3rd Annual Convention

American Association of Bangladeshi Pharmaceutical Scientists (AABPS)

Philadelphia Marriott Downtown, PA

August 8th, 2015

Innovation in Science and Technology for Drug Development

www.aabps.org

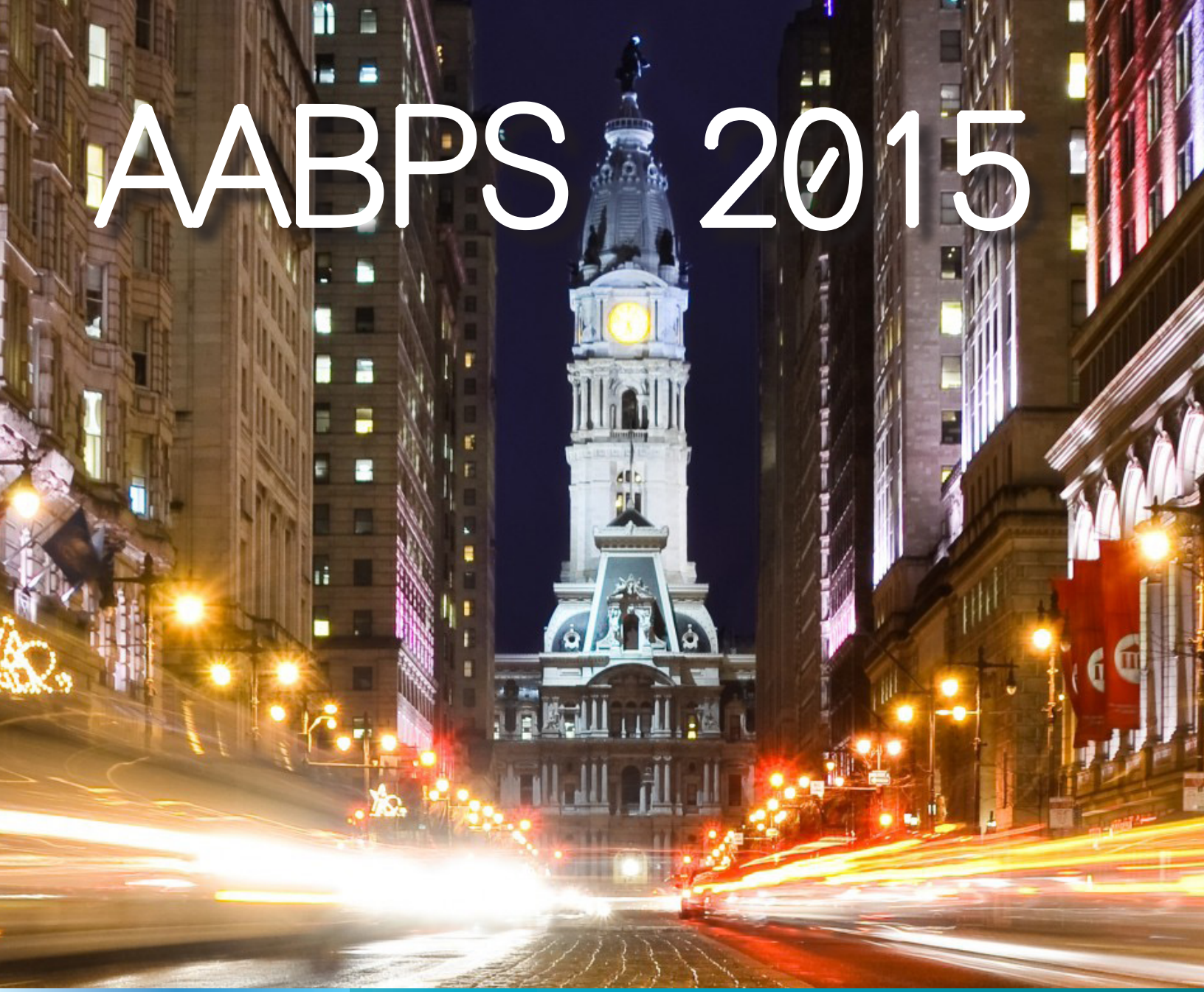
www.squarepharma.com.bd

Journey started in 1958, currently we are at the top.
Our current market share is close to 20% and we are the
Bangladesh pharma market leader since 1985.

We aim at reaching you in U.S.A. soon and our people and the plants are
ready to take on the challenges.

See you soon!

SQUARE
PHARMACEUTICALS LTD.
BANGLADESH



AABPS 2015

3rd Annual Convention
Saturday, August 8
Philadelphia Marriott Downtown
1201 Market Street, Philadelphia, PA 19107

Innovation in Science and Technology for Drug Development

D I S C L A I M E R

AABPS is a non-profit, US tax exempt [501(c)(3)], volunteer-driven, professional organization. Information published in this magazine has been provided by individuals and organizations.
AABPS is not responsible for the accuracy of the presented information.

Cosponsored by

aaps®
American Association of Pharmaceutical Scientists

AABPS 2015 Brochure: List of Contents

PLATINUM SPONSORS

- Mr. Salim Joardar
- Heritage Pharma
- ACI Healthcare
- Square Pharma
- Apogee Pharma
- Merck
- United Hospital

DIAMOND SPONSORS

- BayLink
- MetLife

GOLD SPONSORS

- Crown Consulting Solutions
- Dr. Zahur Islam

SILVER SPONSOR

- Dr. Nazrul Islam

بسم الله الرحمن الرحيم

PRESIDENT

PEOPLE'S REPUBLIC OF BANGLADESH
DHAKA

24 Srabon 1422
08 August 2015

It gives me immense pleasure to learn that the American Association of Bangladeshi Pharmaceutical Scientists (AABPS) is going to hold its 3rd annual Convention at the Philadelphia Marriott Downtown in Philadelphia, USA on August 8, 2015. On the august occasion, I convey my warmest greetings and felicitations to the valued members of AABPS.

Nowadays, pharmaceutical industry of Bangladesh has been playing a very significant role both at home and abroad. Therefore, ensuring access to quality medicine is one of the most cherished goals of the Government of Bangladesh. It is on this principle that the Government always motivates and supports the pharmaceutical industry in Bangladesh to flourish this sector to a great extent. I have been informed that today pharmaceutical industry is one of the most thrust and rich sectors of the country and it is making praiseworthy contributions to the country's socio-economic development by fulfilling about 97 per cent of the total domestic demand of medicine as well as by earning valuable foreign currencies through exporting medicine around the world.

I am happy to note that the AABPS is working at global arena with reputation and I hope that this organization would extend its expertise in pharmaceutical developments, manufacturing, regulatory issues and pharmacy education, and thereby eventually help Bangladesh in demonstrating a significant presence in the global healthcare market. I also encourage its members to work side by side with similar professional organizations in the healthcare, pharmaceutical industry and academia in Bangladesh.

Finally, I extend my best wishes to the organizers and members of AABPS and wish more success in the days to come.

Khoda Hafez, May Bangladesh Live Forever.

Md. Abdul Hamid

Message from AABPS President and Executive Committee

On behalf of the Executive Committee, American Association of Bangladeshi Pharmaceutical Scientists (AABPS), I am excited to welcome you to the 3rd AABPS Convention in this historic city, Philadelphia. It is really a remarkable time for all of us to learn novel researches, exciting initiatives, and new prospects for professional growth. We will have the opportunities for networking and exchange of ideas with peers, colleagues and professionals from different parts of our globe. The convention is a signature event of AABPS and continuation of our journey for establishing a stronger professional organization.

AABPS is increasing the professional enrichment, collaboration, leadership skills, and graduate/professional education of its members. Also, AABPS provides a common platform for its members to work with other professional organizations in the health care, pharmacy, pharmaceutical industry, regulatory agency and academic institution to advance human health and their well-being. The executive committee firmly believes that the commitment and dedication of our members have made AABPS a successful professional organization.

We are proud that AABPS members with their cutting-edge knowledge, expertise and innovations, are contributing tremendously for improvement of the pharmacy profession and global healthcare. In this regard the theme of this year's convention "**Innovations in Science and Technology for Drug Development**" is very appropriate. Through this 3rd convention, we would also like to advance its mission and increase further the visibility of AABPS. The combination of the historical location, internationally recognized speakers, great professional programs, and excellent cultural event during this convention are results of the hard work of the conveners, M. Zahur Islam and Mohammed Shameem, and all the convention committee members listed in the convention magazine. We are honored to recognize them for their diligent work and dedication for this 3rd convention. Also, we would like to specially acknowledge and thank our families for their sacrifice and support during organizing of the convention.

We hope, you will have a productive and exciting time at the convention. Please remember, if you have any questions about AABPS and the convention, please let us know. We are eager to greet you during the welcome session at 9:00 AM, Saturday, August 8th, 2015.

Best Wishes.

On behalf of the Executive Committee,

DHussain

Muhammad Delwar Hussain, M.Pharm., Ph.D.
President, AABPS

Message from the Convention Committee Chairs

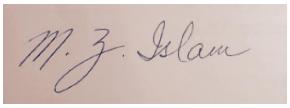
It is with great pleasure that we welcome you to the 3rd Annual Convention of the American Association of Bangladeshi Pharmaceutical Scientists (AABPS) in the historic city of Philadelphia. This will be our third convention in a row in the last three years showcasing the excitement and commitment of our members, volunteers and sponsors for this growing organization. This year we are adding more scientific sessions, leadership training and keynote speeches by internationally recognized leaders from FDA, industry and academia.

The theme for this convention is, "Innovation in Science and Technology for Drug Development." The scientific sessions on ophthalmic and biologics product development, Analytical Scirnces, clinical research and quality are designed in keeping with that theme in mind and to cover a wide range of areas in drug development. The need for innovation to develop cost-effective medicine is more than ever before and we are in the forefront as pharmaceutical scientists. However, the constantly changing business environment to relieve the financial pressure through mergers and acquisitions can be a serious distraction to innovation and future drug development. The key to success in this environment is to concentrate on being flexible and continuously benchmark for improvement. The revolution of digital information technology is also an area where the pharmaceutical industry is playing a catch up game compared to other consumer driven sectors. The processing of enormous patient care data available to the government and private businesses is key to managing diseases in the future and for better patient care of the aging population with existing therapeutic options. The discovery of new targets for novel therapies has become difficult. Therefore, maximization of the value of approved medicines at hand via better patient access, patient compliance, and individualized use of medicines is paramount to the success of health care industry.

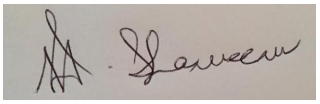
It requires a lot of sincere effort and resources to organize a convention. Our best regards to the volunteers who stretched their ever busy schedule to help us in making this convention a reality. Here we must acknowledge a few among them; without their efforts and dedication to the association we could not have arranged this convention: Dr. Mohammad Hossain, who guided and helped us at every step of the preparation in his typical calm and cool manner; Professor Delwar Hussain for his leadership of the organization and guidance; Professor Jamil Habib for leading the effort in finding our keynote speakers; Mr. Milad Khan for leading the publicity committee; Mr. Naushad Islam for his persuasive fundraising; Mr. Ahsan Akbar for organizing and managing student participation and program; Mr. Rajib Paul for organizing the entertainment program; Mr. Abdus Salam for managing the registration; and Mr. Mamoon Rashid for design and development of the convention brochure. We appreciate and express our gratitude to our donors and sponsors. Your financial support was essential to cover the costs for this program. Many thanks to our young students and our spouses who volunteered to serve at our registration desk and for facilitating activities related to the convention. Also, many thanks to the amateur and professional entertainers for presenting a lively night of entertainment at the end of the program. Finally we thank the Executive Committee of the AABPS for their confidence in us.

We wish that you have a pleasant stay in Philadelphia and hope that you get some opportunity, to explore with your family and friends, the rich history and excellent food the city has to offer.

Thank you.



M. Zahur Islam, Ph.D.



Mohammed Shameem, Ph.D.

CITY OF PHILADELPHIA

MICHAEL A. NUTTER
Mayor

August 8, 2015

Greetings!

It is a pleasure and a privilege to welcome the Annual Convening of the American Association of Bangladeshi Pharmaceutical Scientists to Philadelphia.

Philadelphia's proud history in pharmaceutical sciences began in 1821 with the founding of the Philadelphia College of Pharmacy (now the University of the Sciences), the first college of pharmacy in North America and the birthplace of the American Pharmaceutical Association.

The City of Philadelphia applauds the mission of the American Association of Bangladeshi Pharmaceutical Scientists (AABPS) to provide a forum for communication, discussion, and the exchange of ideas and cooperation among Bangladeshi pharmaceutical scientists and professionals employed in academia, industry, government, and other institutions.

Through the Third Annual Convention's "Innovations in Science and Technology" program agenda, attendees have the opportunity to participate in workshops and presentations led by distinguished speakers who will share important information on scientific and developmental advances in the pharmaceutical field. Keynote speakers will offer insights into the changing demands of the healthcare industry and other relevant topics that will educate students seeking a career in pharmaceutical sciences, as well as benefit individuals in current practice.

While you are in Philadelphia, we encourage you to take the time to visit our singular landmarks of American history and world class institutions of arts and culture, as well as enjoy the welcoming hospitality of our City's unrivalled dining establishments and shopping in our diverse retail corridors.

We wish you a most rewarding and productive Convention and invite you to return to Philadelphia often and soon.

Sincerely,

Michael A. Nutter

Mayor

Ad-hoc Executive Committee

Delwar Hussain	President/Chair EC
Mohammad Hossain	Vice-President
Mohammed Shameem	General Secretary
Zahur Islam	Treasurer
Jamil Habib	Head of the Education Committee

Convention Committee Teams and Members

1. Logistics Team
- Lead: Mohammad Hossain
- Members: Zahur Islam, Utpal Mondal, Raqibul Alam

2. Registration Team
- Lead: Abdus Salam
- Members: Anwar Hussain, Rebecca Islam, Zahur Islam, Mohammed Shameem, Mohammad Hossain

3. Publicity Team
- Lead: Milad Khan
- Shahid Alam, Nahid Banu, Mohammad Rahman

4. Publication Team
- Lead: Mamoon Rashid
- Mohammad Hossain, Milad Khan, Farid Kianifard

5. Fundraising Team
- Lead: Naushad Islam
- Milad Khan, Saleh Hussain

6. Student Affairs Team
- Lead: Mohammad Ahsanul Akbar.
- Ehtesham Reza, Md. Jahidur Rashid, Utpal Kumar Mondal, Khondokar Didarul Alam, Md. Raqibul Alam, Afsana Bahar Trini, KM Shams Ud Doha, Chowdhury Farhana Faruquee

7. Keynote Speaker Team
- Jamil Habib
- Mohammad Hossain, Delwar Hussain, N.A.M. Atiqur Rahman, A.K.M. Khairuzzaman

8. Award & Recognition Team
- Lead: Delwar Hossain
- Mohammed Shameem, Jamil Habib

9. Entertainment Team
- Lead: Rajib K. Paul
- Shahid Khandker, Shaheen Khan, Swapan K. Das, Nahid Kamal

10. Program Sub-team
- Lead: Zahur Islam
- Members: Mohammed Shameem, Shamim Ahmed

11. Abstract Selection Sub-team
- Lead: Muhammad Shameem
- Members: Delwar Hussain, Mohammad Hossain, Jamil Habib

12. Registration Desk
- Lead: Abdus Salam
- Members: Rebecca Islam, Rubana Islam, Shafkat Salam, Ajmain Hossain, Tasnia Habib, Maniza Habib, Mahnaz Habib, Raed Salam

Convention Program

Friday, August 7th

Preparatory Meeting

6:30 PM – 8:00 PM	Meeting of the Convention Committee team leaders and members **Zahur Islam**	Conference Room **306**
6:00 PM – 8:00 PM	Set-up and Registration **Abdus Salam/Rebecca Islam**	Franklin Hall **11 - Foyer**
8:00 PM – 10:30 PM	Optional group dinner (Not sponsored by AABPS)	

Saturday, August 8th

MORNING SESSION

8:00 AM – 6:00 PM	Registration	Franklin Hall **11 - Foyer**
8:00 AM – 8:45 AM	Breakfast and Networking	Franklin Hall **11 & 12**

9.00 AM Session 1: Welcome

Franklin Hall **11 & 12**

9:00 AM – 9:15 AM	Welcome Address **Delwar Hussain, PhD**; President, AABPS
9:15 AM – 9:30 AM	Opening Remarks **Mohammed Shameem, PhD**; Merck **Zahur Islam, PhD**; Novartis

9.30 AM Session 2: Keynote Speech 1

Franklin Hall **11 & 12**

Session Moderator M. Jamil Habib, PhD; Howard University

9:30 AM – 10:15 AM	Why membership in a professional organization is important for your career **Marilyn E. Morris, PhD**; President AAPS 2014 and Distinguished Professor, Pharmaceutical Sciences, University at Buffalo, New York
10:15 AM – 10:30 AM	**MORNING BREAK**

10.30 AM Parallel Session 3a: Ophthalmic and Biologics Product Development

Franklin Hall **11 & 12**

Session Moderator Mohammed Shameem, PhD

10:30 AM – 10:55 AM	Ocular Gene Therapy **Reza Haque, MD, PhD**; Shire
10:55 AM – 11:20 AM	Chemistry, Manufacturing and Control of Ophthalmic Formulations **Imran Ahmed, PhD**; Alcon, Novartis
11:20 AM – 11:45 PM	Biotechnology (Biologics) Products **Iftekhar Mahmood, PhD**; CBER, FDA
11:45 AM – 12:10 PM	Biosimilar: Landscape of current events and opportunities **Musaddeq Hussain, PhD**; Merck

10.30 AM Parallel Session 3b: Analytical Sciences

Franklin Hall 10

Session Moderator Delwar Hussain, PhD

10:30 AM – 10:55 AM QbD Approach to Investigate Product and Process Variabilities for Brain Targeted Liposomes
Nahid Kamal, PhD; CDER, FDA

10:55 AM – 11:20 AM Missense Mutants of p53 Tumor Suppressor Contributes to Drug Resistance and Epithelial-Mesenchymal Transition in Colon Cancer Cells
Salman B. Hosain, B.Pharm; University of Louisiana

11:20 AM – 11:45 PM Co-targeting EGFR and PI3K in Head and Neck Cancer: Mechanisms of Synergy and Resistance
A.R.M. Ruhul Amin, PhD; Emory University

11:45 AM – 12:10 PM Quality evaluation of compounded ondansetron topical gel for chemotherapy patients
Mamoon Rashid, PhD; Appalachian College of Pharmacy

12:10 PM – 1:00 PM **GROUP LUNCH BUFFET**

Franklin Hall 8 & 9

AFTERNOON SESSION

1:00 PM Session 4: Keynote Speech 2

Franklin Hall 11 & 12

Session Moderator Naushad Islam, MS; J&J

1:00 PM – 1:45 PM Evolving Pharmaceutical Product Quality
Lawrence X. Yu, PhD; Deputy Director, Office of Pharmaceutical Quality, US FDA

1:45 PM Parallel Session 5a: Manufacturing and Quality

Franklin Hall 11 & 12

Session Moderator Mamoon Rashid, PhD

1:45 PM – 2:10 PM Contract Manufacturing Organizations/Opportunities
Shamim Ahmed, PhD, MBA; Pfizer

2:10 PM – 2:35 PM What is Culture of Quality?
Ajaz Hussain, PhD; Insight Advice & Solutions LLC

1:45 PM Parallel Session 5b: Student Affairs

Franklin Hall 10

Session Moderator Mohammad Ahsanul Akbar, MPharm; University of Florida

1:45 PM – 2:15 PM Mentor-mentee program initiative

2:15 PM – 3:00 PM Research posters by students:

Franklin Hall 11 - Foyer

- *Alpha-1 antitrypsin (AAT) Gene Delivery by Recombinant Adeno Associated Virus Vector for the Treatment of Osteoporosis.* **Mohammad Ahsanul Akbar, MPharm**; University of Florida
- *Respirable PLGA-based Microparticles for the Pulmonary Delivery of Sildenafil in Pulmonary Arterial Hypertension.* **Jahidur Rashid, MPharm**; Texas Tech University
- *Aromatic and heterocyclic (bis-) sulfonamides as potent carbonic anhydrase inhibitors with potential anti-tumor activity.* **Md. Raqibul Alam, MPharm**; Temple University
- *Carbonic anhydrase activation and isozyme selectivity studies with a series of aromatic bis-imidazoles.* **U. K. Mondal, MPharm**; Temple University

2:35 PM – 3:00 PM **AFTERNOON BREAK/TEA**

Franklin Hall 11 & 12

3:00 PM Parallel Session 6a: Leadership Training

Franklin Hall 10

Session Moderator Zahur Islam, PhD; Novartis

3:00 PM – 3:30 PM Persuasive presentation
Shamim Ahmed, PhD, MBA; Pfizer

3:30 PM – 4:00 PM Behavioral interview
Imran Ahmed, PhD, Alcon, Novartis

3:00 PM Parallel Session 6b: Clinical Research

Franklin Hall 11 & 12

Session Moderator N.A.M. Atiqur Rahman, PhD; CDER, FDA

3:00 PM – 3:25 PM Evolution of the management of Rheumatoid Arthritis:
Where we are and where we need to go and the role played by the pharmaceutical industry in this journey
Mahboob Rahman, MD, PhD; Novartis

3:25 PM – 3:50 PM Role of First-Time-in-Human Studies in Drug Development
Mohammad Hossain, PhD; GlaxoSmithKline

3:50 PM – 4:15 PM A Paradigm Shift in Generic Drug Development
Zafar Iqbal, PhD, MBA; Teva

4:15 PM Session 7: Forum Discussion

Franklin Hall 11 & 12

Session Moderator Abu T Serajuddin, PhD; Professor Industrial Pharmacy, St. John's University

4:15 PM – 5:00 PM Opportunities: What Bangladesh can do in the Era of Global Drug Development and Marketing?
Ajaz Hussain, PhD, Jamil Habib, PhD, Naushad Islam, MS, Shamim Ahmed, PhD, MBA

5:00 PM Session 8: AABPS Business

Franklin Hall 11 & 12

5:00 PM – 5:15 PM Future plan for AABPS
Delwar Hussain, PhD

5:15 PM – 5:30 PM Financial report and fundraising
Mohammad Hossain, PhD/ Zahur Islam, PhD

5:30 PM Session 9: Closing Remarks

Franklin Hall 11 & 12

Delwar Hussain, PhD; President, AABPS

EVENING SESSION

6:15 PM **GROUP DINNER BUFFET** — Liberty Ball Room

6:45 PM Session 10: Dinner Speech

Liberty Ball Room

Session Moderator Mohammad Hossain, PhD; GlaxoSmithKline

6:45 PM – 7:15 PM Your Part in the American Tapestry
Nina Ahmad, PhD; Member, President Barack Obama's Advisory Commission on Asian Americans and Pacific Islanders (AAPI)

7:15 PM – 7:30 PM Awards and recognitions
Delwar Hussain, PhD

7:45 PM Session 11: Cultural Program

Liberty Ball Room

Program Director Rajib Paul, PhD

Emcees: **Shaheen Khan, MS**; **Nahid Kamal, PhD**

10:30 PM Closing

Keynote Speaker

Marilyn E. Morris, Ph.D.
UB Distinguished Professor and Vice-Chair, Department of Pharmaceutical Sciences, University at Buffalo, USA

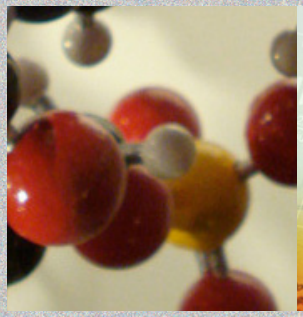
Dr. Morris is Distinguished Professor and Vice-Chair in the Department of Pharmaceutical Sciences, School of Pharmacy and Pharmaceutical Sciences University at Buffalo, State University of New York. She received her B.Sc. (Pharmacy) from the University of Manitoba, Canada, M.Sc. (Pharmacology) from the University of Ottawa, Canada, and Ph.D. (Pharmaceutics) from the University at Buffalo. She was a Medical Research Council Fellow at the University of Toronto, Canada, before joining the University at Buffalo as an Assistant Professor. She served as Associate Dean in the Graduate School at the University at Buffalo from 2006-2012. Her NIH-funded research focuses on the influence of drug transporters on drug pharmacokinetics and pharmacodynamics and the identification of transporters as therapeutic targets. Her current research focuses on monocarboxylate transporters. Additionally, she has been funded through the University at Buffalo Center for Protein Therapeutics for a number of years for studies evaluating determinants of the disposition of monoclonal antibodies and the effect of disease on protein therapeutics. Her overall research contributions have been recognized through the presentation of a number of awards including the State University of New York Chancellor's award for excellence in research and creative activities, a Francis Dudley Meyer Award for Breast Cancer Research, Cancer Research and Prevention Foundation, and election as a Fellow of the American Association of Pharmaceutical Scientists and Fellow of the American Association for the Advancement of Science. She was the recipient of the Faculty of Pharmacy University of Manitoba Distinguished Alumni 2013 award and the University at Buffalo Distinguished Postdoctoral Mentor Award in 2012, and an AAPS innovation in Biotechnology Award in 2015.

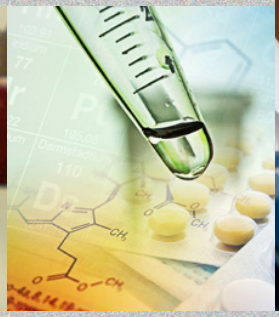
Dr. Morris has provided significant contributions to the Pharmaceutical Sciences through her role as elected President of the American Association of Pharmaceutical Sciences (AAPS) 2012-15. She currently serves as Past-President. She has served since 2006 on the Food and Drug Administration (FDA) Advisory Committee in the Pharmaceutical Sciences and Clinical Pharmacology, as well as on National Institutes of Health and other grant review and advisory panels. She is currently an elected member on the Executive Committee of the Board of Pharmaceutical Sciences for the International Federation of Pharmacy (FIP). Dr. Morris is an Associate Editor for the AAPS Journal.

Keynote Speaker

Lawrence X. Yu, Ph.D.
Deputy Director, Office of Pharmaceutical Quality,
Food and Drug Administration, USA

Lawrence X. Yu, Ph.D., is the Deputy Director, Office of Pharmaceutical Quality, Food and Drug Administration, USA. He is also adjunct Professor of Pharmaceutical Engineering at the University of Michigan. Prior to joining the FDA, Dr. Yu had worked at Pfizer (Upjohn) and GlaxoWellcome for 8 years. Dr. Yu joined the FDA in 1999 and has served as Team Leader, Deputy Division Director, Division Director, and Deputy Office Director. Dr. Yu's research interests have centered on the prediction of oral drug delivery and the development of pharmaceutical Quality by Design. His compartmental absorption and transit (CAT) model has laid the foundation for the commercial software, GastroPLUS™ and Simcyp®, which are being widely used in the pharmaceutical industry. Dr. Yu is a fellow and the past section Chair of the American Association of Pharmaceutical Scientists and an Associate Editor of the *AAPS Journal*. Dr. Yu has authored/co-authored over 130 papers, and presented over 100 abstracts, and given over 200 invited presentations. He is a co-editor of the books entitled "*Biopharmaceutics Applications in Drug Development*" and "*FDA Bioequivalence Standards*". Dr. Yu is the winner of numerous awards including AAPS Regulatory Science Achievement award, AIChE PD2M Drug Product QbD Achievement Award, Japan Naigai Foundation Distinguished Lectureship, China Beijing University IPEM graduation commencement address, Department of Health and Human Service Outstanding Leadership Award, FDA Commissioner's Special Citation, Outstanding Achievement, Group Recognition, and Team Excellence awards.





Dinner Speaker

N. Nina Ahmad, Ph.D., co-founder/co-owner of JNA Capital, Inc., directs all matters pertaining to Investor Relations, Government & Public Affairs. Dr. Ahmad is a Court qualified Expert Witness in Forensic DNA Analysis. She received her Doctoral degree in 1990 from Chemistry Department of the University of Pennsylvania and Postdoctoral training with noted collagen expert, Darwin Prockop, M.D., Ph.D. at Thomas Jefferson University. She discovered the first direct evidence of collagen type II gene mutation in the Stickler syndrome (joint-eye disease), which expanded the field providing a starting point for molecular genetic research into the generalized disease of osteoarthritis. She is one of the patent holders of "Methods of detecting a Genetic Predisposition for Osteoarthritis". At Wills Eye Hospital from 1992-2005, she was a Bower Research fellow, and then held a joint Assistant Professorship with the Ophthalmology Department of Jefferson Medical College and subsequent Directorship of Molecular Biology of the Research Department.

Active in various political campaigns at the local, state and federal levels, Dr. Ahmad also focused her outreach efforts on re-election campaign for President Obama as a Senior Advisor for Obama For America, PA (OFA-PA). She was involved in Senator Casey's re-election campaigns and served as an Advisor to Cindy Bass for the 8th City Council district race. Dr. Ahmad attended the Democratic Nation Convention of 2012 as a Delegate at Large of the PA Delegation.

Dr. Ahmad's involvement in the community and specifically Philanthropy is expansive. She was appointed to the Philadelphia Community Foundation's Board in 2011 (Member, Investment Committee; Grantmaking Service Committee Chair, 2013) and was a founding member of the Asian Mosaic Fund giving circle, and continues to serve on its advisory committee. Dr. Ahmad serves on the national board of Asian Americans/Pacific Islanders in Philanthropy, is a member of the Diversity Committee of William Penn Charter School (oldest Quaker School in the United States) and was one of the founding members of Asian Pacific Americans for Progress. Mayor Nutter of Philadelphia appointed Dr. Ahmad as the Chair of the Mayor's Commission on Asian American Affairs in 2009 and President Obama recently appointed Dr. Ahmad to the President's Advisory Commission on Asian Americans and Pacific Islanders. She serves on the Board of the Pennsylvania Immigration and Citizenship Coalition (PICC) as well as on the Board of Women's Campaign International. She was most recently elected to serve as the President of the Philadelphia Chapter of the National Organization of Women (NOW). Dr. Ahmad serves on the Richardson Dilworth Award Selection Panel, and was on the Taskforce for Racial and Cultural Harmony of the School District of Philadelphia. Dr. Ahmad is a recognized leader amongst Pennsylvania's critical stakeholders in government, private, non-profit, creative and grassroots sectors. Hence, she has been invited by the White House Office of Public Engagement to participate in multiple roundtables over the last few years.

Dr. Ahmad resides in the Mt. Airy neighborhood of Philadelphia with her husband, Ahsan Nasratullah and two daughters.

President Obama said:

"I am pleased to announce that these experienced and committed individuals have agreed to join this Administration, and I look forward to working with them in the coming months and years."

"We are so fortunate to have Nina join the AAPIP Board of Directors. Her deep knowledge of the AAPI community in Philadelphia, and her demonstrated commitment to community-based philanthropy, are incredible assets for our work not just in the Philadelphia region, but across the nation"

stated AAPIP President-Executive Director, Peggy Saika.

Heartiest felicitations for the 3rd Annual Convention of AABPS

Mr. Mayur Doshi

President

Apogee Pharma Inc.

20 Corrielle street

Fords, NJ 08863

Sponsored

by

Merck

Wishing AABPS grand success at the
3rd Convention in Philadelphia

Mr. Shafi Rahman

CEO

Crown Consulting Solutions

4280 NW 63rd Avenue

Coral Spring, FL 33067

UNITED HOSPITAL
CANCER CARE CENTRE

Only Comprehensive & Integrated Cancer Care Centre in Bangladesh

Experienced skilled empathetic Oncology Consultation and Nursing Supervision

Finest and Most Precise Cancer Diagnosis Facility

- The first **PET-CT** along with the only **Medical Cyclotron** in Bangladesh for accurate cancer diagnosis using Molecular Imaging
- The only centre in the country with the facility of **PET-CT based Radiotherapy Treatment Planning**
- Latest **SPECT-CT** scanner facilitates high quality Functional Imaging including DMSA, DTPA, MAG3

360⁰ Holistic Approach with the Best Tools for Cancer Treatment

- **Linear Accelerator** with **IMRT, IGRT, Respiratory Gating** with the first **Rapid Arc** technology in Bangladesh
- Faster and more precise image-guided radiotherapy further strengthened with the world latest **TrueBeam** technology
- High dose rate **Brachytherapy** Unit
- Exclusive **Chemotherapy Unit** for the most updated cancer management as per international guidelines
- Radiation Oncology Medical Physicists for monitoring and ensuring best and safe radiation therapy
- Palliative care to improve quality of life of patients and families living with cancer
- Counselor support to help patients cope with the psychological impact of cancer

United Hospital
Exceptional People... Exceptional Care

Hotline 10666

UNITED HOSPITAL LIMITED

Plot 15 Road 71 Gulshan, Dhaka 1212 Tel : 8836000 8836444 Emergency : 01914001234
Chittagong Info Centre: 23/A M M Ali Road Golpahar Mor Mehdibag Cell : 01914001210
Sylhet Info Centre: 69 Osmani Medical College Road, Kajol Shah Cell : 01914001211

www.uhlbd.com

AABPS 3RD ANNUAL CONVENTION 2015

Abstracts

What is Culture of Quality?

Ajaz S. Hussain, Ph.D.
Insight Advice & Solutions LLC

Periodically we encounter major failures, e.g., 2007 Heparin Disaster. Currently FDA is noting growing cluster of lapses in data integrity findings at foreign facilities and is urging industry to strengthening 'culture of quality' (1). Describe 'culture of quality', identify human actors that strengthen it, and develop a training program and score-card. Building on quality by design, the contributions of Edward Deming (2), James Reason (3) and Daniel Kahneman (4) integrated. Factors that predict a culture of quality (5) linked to Quality Management System based on the System of Profound Knowledge (2). QMS supports proactive behaviors by removing fear of error (6). Awareness improved on behaviors that are predictably irrational (7). Case examples of irrational behaviors discussed to highlight blind spots and to remove reasons for rationalizing of deviations. Training conducted in India (n= 2000+). Anonymous survey data collected. Learnings on why "testing into compliance" will be discussed. Program well received, a basis to identify and address blind spots - a basis to rationalize certain deviant behaviors. Classroom & 'walk the talk' a means to observe behaviors; observations translated into a score-card on culture of quality.

References:

1. Lawrence X. Yu. From our perspective: Patients deserve quality medications. FDA, CDER http://www.fda.gov/Drugs/NewsEvents/ucm428298.htm (Accessed 12 May 2015)
2. Edward Deming. Out of the Crisis. MIT Press (2000)
3. J. Reason. Human error: models and management. BMJ. 320: 768–770 (2000).
4. Amos Tversky; Daniel Kahneman. Prospect Theory: An Analysis of Decision under Risk. Econometrica, 47(2). 263-291 (1979)
5. Ashwin Srinivasan and Bryan Kurey. Creating a Culture of Quality: Financial Incentives Don't Reduce Errors. Employees must be passionate about eliminating mistakes. Harvard Business Review, April 2014
6. C. van Dyck. Putting Errors to Good Use: Error management culture in organizations. Doctoral Dissertation. Faculty of Social and Behavioural Sciences. The University of Amsterdam (2000).
7. Dan Ariely. Predictably Irrational: The Hidden Forces That Shape Our Decisions. HarperCollins Publishers (2010)

Study supported by: Work experience; several generic manufacturers.
Disclosures: Work experience; several generic manufacturers.

A Paradigm Shift in Generic Drug Development

Zafar Iqbal, PhD, RPh, MBA,
Associate Director and Head of R&D Process Engineering & Pilot Plant, Teva North America

Perfection is not an accident. Research has always been a journey towards finding a novel solution to the problem. Einstein once said if we knew the outcome, it would not be a research. This curiosity will always get the scientists in generic industry going but the paradigm has been shifted forever when the industry endorsed GDUFA. In this new environment, the generic product is required to be developed with compressive understanding of the end product and thus the development process must go through a series of rigorous and systematic exercises to achieve the perfect product intended. This interactive and interesting presentation will reveal some of the exercises the scientists in generic industry to follow through to achieve perfection.

Chemistry, Manufacturing and Control of Ophthalmic Formulations

Imran Ahmed and **Malay Ghosh**
Alcon, Ltd, a Novartis Company, 6201 South Freeway,
Fort Worth, TX 76134-2099, USA

Ophthalmic preparations may be administered topically or injected into ocular tissue compartments in the anterior or posterior segments of the eye. While there is considerable similarity between ophthalmic formulations and parenteral formulations there are also important differences with regards to formulation design, dose delivery, packaging, specifications and controls and regulatory requirements. This critical review provides guidance and specific chemistry manufacturing and control (CMC) information to be employed in the design and development of ophthalmic formulations for topical application to the eye to treat ocular disease. The approach described herein is based upon industry best practices, rational formulation design concepts and Quality by Design (QbD) approaches for selecting the preferred drug product composition consistent with regulatory guidance. The candidate molecule should meet the druggability criteria for ophthalmic. The raw material should be fully characterized to provide formulation options and design space recommendation. Appropriate formulations must be developed which are safe, manufacturable and provide the right spatial and temporal drug levels to the target tissues required for efficacy. Finally, a risk plan must be invoked to ensure that the critical quality attributes (CQAs) and process parameters (CPPs) are identified and de risked to ensure product robustness and regulatory filing requirements. Successful ophthalmic formulation development is highly interdisciplinary and challenging; and, requires specialized skills, competencies and hard-earned product development experience. This critical analysis seeks to expedite this learning curve by pointing to essential elements that can be integrated into the planning and decision making at every stage during development.

REFERENCES: M. Ghosh and **I. Ahmed**, Chemistry, Manufacturing, and Controls of Ophthalmic Formulations, In: *Methods in Pharmacology and Toxicology*, Spinger Science (2013)

Role of First-Time-in-Human Studies in Drug Development

Mohammad Hossain, Ph.D.
Clinical Pharmacology Modeling and Simulation,
GlaxoSmithKline

A First-Time-in-Human (FTIH) study is a clinical trial where an investigational medicinal product is tested in human subjects for the first time. The purpose of the first administration of a new chemical entity to humans (healthy subjects or patients) is to evaluate the compounds short-term safety profile over a given dose range and to establish an initial pharmacokinetic and pharmacodynamic profile. FTIH studies plays a critical role in Go/No-Go decision in the early stage of drug development. Major considerations in the conduct of an FTIH study include preclinical safety findings to identify NOAEL, choice of study site (US vs non-US), formulation, analytical sensitivity, study design and initial dose selection for the study. Dose selection in FTIH study is based on regulatory guidance documents issued by FDA, EMEA, BfArM, and AFSSaPS. Determination of an initial dose for FTIH studies is not easy and involves use of multiple approaches including modeling and simulation. Conservative and consistent approach is required because safety is the most important factor in conducting such trials. QT assessment using exposure response analysis in FTIH study has been recently proposed as an alternative to the TQT study. Microdose approach in FTIH study has been used to reduce time and cost (i.e., less preclinical package) for early decision-making in drug development. FTIH studies underscores the importance of translational science, clinical pharmacology and study design for safe dosing in humans.

Co-targeting EGFR and PI3K in Head and Neck Cancer: Mechanisms of Synergy and Resistance

A.R.M. Ruhul Amin
Department of Hematology and Medical Oncology, Winship Cancer Institute of Emory University, Atlanta, GA, 30084

The next generation of cancer treatments will be guided by personalized approaches and molecularly-targeted drugs will be the major players in designing such therapies. However, the limited initial response rate and the rapid development of acquired resistance to targeted agents continuously pose challenges to their success. This study aimed to investigate whether co-targeting of EGFR and PI3K in head and neck cancer (HNC) has synergistic anti-cancer activity, and to study the mechanisms of synergy. HNC cell lines were treated with the EGFR inhibitor erlotinib and the pan-PI3K inhibitor BKM120, alone and in combination. SRB assay was used for cell growth measurement and CalcuSyn software was used to determine synergy. Apoptosis was measured by annexin V-PE staining. Western blotting and real-time qPCR were used to analyze the expression of specific proteins or mRNA. A nude mouse xenograft model was used for *in vivo* studies. Although the response to individual drugs varied among the cell lines, the combination of the two agents was highly synergistic in all except the JHU022 cell line. Moreover, there were drastic dose reductions for both drugs when used in combination. The combination also induced apoptosis, 93-VU-14T and 686 being more sensitive and SCC2 and MSK-LEUK1 being relatively resistant. Further mechanistic studies revealed that the combination of the two drugs more effectively inhibited the protein translational pathway and inhibited the expression of Bcl-2, Bcl-xL and Mcl-1 at the translational level, as compared to either single agent. In the resistant cell lines, the drugs failed to inhibit protein translational pathways. Finally, the combination of erlotinib and BKM120 significantly inhibited HNC xenograft growth in nude mice. The combination of erlotinib and BKM120 synergistically inhibited HNC growth *in vitro* and *in vivo* by inhibiting the protein translational pathway and inhibiting the expression of anti-apoptotic Bcl-2 proteins.

Study Supported by: NCI, Emory University
Disclosure: None

QbD Approach to Investigate Product and Process Variabilities for Brain Targeted Liposomes.

Nahid Kamal[1, 2], Anthony J. Cutie[2], Muhammad J Habib [1], Ahmed S. Zidan[3, 4]

[1]Department of Pharmaceutical Sciences, College of Pharmacy, Howard University, Washington, DC, USA, [2]Department of Pharmaceutics, Arnold & Marie Schwartz College of Pharmacy & Health Science, Long Island University, Brooklyn, NY, USA, [3]Department of Pharmaceutics and Industrial Pharmacy, Faculty of Pharmacy, Zagazig University, Zagazig, Egypt, and [4]Department of Pharmaceutics and Industrial Pharmacy, Faculty of Pharmacy, King Abdul-Aziz University, Jeddah.

Efficacy of central nervous system-acting medications is limited by its localization and ability to cross the blood-brain barrier (BBB); therefore, the crux is in designing delivery systems targeted to cross the BBB. Toward this objective, this study proposed pegylated and glycosylated citalopram hydro bromide (Cit-HBr) liposomes as a delivery approach for brain targeting. The multicomponent liposomes were evaluated for drug encapsulation, vesicular size, size distribution, conductivity and drug release characteristics. Moreover, the interaction among the employed components was evaluated by Fourier transform infrared, differential scanning calorimetric and X-ray diffraction analysis. Through a systematic screening design of formulation and process variables in the optimization phase, an improvement of Cit-HBr loading, fine vesicular size with narrow size distribution, greater stability and sustained release features were achieved. The compatibility studies unveiled a significant interaction between Cit-HBr and dicetyl phosphate to control drug encapsulation and release properties. The optimization process showed a minimal range of design space to achieve the preset desirability; more precisely dicetyl phosphate, polyethylene glycol, N-acetyl glucosamine and freeze-thaw cycles of 3%, 5%, 4% and 2 cycles, respectively, were used. Using brain endothelial cell models, the optimized formulations showed acceptable cell viability with preserved monolayer integrity and an enhanced flux and permeability. Thus, this study has proposed an optimized pegylated and glycosylated vector that is a promising step for brain targeting.

Development of Generic Oral Solid Form

Deepak Gondaliya, Ph.D., Senior Director, R&D, Emcure Pharmaceuticals, limited, Pune, India
Fakrul Sayeed, Global Head, Regulatory & Compliance Chief Scientific Advisor, Emcure Pharmaceuticals (USA), Jamesburg, NJ 08831, USA

Generic Pharmaceutical Companies tend to improve their market position by being first in the market when a patent/exclusivity of an original product expires. The time-to-market of new products is an important source of their competitive advantages. Oral Solid Dosage (OSD) development is more than just deciding which excipients to use in the product formulation. The development of OSD form requires that specific critical quality attributes be considered and evaluated. The overview of Generic Product Development is covered in ICH Q8, ICH Q9 and highlighted by FDA in documents related to Quality by Design (QbD) expectations with regard to raw materials, packaging, and manufacturing processes. The key steps, in generic product development, are characterization of the Reference Listed Product (RLD), design of a pharmaceutically equivalent and bioequivalent product, design of a consistent manufacturing process and successful pivotal bioequivalence study. Each of the various stages of formulation and product development is then explored, from API and excipient characterization, formulation identification and development, stability and compatibility, process requirements, patient in-use studies, etc. There are several areas of opportunity, e.g. expansion of BCS waivers, highly variable drugs where industry should work with the regulators based on science to accelerate the development and approval of generic products thereby expanding the range of products for which generic versions are available, while maintaining high standards for quality, safety, and efficacy. Implementation of QbD will enable transformation of the chemistry, manufacturing, and controls (CMC) review of Abbreviated New Drug Applications (ANDAs) into a science-based pharmaceutical quality assessment. Selected aspects of drug substance and drug product development are used to demonstrate principles of risk management that may contribute to building a common understanding of this quality risk management among the various functional groups involved in developing, testing, manufacturing, and approving of the drug products. This article will discuss the development pathway of OSD product, highlighting the concept of QbD, Risk Management and Mitigation, and experimental design to ensure highest rate of success in developing a pharmaceutically and bioequivalent product.

Reference:

(1) Matthew H. Hulbert & Liam C. Feely & Eugene L. Inman & Alton D. Johnson & Albert S. Kearney & James Michaels & Michael Mitchell & Elena Zour, Risk Management in the Pharmaceutical Product Development Process, *International Society for Pharmaceutical Engineering* 2008 (Published as white paper)
(2) Barbara M Davit, Patrick E Nwakama, Gary J Buehler, Dale P Conner, Sam H Haidar, Devvrat T Patel, Yongsheng Yang, Lawrence X Yu, and Janet Woodcock, Comparing Generic and Innovator Drugs: A Review of 12 Years of Bioequivalence Data from the United States Food and Drug Administration, *The Annals of Pharmacotherapy*, october 2009, vol:43, p.no1583-1597
(3) Garth Boehm, LixinYao, LiangHana, QiangZheng, Development of the generic drug industry in the US after the Hatch-WaxmanActof1984, *Acta Pharmaceutica Sinica B*, 2013; 3(5):297–311
(4) Lawrence X. Yu, Pharmaceutical Quality by Design: Product and Process Development, Understanding, and Control, *Pharmaceutical Research*, Vol. 25, No. 4, April 2008
(5) Robert A. Lionberger, FDA Critical Path Initiatives: Opportunities for Generic Drug Development, *The AAPS Journal,* Vol. 10, No. 1, March 2008

Contract Manufacturing Organizations/ Opportunities

Shamim Ahmed, PhD, MBA
Pfizer

Contract manufacturing is a high growth industry which allows sponsor companies a more flexible approach to resource allocation and investment strategies. In 2014, total global spending on outsourced drug manufacturing (clinical and final dosage manufacturing) reached about $45 billion, having expanded at a double-digit pace over the past two decades. Over the next few years, contract manufacturing industry will continue to record strong gains, with total revenues rising by about 12% per year, on average and is expected to reach approximately $88 billion by 2020. Growth will be strongest, over 15% per year, in the emerging regions of Latin America, Eastern Europe, China, India and Other Asia.

Sorption Behavior of Ibuprofen and Naproxen in Simulated Domestic Wastewater

Samir C. Paul,[1] Leonard J.M. Githinji,[2] Ramble O. Ankumah,[3] Kyle R. Willian,[1] & Gregory Pritchett[4]
[1]Department of Chemistry and Biochemistry, Auburn University, Auburn, AL 36849, USA
[2]School of Agriculture, Fisheries & Human Sciences, University of Arkansas Pine Bluff, AR 71601, USA
[3]Department of Agricultural and Environmental Sciences, Tuskegee University, Tuskegee, AL 36088, USA
[4]Department of Chemistry, Tuskegee University, Tuskegee, AL 36088, USA

Detectable concentrations of pharmaceuticals have been reported in sewage treatment plant (STP) effluents and surface waters, and agricultural lands that received treated waste water in the U.S and other countries. The Reduction in the concentration of pharmaceuticals present in wastewater has been attributed to sorption and biodegradation. However, the contribution of these processes has not been fully characterized. Previous studies have reported varying effects of solution pH and concentration on sorption behavior of pharmaceuticals in different absorbents including activated carbon waste and zeolites. Here we report the pH and concentration effect on sorption of two common anti-inflammatory drugs, viz., ibuprofen and naproxen, on suspended solids in simulated domestic wastewater (SDWW). Batch experiments were conducted at various pH levels, viz., 3.5, 6.5, 7.5, and 8.5, and concentration, viz., 125, 250, 500, 750, and 1,000 μg L−1. The results showed that both ibuprofen and naproxen have higher sorption at lower pH values and at higher concentration. It was found that the data were comparatively well fitted to the Redlich–Peterson isotherm. The study revealed that both ibuprofen and naproxen can be removed from wastewater by the sorption process achieved by lowering the pH to values lower than pKa and maintaining the concentration at an optimal value.

Self-Medication Practice among Patients at the Primary Health Care Hospitals in Bangladesh

Md Motiur Rahman, [*1, 3] **Chih-hsuan Wang**, [2] **Abul Kalam Lutful Kabir** [3]
[*1] Department of Health Outcomes Research and Policy, Auburn University Harrison School of Pharmacy, Auburn, AL- 36849, U.S.A
[2] Department of Educational Foundations, Leadership, and Technology, Auburn University, Auburn, AL- 36849, U.S.A
[3] Department of Pharmaceutical Technology, University of Dhaka, Dhaka-1000, Bangladesh.

In Bangladesh, retail pharmacies are the most accessible health facilities and people can obtain most types of medication without a prescription, which makes self-medication easy to practice. The purpose of this study is to assess the practices and factors associated with self medication in Primary Health Complexes (PHC) in Dhaka, Bangladesh. A descriptive cross-sectional structured and pre-tested questionnaire-based study will be carried out in five PHC of Dhaka district. In each PHC centre, a sample of 100 adult patients (19–65 years) will be selected using systematic random sampling. A pilot survey of 20 adults (10 males and 10 females) was conducted in April 2015 among the Bangladeshi students of Auburn University. Among the participants of the pilot study, 11 were males and 10 were females with a mean age of 27.81 years (sd 2.04). The most frequently reported drug categories for self medication were analgesics (100%), antipyretics (100%), drugs for nausea or vomiting (100%), and gastric disorders (100%) with the main reasons being less severity of the disease, prior experience and less expensive. Friends and family (100%), previous prescription (100%), TV commercials (80.95%), internet (47.62%), and newspaper (47.62%) were the most frequently reported sources of information for self medication. Majority of the drug consumers made their purchase requests by mentioning the specific drug names, telling their symptoms, showing old packages or samples and mentioning the group to which the drug belongs. Most of the consumers considered that the self medication has somewhat improved or cured their illnesses without adverse drug events. Price and brand of the medication have often guided their self medication decision. The results of the pilot study have demonstrated that self medication is common practice for people of all sociodemographic characteristics in a wide variety of indications.
Study supported by: Self
Disclosures: Not Applicable

Rapid And Quantitative Screening Of Human Milk Oligosaccharide Libraries Against Lectins Using The Proxy Protein ESI-MS Assay

Km Shams-Ud-Doha, Elena N. Kitova and John S. Klassen*
Department of Chemistry, University of Alberta, Edmonton, Alberta, Canada T6G 2G2

Human milk oligosaccharides (HMOs) have variety of biological functions such as blocking of binding of pathogenic microbes, including viruses and bacteria, and parasites to epithelial cell and serve as prebiotic. To explore the interaction between related proteins and HMOs rapid and quantitative screening tools and approaches are needed. Electrospray ionization mass spectrometry (ESI-MS) method for screening human milk oligosaccharide (HMOs) libraries against target proteins (P_T) offers a new way to quantify protein-carbohydrate interaction. The novel assay proposed in this work utilizes the *proxy protein* ESI-MS method which combines direct ESI-MS binding measurements with competitive protein-carbohydrate binding, to simultaneously detect and quantify carbohydrate interactions with the target protein. The formation of carbohydrate-P_T interactions and determination of their affinities is achieved through direct ESI-MS detection of carbohydrate binding to a proxy protein (P_{proxy}), which interacts specifically with the carbohydrate with known affinity. Application of the method to screen a small library of HMOs against a hexavalent fucose binding protein (*ralstonia solanacearum,* RSL) and a divalent sialic acid binding protein (*Agrocybe cylindracea,* ACG) as P_T using human galectin-3 carbohydrate recognition domain (Gal3C) as P_{proxy} is described. In summary, the *proxy protein* ESI-MS method is a new method, for quantifying protein–ligand complexes that is not possible to detect directly by ESI-MS has been developed. It is expected that this method might be particularly useful for the analysis of libraries of ligand interactions with very large protein of complex structure, such as virus or bacterial particles binding to host–cell receptors, which cannot be quantified using conventional established method.

Nanotechnology in Ophthalmology

Reza Haque, MD, PhD
Vice President and Therapeutic Head, Ophthalmology
Shire Pharmaceutical, Lexington, MA

Nanotechnology is the manipulation of matter at the atomic and molecular scale to create materials with new and enhanced properties. Nanoparticles have unique attributes owing to their small size: will not clog bloodstream, can penetrate into cells intact, significantly greater surface area than traditional particles and can create new surface patterns. Scientists currently debate the future implications of nanotechnology. Nanotechnology may be able to create many new materials and devices with a vast range of applications, such as in medicine, electronics, biomaterials energy production, and consumer products. One nanometer (nm) is one billionth, or 10^{-9}, of a meter. By comparison, typical carbon-carbon bond lengths, and a DNA double-helix has a diameter around 2nm. On the other hand, the smallest cellular life-forms, the bacteria of the genus *Mycoplasma*, are around 200 nm in length In medicine, it can aid targeted drug delivery, non-viral gene delivery, enabling new drug therapies (siRNA and DNA), more sensitive diagnostics (e.g., lab on chip), and enhanced imaging technique and nanostructured surfaces for tissue regeneration. There are many nanotechnology based medicines in the market, covering wide range of indications. As of 2014, 130 IND was approved for a wide range of indications. In Ophthalmology, there are three most important applications: Enhanced delivery without need for viscous formulations, Non-viral gene delivery, Drug delivery to the back of the eye via topical dosing. Nanotechnology offer significant promise in enhancing the treatment of eye disease and significant work is ongoing and there is potential for game changing applications in our approach to eye disease.

BIOTECHNOLOGY (Biologics) PRODUCTS

Iftekhar Mahmood, Ph. D.
Division of Hematology Clinical Review Branch, Office of Blood Review & Research (OBRR), Center for Biologics Evaluation and Research, US Food and Drug Administration, Silver Spring, MD 20993-0002, USA.

The term "biotechnology" was first used by Kark Ereky, a Hungarian agricultural economist, to describe how certain products could be produced from raw materials with the help of living organisms. Over the last 30 years, biotechnology has transformed the pharmaceutical industry and has brought a whole new series of challenges to those who are involved in drug development. There are wide varieties of biologic products such as recombinant therapeutic proteins, blood and tissue extracts, therapeutic and diagnostic antibodies, vaccines, and cell and gene-based therapies. Modern biologics are biotechnology-derived products that are mostly used for diagnosis, prevention and treatment of serious and chronic diseases. Although there are considerable differences between conventional drugs (small molecules) and biotechnology derived-products (macromolecules), the processes from discovery to non-clinical and clinical evaluation and final regulatory approval for the marketing of both these molecules are similar. However, as compared to small molecule drugs, biologic drug products pose many unique challenges during drug development. The presentation will highlight the issues and challenges faced during the manufacturing of biologics.

The views expressed in this presentation will be of the presenter and do not reflect the official policy of the FDA. No official support or endorsement by the FDA is intended or should be inferred. This presentation is not supported by any private or government fund and there is no conflict of interest with this presentation.

Quality evaluation of compounded ondansetron topical gel for chemotherapy patients

Quamrun Masuda, PhD, RPh, Mamoon Rashid, PhD, Nasheed Shams, MD and Randy Mullins, PharmD, FASCP
Appalachian College of Pharmacy, Oakwood, VA-24631

The serotonin/5-HT_3R antagonist ondansetron is a centrally and peripherally acting antiemetic, frequently used to treat post-operative and chemotherapy induced nausea and vomiting. The conventional orally administered solid dosage forms have limitation of ingesting by many cancer patients. Therefore, a carbomer-based topical gel of ondansetron 2.5% w/w was compounded and analyzed with reverse phase HPLC coupled to photodiode array detector. The used analytical method was validated for specificity, accuracy as well as precision. The triplicated assay of the compounded ondansetron gel was found to have 98.3% recovery. Our study concludes that this gel is comparable to the marketed products of ondansetron.

AABPS Travel Award 2015

AABPS is proud to offer Travel Awards to graduate students to attend AABPS conventions

This highly competitive award has been given to the most qualified applicants on the basis of following eligibility and selection criteria.

Eligibility:

1. Currently enrolled as a full-time graduate student.
2. Must have a poster/podium presentation during the annual convention
3. Must register for the 2015 AABPS annual convention
4. To support more students to participate at the AABPS meetings, Travel Award is a one-time award; previous winners will be excluded from the selection process.

Criteria for the selection of the Award:

1. Cumulative GPA.
2. Publications: Peer reviewed, Published, Accepted or Submitted, Research Articles, Book Chapters, Review Articles, Communications, Letter to the Editor or Miscellaneous.
3. Patent Applications: Submitted, Accepted or Awarded.
4. Research Presentations: Published/Accepted Research/Conference Abstracts/Oral presentations.
5. Meritorious Achievements: Submitted Grant Applications (As a Student PI or Co-PI) Funded Grant Application (As a Student PI or Co-PI) Recipient of Prestigious Awards (External).
6. Service Activities: Significant contributions to AABPS activities, student organizations (as an officer), community outreach, scientific, or college/graduate school/university level services as committee members or officers.
7. Teaching Experience: As a Teaching Assistant in the classroom, laboratory or small group teaching.

The Travel Award for the Graduate Students on the occassion of the 3rd AABPS Convention is being given to the following students:

Mohammad Akbar
University of Florida

Salman B Hosain
University of Louisiana at Monroe

Jahidur Rashid
Texas Tech University Health Sciences Center

Alpha-1 antitrypsin (AAT) Gene Delivery by Recombinant Adeno Associated Virus Vector for the Treatment of Osteoporosis

Mohammad Akbar1, Yuanqing Lu2, Ahmed S. Elshikha1, Rubina Ahamed1, Mark Brantly2, L. Shannon Holliday3, Jay J. Cao4 and Sihong Song1

Departments of 1Pharmaceutics, 2Medicine, and 3Orthodontics, University of Florida, USA; 4USDA, ARS Grand Forks Human Nutrition Research Center, North Dakota, USA

Inflammation is involved in osteoporosis development. Therefore, anti-inflammatory strategy holds great potential for osteoporosis treatment. Alpha 1 antitrypsin (AAT) is an anti-inflammatory protein. We showed that AAT protein therapy reduced bone loss in ovariectomized (OVX) osteoporosis mice. AAT protein therapy is expensive and requires continuous treatment. Therefore, AAT gene therapy may provide a great advantage for osteoporosis treatment. Here, we investigated the therapeutic potential of AAT on preventing bone loss in an OVX mouse model using recombinant adeno associated virus (rAAV) as a vector of gene delivery approach. We generated osteoclast from mouse bone marrow cells and rAAV vector expressing AAT (rAAV8-CB-AAT) as AAT gene delivery vector. Overeictomized mice were i.p. injected with either rAAV8-CB-AAT or PBS. Eight weeks after the rAAV-CB-AAT administration, all animals were sacrificed and subjected to μCT scanning for the evaluation of vertebral bone microarchitecture. *In vitro* studies showed that AAT significantly inhibited osteoclast formation by inhibiting TNF-α production and cell surface Receptor Activator Nuclear Factor κB (RANK) expression. *In vivo* results showed that rAAV-CB-AAT administration significantly increased bone volume density, trabecular number, trabecular thickness and connectivity density, and decreased structural model index (SMI) compared to PBS injection in OVX mice. These results demonstrate that AAT gene delivery by rAAV vector mitigates ovariectomy-induced bone loss in mouse model. Since rAAV vector has been proven to be safe in humans, AAT gene delivery by rAAV-CB-AAT vector could be a new strategy for the treatment of osteoporosis.

Missense Mutants of p53 Tumor Suppressor Contributes to Epithelial-Mesenchymal Transition and Induced Cancer Stem Cells During Chemotherapy

Salman B Hosain1, Sachine K. Khiste1, Mohammad B. Uddin1, Catherine Ingram1, Xin Gu2, Yong-Yu Liu1,*

1Department of Basic Pharmaceutical Sciences, University of Louisiana at Monroe, Monroe, LA 71201, USA

2Department of Pathology, Louisiana State University Health Sciences Center, Shreveport, LA 71130

*Corresponding author: Yong-Yu Liu, Department of Basic Pharmaceutical Sciences, University of Louisiana at Monroe, 700 University Avenue, Monroe, Louisiana 71201; Phone: 318-342-1709; Fax: 318-342-1737; E-mail: yliu@ulm.edu

Missense mutants of p53 tumor suppressor, which gain oncogenic function, promote tumor progression and diminish the therapeutic efficacy of cancer treatments. However, it is still unclear how these missense mutants contribute to induced cancer stem cells (iCSCs) in tumors that are exposed to drugs during chemotherapy. More importantly, whether or not it is possible to target the gained oncogenic function of p53 mutants without heterotetramer effect that often eliminates the efficacy of current approaches used to restore p53 functions. We report herewith that p53 missense mutant urges cancer cells to cancer stem cells. SW48/TP53 cells, which carry heterozygous p53 missense R273H (R273H/+ introduced by CRISPR/Casp9 system), and parental SW48 (wild-type p53) colon cancer cells were exposed to doxorubicin in cell culture and in tumor-bearing mice. The p53 mutant cells (SW48/TP53i) and its tumor xenografts, but p53 wild-type ones (SW48i), were resistant to anticancer drugs, and displayed increased numbers of cancer stem cells (CSCs) (CD44+/CD133+, ALDH+). Epithelial-mesenchymal transition (EMT) presented in SW48/TP53 cells that displayed increased wound healing and tumor-sphere formation. Inhibition of glucosylceramide synthase with PDMP sensitized SW48/TP53i cells and tumors to doxorubicin treatments. Intriguingly, it is discovered that PDMP treatments restored wild-type p53 expression in heterozygous SW48/TP53i cells, thus reversing EMT and decreasing CSC population. These findings demonstrate that p53 missense mutant promotes EMT and enhances iCSCs in cancers during chemotherapy. Restoration of wild-type p53 expression through suppression of ceramide glycosylation might be an effective approach for targeting heterozygous p53 missense cancers.

Respirable PLGA-based Microparticles for the Pulmonary Delivery of Sildenafil in Pulmonary Arterial Hypertension

Jahidur Rashid1 and Fakhrul Ahsan1
1Department of Pharmaceutical Sciences, Texas Tech University Health Sciences Center School of Pharmacy, Amarillo, TX 79106, USA

Pulmonary Arterial Hypertension (PAH) is a disease characterized by increased pulmonary vascular resistance and progressive remodelling of pulmonary arteries resulting in right ventricular failure. Sildenafil, a potent inhibitor of phosphodiesterase 5 (PDE5), is indicated as a targeted therapy in PAH. However, long term use of oral sildenafil is often limited due to increased incidence of systemic side-effects and higher dose frequency. In this study, we aim to develop an orally inhalable sustained release sildenafil preparation that will ensure pulmonary selective vasodilation, reduced dose frequency and lower systemic exposure of this drug. Poly-lactic-co-glycolic acid (PLGA) based microparticles of sildenafil were prepared by double emulsion solvent evaporation method having two variables: lactate-to-glycolate ratio of the polymer and the concentration of polyethyleneimine (PEI) in the internal aqueous phase. Formulations were characterized for their size, zeta potential, surface morphology, mass median aerodynamic diameter, drug entrapment, in-vitro release pattern, cytotoxic potential in rat pulmonary arterial smooth muscle cells (PASMC) and safety after intra-tracheal administration in rats. Incorporation of PEI within the formulation increased the entrapment efficiency of sildenafil from 26.7±5.4% to 93.1±1.1%. An increase in volume based mean diameter (ranging from 0.87±0.03μM to 19.2±4.0μM) and porosity was observed with the increase in PEI concentration. The MMAD of the particles were between 2.0±0.2μM and 8.0±0.2μM. The amount of cumulative drug released into the simulated interstitial lung fluid over 36 hours was between 29.8±0.9% and 45.3±4.9% for the formulations without PEI and 53.1±1.9% and 61.9±8.6% for the formulations containing PEI. Formulations were non-cytotoxic to the rat PASM cells and relatively safe to the lungs. PLGA microspheres of sildenafil shows desired properties to be considered as a career for pulmonary specific delivery of sildenafil.

Study supported by: NIH R01
Disclosures: None

Cultural Performers

Sumon

Sumon was born and brought up in a progressive musical family. He learnt to sing and play the harmonium at a very young age. His father, Syed Abdus Sattar was one of the activists of the 1952 language movement. He was the Vice President of Bangladesh Udichi Shilpi Goshti Central committee. These roots were passed on to Sumon as he was an active member and performer of "KHELA GHOR" which is a youth organization. He was also sent to India to participate in "Children's International Summer Village" for a month due to his success as a performer. Sumon grew up to become the founding secretary of the bangladesh Udichi Shilpi Goshti of Canada. He has maintained to be a prominent and respected member of Udichi for 14 years. He primarily performs and is well known as a Gonoshongit singer. Sumon has successfully kept Bengali music appreciated in Canada and will work to keep our rich culture alive.

Shabnam Tonuka

Shabnam Tonuka's musical journey started at the age of 7. Her first guruji, Osthad Rajendro Kormokar, enriched her music knowledge with his endless knowledge in classical music. After migrating in Canada, Tonuka didn't give up her passion towards music and still continuing to learn classical music under Guruji Proshenjit Deoghoriya, a gold medallist in classical music in India. As a stage performer Tonuka always put her audience first and that encourages her to learn and perform different genre of music but when it comes to her own songs she is always a big lover of melody. Tonuka has released three albums so far and also working for her next solo music album and for various other mix and duet music albums. Her songs have been used in TV Drama with great success. Beside stages she is also busy with TV and radio live shows. A big dream about music keeps Tonuka alive everyday.

Cultural Performers

Mahbubul Haque

Mahbub started taking music lessons at the age of five from renowned teachers and graduated in Tagore Songs/Semi Classical from Shangeet Bhaban under the direct mentorship of Late Ustad Kalim Sharafi. In the last 20 years, he has played, performed and recorded albums with accomplished bands namely The Trap, Faith, Pentagon, Warfaze, Ark, Winning, Jahmalama (Canada), and composed original music for various artists from all over the world including Bangladeshi top celebrities. Currently Mahbub is primarily focused on fusion projects for revitalizing Bangladeshi rare root music with the blend of world music for making it more appeling to the new generation. He is also a subject matter expert in audiovisual pre/post production technologies and event management.

Mahbub has graduated in Economics from the University of Toronto, works as a Senior Business Analyst/Project Manager in the financial industry, and is happily married with Asma Anjuman Ara with one daughter, Afsheen Haque.

Moyukh

Since the day she was born, Moyukh has been exposed to music. Growing up in a very artistic family led to her love of the arts. She began her classical music training at the age of 6 with Guruji Prosenjit Deoghoria. She has participated and won many music competitions and has established herself as a successful Bengali youth singer in Ontario. Moyukh has released a cover album in Bangladesh, and is currently working on an album with various other musicians. She has been featured on several TV shows in Bangladesh and Canada. Moyukh hopes to establish herself in music and one day share her love of music with the world.

Cultural Program Sequence:

1. Dance with “Dhoom Machale Dhoom” Hindi song: Maniza Habib and Mahnaz Habib
2. Small Act: Arshad Jamil and Hosne Arshad
3. Song: Md Masudul Alam
4. Violin: Ajmain Hossain
5. Dance with “Chittiyaan-kalaiyaan” Hindi Song: Maniza Habib and Mahnaz Habib
6. Jokes: Shamim Ahmed
7. Song: Shahid Khandker
8. Tabla (Guest): Mridul Rahman
9. Song (Guest): Sumon, Tonuka, Moyukh and Mahbub

Welcome

To the 3rd Annual AABPS Convention

From your local Bangladeshi-owned Domino's Pizza

Absecon 609-646-8808
Atco/Berlin 856-768-5522
Atlantic City 609-347-0303
Bayville 732-269-7800
Brick 732-206-0002
Bridgeton 856-455-6800
Burlington 609-387-8400
Camden 856-225-0400
Cape May Court House 609-465-9090
Egg Harbor Township 609-646-8222
Gibbstown 856-224-8700
Glassboro 856-881-8100
Hammonton 609-567-5111
Little Egg Harbor Township 609-296-2900
Lumberton/Mt Holly 609-265-1300
Maple Shade 856-866-1500
Marlton 856-596-5900
Millville 856-327-4900
Pennsauken 856-663-2522
Toms River 732-929-1818
Vineland 856794-3030
Westmont 856-854-5600
West Philadelphia 215-477-6000
Williamstown 856-728-5533
Willingboro 609-871-8800
Woodbury 856-845-6444

Call Salim Joarder, Owner, with any concerns
856-524-1200

Domino's

Best Wishes from

MIZAN RAHMAN

Blue Ocean Wealth Solutions

An Office of MetLife

Part of the MetLife Premier Client Group

EAST HILLS BUSINESS & MEDICAL PARK

2200 Northern Boulevard, Suite 200
East Hills, NY 11548

Mizan Rahman, MBA, M.S. (Finance)
Financial Advisor, Financial Planner
Registered Representative
Financial Services Executive
Investment Advisor Representative
CA Insurance Lic # 0D19200

MetLife Presidents Conference - 9 Times
MetLife Leaders Conference - 9 Times
Qualifying & Life Member, Million Dollar Round Table (MDRT) - 18 Years
Member, National Association of Insurance and Financial Advisors (NAIFA)
National Quality Award For Excellent Client Service, NAIFA, Since 1997

PLEASE CALL/CONTACT:

Mizan Rahman

Tel : (516) 326-7035
Fax: (516) 326-7055
Cell: (917) 796-2979
mrahman1@metlife.com
www.MizanRahman.com

RISK MANAGEMENT
- **Life Insurance**
- **Disability Income Insurance**
- **Long-Term Care Insurance**

INVESTMENT ADVISORY
- **Investment Management Strategies**
- **Asset Allocation & Diversification**
- **Personalized Portfolio Creation**
- **Socially Responsive Investment**
- **Education Funding Strategies**

BUSINESS OWNER & EMPLOYEE BENEFITS
- **Business Continuation Strategies for Professionals and Business Owners**
  - Funding Buy-Sell Agreement
  - Executive Bonus Plans
- **Group Employee Benefit Planning**
  - Group Life Insurance
  - Group Disability Insurance
  - Group Vision and Dental
  - Group Health
- **Supplemental Voluntary Benefits**

RETIREMENT PLANNING
- **Traditional and Roth IRA Consolidation/Rollovers**
- **SEP, SIMPLE, 401(k) Plans**
- **Profit-Sharing Plans**
- **Defined Benefit Plans**
- **Pension Payout Alternatives**
- **Lifetime Income Planning**
  - Fixed Annuities
  - Immediate Annuities
  - Variable Annuities

ADVANCED SERVICES
- **Financial Planning**
- **Gift-Giving Strategies**
- **Charitable Giving Strategies**
- **Family Legacy Planning**
- **Estate Planning Strategies**
- **Asset Protection Strategies**
- **Wealth Accumulation Strategies**
- **Profile Financial Analysis**

MetLife

AABPS Convention 2015

List of Early Registrants

1.	Nina	Ahmad
2.	Imran	Ahmed
3.	Shamim	Ahmed
4.	Sarah	Ahmed
5.	Sharif	Ahmed
6.	Mohammad Ahsanul	Akbar
7.	Md. Raqibul	Alam
8.	Shahid	Alam
9.	Md Anik	Alam
10.	Md Masudul	Alam
11.	Muhammad Amir	Ali
12.	Parijat	Ali
13.	A.R.M. Ruhul	Amin
14.	Hosne	Arshad
15.	Naheed	Banu
16.	Swapan Kumar	Das
17.	Jagannath	Ghosh
18.	Sandip	Gupta
19.	Muhammad Jamil	Habib
20.	Tasnia	Habib
21.	Maniza	Habib
22.	Reza	Haque
23.	Mohammad Mahbubul	Haque
24.	Shamim	Hasan
25.	Salman Bin	Hosain
26.	Anwar	Hossain
27.	Maher	Hossain
28.	Mohammad	Hossain
29.	Rumana	Hossain
30.	Alisha T	Hossain
31.	Ajmain M	Hossain
32.	Ajaz	Hussain
33.	Muhammad Delwar	Hussain
34.	Musaddeq	Hussain
35.	Lubna	Huq
36.	Mominul	Islam
37.	Naushad	Islam
38.	Zahur	Islam
39.	Rubana	Islam
40.	Rebecca	Islam
41.	Zafar	Iqbal
42.	Arshad	Jamil
43.	Nahid	Kamal
44.	Ashraf	Khan
45.	Milad	Khan
46.	Shaheen S	Khan
47.	Oliza	Khanam
48.	Shahid	Khandker
49.	Badrur	Khundkar
50.	Zaman	Khundkar
51.	Abdullah	Loman
52.	Md Abdullah Al	Mahmud
53.	Iftekhar	Mahmood
54.	Sifat	Maria
55.	Utpal Kumar	Mondal
56.	Marilyn E	Morris
57.	Md	Mohiuddin
58.	Md	Muniruzzaman
59.	Md Junayed	Nayeen
60.	Mohammed	Nooruzzaman
61.	Rajib K	Paul
62.	NAM Atiqur	Rahman
63.	Mahboob	Rahman
64.	Mehbuba	Rahman
65.	Mamoon	Rashid
66.	Mohammad Jahidur	Rashid
67.	Shah	Rashid
68.	Ehtesham	Reza
69.	Abdus	Salam
70.	Raed	Salam
71.	Sushanta	Sarkar
72.	Abu T	Serajuddin
73.	Syed	Shahriyar
74.	Mohammed	Shameem
75.	Sara	Shameem
76.	Farihah	Shameem
77.	Afsana Bahar	Trini
78.	Mohammad	Uddin
79.	Muhammad Erfan	Uddin
80.	Lawrence X	Yu

Food Menu

Continental Breakfast

- Orange & Apple juice
- Fruit Preserves
- Seasonal whole fruit
- Variety of breakfast breads and pastries
- Freshly brewed Starbucks coffee, decaffainated coffee & Taylor teas

Lunch Buffet

- Homemade cole slaw
- Assortment of Freshly baked gourmet bread rolls
- Soup du Jour
- Market style pasta salad
- Deli meat platter
- Roasted beef (Halal), Chicken breast and tuna salad
- Assorted domestic cheese display
- Deli tray condiments
- Herbed Mayo, whole grain Mustard, Dijon Mustard, Horseradish
- Individual bag of chips
- Chef's selection of assorted desserts
- Freshly brewed Starbucks coffee
- Decaffainated coffe, Taylor teas and Iced tea

Afternoon Coffee Breaks

- Seasonal whole fruit
- Freshly baked brownies and blondies
- Starbucks Coffee, Decaf & Taylor teas

Dinner Buffet

- Garden salad
- With two (2) choices of dressings
- Assortment of Freshly baked grourmet breads and rolls
- Grilled Chicken breast , Halal
- Baked herb talapia
- Penne pasta Mariana
- Seasonal vegetable
- Rice pilaf
- Chef's selection of dessert
- Starbucks coffee & Decaf, Taylor Tazo Teas, Iced tea

Photo from previous AABPS convention

A Warm Welcome to the Convention Attendees in Philadelphia

Best Wishes for a Highly Successful Event

Heritage Pharma Labs Inc.

21-B Cotters Lane

East Brunswick,

NJ 08816, USA

American Association of Bangladeshi Pharmaceutical Scientists (AABPS)

Purpose:

The primary purpose of the AABPS, is to serve its membership, and, in specific- the pharmaceutical professionals of Bangladeshi origin residing in North America working in academia, industry, hospitals, health insurance companies, pharmacies, government and other research institutions- by providing a forum for the interchange of knowledge. AABPS is a non-political, non-religious, not-for-profit, US tax exempt educational organization.

Objectives:

1. To foster communication and collaboration among pharmaceutical scientists and professionals of Bangladeshi origin and residing in North America.
2. To support its members in achieving their highest level of professional career through collaboration, consultation, mentoring, education and exchange of knowledge.
3. To provide timely scientific programs, ongoing education, publications and networking opportunities for the scientists and professionals involved in discovery, development, manufacture and marketing of pharmaceutical products and services.
4. To facilitate communication and contacts between the Association Members and interested personnel in Bangladeshi pharmaceutical industry, government regulatory agency, and academic institutions regarding transfer of knowledge and consulting services on pharmaceutical sciences.
5. To promote fraternity and solidarity among the pharmaceutical scientists and professionals.

Become a member of AABPS, achieve our career goals and enjoy collaboration and friendship of people with similar background and interest. Our career goals should be your career goals.

Visit www.aabps.org

ACI

Advancing Possibilities

ACI HealthCare Limited

245 Tejgaon Industrial Area, Dhaka-1208, Bangladesh | Telephone: (8802) 8878603 | Fax: (8802) 8878619
Website: www.aci-bd.com | Email: info@aci-bd.com