Temple University
School of Pharmacy
RAQA Graduate Program

James S. Benson FDA Alumni Association FDA Centennial Scholarship Awardees

Biographies and Testimonials

2006-2021

RA
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Biographies and Testimonials of the
James S. Benson FDA Alumni Association Centennial Scholarship Awardees

2021 Recipient
Jonathan Chapman

2020 Recipients
Jonathan Chapman
Bethany Vibbart

2019 Recipients
Jonathan Chapman
Hilda Guerrero
James Mason
Lauren Pfeiffer

2018 Recipients
Jonathan Chapman
Christopher Ganter
James Mason

2017 Recipients
Jonathan Chapman
Ebern Dobbin
James Mason

2016 Recipients
Jonathan Chapman
Ebern Dobbin
Megan Eastman (Licari)
Kevin Lin
James Mason
Michelle Natalie
Artur Shchukin
Ksenia Sidorova
Erin R. Smith

2015 Recipients
Kaylene Charles
Layne Chaya
Tiffany Elle Connelly
Ebern Dobbin
Priscilla Herpai
James Mason
Ezinne Okwuego
Ksenia Sidorova
Mark Zappacosta

2014 Recipients
Jeffrey Bonnie-Baffoe
Bobby Nguyen
Vishalkumar Patel
Lia Shields

2013 Recipients
Margery Dillenbeck
Ding Ding
Donald Ertel

2012 Recipients
Anshoo Chowdhary
Donald Ertel
Laxmi Padmini Kasichayanula
Vishalkumar Patel
Boriana Tserovski

2011 Recipients
Anshoo Chowdhary
Shannon Schrier

2010 Recipient
Paul Mouris
Poonam Rajput

2009 Recipients
Megan Daly
Paul Mouris
Troy Timbrook

2008 Recipient
Khyati Dave

2007 Recipient
Katherine McKinney

2006 Recipient
Yevgeny Tkachuk

Note: some students were rewarded a combination of FDAAA and RAQA Scholarships.

JEFFREY BAFFOE-BONNIE earned a BS in Biology at Pennsylvania State University from the Eberly College of Science and also minored in history. While an undergraduate, he focused on the neurobiology and pharmacological aspects of health, performing scientific research at Fox Chase Cancer Center and Penn State. Prior to this he joined a health mission team to Guatemala and studied the health of young children in Ghana. With this background he has developed a strong desire to help protect the public health with regards to medicines that they're engaged with. He furthered his education at Temple's QA/RA program to gain a deeper understanding of drug development.

TAJAH BLACKBURN received her Bachelor's in Biology from DePauw University in 1995, her Master's of Public Health from Johns Hopkins in 2013, and her PhD in Biomedical Sciences in from Morehouse School of Medicine. She works as a Consumer Safety Officer for the United States Food and Drug Administration Office of Regulatory Affairs in Washington, DC. She inspects international drug firms in India and China to ensure that more than 5 million generic drugs that reach the U.S. are safe, effective, and comply with the Federal Food, Drug, and Cosmetic Act. Tajah also works as a Biosurveillance Operations Analyst for the U.S. Department of Homeland Security.

JONATHAN CHAPMAN is an Associate Country Director with the FDA's OGPS Beijing China Office, where he supervises a group of Drug, Device, and BIMO Investigators who perform inspections of pharmaceutical, device, and clinical trial facilities located in China. Prior to becoming the Medical Products Supervisor, Mr. Chapman was a drug investigator for OGPS' Beijing China Office and ORA's Baltimore District Office. In these roles Mr. Chapman performed a broad range of domestic and foreign drug inspections as well as monitoring activities. He earned a BS in Human Nutrition, Foods, and Exercise with a Minor in Medicine and Society from Virginia Polytechnic Institute and State University.

Jonathan graduated with an MS in RAQA from Temple University in Fall 2021, completing some of his final courses from China.

KAYLENE CHARLES is a Document Control Specialist within a clinical research lab. She pursued her studies at Temple's Regulatory Affairs and Quality Assurance Graduate Program to develop more skills and gain more knowledge in the area of quality. She hopes to focus on compliance and auditing. Her career goal is to assist in protecting the public's health by assuring the safety, effectiveness, quality and security of food, drugs and cosmetics. Kaylene said that the the technical expertise of Temple's RAQA MS program and the generosity of the FDAAAA helped her attain her goals.

Kaylene graduated from Temple University with an MS in RAQA in Fall 2016.

LAYNE CHAYA, VMD, is a 2011 graduate of the University of Pennsylvania where she obtained a degree in Veterinary Medicine. Prior to veterinary school, she attended Smith College in Northampton, Massachusetts, where she completed a Bachelor of Arts in Biology in 2006. She currently works as a senior specialist in Global Pharmacovigilance for Merck Animal Health.

Layne graduated from Temple University with an MS in RAQA in Fall 2019.

ANSHOO CHOWDHARY pursued her MS in Quality Assurance and Regulatory Affairs. She did her BS in Pharmacy from India and was awarded the Global Public Foundation Award and scholarships for an Outstanding Academic achievement at the University. As a pharmacy undergraduate, she always wanted to take her education to the next level and increase her abilities through an advance degree and more practical exposures.

Prior to coming to US, she worked for a pharmaceutical company in India. There she performed a key role in the Total Quality Management team and learned about strict quality standards (GMPs) involved at every step of the drug development. Since then, she had a deep desire to explore more in this field and broaden her knowledge. After coming to USA she decided to opt for Temple's renowned QA/RA program, to gain the best knowledge of the Quality and Regulatory world.

She is grateful to FDAAA for honoring her with the Scholarship, which inspires her to keep working hard to attain excellence in her field and to make a valuable contribution to society.

Anshoo graduated from Temple University with an MS in RAQA in Spring 2013.

TIFFANY CONNELLY explored her passion for academics, research, and creating opportunity through peer mentoring during her undergraduate studies at Neumann University. She acted as a supplemental instructor in chemistry and was an active member in the Sigma Zeta Honor Society for Science and Mathematics along with the American Chemical Society in her local branch. In her senior year, Tiffany completed a one-year internship with the University of Pennsylvania performing research in flow cytometry. When she was not in a lab or classroom, she could be found in the dormitories as a Resident Assistant and mentored over 100 freshmen women a semester. Tiffany is now working full time as a QA Compliance Specialist at IGI Laboratories, Inc., while pursuing her MS in RAQA. Tiffany continues to support young women pursing STEM degrees and assists Neumann University in creating internship programs with pharmaceutical companies in the Greater Philadelphia Area to provide educational experiences for aspiring chemists.

Tiffany graduated from Temple University with an MS in RAQA in Summer 2017.

MEGAN DALY received her Associate of Liberal Arts degree in Biological Science from Montgomery County Community College, PA in 1998. She qualified as a Medical Laboratory Technician and received an Associate's degree in Applied Science in 2001. She then became an analyst performing clinical and forensic toxicological testing in a private laboratory. While employed, she returned to school, enrolling in Gwynedd-Mercy College's Medical Technology program, completing her internship at a local hospital. Megan received her BS degree in 2005. Continuing employment at a private laboratory, she also worked part time in a nearby hospital's chemistry laboratory. In 2006 she began teaching in the Phlebotomy Technician Program at Montgomery County Community College. Two years later she worked in the Microbiology Department of a local generic pharmaceutical company. In spring 2009 she enrolled in Temple University's QA/RA graduate program to attain additional knowledge on how the pharmaceutical industry works. When her employer went through reorganization, she decided to attend classes on a full-time basis.

The background she received from Temple provided her with a broader view of the field, introducing her to many aspects of the industry.

The FDAAA Scholarship inspired Megan to apply for and matriculate into the MS in QA/RA program on a full-time basis as of the spring 2010 semester. She graduated with an MS in RAQA in Summer 2010.

KHYATI DAVE, MPharm, completed the *Pharmaceutical Sciences Certificate* at Temple, following earning a master's degree in Pharmaceutical Sciences and undergraduate studies at Pune University, in India.

Her master's research in India focused on the effects of various surface-active carriers on the dissolution profile of *Valdecoxib*. She also researched formulation and evaluation of fast-dissolving tablets of famotidine and performed similar studies on extended release matrices for venlafaxine hydrochloride, based on glyceryl behenate and glyceryl palmitostearate. Her publications include two articles covering research in these areas in the Indian journals, ***Indian Drugs*** and ***Eastern Pharmacist*****.**

While in India, Mrs. Dave worked as a Quality Assurance Analyst at Ipca Laboratories, Ltd, drafting Annual Product Reviews (APRs) for various analytical tests. She also performed internal audits of various departments at Ipca Laboratories, Ltd. She worked as a Research Assistant in the group of Dr. Marc A. Ilies, Temple University School of Pharmacy, where she synthesized novel carbonic anhydrase activators and gene delivery agents. Her work on carbonic anhydrase activators was presented as a poster at the 236th American Chemical Society National Meeting, Philadelphia, PA. She also worked with Dr. Robert Raffa on delivery of fluorescent markers in Planarians.

Khyati is now working as a Senior Chemist at Merck. She says, "I was very honored and privileged to have received the FDAAA scholarship. It motivated me to work even harder towards earning my MS in QA/RA degree, which certainly helped me in developing my career. After I graduated, I moved into the industry, working in Drug Discovery."

MARGERY DILLENBECK is licensed as a registered professional nurse and as a nurse practitioner in family health with an MS degree in both nursing and education. She is also certified as a public school teacher, having majored in Special and Elementary Education. In her professional nursing career, she has achieved Level III critical care nurse status (the highest level of achievement as a staff nurse), which has proved to be invaluable experience for her subsequent work as a member of global product surveillance teams at pharmaceutical companies. In particular, she learned first-hand about the critical importance of diligent investigation of side effects when she served as a contract worker for Bausch & Lomb and witnessed the recall of ReNu ML.

Currently, she assesses adverse events for both pre- and post-market products as a Drug Associate for Lundbeck, Inc., which specializes in CNS disorders. Residing in Rochester, NY, with her husband and four children, Margery pursued Temple's QA/RA program to enhance her knowledge of pharmacovigilance.

DING DING received a bachelor's degree in Chemistry from Peking University in China before coming to the United States to pursue a master's degree in Chemistry from the Catholic University of America in Washington, D.C. Her career in the pharmaceutical industry started as a scientist at DuPont Pharmaceuticals. Upon joining Pfizer, she initially worked as a Bioanalytical Analyst, developing and validating bioanalytical assays for GLP studies and clinical trials for regulatory submissions. She then became a Regulatory Document Specialist, working within the Submission, Toxicokinetic, and Reporting Group focusing on Pharmacokinetics, Dynamics and Metabolism. While working at Pfizer, she received the company's Individual Performance Award eight times, a distinction that recognizes exceptional performance and excellent leadership.

As an RAQA student, she applied her coursework knowledge to the writing of regulatory reports and documents for submission and to the increased awareness of how global clinical trials are conducted. Ding found the flexibility of the QA/RA program supported her ability to juggle her time between a professional career, family and two small children.

Ding graduated from Temple University with an MS in RAQA in Spring 2014.

EBERN DOBBIN is a Consumer Safety Officer for the Office of Processes and Facilities, Division of Inspection Assessment, for CDER. He obtained his bachelor's degree in chemistry from the University of North Carolina at Charlotte. His career began in the pharmaceutical industry as a Quality Engineer through Abbott Laboratories' Quality Professional Development Program, where he rotated through three divisions (Ross Nutrition, Abbott's Hospital Products, and TAP Pharmaceutical, one of Abbott's joint ventures). He gained experience in various areas, such as chemistry labs, validation, product complaints, product release, division quality assurance and packaging and finishing.

Ebern also worked for Bristol Myers Squib, supervising packaging operations and at Merck & Co, as a Senior Quality Associate in the External Manufacturing QA group. While at Merck, he became an ASQ Certified Quality

Auditor, and then started to pursue his MS in RAQA at Temple. He transitioned into the public sector to work for the FDA. The FDAAA Scholarship helped him to finish his degree.

Ebern graduated from Temple University with an MS in RAQA in Spring 2017.

A Certified Professional IACUC Administrator and Laboratory Animal Technologist, **MEAGAN EASTMAN (LICARI)** earned her BS 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 at SUNY Downstate Medical Center.

Meagan graduated from Temple University with an MS in RAQA in Fall 2020.

DONALD ERTEL MT (ASCP) is a Regulatory Officer for the Division of Manufacturing and Product Quality at the FDA's Center for Biologics Research and Evaluation and also a commissioned officer in the United States Public Health Service. LCDR Ertel holds a B.S. Degree in Medical Technology from the University of Maryland. For almost three years, Donald's primary responsibility at the FDA has been performing scientific regulatory review (CMC) of BLAs, PMAs and supplements. He is a qualified lead inspector for CBER performing pre-license and pre-approval inspections for BLAs and supplements. LCDR Ertel has over 20 years of experience working in Quality Assurance and Compliance in and with regulated industries of Blood Banking & Cell Therapy (prior employment at Johns Hopkins Hospital), Biotechnology, and Pharmaceuticals (prior employment at Shire).

When he is not performing duties to promote and protect the health and safety of our nation, Donald is pursuing nonstop activities with his wife and three daughters or his musical endeavors as a tenor in the USPHS Choral Ensemble and bass player. Having received the *Drug Development Certificate*, Donald was grateful and honored to receive this award and thrilled to continue his pursuit of the QA/RA Master's degree at Temple.

Donald graduated from Temple University with an MS in QA/RA in Spring 2015.

PRISCILA HERPAI currently works as a Regulatory Specialist for a medical device company that makes dialysis catheters, ports for chemotherapy, and PICC lines. She had been in the pharmaceutical and medical device industry for over nine years in both QA and RA. The FDAAA Scholarship enabled her to finish the last course in the program.

Priscilla graduated from Temple University with an MS in RAQA in Spring 2016.

CHRISTOPHER GANTER holds a BS in Chemistry from Drexel University in Philadelphia. He has ten years of combined QA experience in pharma R&D and marketed product stability. As a Senior Scientist in the GMP quality laboratories, he was responsible for analytical investigations of marketed drug products. He then served as Senior QA Specialist in Global R&D QA at Johnson & Johnson and currently as Senior Quality Lead, in Global Product Development Quality Assurance for Genentech conducting quality audits for GLP, GCP and GVP and computerized systems audits.

Chris entered the RAQA graduate program after temporarily pursuing a successful professional athletic career. He was excited to expand his knowledge base at time when new technology is driving innovation and posing fresh challenges in data integrity and GxP compliance. With sincere gratitude, he wishes to thank the FDA Alumni Association for the opportunity to receive the James S. Benson FDA Alumni Association Centennial Scholarship.

HILDA GUERRERO holds a BS in Chemistry from Texas A&M University in Corpus Christi, Texas. She has fifteen years of combined QA and QC experience in the pharmaceutical and biopharmaceutical fields. She started her career working as a QC Research Technician at Hoechst-Celanese followed by a position at Professional Compounding Centers of America, a pharmaceutical distribution center for drugs used in compounded medicine. She then moved to VGXI Biopharmaceutical as a QA Specialist, focusing on internal auditing and supplier auditing in GMP and regulatory compliance, gaining knowledge in the downstream and upstream aspect of biopharmaceutical manufacturing. Currently Director of QA/RA for Baylor College of Medicine, National School of Tropical Medicine, Houston, Texas, she is responsible for GMP and FDA regulatory activities for neglected tropical disease (NTD) vaccines currently in clinical phase I/II trials in the U.S., Brazil and Africa. In order to comply with eCTD IND submissions, she initiated and setup the validation software system that is currently used at BCM to submit regulatory applications through the FDA ESG system.

Hilda entered the RAQA graduate program in the Fall 2016, completing the *Drug Development Certificate* before matriculating into the MS in Spring 2018. She particularly enjoyed that she could immediately apply concepts from her courses to her daily work. With sincere appreciation and gratitude, she wishes to thank the FDA Alumni Association for the honor of receiving the 2019 James S. Benson FDAAA Centennial Scholarship.

Hilda graduated from Temple University with an MS in RAQA in Fall 2019.

LAXMI PADMINI KASICHAYANULA is a trained pharmacist and an active participant in the RAPS NY/NJ Chapter. She holds a RAPS Certificate in Pharmaceutical Regulatory Affairs and is currently pursuing a MS degree in Regulatory Affairs from Temple University. Ms. Kasichayanula worked as an Associate Professor in Pharmacology in a recognized pharmacy school in India, where she actively participated in several extramural activities related the role of pharmacy in patient education and disease awareness. She hopes to pursue a career in regulatory affairs and looks forward to gaining expertise in biologics and small molecule regulatory strategy.

Laxmi graduated from Temple University with an MS in RAQA in Summer 2014.

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 BS 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 pursue a career in the pharmaceutical industry with the hope of better integrating western and Chinese traditional medicine. Kevin was honored and grateful to receive the FDAAA Centennial Scholarship Award and finished his MS in RAQA in December 2017.

RHONDA LYONS works as a Manager in a dual role, managing the Nucleic Acid Testing Laboratory and serving as the Manager/Project Lead for all validations of the Laboratory. She has a Bachelor of Science in Medical Technology and is a Medical Technologies Supervisor licensed by the State of Tennessee and certified by the American Society of Clinical Pathologist. As the Manager/Project Lead of Validations, she writes all validation protocols, leads the project path, and reviews and approves the executed texting. She has also had the opportunity to participate in clinical trials with Abbott Healthcare as a Clinical Coordinator.

JAMES MASON received his Doctor of Pharmacy degree in 2006 and then served as an officer in the U.S. Air Force. In 2009, he was commissioned as an officer in the U.S. Public Health Service and began working for FDA as a Field Investigator (CSO) conducting domestic and international drug GMP inspections. In 2016, he became a Pharmaceutical Specialist and now serves as a Compliance Officer for the Office of Pharmaceutical Quality Operations in Parsippany, NJ, where his primary responsibility is handling violative pharmaceutical inspections for FDA regulatory actions. He is a Board Certified Sterile Compounding Pharmacist (BCSCP) and Pharmaceutical GMP professional (ASQ CPGP).

James graduated from Temple University with an MS in RAQA in Fall 2020.

KATHERINE L. MCKINNEY, PhD, MS, is a Technical Writer and Biochemical Engineer with 11 years of pharmaceutical industry experience. Her background includes preparation and filing of Chemistry, Manufacturing, and Controls (CMC) sections of international regulatory documents (BLAs and INDs) leading to licensure of vaccines or approval to conduct clinical trials as well as an NDA currently under review. Ms. McKinney is a consultant at Hemispherx Biopharma, Inc., (New Brunswick, NJ) preparing CMC and process validation documents. Prior to that she worked at Merck Research Laboratories (West Point, PA) in Bioprocess Research and Development as a Senior Research Biochemical Engineer and Technical Writer. Ms. McKinney earned both her PhD and MS in Chemical Engineering at Rensselaer Polytechnic Institute. She completed her undergraduate work at Columbia University earning a BS in Bioengineering.

Katherine has worked as a part-time consultant on and off for the last several years, primarily writing CMC sections for New Drug Applications (NDAs) as well as process validation documentation. She is caring for three children between the ages of four and nine, so she plans to continue being a consultant for another two years until all of them are in school for the full day. She states, “The FDAAA scholarship was a great help in allowing

me to continue my education in the QA/RA program at Temple. The QA/RA program has helped me to stay current in my field and be able to do the kind of consulting work that I enjoy. The faculty has been outstanding and extremely knowledgeable. I'm looking forward to learning more over the next few years as I complete my Master's degree and transition back to full-time work."

Katherine graduated from Temple University with an MS in QA/RA in Spring 2012.

NICOLA MICOLUCCI works as a Sterile Operations Manager reviewing and approving batch records, generating and/or reviewing process validation documentation, and maintaining an efficient work flow between all company functions. Nicola is originally from Italy where he earned his Master's Degree in Chemistry and Pharmaceutical Technologies, lectured in Aseptic training courses, and worked as a pharmacist. In 2019, Mr. Micolucci received the *Certificate in Pharmaceutical Manufacturing: Process Development and Analysis* from Temple University's RAQA Graduate Program.

PAUL MOURIS was awarded the FDAAA Scholarship twice, completing the four-course *Drug Development Certificate* at the end of the Fall 2010 semester. Having served as a nuclear reactor mechanic in the Navy and worked as a licensed pharmacist in Connecticut, Paul has been an FDA inspector in White Plains, NY, for the past seven years. His goal is to achieve a Level III Drug Investigator Certification with the expertise learned from pursuing the MS in Quality Assurance/Regulatory Affairs at Temple University. He is committed to staying on the cutting edge of technology and pharmaceutical development.

Paul graduated from Temple University with an MS in QA/RA in Summer 2012.

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.

Michelle graduated from Temple University with an MS in RAQA in Spring 2018.

A first generation Vietnamese American raised in Philadelphia, **BOBBY NGUYEN** was inspired by his parents' work ethic. He financed nearly all of his college education through grants and scholarships at LaSalle University, focusing on Biotechnology/Information and Knowledge Management, which blends science and technology into an interdisciplinary field in medical science. After graduation, Mr. Nguyen worked at DuPont Performance Coatings (now Axalta Coating Systems). In his position in the Product Stewardship & Regulatory Group, he was responsible for the regulation and support of raw materials in

manufacturing and R&D sites. He focused on Medical Devices courses as he pursued Temple's QA/RA Graduate Program so he can contribute to medical technology, providing happier and healthier lives for all.

Bobby graduated from Temple University with an MS in RAQA in Spring 2017.

EZINNE OKWUEGO pursued an undergraduate degree in Biochemistry. While completing an internship at GSK, she wanted to gain more knowledge on how drugs were made and marketed. After earning an MS in molecular biotechnology from the University of Pennsylvania, she worked as a research analyst in Pfizer. Her passion for healthcare and wanting to learn how healthcare professionals can contribute to drug development led her to complete the PharmD at Temple University School of Pharmacy. After becoming a licensed pharmacist, Novartis Consumer Health offered her a position as a medical information specialist, where she worked with the Regulatory Affairs team on projects, which spurred her interest in learning more about FDA regulations and post approval requirements. She enrolled in Temple's RAQA Graduate Program with a focus on regulatory affairs.

Ezinne graduated from Temple University with an MS in RAQA in Fall 2017.

VISHALKUMAR PATEL earned his Pharmacy degree with honors from the School of Pharmacy at Nirma University. Currently, he works as a pharmacist in the state of New Jersey. His professional interests include: academia, research, drug regulation and administration, which inspired him to pursue the Master of Science degree program in QA/RA at Temple University. His professional goal is to improve access to medicines in developing countries, while also providing health care to underserved areas both in the U.S. and overseas. He wishes to thank the FDAAA for their scholarship and also wishes to thank his family, friends and mentors for their continued support and encouragement.

Vishalkumar graduated from Temple University with an MS in QA/RA in Spring 2015.

LAUREN PFEIFFER received her Biology degree from Arcadia University in 2018 and works for DOCS ICON Clinical Research, supporting Janssen Oncology Clinical Trials. The FDAAA Scholarship enabled her to start her graduate studies in the RAQA program.

POONAM RAJPUT has industry experience in pharmaceutical and clinical research. She has worked as a Clinical Research Associate in various therapeutic areas (Oncology, Diabetes, and Cardiovascular) with PPD and iGATE Clinical Research International. Prior to this, Poonam worked as a Marketing Executive for USV Ltd., GlaxoSmithKline. She handled their Mumbai territory in India, achieving the Best Performance award at USV. With a BS in Pharmacy and a post-graduate Diploma in Clinical Research from India, Poonam graduated from Temple University with an MS in QA/RA in Summer 2011.

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.

Artur graduated from Temple University with an MS in RAQA in Spring 2017.

LIA SHIELDS graduated from Drexel University in 1999 with a BS and MS in Organic Chemistry and has worked in the pharmaceutical industry for 15 years, with one foot in the business and the other in IT. Though she has worked in pharmacovigilance, sterile manufacturing, research and development, devices, and nutrition, the main focus of her work has been systems validation and regulatory compliance. She was recently recognized as a “Quality Star” for her work supporting the validation of systems for a new manufacturing facility in Singapore. In her current position, she works from her home office in Hammonton, NJ, for a multi-national pharmaceutical company’s nutrition division.

Lia graduated from Temple University with an MS in RAQA in Fall 2018.

SHANNON SCHRIER has been involved as a Clinical Quality Assurance Auditor, specializing in the detailed review of various types of clinical and regulatory documents generated during the drug development process and FDA submission. She has also held positions in medical device research and development, and in monitoring and auditing all phases of clinical trials. She has always taken great pride in her professional work, but rarely had opportunities to progress in her education. At one of the 2008 Quality Assurance/Regulatory Affairs program’s Open Houses, she learned of the vast range of courses offered in this graduate program and was encouraged by considerations made for students working full time. Returning to the University was a great challenge and required discipline and sacrifice, but she says it has more than paid off. She is proud to have earned A’s in every course completed in the QA/RA Master’s Program. As a result of recent company restructuring, her position was eliminated, and she was forced to put her studies on hold until she learned of the FDAAA Scholarship. Shannon was deeply honored to have been awarded this honor.

Shannon graduated from Temple University with an MS in QA/RA in Spring 2014.

KSENIA SIDOROVA received her MD 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.

ERIN SMITH holds a BA 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 then became a Regulatory Compliance Specialist, focusing on internal auditing, supplier auditing, inspection management and DEA compliance. Erin completed Temple's *Drug Development Certificate* in Spring 2016 and matriculated into the RAQA Graduate Program that summer. 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.

Erin graduated from Temple University with an MS in RAQA in Summer 2017.

TROY TIMBROOK graduated from Grove City College, OH, in 1991, where he was inducted into Beta Beta Beta National Biology Honorary Society and earned a BS in Biology. An active member of the national service fraternity, Alpha Phi Omega (APO), Troy became an advisor of the APO chapter at The Ohio State University. He continued his volunteer APO work as Sectional Chair of Eastern Ohio and was subsequently elected to the national board of directors for two years as a Regional Director. His first professional position was with AmeriFlora'92 as a Volunteer Coordinator, assisting site development. Soon after, he began his sixteen year career with Boehringer Ingelheim-Roxane Inc., where he is currently employed. Starting as a Technician in the Quality Assurance Department, Troy was later promoted to Scientist in the Quality Control Department and matriculated in Temple University's MS program in QA/RA.

Troy commented, "The FDAAA scholarship has helped me to finish my degree a year earlier than was originally planned. I was only able to budget one class a semester. The scholarship allowed me to finish my master's degree in May 2010, since I was able to complete two courses during my final semester. I am very grateful to the FDAAA for their generous scholarship. My MS in QA/RA will enable me to transition my career from QA inspections and QC laboratory testing (which I've been doing for 14 years) to applying for new positions in regulatory within the company. Thank you Temple and FDAAA!"

Troy graduated from Temple University with an MS in QA/RA in Spring 2010.

YEVGENY (GENE) TKACHUK completed a highly selective Physician's Assistant program overseas, before pursuing a Bachelor of Science in Biology at Rutgers University where he participated in laboratory research devoted to the long-term reduction of malaria through genetic studies of disease-transmitting mosquitoes. His findings were presented at the New Jersey Academy of Science in 1994.

Subsequently he joined a management consulting firm where he oversaw an off-shore consulting division developing software applications for U.S. and European clients. Subsequently he was assigned to a division devoted to the development of international clinical research projects. The job entailed extensive coordination with foreign hospitals and regulatory agencies (such as the Russian Ministry of Health), adapting research methodologies, documenting regulatory conformance, and hiring and managing personnel. He quickly assimilated pharmaceutical and clinical trial development in an environment of regulatory adversity and organizational obstacles. In 1999, he earned a Master's in Business Administration at Farleigh Dickinson University.

In 2004, he became a Research Associate at Hackensack University Medical Center, where he helped pursue the hospital's goal of elucidating the immunopathological mechanism to prevent graft versus host disease, a major complication of clinical allogeneic hematopoietic cell transplantation. This research utilized animal-to-human translational studies with important oncology applications, taking Gene's research skills to a higher level, while also providing him with an up-close, practical view of the many facets of drug development.

Gene was the first recipient of the FDAAA Centennial Scholarship in fall 2006. The scholarship enabled him to complete the certificate in *Clinical Trial Management*. He subsequently received the MS in QA/RA in January 2010 and worked as a Services Project Manager for CA, Inc. (an IT company).

Yevgeny graduated from Temple University with an MS in QA/RA in Fall 2009.

After graduating with a BS in Genetics and Psychology from Iowa State University, **BORIANA TSEROVSKI** worked as a microbiologist at the Microbial Food Safety Unit at the USDA on a Hatfield Quality Meats project devising processing strategies to detect and eliminate pathogenic bacteria in meats. While subsequently working as a senior microbiologist in biopharmaceutical testing services at CRL, she pursued graduate courses in advanced diagnostic microbiology.

While raising her family, she enrolled in courses leading to the *Drug Development Certificate* in Quality Assurance/Regulatory Affairs offered at Temple University School of Pharmacy to stay in touch with the developments in the field as well to gain understanding of the full picture of drug development. After excelling in the courses required for the certificate, she was accepted into the Master's Program in Quality Assurance and Regulatory Affairs.

Boriana says, "I am deeply honored to receive the FDA Alumni Association Centennial Scholarship and I hope someday to make a contribution to public health worthy of this award. Having gained technical understanding of microbiological quality control in my education and experience, I believe that a quality/regulatory mindset will prepare me to be a part of the industry shift towards microbiological risk assessment and the adoption of new technologies. In light of the many challenges facing the industry in regards to product quality and patient safety, I hope to be part of the effort to enhance the quality of pharmaceutical products."

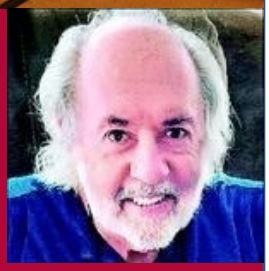
Boriana graduated from Temple University with an MS in QA/RA in Fall 2014.

BETHANY VIBBART is a Research Compliance Specialist at the University of Michigan Medical School IRB (IRBMED). She has a bachelor's degree in Sociology from Eastern Michigan University and holds the Certified IRB Professional certification from Public Responsibility in Medicine and Research (PRIM&R). She completed the *Drug Development Certificate* in February of 2019 as part of the RAQA program. She has worked for the University of Michigan for over 11 years, with nearly 7 of those years being in the IRBMED office. In her current role, she reviews research protocols involving drugs and devices to ensure that they comply with federal regulations for human subjects research and is the lead of an Oncology review board. Bethany has enjoyed the RAQA program, which has helped to further her knowledge of drug and device regulations, and immediately apply new knowledge in her daily work

MARK ZAPPACOSTA is a 2010 Temple graduate from the College of Public Health and started the QARA master's program in spring 2014. His foundation in this industry started at J&J as a Biotechnician where he supported commercial pharmaceutical manufacturing and learned about GMPs. He is now working for Merck in clinical QA and is starting to understand how complex the drug lifecycle really is. Completing the QA/RA graduate program will provide him the knowledge and abilities to better contribute to this complex and ever-changing industry.

Mark graduated from Temple University with an MS in RAQA in Spring 2018.

The Spirit of Giving and Service



Top (L to R): Bob Sauer, John Villforth, Burton Love, Peter H. Doukas, Christopher VanVessem, Wendy Lebing

Right: James S. Benson

Bottom: Bob and Kelly Sauer

In April 2006, Temple's School of Pharmacy received a prestigious endowment from the FDA Alumni Association (FDAAA) creating the first scholarship for students for the School's graduate program in Regulatory Affairs and Quality Assurance (RAQA).

Created in 2000, the FDA Alumni Association is a non-profit, volunteer service organization dedicated to educating the public about the FDA's ever-expanding mission. Members are former Agency employees who use their specialized technical, scientific and institutional knowledge to perform public service related to the FDA.

In 2006, the FDAAA established an endowment to commemorate the 100th anniversary of the Pure Food and Drugs Act and to encourage academic training in regulatory and quality issues. After reviewing graduate programs of schools nationwide, the FDAAA selected Temple University School of Pharmacy to receive the endowment based on the excellence of the RAQA program and the School's long-standing relationship with the Agency.

Three individuals at the FDAAA had key roles in the development of the endowment:

As President of the FDAAA, **John Villforth** enthusiastically embraced the idea of establishing an endowment that would be used to encourage individuals to pursue advanced studies in regulations and quality practices.

Founding member of the FDAAA Board, and FDA's former Acting/Deputy Commissioner and DCRH Director, **James S. Benson** tirelessly reached out to various corporations for contributions to fund the endowment. When he passed away in 2018, the FDAAA unanimously approved renaming the Centennial Scholarship Endowment as the **James S. Benson FDA Alumni Association Centennial Scholarship**.

Robert William Sauer (Bob) was a driving force in creating the Centennial Scholarship fund endowment and determining which educational institution would receive it. He was responsible for reviewing and visiting various regulatory affairs graduate programs across the country between 2005 - 2006. During this period, he met with Temple U School of Pharmacy administrators, including (former) Dean Peter Doukas and Assistant Dean Wendy Lebing. Upon Bob's recommendation, Dean Doukas and Assistant Dean Lebing were invited to meet with the executive staff of the FDAAA in Rockville, MD, to answer their questions about the RAQA program, which was ultimately selected to receive the FDAAA scholarship endowment.

Since 2006, the RAQA program enjoyed regular meetings with Bob to discuss recipients of the FDAAA Centennial Scholarship and fund-raising efforts to increase its endowment so more scholarships could be made available to RAQA students. Over time, Bob's beautiful wife, Kelly, joined Bob in raising awareness of the FDAAA Centennial Scholarship and raising funds for the endowment. The School is deeply indebted to Bob and Kelly for their unwavering support of the School, the RAQA program, and the FDAAA Scholarship, which helped so many students to start, continue or finish certificate and degree programs.

There is no greater gift than providing scholarships to deserving students, since education provides boundless windows of opportunity for years to come. As we continue to receive beautiful and heartfelt thank-you notes from students receiving FDAAA Centennial Scholarships, we will always remember and thank all of the members of the FDAAA, including John Villforth, James Benson, and Robert and Kelly Sauer for their vision, energy, and indefatigable spirit and generosity.

Wendy Lebing, MALD, MS

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