Food and Drug Administration Alumni Association

Serving Those Who Have Served ™

The Annual Report
15th Edition

FDA ALUMNI ASSOCIATION

2016 Achievement Highlights

Our thanks go to the many people who volunteered their time in support of FDAAA programs and operations over the past year. The FDAAA also appreciated the support of the following organizations:

- Arnold & Porter LLP (*www.apks.com*)
- Biotech Policy Group (*www.biotechpolicygroup.com*)
- Catalyst Healthcare Consulting (*www.catalysthcc.com*)
- Covington & Burling LLP (*www.cov.com*)
- EAS Consulting Group (*www.easconsultinggroup.com*)
- Greenleaf Health (*www.greenleafhealthllc.com*)
- Hogan Lovells US LLP (*www.hoganlovells.com*)
- Hyman Phelps & McNamara PC (*www.hpm.com*)
- Keller & Heckman LLP (*www.khlaw.com*)
- Polsinelli PC (*www.polsinelli.com*)
- Sidley Austin LLP (*www.sidley.com*)

Thank you to FDAAA member Pam Pisner for helping to compile this report, Wayne Pines for advancing our communications efforts, and to Jason Steele for designing the Annual Report.

This Annual Report covers the period from the April 2016 Annual Meeting to the May 2017 Annual Meeting.

FDAAA's Mission

The Association's core mission is to help alumni stay in touch with the issues of the day facing the FDA and support the Agency's public health mission through expertise– and experience-sharing, training and outreach opportunities. Membership is open to the thousands of FDA alumni and current employees nationwide. FDAAA's activities designed to support this mission are:

- Periodic educational seminars and conferences on major public health and FDA issues
- Expertise-sharing opportunities with the FDA
- Outreach programs designed to stimulate interest in FDA employment
- Consultations with national health authorities on regulatory strategies and programs.
- FDAAA Updates, providing members with frequent email communications
- FDAAA Website with links to the FDA and other informative sites
- Organization of frequent social events intended to strengthen and engage the alumni community
- Membership Directory

Message from the Chairman

Nancy Myers
Chairman

There is an undeniable air of change in Washington as spring unfolds. Whether you're focused on the change in temperature, foliage, politics or global mood, we at the FDA Alumni Association Board are hoping to take advantage of the current environment to improve and energize the Association.

Over the past year, the FDAAA leadership has been engaged inNaancylMoyenrs g-term, in- depth strategic planning effort. Our goal is to examine what weChaairrmeandoing well, and where we could improve, to prepare for our membership's evolving needs.

This process has been coordinated over the year by former Board Chair, Joe Levitt.

We continue to work hard to understand the current and future needs of the membership; our strategic planning effort is reaching its apex with the membership survey that was recently sent out. Through this survey, we hope to gain valuable insights and alignment that will facilitate the continued success of FDAAA and enhance its value to its current and future members.

In another strategic development, one of the last MOUs FDA signed during Commissioner Rob Califf's tenure was with the FDAAA; this MOU reinvigorates our commitment and brings our mutual goals to the forefront.

All in all, this has been a year of proactively assessing the needs of the organization, and planning for its future. We have taken a number of steps and put processes in place to ensure that we continue to grow and improve as an organization focused on

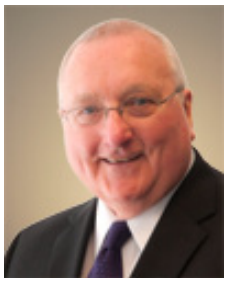
I'd like to just take a moment and thank our Executive Committee members, Ed Steele, Andy Bonanno, CK Gund, Bryan Coleman, Jessica O'Connell, our indefatigable FDAAA Update writer Alan Anderson, and ever enthusiastic volunteer Joe Levitt. These are the people who form our organization's backbone and with there hard work, the organization is financially healthy and members happy.

We appreciate you taking the time to read our annual report. Please consider getting more involved with FDAAA. We need you and want you to participate!

Thank you,

Nancy Myers, FDAAA Chair

Report from President



Edward A. Steele
President

I am pleased that this past year has been another great year for the FDA Alumni Association (FDAAA). While the FDA leadership has changed in the wake of Commissioner Hamburg's departure, we continue to enjoy strong support from the Agency. Hamburg's successor, Commissioner Robert Califf, and Nancy Bradish Myers, FDA Alumni Association (FDAAA) Board Chair, renewed the two organizations' commitment to working collaboratively to benefit FDA alumni and current FDA staff by signing a refreshed MOU on December 2, 2016.

The FDA Alumni Association is the official global network of former and current FDA employees, connecting and supporting alumni, the Agency, and the public health community. This is our vision that guides what we do.

For example, during the past year the Alumni Association mentored ORA management staff as part of a very successful FDA Alumni Advisory Program, held luncheons for members in the D.C., Chicago and San Francisco areas, honored the accomplishments of Association and Agency leaders, held our annual "Spring Fling" luncheon for Agency management, continued support for our scholarship program at Temple University's School of Pharmacy, shared our FDA experiences with FDA Commissioner's Fellows, continued the good work of our International Network, and honored FDA present and former Chief Counsels (and their Deputies) at our Annual Fall Gala Reception. The Association was also pleased to present the 2016 Harvey W. Wiley Lecturer Award to former Commissioner Mark B. McClellan, M.D., Ph.D., at the FDLI Annual Meeting held in Washington. D.C. Dr. McClellan signed the original MOU on behalf of FDA that established the FDA Alumni Association in 2003.

We continue to look for ways we can help the FDA carry out its consumer protection mission in an era where its responsibilities have far exceeded the resources Congress has provided. In this annual report, we have summarized the specific achievements of the Association during the past year. It is impressive to think that these accomplishments are only made possible through the voluntary contribution of time and efforts of our members. For it is the Board members, Officers and most importantly, the Committee Chairs and their members, that allow this organization to do what it does.

Our success going forward will depend on more and more members being willing to get involved in some way. This may include serving on the Board, joining a committee or actively participating in FDAAA-sponsored events. We are always

looking for more members to volunteer to participate in the various committees that are so vital to the smooth operation of this organization.

For those of you who are actively employed and/or who have previously been employed by FDA and who are not yet members, I extend a warm invitation to you to become a member of the FDAAA. I am certain you will agree that the benefits of joining will far exceed the small cost of membership.

Let me conclude by thanking Nancy Myers and the Board for their leadership, the Officers for managing the

daily affairs of the Association, the Committees for keeping things running, and you – our valued members - for making 2016 another outstanding year for the FDAAA.

Edward A. Steele, FDAAA President

The Year in Review – Highlights of FDAAA Activities

Annual Meeting

The Annual Meeting was held on May 18, 2016 on the White Oak Campus of the Food and Drug Administration in Silver Spring, Maryland. Nancy Myers, FDAAA Board chair, summarized the past year's many accomplishments during 2015, which are listed in the Annual Report, and expressed optimism that 2016 would be even more productive and valuable for members.

Awards

Harvey W. Wiley Lecture Award Presented to Mark B. McClellan, MD, PhD

The Harvey W. Wiley Lectureship Award was presented by the FDAAA at the Food and Drug Law Institute's Annual Conference. The lectureship is named in honor of Dr. Harvey W. Wiley, the renowned physician-chemist who, at the turn of the 20th century, championed a legislative crusade against food adulteration, earning him the title of "Father of the Pure Food and Drugs Act" when it was enacted into law in 1906.

Mark B. McClellan, MD, PhD

For Dr. Mark McClellan's lifetime commitment to consumer protection, addressing a wide range of strategies and policy reforms to improve health care, including methods for development and implementation of real-world evidence based on actions that also enabled more effective drug and device innovations, the FDA Alumni Association presented him with the Harvey W. Wiley Award for 2016.

Dr. McClellan's accomplishments and dedication to integrate technical expertise and practical capabilities to develop and apply policy solutions that improve health and the value of health care is remarkable. His research studies have addressed measuring and improving the quality of health care, the economic and policy factors influencing medical treatment decisions and health outcomes, estimating the effects of medical treatments and the relationship between health and economic well-being.

Dr. McClellan's service as the founding Chair and a current Board Member for the Reagan-Udall Foundation for the FDA, a public-private partnership between the FDA and industry, is yet another testimony to his outstanding public service. His service as the inaugural Director of the new health policy Center at Duke University, whose goal is to develop ideas on health reform and move them into practical implementation, continues to reinforce his superb contributions.

FDA Honors Kathryn Zoon, PhD, with the FDA Distinguished Alumni Award

The FDA Distinguished Alumni Award was presented to Dr. Kathryn Zoon, NIAID/NIH.

Dr. Kathryn Zoon

The FDA Distinguished Alumni Award is an FDA-sponsored award for which FDAAA is asked to nominate candidates. Recipients receive a personal letter signed by the Commissioner, plus an engraved crystal.

Certificate of Appreciation Awarded to Karen L. Carson

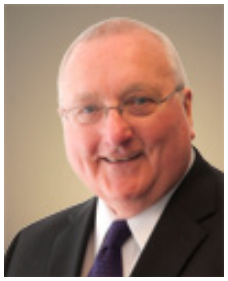
Karen L. Carson

Karen Carson received the FDA Alumni Association's Certificate of Appreciation for her efforts as Chair of the Members Services Committee and her efforts to assist with Secretarial duties.

When Mr. Morrison stepped down as Chair of the Members Services Committee, she willingly took on the position as the new Chair. She can be commended for keeping full, timely and precise accounts of membership numbers and payment of dues. Karen is always promptly responsive to requests for information, and assisted the Recruitment Commitment on recruitment–related inquiries.

In addition to the duties of the Members Services Committee, Karen took on additional responsibilities, serving as a relief Secretary, as needed when the Secretary was not available. She provided excellent suggestions and recommendations related to this position.

FDAAA Founder's Award



Edward A. Steele

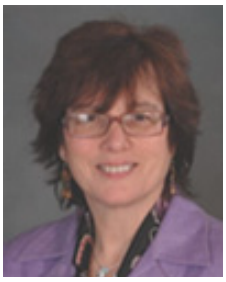
Edward Steele was the recipient of the 2016 Founders Award for his leadership as Chair of the Communications Committee and later President of the FDA Alumni Association. The FDAAA supports the Agency's public health mission.

The Founder's Award honors those who exemplify the highest ideals of the FDA Alumni Association. Specifically, the Founder's Award honors members of the FDAAA who have served with distinction in a leadership capacity and:

- Made significant and visible contributions to promoting the growth and/or visibility of the FDAAA;
- Have served more than one term on the Board and in so doing have advanced the organization's goals and mission; and
- Exemplifies the true spirit and intention of the motto: "Serving those who have served."

As Chair of the Communications Committee, he was responsible for building and maintaining the FDAAA website. When Alan Andersen stepped down as President, Ed willingly took over as President. During his tenure as President, improved systems were put in place for dues collection, he fully supported awards and recognition, and was instrumental in the success of the International Program and the Mentoring Program. Ed is passionate about the FDAAA mission and exemplifies this in his leadership and dedication to that mission.

FDAAA Service Recognition Award



Fredda C. Shere-Valenti

Donald J. Sauer

This is awarded to persons who serve in leadership positions of the Association and whose service has a demonstrably positive effect on the growth, operational success and/or public image of the organization. This year, the FDAAA Service Recognition Award was given to Fredda C. Shere-Valenti and Donald J. Sauer.

Fredda C. Shere-Valenti received this Award in acknowledgement of her selfless volunteering efforts to advance the FDAAA's mission, since becoming an Associate member in 2003. During her time at FDA, while serving as FDAAA liaison, she frequently volunteered to help with FDAAA luncheons, dinners, and the Spring Fling with FDA leadership. At FDA, Fredda consistently promoted membership with the Association explaining the benefits of joining the FDAAA. She also promoted FDAAA membership by providing literature at numerous FDA events.

Don Sauer received this Award for his efforts in providing guidance over the years on financial and administrative matters. He has helped the Finance Committee, Treasurers and FDAAA leadership by providing advice, spreadsheets, review of accounting and guiding the FDAAA to a better understanding of its financial footing. The Association sought Don's guidance on special issues, often when matters were pressing. Because of his efforts, there is a better realization of financial accounting needs for the organization.

Innovator's Award

This is a newly created awrd to recognize innovation with current FDA employees. In 2016, this award was presented to the FDA Alumni Advisor Design Group. This was a group award for the following FDA employees who successfully developed a process to re-hire FDA retirees to mentor current employees in leadership skills and career development, having an immediate and positive impact on FDA.

2016

- Patricia Alcock - Director, Division of Human Resource Development, ORA
- Loney Nunemaker - Deputy Director, Division of Human Resource Development, ORA
- Brooke Mullican - Manager, Division of Human Resource Development, ORA
- Denise Collins - Program Lead/Training Officer, Division of Human Resource Development, ORA
- Rosemary Warneke - Consultant, Office of Resource Management, ORA

These employees worked collaboratively to design a process to re-hire twelve former senior FDA employees who had retired with many years of management and leadership experience, and to return them on a part time basis as rehired annuitants. Their areas of strength were identified and they were matched with all level managers from the Office of Regulatory Affairs (ORA) who had identified the same leadership competencies as developmental needs. The resulting advisor/learner relationships were nurtured in a pilot program called the FDA Alumni Advisor Program that began in June 2015 and concluded in March 2016.

Seventh Annual FDAAA Spring Fling – May 18, 2016

On May18, 2016, FDAAA hosted its annual Commissioner's Spring Fling at White Oak celebrating the new leadership of Commissioner Robert Califf. This event attracts not only members of the FDAAA but also the senior leadership of FDA. As usual, the turn out was tremendous. After enoying time for mingling and eating delicious food from Red Hot and Blue BBQ, Dr. Califf spoke about his plans moving forward. He praised the FDAAA's work to support FDA and discussed the critical importance for alumni associations as an institutional memory. He raised the specter of fake news and challenges ahead. In addition, he methodically laid out his priorities for FDA: workforce development, real world data, maternal health, and many others.

FDAAA's Hail to the Chief Counsels and Their Deputies a Resounding Success

On the rainy evening of December 6, 2016, more than 130 FDAAA members and their guests gathered at the shiny, new offices of Arnold & Porter to pay tribute to of FDA Chief Counsels and their deputies who had served over the past 45 years.

Mark Raza, Current Deputy Chief Counsel; Ed Steele, FDAAA Presdient; Jeff Springer, Deputy Chief Counsel 2005 - 2007; Jeff Senger, Deputy Chief Counsel - 2011; Jerry Masoudi, Deputy Chief Counsel - 2010 - 2011, Chief Counsel - 2007 - 2009; Liz Dickinson, Current Chief Counsel; Richard Cooper, Chief Counsel - 1977 - 1979; Peter Barton Hutt, Chief Counsel 1971- 1975; Nancy Myers, Chairwoman of the Board, FDAAA; and Sheldon Bradshaw, Chief Counsel 2005 - 2007.

The event was attended by a diverse audience of FDA staff and FDA alumni of all different backgrounds and professions. Many of the attendees had served under one or more of the honorees at some point during their FDA career.

Each Chief Counsel or Deputy Chief Counsel was asked to introduce his successor. It was clear from the warm and wise-cracking tone of the introductions that there is a true camaraderie and respect that is passed from one generation to the next at the FDA Chief Counselâ??s office. The weight of the importance of the role in shaping food and drug law was not lost on any of those who had served or who currently serve.

Guests mixed and mingled while overlooking the DC skyline.

Dan Krakov, Stuart Pape, and Joe Levitt

Jessica O'Connell, Nicole Smith, and Haley Kropa

Jerry Masoudi and Peter Barton Hutt

Kirsten Paulson and Mitchell Stein

The event was generously hosted by Arnold & Porter LLP, and sponsored by: Biotech Policy Group, Catalyst Healthcare Consulting, Covington & Burling LLP, EAS Consulting Group, Greenleaf Health, Hogan Lovells US LLP, Hyman Phelps & McNamara, PC, Keller & Heckman LLP, Polsinelli PC, and Sidley Austin LLP.

FDA Celebrates 40th Anniversary of Medical Device Amendments

It was 40 years ago, in 1976, when the Congress enacted and President Ford signed the Medical Device Amendments, which led to the creation of the Center for Medical Devices and Radiological Health.

On June 22, CDRH held a celebration to commemorate the occasion. CDRH now has 1,700 staffers compared to 180 in 1976.

Jeff Shuren, the CDRH director, spoke at the celebration and also posted a blog to mark the anniversary. In the blog, Jeff wrote: CDRH is "a vibrant family of individuals with a wide range of scientific, clinical, engineering, legal, and other expertise, who hail from a variety of backgrounds, and who are ready to tackle the latest scientific advancement."

Here is a link to the blog: *http://blogs.fda.gov/fdavoice/index.php/2016/06/fda-celebrates-the-40th-anniversary-of-the-medical-device-amendments/*

Pictured here are former CDRHers and current FDAAA members: (left to right) Jim Benson, Bob Sauer, John Villforth and David Feigel. (Jim, Bob and John all were intimately involved in the founding of both CDRH and FDAAA, while Dave served later as CDRH director.)

FDAAA Midwest Inaugural Luncheon Held in Chicago

FDAAA members from Illinois, Wisconsin and Ohio gathered on October 7th for the first FDAAA Midwest Luncheon. Terrance Ocheltree of Abbvie organized the event at the Mansion at Trinity University in Deerfield, IL.

FDA Chicago District Director William (Bill) Weissinger addressed the gathering. Bill described the challenges of doing more with less in government administration and identified several areas of potential cooperation with FDAAA members.

For example, the Chicago District faces increasing hiring challenges for field based positions with greater travel requirements (some positions are advertised with nearly 100% travel) and Bill encouraged FDAAA members to refer qualified applicants as he is looking for no fewer than six inspectors.

Bill discussed the agency's implementation of risk informed decision making and described the new systems based inspection software.

He described how the agency uses new ways to communicate with regulated industry, and CHI-DO now issues an imports newsletter which has cut down the number of inquiries from one to two a day to one a month.

FDAAA members inquired about the challenges of budgeting while under a continuing resolution and Bill said he has not had a regular annualized budget in over 13 years, so he has learned to work with the seasonality of the situation.

Bill solicited input from FDAAA members now working in industry on how agency-industry interactions could be improved. Several members made excellent suggestions for improvements in the 483 process to allow prioritization in observations, which could have a significant impact in more focused industry compliance.

Additional events for the Chicago region are planned for the near future.

FDA and FDAAA Refresh MOU After 13 Years

Pens in hand, cameras clicking, redrafted MOU before them in the Commissioner's Conference Room in White Oak's Building One, FDA Commissioner Robert Califf and Nancy Bradish Myers, FDA Alumni Association (FDAAA) Board Chair, renewed the two organizations' commitment to working collaboratively in order to benefit FDA alumni and current FDA staff.

The MOU refresh, an idea proposed by FDA earlier this Fall, renewed the commitment of both organizations' leadership to appreciate the synergies and unique relationship we enjoy, and signaled a "go-ahead" for FDAAA leaders and volunteers to envision programing that goes beyond what we are doing now. It was a nod toward breaking out of the grooved routines and familiarity we have had with the FDA and advancing further.

It was a very different level of pomp and circumstance than when the first MOU was announced by Commissioner Mark McClellan before a 600-person crowd at the 2003 FDLI Annual Meeting. Friday's signing was an intimate, thoughtful ceremony with supporters around a large conference table. It was lined with people familiar with the good work of FDAAA, like Mel Plaisier, Associate Commissioner for Regulatory Affairs, who praised our mentor program and international work; Suzanne Junod, representing the History Office; and Heidi Marchand and Pat Kuntze in FDA's Health and Constituent Affairs Office. Ed Steele, FDAAA President, also was present.

The refresh could not have come at a better time for the Alumni Association. As the Board of Directors is undergoing a strategic planning process and aligning on an updated vision for the organization, this MOU signing provided the opportunity to think even bigger.

"The cooperative relationship we have with the leadership of the FDA has been nothing short of outstanding. The signing of this refreshed MOU signals a commitment to build on our past successes so that the FDAAA can increase our support of FDA's consumer protection mission" "said, EAS President Ed Steele

In the conversation, Dr. Califf praised the unique relationship between the organizations. He pointed out that the alumni association is the institutional memory of the FDA. He used the example of the "fake news" phenomena and towns in Eastern Europe thriving on work using algorithms to develop fake news to feed to the American public. He pointed out how dangerous this is and highlighted the importance of institutional memory and that organizations with people steeped in the history of an institution like the Alumni Association will be invaluable in the future. Dr. Califf, himself a strong supporter of alumni groups stemming from his positive experience with Duke, has said, "I am delighted that we have so many active and engaged alumni and advocate that the relationship between FDA and FDAAA continue to strengthen."

During the ceremony, Myers took time reminded those around the table that the visionaries who hatched the idea of FDAAA in 2000 were Bob Eccleston, at the time with CDRH, and Kelly Sauer, a CDRH alumna. They recruited an enthusiastic John Villforth, former US Assistant Surgeon General and Director of CDRH, to "roll out" the organization in March of 2002. Obviously, there were many other FDAers who helped launch it, like: Burton Love, Liz Krell, Jim Bensen, Ron Chesemore and many others. The group accomplished a very important milestone: on March 3, 2003, Dr. Mark McClellan and John Villforth signed an MOU at FDLI's annual meeting. For more information, please read the following history.

The next step will be a "refresh meeting" between FDA and FDAA in January or February, in order to explore expansion of our current programs and brainstorming for new initiatives.

One key point came up again and again, and was echoed in a comment by Dr. Kathy Zoon, former CBER Director, at a recent Board meeting; everyone agrees that "Once an FDAer, Always an FDAer." It gets in your soul.

To read the new MOU click here. To see a list of other MOUs FDA has signed in the past, click here.

FDA Commissioner Rob Califf and Nancy Bradish Myers, FDAAA Board Chair, show off the pen and signed MOU following the signing ceremony.

Participants in the MOU signing from left to right: Laurie Lenkel , Suzanne Jenod, Heidi Marchand, Rob Califf, Nancy Bradish Myers, Ed Steele, Mel Plaisier, and Pat Kuntze.

FDAAA Members Are Updated on Combination Products

Combination drugs/devices/diagnostic products are becoming increasingly more common. They enable patients to be treated and diagnosed with multiple products that are designed and approved to be used together.

Thirty FDAAA members joined Thinh Nguyen, Director, Office of Combination Products (OCP), and Barr Weiner, Associate Director for Policy, OCP, for a lively luncheon discussion on April 8 about FDA's latest initiative in reviewing combination products.

Thinh and Barr gave a brief overview of OCP's current activities and then discussed some of the major "hot topics" in combination products, including the formation of a new combination products policy council, implementing "lean process" mapping, improved reviewer training, and forthcoming guidances and regulations.

Thinh and Barr were extremely generous with their time and willingness to engage. Their participation underscores the ongoing close relationship between FDA and FDAAA.

A great combination: Barr Weiner, Associate Director for Policy, OCP (left) and Thinh Nguyen, Director, Office of Combination Products (OCP)(right), offered FDAAA members insight into the increasingly important future of combination products and the collaborative cross-center efforts the FDA is implementing to meet future opportunities. The lunch took place at Mrs. K's Toll House in Silver Spring.

FDAAA Luncheon on West Coast

FDAAA hosted its first official West Coast luncheon at the Italian eatery 54 Mint in San Francisco. Organized by Mike Beatrice and Nancy Myers during the JP Morgan Healthcare Conference, the get together proved to be enjoyable and a wonderful way to meet new, yet connected friends. Our participants ranged from fully retired folks, to busy consultants to interesting guests. All who participated agreed that this was a great launch and that there is a real interest in organizing more West Coast events.

Thanks to VALIDANT for helping to underwrite our activity!

Left to right : Marcia Madrigal, Janet McDonald, Brian Harvey, Brian Healy, Mike Beatrice, James Bilstad, Emannuelle Voisin, Nancy Myers, Mamata Gokhale, John Shane and Jenen Jingwen Tan.

FDAAA Briefs FDA Fellows Class on FDA History, Perspective

FDAAA each year sponsors an afternoon session for the FDA Fellows Class. The session consisted this year of a presentation by FDA Historian Suzanne Junod, followed by a session where FDA alumni discuss their experiences at FDA and the lessons they learned. The alumni who participate come from many different offices across the agency to give the Fellows a broad series of insights into the agency.

Seven alumni/FDAAA members participated in the session on January 23 at the White Oak building. See the photo for the alumni presenters.

Some of the themes underscored by the alumni were to advise the Fellows to take advantage of the unique opportunities presented by the FDA, and what specific steps the FDA Fellows can take to maximize their experience at FDA.

This is the eighth year that the FDAAA has sponsored this briefing. Many Fellows have turned into permanent FDA employees.

FDAAA members and FDA alumni brief the FDA Fellows. Left to right are Bill Vodra, Susan Winckler, Jeanne Ireland, Debbie Henderson, Nancy Myers, Ed Steele and Wayne Pines

FDA Alumni Advisor Program

The FDA is busy working with OPM to roll out a new and redesigned Alumni Advisor Program, estimated launch in the fall of 2017.

The new program is being built on the successful pilot that was developed in cooperation with the FDA Alumni Association by the FDA / ORA's Division of Human Resource Development's (DHRD) Management and Leadership Development Program (MLDP).

The pilot, which ran for 9 months and ended March 2016, met its objectives and was successful in bringing back retirees to mentor current employees.

The advisors (mentors) in the pilot program were primarily retired former FDA regional and district directors. They mentored current employees from June, 2015 through March 2016 on leadership skills and career development.

Nancy Myers, FDAAA chairman said: "This is a prime example of how FDAAA can work with the FDA on a program that enables alumni to contribute their experience, talent and wisdom, while helping FDA employees benefit from alumni experience"

Andy Bonanno, VP FDAAA, and colleague and fellow FDA alum Dan Michels, worked with FDA to develop the program.

International Network Helps FDAAA Continue to Expand Its Global Footprint

Since February 2009, FDAAA's Activities Committee subcommittee, the FDAAA International Network, has been acting as a clearinghouse for requests for FDA alumni assistance by foreign health authorities and to provide conultation with foreign regulatory authorities on the establishment and operations of regulatory programs. The Committee is chaired by Jinjie Hu. She manages the monthly committee tel-con with help from Flo Houn and Les Weinstein.

We have contacted Dr. Gang Wang, who was the assistant director in FDA China office and recently left FDA. Active effort is made to recruit additional committee members to continue the support and engagement to regulatory parties in African region.

Activities

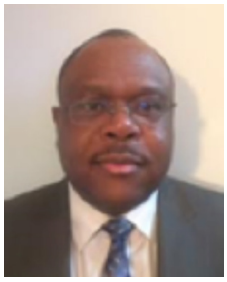
- FDAAA IN continue monthly tel-con to discuss activities and strategies to support FDAAA's mission.
- Several FDAAA IN members will participate DIA China. A no host gathering is in planning for FDAAA members to meet in Shanghai.
- Justina continue participating WHO activates on regulatory harmonization effort
- Effort is made to engage African region in supporting regulatory copacity building.

FDAAA Scholarship Program at Temple

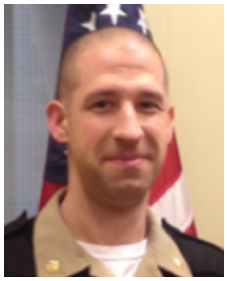
The FDAAA scholarship program is attributed largely to the efforts of Bob Sauer, Past FDAAA Board Chairman, who established and oversees this program.

FDAAA established this endowment to commemorate the 100th anniversary of the Pure Food and Drugs Act and to encourage academic training in regulatory and quality issues. You can find more information on the program, and take advantage of the opportunity to donate to the program, on our website at: *http://www.fdaaa.org/centennial_scholarship_award.php*.

Wendy Lebing, the Assistant Dean in the Regulatory Affairs and Quality Assurance Graduate Program at Temple University's School of Pharmacy has announced the following scholarship recipients for 2016-2017:

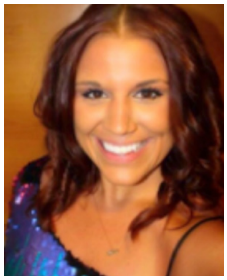


Ebern Dobbin is a Consumer Safety Officer for the Office of Processes and Facilities, Division of Inspection Assessment at FDA's Center for Drug Evaluation and Research. Ebern holds a B.A. Degree in Chemistry from the University of North Carolina at Charlotte. His career began in the pharmaceutical industry as a Quality Engineer in Abbott Laboratories Quality Professional Development Program. During the program he rotated through three divisions of Abbott (Ross Nutrition, Abbott's Hospital Products Division and Abbott's joint venture "TAP Pharmaceutical's") working in various areas such as the chemistry lab, validation, product complaints, product release, division quality assurance and packaging and finishing. Ebern also worked for Bristol Myers Squib and Merck & Co., Inc. supervising packaging operations and finally working as a Senior Quality Associate in Merck's External Manufacturing QA group. He then transitioned into the public sector to work for the FDA. Prior to leaving Merck, Ebern obtained a certification as an ASQ Certified Quality Auditor and began pursuing a Masters degree in QA/RA at Temple. In his spare time he enjoys spending time with his wife and son biking, fishing and camping.



James Mason is a Consumer Safety Officer (CSO) for the FDA Philadelphia District Office of Regulatory Affairs (ORA). After receiving a PharmD in 2006 from Wilkes University, he served as a pharmacy officer in the U.S. Air Force at Nellis Air Force Base in Las Vegas, NV. In 2008, he was deployed to Bagram Air Base, Afghanistan. He became a commissioned officer in the U.S. Public Health Service in 2009 and started working as a CS0 in the Philadelphia District Office of ORA. His primary responsibility consists of conducting onsite audits of pharmaceutical firms for compliance with current Good Manufacturing Practices (cGMPs). James believes that furthering his education in the QA/RA program will better enable him to support the FDA mission of promoting and protecting the public health.

Jonathan W. Chapman is a Drug Investigator and District Drug Monitor for the Baltimore District Office Investigations Branch within the Office of Regulatory Affairs (ORA). Mr. Chapman started working for the agency in January 2013 and is responsible for performing drug manufacturing inspections (both domestic and foreign), Field Alert Report (FAR) Monitoring, Drug Quality Reporting System (DQRS) Monitoring, Drug Registration Monitoring, and Work Planning Activities for the Baltimore District Office. Mr. Chapman received a B.S. in Health, Nutrition, Food, and Exercise with a Minor in Medicine & Society from Virginia Tech and is currently pursuing a M.S. in Regulatory Affairs and Quality Assurance at Temple University.



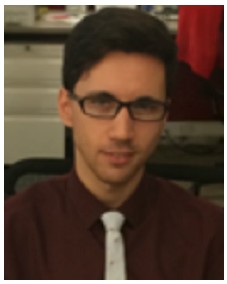
Originally from Clinton, Indiana, **Michelle Natalie** received her BA in Human Biology from the University of Indianapolis. In 2014, she moved to Tampa, FL, and started as a Compliance Specialist at the Pinellas Park CSL Plasma. Two years later, she became the Quality Manger for the Tampa CSL. At the end of 2016, she will have earned the Drug Development Certificate from the RAQA graduate program and will also be promoted to the position of Technical Consultant for CSL. She plans to graduate with the MS in RAQA in 2018 and eventually become an auditor. She enjoys kayaking, going to the gym, and traveling.

Ksenia Sidorova received her M.D. degree from Siberian State Medical University in Russia. Since coming to the United States she has worked in pharmaceutical marketing in a regulatory and clinical consulting capacity. Passionate about pharmaceuticals, she is pursuing her MS degree in Quality Assurance and Regulatory Affairs at Temple University. Ksenia currently works as a safety reviewer in clinical research. She strives to deepen her regulatory knowledge and focus her career on Pharmacovigilance. She believes that patients' safety is the backbone of a successful pharmaceutical industry. She is grateful to accept the FDAAA scholarship.

Originally from Fujian province in China, **Kevin Lin** came to the United States at the age of 12 and speaks Mandarin fluently. He received his B.S. in Molecular Biology from the University of Maryland in 2011. An ASCP licensed Cytogenetics Technologist at Integrated Oncology/Integrated Genetics since 2012, Kevin started his career as a technologist analyzing chromosome karyotypes in bone marrow, blood and tumor tissue samples. After successfully initiating and implementing a more efficient re-testing method for his department, Kevin received the Outstanding Performer in Quality Improvement Award in 2016. He plans to pursuit a career in the pharmaceutical industry with the hope of better integrating western and Chinese traditional medicine. Kevin is honored and grateful to receive the FDAAA Centennial Scholarship Award and expects to finish his MS in RAQA in December 2017.

A Certified Professional IACUC Administrator and Laboratory Animal Technologist, **Megan Eastman** (Licardi) earned her B.S. degree from Quinnipiac University. She started her career as a Veterinary Technician, practicing in emergency animal hospitals, before transitioning to the role of Senior Associate Scientist at Pfizer in 2009. In 2011, she started as a Compliance and Training Coordinator at Columbia University. Currently she is the Assistant Director of the Office of Animal Welfare at SUNY Downstate Medical Center.

Erin Smith holds a B.A. in Biology from Denison University and has more than 10 years of experience working in FDA-regulated industry. After completing her degree, she worked for the American Red Cross, where she performed quality control testing on blood products. In 2009, Erin began working as a Quality Control Scientist for West-Ward Pharmaceuticals Corp (formerly Boehringer Ingelheim Roxane, Inc.), where she performed chemical analysis of finished oral solid dosage forms. She subsequently became a Regulatory Compliance Specialist, focusing on internal auditing, supplier auditing, inspection management and DEA compliance. Erin completed the Drug Development Certificate in Spring 2016 and matriculated into the RAQA Graduate Program in Summer 2016. One of the things she enjoys most about the RAQA program is that she can immediately apply concepts from her courses to her daily work.



Born in Russia, **Artur Shchukin** moved to the U.S. after finishing high school. As he entered college, he selected a pre-med major and spent months shadowing physicians, volunteering, and working in three hospitals. When he applied for an internship with Propper, a medical device company, he was immediately hired as a full time Research and Development Chemist due to his academic achievements and healthcare-related experience. He was subsequently transferred to Propper's QA and RA Department and studied CDRH Learn on the FDA website to learn more about Quality Systems. In that role, he enjoyed being part of a team that helped medical organizations provide quality service to patients and prevent adverse events through the creation of understandable and functional procedures. Artur changed his career plans when he realized that as part of a Quality Assurance Team, he could help countless people. Currently Artur is Director of Regulatory Compliance at Ampak Company, Inc, where he created the company's first Quality Management System and continues to monitor its compliance to the FDA, USDA and other state and federal regulations.

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