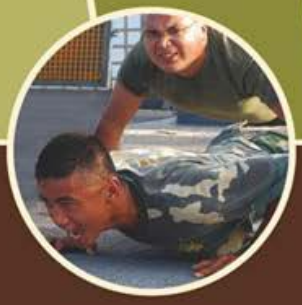
Drug Development Boot Camp™

An Intensive Two Day Course
for Biotech, Pharma Executives,
and Harvard University Investigators

November 16-17, 2016
The Harvard Club
Boston, MA





HARVARD
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SPEEDING NEW DRUGS TO MARKET®

What is the Drug Development Boot Camp™?

The Boot Camp is intensive! It accomplishes in two days what some courses cannot achieve in five days.

*Someone from the SAS said, "**They train you to do certain things, and then you have to do them tired.**" The Drug Development Boot Camp is a little like that. Come prepared to work very hard. If you want to sit back, fall asleep, and drop in and out of lectures for two days, Drug Development Boot Camp is not for you."* - **Dr. Lorna Speid, Founder and Co-chair**

Level of Experience Needed

A good level of understanding of the drug development process is presumed. Background reading will be provided, and should be completed before attending this Boot Camp. This will ensure that you will gain the maximum benefit from the Boot Camp.

Overview

The process of drug development is becoming more and more complex. At the same time, it is becoming more and more expensive. Only 11% of drugs will make it through the drug development and registration processes to commercialization. Those involved with the process of developing new therapeutics (drugs, devices, combination products and diagnostics) must understand the process and be able to navigate it with great skill because failure is incredibly expensive. Those working in drug development must "get it right first time". Drug development skills are difficult to acquire.

The Drug Development Boot Camp™ uses accelerated learning approaches to simulate the drug development process so that hands-on experience can be gained. A mixture of large pharma, small pharma and expert panel members will ensure panel discussions are relevant, responsive and applicable to everyday situations that participants face. This program will consider the process from drug discovery (designation of a development lead) to registration. The major aspects of development will be considered in a unique, systematic and coordinated way.

Who should attend?

- Pharma, Large Biotech, NIH, NCI, Reviewers from Health Authorities, Decision Makers
- CEOs, CFOs, COOs of biotech companies
- Executives involved with the drug development process
- Small and virtual company executives, scientists, and professionals involved with drug discovery and development
- Large pharma professionals involved with drug development
- Regulatory affairs professionals, clinical research professionals, senior research scientists, toxicologists
- Clinical investigators who would like to gain an understanding of drug development, or improve their understanding of the drug development process
- Senior scientists wishing to transition into drug development
- Physician investigators, Pharmaceutical Physicians
- Translational Senior Scientists
- Scientists from Academia

Why should my company be represented at the Drug Development Boot Camp™?

- You sit on project teams. You know the jargon, but don't know the details.
- You are an executive that makes important decisions on drug development programs – you know that you are lacking in the knowledge of key areas of the drug development process
- Your firm uses a lot of consultants, but you cannot interrogate their decisions because you do not have the experience to do so
- Your firm is spending a lot of money on its development programs. Failure will be very expensive.
- You have many years of experience in the pharmaceutical industry, but have worked in one silo for all of that time.
- You are leading a project team but the team struggles to make decisions.

What can I expect from Boot Camp?

- You will learn about drug development in a hands-on manner
- You will learn how to move hypothetical drugs through the process of drug development in a step-wise manner
- You will hear from large pharma and successful small and mid-size companies about the lessons that they have learned in developing their drugs
- There will be many opportunities for networking and working through challenges with peers

What benefit can I expect from participating in Boot Camp?

- You will leave with knowledge and experience that you can apply to your company's drug development challenges.
- From interacting with large pharma experts, you will gain invaluable insights into what you need to do to make your program attractive to them for exit purposes

What Will I Learn?

This is not an entry level program. It is intensive and intended for executive level individuals who make drug development decisions on a daily basis. A minimum of 5 years of relevant drug development experience is required in order to be accepted onto the Drug Development Boot Camp because of the depth and intensity of the program. This is a unique opportunity to be completely immersed in drug development for two days.

Those who do not attend the Drug Development Boot Camp™ or a similar program are at risk of the following:

- Wasting huge sums of investors' money on patent prosecution which will ultimately be useless, lead to costly litigation and prevent the asset from finding an appropriate exit.
- Spending many years and huge sums of money developing a drug or drugs that the market does not want, and will not pay for.
- Making costly mistakes throughout the development process, which will ultimately cost the company, one's reputation and may even lead to safety problems in those administered the company's products.
- Experiencing a lack of direction from the top management team because of a failure to take the time to receive real training in drug development.

- Clinical hold situations which are extremely costly.
- Failure to design a clinical program/clinical programs which could lead to registration of the drug.
- A US-centric approach, rather than a global approach to drug development. This will lead to many problems later in development.
- Ending up with a "*good drug bad development syndrome*".
- Facing expensive CRO and consulting bills, with no additional assurance of success.
- Being forced to rely on the input from CROs. There is a likelihood that you will be assigned the E Team by the CRO because of inability to tell the difference between an A Team and an E Team.
- Inability to take the drug to the market in the timeframe promised to investors, analysts, the Board of Directors and patient groups.
- Inability to manage the expectations of the Board of Directors.
- Ineffective decision making mechanisms.
- Inability to raise funds or to find an appropriate exit.
- Inability to work effectively with major health authorities.
- Loss of company, job and reputation.

Participant Feedback from the 2015 Drug Development Boot Camp™

Participants for the 2015 Drug Development Boot Camp™ came from Canada, Germany, Israel, Belgium, The Netherlands, Spain, and the USA.

Overall Boot Camp Experience

"I think the breadth and depth of the camp was excellent."

"Janis Fraser - Excellent talk which taught me that should try to patent anything (might not work though)."

Commercial Session

"Helped me better understand how pharma selects candidates. Ironically uses the SAME financial models we use to select products to develop. Was GREAT!"

"This session made me realize that it's very valuable to think about the target product profile very early and that the commercial assessment should be considered earlier."

"Thrilled by Paul Gallagher."

"Great"

Tony Sarraino's talk was fantastic

Global and Strategic Regulatory Affairs Session

"All talks were great - especially on a topic such as this which can be DRY!"

"Good overview of modules needed for IND and CTA packages. Important to have a good regulatory strategy at an early stage of the process."

"The slide that showed a side by side comparison was helpful."

"I liked Lorna's examples of Tegenero/U Penn cases of mistakes."

"Seven Mistakes to Avoid with IND/CTAs was concise and fantastic takeaway points."

"The mistakes session (7 Mistakes) was great"

Preclinical Efficacy Session

"This was an interesting session - Lots presented in short time."

"Great PK/PD session. Very helpful to use the PK/PD models."

"Iain M. was charismatic and engaging. I liked his slides. Some didn't make sense (picture of bath) but overall I liked his method of explanation."

"Nice workshop / case study: easy to understand for a not subject matter expert."

"I gained an appreciation for PK/PD modeling and its impact and effectiveness."

"Great workshop! Hands-on Matlabs software was very informative"

"Very informative. The conversion chart between species very useful!"

"I did like John Burke's session a lot."

Toxicology Session

"Scott was GREAT!"

"I learned the comprehensive nature of toxicology considerations companies go through, including how drugs are assessed if being in-licensed."

"Allometric scaling is not as complex as I thought it was."

"Understanding that nonclinical safety studies objective and scope allows me to better understand the design of the safety studies in my current projects."

"Great session! Learned lot about small molecules vs biopharmaceuticals Workshop was very informative."

"That was a good session."

"Scott Boley was the best speaker. He brought us from the basic to complex. Very good and helpful tox information."

Chemistry Manufacturing Controls Session

"Better understanding of tech transfer and how we can modify our messages and products to address the needs of pharma."

"Really well presented."

"Eye opening session due to my lack of expertise and also importance of the process and non-clinical toxicology."

"Seshu spoke easily about her topic. I didn't understand all of her presentation but it was good - easier to relate to what she was saying than some other presentations and logical presentation."

"Like the presentation of highlights of both small molecules and biologics."

"One REALLY has to plan early. I now understand my CMC colleagues a lot better."

"It was a good session."

Clinical Session

"I enjoyed the clinical design information, especially the augmented design."

"Great case study and workshop"

"Benefits of adaptive design. Great discussion after the Workshop."

" Excellent and would like longer session in future"

"Adaptive design was very informative."

Day 2 Workshop Session

"Great experience!"

"Good example of team work as we had good discussion."

"Good to see what really happened to the drug in the case study."

"Great workshop. Enjoyed working in group as a team."

"Experience of other attendees was very high."

Final Session: ***Sending Out the Special Forces!***

"Great talks; very inspiring!"

"Fantastic talk about how important innovation is."

"The whole session was incredibly interesting!"

"Pravin Chaturvedi, Ph.D. Best presenter and most motivating sessions."

Outline Agenda

Special Guest Speaker – Dr. Leeza Osipenko, NICE, England

The Drug Development Boot Camp™ is pleased to welcome Dr. Leeza Osipenko from NICE, England as our special guest. She will be giving several keynotes about the English payer reimbursement process during the Boot Camp, including one or two lunchtime Keynotes.

Dr Leeza Osipenko heads the Scientific Advice service at NICE and leads on a number of strategic and international initiatives across the Institute. She holds an Honorary Fellow post at the University of Warwick Medical School and represents NICE as a Chief Analyst at the Department of Health Analytical Directors of Arm's Length Bodies (ALBs) group. Leeza holds a BA in Economics and International Affairs, MSc in Technology Management and a PhD in Systems Engineering. As Senior Research Fellow at University of Warwick she conducted health economic evaluation of non-invasive prenatal diagnostic tests. In 2010 she became a Principal Economist at a London-based public sector consultancy, Optimity Matrix, where she led on projects for NICE and other public sector organisations. Leeza has a research and consulting background in health technology assessment and economic evaluation.

Dr. Leeza Osipenko will present several times throughout the Drug Development Boot Camp™

Day 1 Start at 7:00 am EST	**Day 2** Start at 7:00 am EST	**Some Special Features**
COMMERCIAL SESSION **Drug Discovery to Product Candidate** The criteria for selecting the lead candidate will be explored. Dr. Leeza Osipenko will be a special guest on this panel.	**CHEMISTRY MANUFACTURING CONTROLS (CMC)** The inter-relationship of CMC to safety and efficacy will be explored in a lot of detail. The CMC session will also cover Process analytical technologies (PAT) and manufacturing scale-up.	This two day intensive Boot Camp will be interspersed with workshops, breakout sessions, case study analyses and puzzles. The hands-on approach will enable those with experience in drug development to gain an understanding of areas that they are as yet unfamiliar with. Those with 5 years or less experience in drug development will leave with an understanding of how to effectively move a compound through the drug development process. Those with 5 to 10 years of experience will deepen their knowledge of the drug development process and will be able to apply their knowledge to complex drug development situations in carefully constructed Workshops. The Drug Development Boot Camp is extremely interactive. It is taught by expert drug developers. The Faculty are experts in their fields. The course content has been put together very carefully to achieve the goals of teaching about the Drug Development process in a lot of detail. Because of the workshops and case studies that you will work on, the learning process is fun and hands-on, but intensive. Information is imparted by the Faculty, but the understanding of this material is reinforced and tested throughout the Boot Camp as participants interact together. Participants are able to work on the material provided with other participants using case studies.
REGULATORY AFFAIRS The Target Product Profile and Development of the Regulatory Strategy The critical importance of the Target Product Profile and the process for defining it will be presented. The interfaces of marketing, clinical and reimbursement will be explored. The importance of developing a global regulatory strategy will be considered. A method for developing the global regulatory strategy will be presented.	**The CLINICAL PHASE** The four phases of clinical development, the goals of each, and the potential issues to be managed will be identified and explored in detail. Dr. Leeza Osipenko will be a special guest on this panel. A clinical Workshop featuring a real case study will be presented.	
PRECLINICAL DEVELOPMENT Preclinical Efficacy Different methods for demonstrating proof of concept during the preclinical phase will be presented and considered in detail. Scale up of the data obtained to preclinical toxicology studies will be considered. An interactive workshop on PK/PD will be presented.	**WORKSHOPS - AFTERNOON OF DAY 2** Participants will be divided into project teams according to their levels of previous drug development experience, skills, and their objectives stated on a questionnaire. The Project Teams will work on drug development case studies. Each project team will report back to the whole group regarding how their case studies. The Faculty will present the responses. This is a time to consolidate all that has been learnt during the Boot Camp.	

Day 1 Start at 7:00 am EST	**Day 2** Start at 7:00 am EST	**Some Special Features**
PRECLINICAL TOXICOLOGY **Clinical Development and the inter-relationship with toxicological evaluation up to registration** The interface of GLP toxicology studies, CMC and clinical will be considered in detail.	**THE INDUSTRY – WHERE IT HAS BEEN, AND WHERE IT IS GOING** Consideration will be given to how those who have completed the Drug Development Boot Camp can make a strategic contribution. Dr. Leeza Osipenko will be a special guest speaker on this panel. Participants will have an opportunity to ask her questions.	
Reception and Networking - optional This is a time to relax after a day of intensive learning. Network with your colleagues, make new connections and exchange experiences that were learnt during Day 1. Background reading will be provided for overnight reading, in preparation for Day 2.	**PANEL Q&A AND DISCUSSION** **Your opportunity to ask remaining questions, discuss your individual project challenges, etc.** Experts will take questions from the participants. These questions may be questions arising from the course or questions from their own drug development situations.	**Certificates of Attendance** for continuing education purposes will be provided to all who complete the complete two day intensive course. Day 2 will end at about 6:15 pm EST. Certificates can only be provided to those who remain to the end of the Boot Camp.

Laptops and iPads

Participants will be provided the Briefing Book in an electronic format. The electronic Briefing Book will also be available for viewing for those that want to bring their iPads. At the request of past participants that we move into the 21st Century, save the trees, and provide everything electronically, hard copies of the materials will not be provided. All participants must ensure that they bring a laptop or an iPad with them to the Boot Camp.

Reading Assignments

All registered participants will be given reading assignments which should be read before the Boot Camp.

We regret that the electronic Briefing Book will only be provided at the Boot Camp itself.

Speakers and Panel Members: Faculty

The following Faculty are representative for the 2016 Drug Development Boot Camp. We regret that changes may be necessary due to scheduling and personal conflicts nearer the Boot Camp.

Special Guest Speaker: Leeza Osipenko, BSc, MSc. Ph.D., Head of Scientific Advice Service, NICE, United Kingdom

Areas to be covered: Reimbursement and Appraisals in the United Kingdom

Dr Leeza Osipenko heads the Scientific Advice service at NICE and leads on a number of strategic and international initiatives across the Institute. She holds an Honorary Fellow post at the University of Warwick Medical School and represents NICE as a Chief Analyst at the Department of Health Analytical Directors of Arm's Length Bodies (ALBs) group. Leeza holds a BA in Economics and International Affairs, MSc in Technology Management and a PhD in Systems Engineering. As Senior Research Fellow at University of Warwick she conducted health economic evaluation of non-invasive prenatal diagnostic tests. In 2010 she became a Principal Economist at a London-based public sector consultancy, Optimity Matrix, where she led on projects for NICE and other public sector organisations. Leeza has a research and consulting background in health technology assessment and economic evaluation.

June Almenoff, MD, Ph.D.

Areas to be covered: Drug Safety, Last Session Panel Member

June S. Almenoff MD, PhD, is an accomplished pharmaceutical executive with close to 20 years of industry experience. She has extensive expertise in clinical development, translational medicine and business development. Dr. Almenoff recently served as President, Principal Executive Officer and Chief Medical Officer of Furiex Pharmaceuticals. During her 4-year tenure, the company's valuation increased ~10-fold, culminating in its acquisition by Forest Labs/Actavis plc for ~$1.2B in 2014. Furiex's lead product, eluxadoline (Viberzi TM), a novel gastrointestinal drug, received FDA approval in 2015. Prior to joining Furiex, Dr. Almenoff was at GlaxoSmithKline (GSK), where she held positions of increasing responsibility. During her 12 years at GSK, she was a Vice President in the Clinical Safety organization, chaired a PhRMA-FDA working group and also worked in the area of scientific licensing. Dr. Almenoff led the development of pioneering systems for minimizing risk in early- and late-stage drug development which are now widely used by pharmaceutical companies and regulatory agencies. Dr. Almenoff is currently an independent biopharma consultant and Board Director: she is the Executive Chair of RDD Pharma and a member of the Boards of Ohr Pharmaceuticals (Nasdaq: OHRP) and Valanbio. She also serves on the investment advisory board of the Harrington Discovery Institute (Case Western Univ) and the scientific advisory board of Redhill Biopharma (Nasdaq: RDHL). Dr. Almenoff received her B.A. cum laude from Smith College and graduated with AOA honors from the M.D.-Ph.D. program at the Icahn (Mt. Sinai) School of Medicine. She completed post-graduate medical training at Stanford University Medical Center (Internal Medicine, Infectious Diseases) and served on the faculty of Duke University School of Medicine. She is an adjunct Professor at Duke and a Fellow of the American College of Physicians.

Lewis Barrett, Owner and President, LLBarrett Biopharmaceutical Consulting, LLC

Areas to be covered: Marketing and Commercialization

Mr. Barrett is a Global Pharmaceutical Executive with broad experience leading sales, brand and therapeutic area marketing and strategic planning teams. He is a leader who envisions, energizes and empowers winning teams and integrates multifunctional expertise to develop innovative solutions and strategies. He has successfully led, co-chaired or been the senior marketing executive on teams including domestic and global brand, clinical development, Medical Affairs, supply chain, business development, and strategic alliance management. He has successfully managed brands above plan, executed global branding initiatives for several products, successfully launched multiple products across multiple therapeutic categories globally and executed innovative lifecycle management on a worldwide basis. He has extensive experience and P&L responsibility in the US and international markets predominantly for Wyeth (now Pfizer).

Mr. Barrett launched LLBarrett Biopharmaceutical Consulting, LLC in 2010. He has assisted companies, large and small, in strategic planning, asset valuation, market evaluation, clinical trial planning and opinion leader development. Mr. Barrett has also been involved in ongoing policy discussions regarding jumpstarting anti-infective drug development in the U.S. and abroad.

In addition to consulting roles for various early-to-mid stage companies, Mr. Barrett was Senior Vice President of Commercial Strategy for Synthetic Biologics. Synthetic Biologics is a clinical stage biopharma company focused on therapies designed to protect the gut microbiome. At Synthetic Biologics Mr. Barrett's roles included strategy, asset evaluation, asset acquisition as well as scientific, clinical and commercial planning.

Mr. Barrett was selected as a case study and faculty member for the Wyeth Executive Leadership Program focusing on inspirational leadership accomplishments at Wyeth. Additionally, he was a faculty member for the Wyeth Positioning Academy run by the Wharton School at the University of Pennsylvania. More recently Mr. Barrett has served as a panelist at GTC Bio 2013: Anti-infectives Partnering and Deal Making Conference. He is also a returning faculty member of the Harvard Drug Development Bootcamp.

He holds an MBA degree from Temple University, a BS degree in biology from Stockton College, and was a registered Medical Technologist (MT (ASCP)).

Scott Boley, Ph.D., DABT., Senior Director of General Toxicology and Infusion Toxicology, MPI Research

Areas to be covered: Preclinical Development and Toxicology

Dr. Boley, joined MPI Research in 2005 as a Study Director in general toxicology and now serves as Senior Scientific Advisor. As an expert with more than 12 years of experience, Dr. Boley assists Sponsors in the design of nonclinical studies in support of a wide range of novel therapeutics. Before joining the company, he was a research scientist at Eli Lilly and Company in nonclinical safety assessment, where he developed the nonclinical strategy for supporting the development of novel therapeutics for oncology and neurological indications. In addition to designing and managing investigational, screening, and animal studies required for regulatory submission, he authored the toxicology sections for INDs and for clinical investigator brochures. Dr. Boley received his doctorate in biochemistry and environmental toxicology

from Michigan State University in 1998, where his research focused on the malignant transformation of human cells using tissue culture. His postdoctoral work at CIIT Centers for Health Research (Research Triangle Park, North Carolina), involved the use of transgenic mice and molecular biology to examine tumors induced in these mice for characteristics common to human tumor formation. Dr. Boley has presented and published extensively in the field of toxicology and is a member of the Drug Information Association and the American College of Toxicology.

John Burke, Ph.D., President, CEO and Co-Founder of Applied BioMath, LLC.

Areas to be covered: Modeling and Simulation

Dr. Burke is President, CEO and Co-founder of Applied BioMath, LLC., a Systems Biology and Pharmacology company. Dr. Burke's BS and MS are in Applied Mathematics, University of Massachusetts, Lowell. His PhD degree is in Applied Mathematics, Arizona State University, where he studied dynamical systems, singular perturbation theory, and control of signal transduction networks and protein expression. Prior to Applied BioMath, Dr. Burke joined Boehringer Ingelheim (BI), as Global Head of Systems Biology, where he started, developed and managed the Systems Biology group, portfolio, and strategy. The group was responsible for applying systems techniques across all Research sites, Development and Medicine. His group supported over 100 projects in five years, and over 11 transitions into Development or Clinical Trials. Prior to BI, he was a Sr. Fellow in Douglas A. Lauffenburger's lab, Biological Engineering Department, MIT; Co-Scientific Director of the Cell Decision Processes Center, Systems Biology Department, Harvard Medical School; then Merrimack Pharmaceuticals. While at MIT and HMS, Dr. Burke studied apoptosis and growth factor pathways, and provided consulting or advising services for companies, including AstraZeneca, Pfizer, Momenta, Matlab, and Numerica. Research interests include singularly and randomly perturbed differential equations, bifurcation theory, understanding how cells and tissues make decisions in human disease, predicting optimal drug properties and mechanistic PK/PD. He presented at the NIH-Academic-Industry Target Validation Consortia and presently he serves on advisory boards for the MIT "Human Physiome on a Chip" MIT-DARPA Program and the Mathematics Department at the University of Massachusetts, Lowell.

Mark Chang, Ph.D. Senior Vice President of Strategic Statistical Consulting, Veristat.

Areas to be covered: Adaptive Clinical Study Designs

Dr. Chang has more than 20 years of experience as a statistician at both biopharmaceutical firms and CROs, including AMAG Pharmaceuticals, Millenium/Takeda Pharmaceuticals, PAREXEL and MTRA. He is experienced with NDA submissions and working collaboratively with the regulatory agencies throughout the clinical trial and submission process. Dr. Chang is also an adaptive design expert, having authored and co-authored dozens of books and peer- reviewed journal publications on adaptive design methodologies and implementation in clinical trials.

In addition, Dr. Chang is a fellow of the American Statistical Association and an adjunct professor of Biostatistics at Boston University. He is a co-founder of the International Society for Biopharmaceutical Statistics, co-chair of the Biotechnology Industry Organization (BIO) Adaptive Design Working Group, and a member of the Multiregional Clinical Trial (MRCT) Expert Group. Throughout his career, he has frequently held advisory posts for numerous industry committees and served as an associate editor for many peer-reviewed publications. He has given over 50 lectures, short courses, and invited speeches at national and international conferences and has been invited twice to present at the FDA.

Joseph A. DiMasi, Ph.D., Director of Economic Analysis, Tufts Center for the Study of Drug Development, Tufts University of Boston, MA

Areas to be covered: Latest pharmaceutical industry benchmarking data

Dr. DiMasi is Director of Economic Analysis at the Tufts Center for the Study of Drug Development. The Center is an independent non-profit multidisciplinary research organization affiliated with Tufts University that is committed to the exploration of scientific, economic, legal, and public policy issues related to pharmaceutical and biotechnology research, development, and regulation throughout the world. Dr. DiMasi serves on the editorial board of Therapeutic Innovation and Regulatory Science, and has served on the editorial boards of the Journal of Research in Pharmaceutical Economics, and the Journal of Pharmaceutical Finance, Economics & Policy. Dr. DiMasi has published in a wide variety of economic, medical, and scientific journals, and has presented his research at numerous professional and industry conferences. Dr. DiMasi testified before the U.S. Congress in hearings leading up to the FDA Modernization Act of 1997 and reauthorization of the Prescription Drug User Fee Act.

Yasha Dwivedi, M.S., PMP, Global Program Manager, Takeda Pharmaceuticals (USA)

Areas to be covered: Project Management

Yasha has extensive experience in managing compounds in different drug-development stages as well as therapeutic areas. Prior to completing her Master's in Bioengineering, Yasha worked for Argonne National Lab, Rush University Medical Center and Roche Diagnostics.

Paul Gallagher, MBA, President, Compass Strategic Consulting, Inc.

Areas to be covered: Reimbursement Strategies, Market Access Strategies

Paul has over 35 years in healthcare that is characterized by its breadth and extensive experience in the development and commercialization of innovations.

Before founding Compass in 1994, Paul worked for legacy companies of Novartis (Ciba-Geigy), Sanofi (Merrell Dow) and Pfizer (Wyeth), holding positions of increasing responsibilities in marketing research, product management, sales management and executive commercial management, including Vice President of Global Marketing.

Compass specializes in global market access intelligence and strategies. Compass provides pricing, value, and access assessments and strategies in the pharma, biotech, and diagnostic sectors.

Paul holds a BA in economics from Columbia University and an MBA in marketing from George Washington University.

He has been a member of the Faculty of the Drug Development Boot Camp at Harvard University from 2011 through 2015, moderated a panel on *Commercialization and Reimbursement of Gene Therapies* at the Genetic Rx Conference, and been a Panelist on *What's Hot & What's Not in Gene Therapies for Rare Disorders*, Webinar sponsored by BIO.

In October 2015, he developed and moderated an industry-payer panel on *Addressing Payer's Heightened Aggressiveness in Managing Price and Access in Forecasting, Valuations, and Deal Terms* at the Licensing Executives Society annual meeting.

Daniel Gant, Ph.D., DABT, Scinovo (GSK) Consultancy/Diligence Director, WWBD Scientific Licensing Director, RD Platform Technology & Science

Areas to be covered: Workshop Leader, Toxicology

Dr. Gant provides integrated drug discovery and development consultancy to GSK's external collaborators, ranging from single-item consultation, through to more ongoing engagement with a program of work, which includes scientific delivery and access to GSK's extensive expert networks.

In collaboration with GSK World Wide Business Development, Dr. Gant leads /orchestrates due diligence on assets or external company competencies for GSK's Platform Technology Services (PTS - Safety Assessment, DMPK, Product Development). He delivers the integrated PTS position and risk assessment strategy. Due diligence across multiple therapeutic areas, early discovery to marketed products covering NCEs, biopharm, gene therapy, platforms and devices.

Carlos R. Langezaal, Ph.D., Director Global Regulatory Affairs, Neuroscience Creation Unit, Eisai Inc.

Areas to be covered: Regulatory Affairs

Carlos R. Langezaal, Ph.D., Director, Global Regulatory Affairs, is heading up the Global Labeling group with Global Regulatory Affairs at Eisai. Previously, he worked at Eisai, Sanofi-Aventis, J&J PRD, Schering-Plough, Core Technologies, Eli Lilly and Baxter in various therapeutic areas, including CNS, oncology, allergy, respiratory and internal medicine. He has more than 20 years of experience in regulatory affairs, having worked in the device, device/drug combination products, CMC and Clinical/non-Clinical development areas primarily with a global focus. In addition, he is an active volunteer in The Organisation for Professionals in Regulatory Affairs (TOPRA), having fulfilled the positions of North America Regional Development Director from 2006 through 2010, and Director without portfolio from 2012 through 2014 and was as such a member of the Board of Directors. In addition, he was a member of the TOPRA Annual Symposium Working Party for 2015 and 2016.

Suzanne Mandala, Ph.D., Suzanne Mandala, Ph.D., Mandala Consulting LLC

Areas to be covered: Licensing

Dr. Suzanne Mandala has over 25 years of drug development experience, leading research and pharmaceutical licensing and business development. Suzanne received her BA degree from Swarthmore College and her PhD from the University of California, Santa Cruz. She was a postdoctoral fellow in the Department of Human Genetics at Yale University. Suzanne joined Merck in 1989 as a research biologist in the Infectious Disease Department. After working on systemic antifungal therapeutic agents for 10 years, she led drug discovery and development efforts in the Immunology and Rheumatology Department. Suzanne was directing a diverse portfolio of projects in immunology, inflammation, and hematology until 2008, when she assumed a position in licensing, working with therapeutic area heads to set licensing strategies. She executed a number of major in-licensing and out-licensing deals in inflammation, oncology, and companion diagnostics. In her most recent position at Merck, Suzanne headed the group of strategic licensing and acquisitions liaisons responsible for the scientific assessment of external opportunities for all therapeutic and technical areas. Suzanne is currently an independent consultant in licensing and business development.

Iain Martin, Ph.D., Distinguished Scientist, Pharmacokinetics, Pharmacodynamics and Drug Metabolism (PPDM), Merck Research Laboratories

Areas to be covered: PK/PD and Modeling and Simulation

Dr Iain Martin is a DMPK scientist with over 25 years' experience in pharmaceutical drug discovery and development. Iain has an honors degree in biochemistry and Ph.D. in drug metabolism from the University of Surrey in the UK. During his career he has held positions of increasing responsibility with Upjohn, AstraZeneca, Organon, Schering Plough and Merck. In 2010, Iain relocated to the US to assume the position of Director and Site Lead for DMPK at Merck's Boston facility. In his current role, he has responsibility for PPDM scientific strategy and licensing activities. He has a broad range of interest and expertise across the field of PPDM; especially the understanding of molecular properties that govern pharmacokinetic behavior and their prediction from in silico models. Whilst in the UK, Iain was an active participant in the Drug Metabolism Discussion Group. He served as chairman in 2007 and founded a residential training course entitled 'Chemistry for DMPK' attended by scientists from all over Europe.

Tom J. Parry, Ph.D., Senior Director of Pharmacology and Safety, Acorda Therapeutics

Areas to be covered: Preclinical Efficacy

Tom J. Parry, Ph.D. joined Acorda Therapeutics in 2009 where he is now Senior Director of Pharmacology and Safety, supporting nonclinical drug development. Dr. Parry served various nonclinical pharmacology/toxicology scientific roles in multiple biotechnology companies including Ribozyme Pharmaceuticals (aka Sirna Therapeutics acquired by Merck) and Human Genome Sciences, where he helped file a number of IND's and supported development. Just prior to joining Acorda Therapeutics, Dr. Parry served as a Principal Scientist at Johnson and Johnson where he worked on multiple products including drug-eluting stents as well as cardiovascular and metabolic disease drugs. Over his 17 year biopharmaceutical career, Dr. Parry has obtained multiple research grants, patents and has authored/co-authored numerous peer-reviewed publications. In addition to his biopharmaceutical company roles, Dr. Parry serves as an adjunct faculty member at Temple University School of Medicine and School of Pharmacy where he teaches a graduate course in Pharmaceutical Biotechnology. Dr. Parry received a B.S. in Chemistry from Moravian College, a Ph.D. in Pharmacology from Temple University and was a post-doctoral fellow in Pharmacology/Psychiatry at the University of Pennsylvania. Dr. Parry also serves on the Executive Committee and was Secretary/Treasurer of the Division of Drug Discovery, Development and Regulatory Affairs of ASPET.

John J. Piwinski, Ph.D., JJPiwinski Pharma Consulting, LLC

Areas to be covered: Chemistry/Medicinal Chemistry/Drug Discovery; Co-chair of the Day 2 Workshop Session

John J. Piwinski has extensive expertise in small molecule drug discovery with over 35 years of experience in medicinal chemistry. During his career, he oversaw discovery programs in chemistry from project initiation to delivery of candidates for clinical development. He received his B.S. degree in Chemistry and Biochemistry from the State University of New York at Stony Brook in 1976 and his Ph.D. in Organic Chemistry from Yale University in 1980. He then joined Revlon Health Care as a Senior Scientist working in the cardiovascular diseases area. In 1983 he moved to Schering-Plough where he worked in the respiratory diseases group. At Schering he held positions of increasing responsibility and eventually oversaw Chemical Research as Vice President from 1999 to 2003 and Group Vice President from 2004 to 2008. In this position he was responsible for overseeing drug discovery in chemistry in Kenilworth, New Jersey in the areas of respiratory, inflammation, cardiovascular, CNS, oncology and infectious diseases. In 2008 he became the Site Head and Group Vice President of Schering-

Plough's Cambridge, Massachusetts site. Research at the site focused on medicinal chemistry, affinity-based screening and optimization, bioNMR, protein science and biologics. Merck acquired Schering-Plough in 2009 and continued to operate the Cambridge site until the end of 2010. He currently consults in the areas of medicinal chemistry and drug discovery, including small molecule lead discovery and optimization. In this role he has consulted with numerous companies, which included conducting program consulting, due diligences and patent work. He has presented numerous talks at scientific meetings and has approximately 150 published research papers, abstracts and approved U.S. patents. He is a member of the Innovation Support Center Advisory Panel for the Harrington Discovery Institute, a Scientific Advisory Board Member for the Center to Develop Therapeutic Countermeasures to Treat Bacterial Agents at Rutgers University, and a member for the Institute of Chemical Biology & Drug Discovery Advisory Board at Stony Brook University. In recognition of his accomplishments, he received the North Jersey American Chemical Society (NJACS) Lifetime Achievement Award in 2013.

Ambarish K. Singh, Ph.D., Senior Director, Global Regulatory Sciences-Chemistry, Manufacturing and Controls, Bristol-Myers Squibb Company

Areas to be covered: Chemistry Manufacturing Controls (small molecules); CMC Workshop Leader

Ambarish holds a PhD in Organic Chemistry from the State University of New York at Stony Brook. He served as a post-doctoral fellow at Fox Chase Cancer Center, Philadelphia and Memorial Sloan Kettering Cancer Center, New York. Ambarish started his industrial career by joining the Process Research and Development department of Bristol-Myers Squibb Company and contributed heavily to the chemical process development of numerous commercial products, such as Fungizone(TM), Pravachol(TM), Taxol(TM), and Baraclude(TM).

Dr. Singh has led several successful "start-ups" to transfer laboratory processes to manufacturing sites in Ireland, Italy and Puerto Rico. In addition, Ambarish also led his Pharmaceutical Development and Technical Operations cross-functional teams for developing, manufacturing and filing of the marketing application for Onglyza(TM), a DPP4 inhibitor for the treatment of Type II diabetes. In 2007, Ambarish transitioned into Global Regulatory Sciences-Chemistry, Manufacturing and Control department and in 2008 he became the worldwide Regulatory-CMC lead for Eliquis(TM), a Factor Xa inhibitor. This was BMS' first holistic Quality-by-Design and near infrared (NIR) based real-time release testing regulatory filing. Due to many "regulatory firsts" for BMS in this filing, he led several Health Authority interactions (FDA, EMA, Health-Canada and TGA).

Currently Ambarish and his group manage a portfolio of drugs in early, late and post-approval phases. He provides technical and regulatory oversight to his direct reports and other members of the department. Ambarish has received several BMS awards (3 President's awards, 8 Triumph awards, 1 Ondetti & Cushman award and many Star awards) for his contributions to the advancement of Science and Technology in Process R&D and for developing risk based CMC filing strategies. He has published >25 scientific articles and holds 6 patents.

Ambarish has given numerous talks on topics related to chemical process development and QbD/PAT/RTRT at universities and professional conferences. He has given workshops (both internal and external to BMS) on topics such as, Organic Chemistry for pharmaceutical scientists, The science of crystallization, Lab automation- a chemist's perspective and Challenges & opportunities in the global submission of QbD/PAT based marketing applications. He has served on the scientific advisory board of Cambridge Healthtech Institute (CHI) and American Chemical Society local chapter-Regulatory-CMC.

Deborah Slipetz, Ph.D., Executive Director, In-Vivo Pharmacology, Early Development and Discovery Sciences, Merck Research Laboratories

Areas to be covered: Preclinical Efficacy Workshop

Deborah Slipetz is an In-vitro and in-vivo pharmacologist with more than 20 years of pharmaceutical industry experience at Merck. Deborah has a bachelor's degree in cell & molecular biology a master's degree in molecular genetics and a PhD in pharmacology all from McGill University, Canada. Deborah is currently an Executive Director in In Vivo Pharmacology responsible for the respiratory, immunology and oncology therapeutic areas. During her career, Deborah has held leadership positions in the Respiratory and Immunology therapeutic areas where she was responsible for the execution of multiple drug discovery projects and earlier in her career, as a team leader on multiple drug development programs. She has extensive experience, spanning multiple therapeutic areas (respiratory, immunology, oncology, pain, inflammation, opthamology, hypertension, diabetes and obesity), in the fields of pre-clinical drug discovery. She has been a team leader or a key contributor on more than 15 pre-clinical drug discovery projects, 8 of which have entered clinical studies, including 4 still in clinical development, one that completed phase III and one approved drug, Singulair. Deborah has extensive experience in supporting regulatory filings for IND and NDA's and also sits on the product development teams for Singulair and Dulera. Deborah has also served as an adjunct professor in the Department of Pharmacology, McGill University.

Lorna Speid, B.Pharm.(Hons.)., M.R.Pharm.S., Ph.D., RAC, Speid & Associates, inc.

Areas to be covered: Global and Strategic Regulatory Affairs, Clinical Strategic, Founder and Co-Chair of the Drug Development Boot Camp

See below for Bio

Michael V. Templin, Ph.D., DABT, Technical Director, SNBL USA Ltd.

Areas to be covered: Toxicology - Biologics

Michael V. Templin has over 15 years of experience in preclinical and early clinical drug development. After receiving (1993) a doctorate in Pharmacology/Toxicology from Washington State University, he completed (1996) a Postdoctoral Fellowship at the Chemical Industry Institute of Toxicology. Pharmaceutical development experience (1996 to 2013) includes Isis Pharmaceuticals, Amgen, Zymogenetics, and Marina Biotech. Within these companies he has held positions of responsibility for toxicology and pharmacology studies for a wide range of drug candidates including small molecules, biologics (antibodies and proteins), peptides, antisense oligonucleotides, and siRNAs. Michael has experience in the design, oversight, and interpretation of research and GLP studies for INDs, NDAs, and ex-US submissions for cancer, inflammation, cardiovascular, metabolic, and antiviral diseases. Additional responsibilities have involved surveillance for candidate in-licensing and out-licensing of candidates/therapeutic programs. Michael currently serves as a Technical Director at SNBL USA to provide guidance to internal teams and external groups to strengthen preclinical development programs.

Seshu Pedapudi Tyagarajan Ph.D., Director/PTR, Cell and Gene Therapy, Novartis Pharmaceuticals

Areas to be covered: Chair, Chemistry Manufacturing Controls; Workshop CMC Biologics

Seshu Tyagarajan has over 14 years of experience in the Biotech/Pharmaceutical industry working in large, mid and small companies. She has a broad range of expertise in biologics, in areas such as project management, process development, manufacturing and research. She has worked extensively with commercial as well as clinical molecules, setting strategy, minimizing risks and managing milestones. She has been consistently recognized for her efforts in process improvements at small, pilot & commercial scales. She has a wealth of experience in cell culture and in life cycle management of mAbs, recombinant proteins and most recently in cellular therapies.

At Novartis Pharmaceuticals she is the Project Technical Representative for a Cell and Gene Therapy molecule, where she is responsible for delivering all the CMC activities, as well as overseeing the

Technology Transfer activities required to be ready for Pivotal Trials and registration. At ImClone Systems she was the Project Manager responsible for delivering the BLA for CYRAMZA®. Seshu was also the CMC team leader for several oncology molecules encompassing different stages of development from Phase 1 through Phase 3, while managing filing related activities for ERBITUX®. Her past expertise also includes investigating, supporting and improving manufacturing processes for AVONEX® and ZENAPAX®.

Seshu has worked at Merck, Roche, Phyton, Biogen, ImClone and Novartis in various capacities. She has the unique combination of small scale R&D, and large scale clinical and commercial manufacturing expertise. She has a Ph.D. in Chemical and Biochemical Engineering from Rutgers University, an MS in Bioengineering from Purdue University and US-RAC certification from RAPS. She has been an invited speaker, has been on the advisory board for conferences, has chaired several conference sessions and launched a novel session on CMC Project Management.

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Co-Chairs

Michal Preminger, Ph.D., MBA

Executive Director, Harvard University Office of Technology Development (OTD)

Michal Preminger, PhD, MBA is currently the Executive Director of the Harvard Office of Technology Development (OTD) at Harvard Medical School. Michal Preminger joined OTD in 2005. Prior to joining Harvard, she held a number of business development and technology development positions at Compugen, most recently as Vice President of Protein Therapeutics, responsible for the business management of the company's emerging drug discovery pipeline. Previously, Michal held several marketing and business development positions in the hi-tech industry, among others for Lucent Technologies. Michal also co-founded Anima Cell Metrology, a biotechnology startup focused on the real-time identification of proteins as they are synthesized in living cells. Michal holds an undergraduate degree in Medicine from the Hebrew University School of Medicine, a PhD from the Weizmann Institute of Science, and an MBA from INSEAD in Fontainebleau, France.

Lorna Speid, B.Pharm.(Hons.)., M.R.Pharm.S., Ph.D., RAC

President, Speid & Associates, Inc.

Dr. Speid works with small and large pharmaceutical companies, assisting them at all stages of the drug development process. She has experience working on US, European, international and global strategic regulatory affairs. Dr. Speid has an excellent track record of success in regulatory affairs, and is considered an expert in her field. She has experience with many therapeutic areas including oncology (solid tumor and hematological), diabetes (Type 1 and Type 2), obesity, dermatology, transplantation, lupus, bone, women's health (hormone replacement therapy and osteoporosis), and pulmonary. Dr. Speid has worked with all therapeutic modalities, including small and large molecules, gene therapy, cellular therapies, combination products [drugs with devices], drugs with diagnostics, and devices. She has worked at all phases of the drug development process, including translational medicine, Phases 1 to 3 and post-marketing.

Dr. Speid began her career as a pharmacist in the UK, after which she completed a Ph.D. at the Centre for Medicines Research International, into the *Safety Assessment of Medicines, Pre and Post Marketing.* She has worked for large as well as small pharma companies, including Sanofi-Winthrop in the UK (now Sanofi-Aventis), Ciba Geigy (HQ in Switzerland), and Novartis (HQ in Switzerland). Small companies that she has worked for include Valentis, Inc. (Director of Regulatory Affairs), NewBiotics (Vice President Regulatory Affairs and Project Management), and Avera, Inc. (Vice President of Regulatory Affairs). Dr. Speid was an officer at the last two companies. She has a Bachelor of Pharmacy degree with Honors from the University of London, UK (Kings College), and a Ph.D. from the University of Wales, College Cardiff, UK.

Dr. Speid is the author of Clinical Trials: What Patients and Healthy Volunteers Need to Know which is published by Oxford University Press. The book is written for patients and healthy volunteers, and explains the process of clinical trials, equipping them to participate in clinical trials more effectively. The book is available to research subjects globally. She is also the Founder and President of **Putting Rare Diseases Patients First!** a 501(c) (3) non-profit that educates patients with rare diseases about the drug development process so that they can effectively engage. This education is provided via Webinars, social media, and using the book on clinical trials as an important tool.