

Room 309

We will have two guest speakers at the meeting. Rhona Shanker, President of Z & B Enterprises, Inc. and Dr. Judy Stone from University of California- San Diego will be speaking about the Hot Topics on FDA & LDT

Speakers

Subject Title:

"Deciphering the FDA Regulatory Process for LDTs"

Speaker Bio:

Rhona Shanker, President of Z & B Enterprises, Inc. is a former FDA official with over 30 years of medical device experience. She was an FDA investigator, a medical device compliance official where she assembled evidence to support regulatory actions against companies and products, and an expert medical device reviewer. Since leaving FDA, Ms. Shanker continues to use her FDA experience in assisting clients with complying with FDA regulations for medical devices.

Subject Title:

"Validating and Monitoring Quality for LC-MSMS Laboratory Developed Tests - Surviving in an Era of Regulatory Uncertainty"

Speaker Bio

Judy Stone, Ph.D., MT(ASCP), DABCC. Judy worked as a CLS in San Jose, CA and then obtained her doctorate in Clinical Biochemistry at the University of Toronto. Her fellowship in Clinical Chemistry was at the University of Minnesota Hospital & Clinics. She has since served as Asst. Professor and Assoc. Director of Clinical Chemistry at the University of Connecticut Health Center, as Asst. Professor and Director of the Core, Immunology and Toxicology Laboratories at the University of Massachusetts Medical Center; and worked with mass spectrometry at Specialty Laboratories, San Francisco General Hospital and Kaiser Regional Laboratories in Northern California. She is currently Senior Technical Specialist in the Clinical Mass Spectrometry Laboratory, Center for Advanced Laboratory Medicine, Univ. of Calif. San Diego Health System. Her research interest is in mass spectrometry applications and automation for clinical toxicology and endocrinology. She was the faculty chair for the 2009 edition of the AACC Online Certificate program "Using Mass Spectrometry in the Clinical Laboratory". She teaches, with a team of colleagues, a two day short course on "Getting Started with Quantitative LC-tandem MS in the Diagnostic Laboratory" at the MSACL meetings in the U.S. and Europe. She is a member of AACC and ASMS and serves as Chair, Board of Editors for the Mass Spectrometry Feature Series, Clinical Laboratory News. Biography of Board Members

Introduction of the Elected Board

President: Wenzhe Li, Ph.D., DABCC

*VP of R&D and Business Development
NMS LABS, Inc.*

Dr. Li is a board certified professional clinical laboratory director with DABCC (Diplomat of American Board of Clinical Chemistry). Her business strength is in the research development and manufacturing operations of medical devices industry and clinical laboratory, focusing on bringing value to the company via quality and efficiency in product design, clinical trials, technical support and services. She believes in innovative design and quality as the key elements in sustainable growth and success. She is a graduate of Peking University and obtained her PhD at the University of Lincoln-Nebraska. She completed a clinical chemistry fellowship in the Department of Laboratory Medicine at the University of Washington. She also earned a healthcare EMBA from the Paul Merage School of Business of the University of California, Irvine. Dr. Li has previously held positions in Siemens Healthcare Diagnostics and the former Diagnostic Product Corporation. Prior to that she practiced as the Director of the clinical labs for Harborview Hospital Labs in Seattle, WA. She is an active member of the AACC and the North American Chinese Clinical Chemistry Association. She has served on the boards of both associations and is a past president of both associations.

President Elect: Judith Finlay, PhD

Clinical Trial Liaison, PRA Health Sciences

Judith has a Ph.D. in biochemistry from the University of Wisconsin-Madison and was a postdoctoral scholar at the University of California Los Angeles. She has extensive research and development experience at a variety of internationally known clinical diagnostic and biotechnology companies such as Hybritech Incorporated, Beckman Coulter, Invitrogen, Gen-Probe and The Binding Site. She has authored numerous peer-reviewed publications on the use of biomarkers for cancer diagnostics. She is currently Clinical Trial Liaison at PRA Health Sciences which is a Clinical Research Organization (CRO). In this position she engages physicians and other stakeholders in clinical trials by explaining the science behind the trial.

Secretary: Stephan Hess

VP of Business Development, Invetech

Steph has an engineering and business background from Rutgers University College of Engineering and Worcester Polytechnical Institute. He has broad and deep experience the research, development, and commercialization of new products. He is currently the VP of Business Development at Invetech and helps clients develop and realize their new IVD instrument and consumable strategy. Steph has been involved with the Industrial Division of AACC since 2014 serving as Treasurer and Secretary.

Treasurer: Peter Harrsch, Ph.D

*Executive Clinical/Forensic Specialist
Waters Corporation*

Board Member at Large: Yi-Shao Liu, Ph.D

Delta Electronics, Singapore

Yi-Shao graduated from School of Electrical and Computer Engineering in Purdue University and finished two- year post-doctoral research training in University of Illinois at Urbana-Champaign under Dr. Rashid Bashir in ECE and Bioengineering department. Dr. Liu’s research focuses on design and fabrication of electrical biosensors as well as integration of microfluidics in the device.

Dr. Liu joined Taiwan Semiconductor Manufacturing Company in 2010 and was in charge of biosensor program until 2015. He recently joined Delta Electronics in Singapore and is in charge of advanced material and life science research focusing on optical and electrochemical biosensors as well as internet of things and energy harvester device development.

Dr. Liu has published 15 peer-reviewed journal papers and filed over 20 patents (10 have been granted US patents) in design, manufacturing and applications of microfluidic devices and biosensors. He is now serving as member at large on the board of AACC industry division.

Past President:

*Director, Abbott Diagnostics R&D Center, China and previously
Director of Global Scientific and Medical Affairs*

**Peng Yin,
M.D., Ph.D, FACB**



Received M.D. from Tianjin Medical School, China and worked as a General Surgeon for 5 years, then received PhD in Molecular Virology from University of Manitoba, Canada and postdoctoral training at Harvard University, Medical School

A Fellow of the National Academy of Clinical Biochemistry (NACB) (U.S.)
Prior joining Abbott, worked as a Senior Scientist in biotech companies in USA Has patent, book chapter and publications in Nature, Cell and Journal of Virology

Invited to give presentations at Australia NRL Annual Meeting, China National Liver Disease’s Laboratory Diagnosis and Clinics Conferences

Honorary Professor, Tianjin Medical University Cardiovascular Institute, TEDA International Cardiovascular Hospital

IFCC Congresses and Conference Executive Committee Member and Chair (2015), Industry Division, AACC

Editorial Board and Advisory Board member, Journal of Human Virology & Retro Virology and Journal of Virology & Current Research.

Dear AACC Industry Division Members

If you'll be visiting Philadelphia this summer to attend the AACC Annual Meeting and Clinical Lab Expo, make sure to visit your colleagues at the following Industry Division functions:

Sunday, July 31, 2016

Joint Mixer

Pediatric and Maternal-Fetal, Industry,
Informatics, and Clinical Translational Science Divisions

7:30 pm – 9:00 pm

Marriott Philadelphia Downtown
Salon II

Monday, August 1, 2016

AACC Industry Division Meeting – Hot Topics on FDA & LDT

Precision Medicine and Laboratory Developed Tests

12:30 pm - 2:30 pm

Marriott Philadelphia Downtown
Room 309

Find out more about Industry Division events and activities on AACC Artery.

Hope to see you in Philadelphia!

The Industry Division Event Committee