# Drug Development Boot Camp®

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

**November 20 -21, 2019**
**The Harvard Club**
**Boston, MA**



Speid & Associates, Inc
SPEEDING NEW DRUGS TO MARKET®

# Contents

**Drug Development Boot Camp® = Intensive training in drug development.**

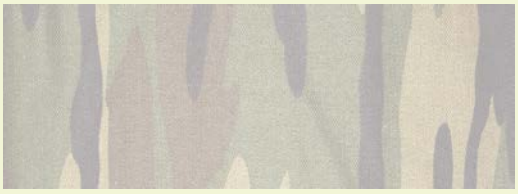
*"They train you to do certain things, and then you have to do them extremely tired." An SAS recruit*

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

*Come prepared to work hard. If you want to sit back, check emails, 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*

# How much experience will I need?

A good level of understanding of the drug development process is presumed. A minimum of 5 years of relevant experience is needed. In addition, all registered participants will be expected to complete reading assignments before the Boot Camp. To help you to get up to speed, and to ensure that you have a very productive two days at Boot Camp, you will be guided through a Pre-Boot Camp preparation process. This involves reading two books. You will also be given access to a special server which has carefully prepared reading materials and slides.



# 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. Failure is incredibly expensive. Unfortunately, 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?

- Researchers and drug developers from Pharma, Large Biotech, NIH, NCI, Reviewers from Health Authorities, Decision Makers
- CEOs, CFOs, COOs of biotech companies
- Researchers and executives involved with the drug development process
- Small and virtual company executives, scientists, and professionals involved with drug discovery and drug 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
- Anyone who is a decision maker or financer of the drug development process, including Venture Capitalists, Analysts, etc.

## Should my company be represented at the Drug Development Boot Camp®?

- Have you recently left academia?
- Do your work for large pharma or biotech?
- Are you an executive with many years of experience developing drugs?
- Does your project team face questions that it cannot answer?
- Do you have knowledge gaps in the drug development area?
- Do you want to understand what you would need to do to get a drug registered or partnered?
- Do you wonder why you are having challenges getting your company's drugs partnered and/or registered?

If you answered yes to any of the above, the answer is Yes!

## What can I expect from Drug Development Boot Camp®?

- You will learn about drug development in a hands-on manner
  - You will learn how to move drugs through the process of drug development
  - You will hear from large pharma and successful small and mid-size companies about the lessons that they have learned in developing their drugs

## 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
- There will be many opportunities for networking and working through challenges with peers

## These are some risks of not taking this training/type of training:

- 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.
- Spend many years and huge sums of money developing a drug or drugs that the market does not want, and will not pay for.
- Make 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.
- Experience 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.
- End up with a "*good drug bad development syndrome*".
- Face expensive CRO and consulting bills, with no additional assurance of success.
- Be 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 your 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.

…. and many other drawbacks, risks, and challenges.

## Participant Feedback from Previous Drug Development Boot Camp®s

Participants for previous Drug Development Boot Camp® s have come Australia, Belgium, Canada, Germany, India, Israel, Sweden, Singapore, Switzerland, The Netherlands, and the USA.

## Feedback on the Overall Boot Camp Experience

*"It takes a Team to create value. Well you have a great Team and this course definitely added a lot of value to me. Thank you."*

*"The Boot Camp provides a great opportunity to see drug development end-2-end, understand how different components play together, and define better ways to achieve the challenging mission to bring a new medicine to patients."*

*"Thorough and digestible approach to learning the key aspects of drug development."*

*"An excellent overview of drug development."*

*"The best overview of a complex industry I've ever been exposed to. Helps to streamline the Thinking process and defines the frame for overall development strategy.*
*Thank you, Lorna and the Faculty!"*

*"The case studies are very interesting and informative."*

*"Worth every minute. By far the best overview of Drug Development I've seen."*

*"Great course for people new to pharma, biotech. Good refresher for others.*
*Workshops are most valuable."*

*"Wonderful materials. Will keep for constant reference."*

*"Well hosted, well run, and lots of enjoyable work. Amazing facility. Thank you."*

*"Definitely recommend to others. Very educational for commercial, CMC and clinical design."*

*"Thank you for including adaptive design. It was important to me, and will be done."*

*"Very informative Tufts data presentation about industry snapshot. "*

*"Cost driver specifics were eye-opening and helpful."*

*"Consider building in the role of Quality in the various puzzle pieces. They touch on all processes and it was disappointing to be excluded."*

*"I enjoyed the Workshop groups and workshop sessions and think it may be worth decreasing the formal presentations and increasing the Workshops further."*

*"I registered for the Boot Camp with quite some doubts about how much we could learn from a short two day period. It turned out the camp was very well organized; with pre-reading, lectures by industry experts, and hands-on practice for each of the major aspects of drug development. "*

*"I had a great experience from learning from the panel members and the attendees through plenty of discussions."*

*"A thorough overview of the drug development process. Great opportunities to share experiences with peers in the workshops."*

*"A great way to see a lot in a very condensed format."*

*"Loved the venue!"*

*"I would definitely recommend this program to my colleagues who are passionate about drug development."*

*"I found the workshops to be very useful and will be recommending it to my colleagues."*

*"I wish I had taken this course 10 years ago. It filled in a lot of gaps in my understanding of drug development."*

## Feedback on the Commercial Session

*"Case study was very good exercise."*

*"This was an excellent session."*

*"Very balanced overview to connect the end to end overview of drug development.""*

*"Excellent session."*

*"Great session. Importance of considerating all the different stakeholders and criteria for making a commercial decision to move forward."*

*"Tony Sarraino is a great presenter"*

*"Enjoyed case."*

*"Understanding payers influence my customers' decisions and the EEF concept for prioritization - my partners are performing that now to justify next year's budget."*

*"Greater understanding of the complexity associates with drug discovery activity."*

*"Liked Workshops very much."*

*"I have many questions to take home to my company."*

*"Enjoyed the case study - vaccine market is not one I'm familiar with so good learnings."*

*"Great session."*

*"Good engaging speakers - the difficulty of reimbursement was well covered."*

*"Considerations regarding market access and commercial value should be considered from the beginning of the development program, and not just during clinical development. It's not just about regulatory approval."*

*"Great session."*

*"Interesting new insights into business strategies."*

*"Increasing benefit of molecular biomarker to predict perspective."*

*"Good insight on how to select leads, and importance of studying metabolites."*

*"Now I understand the marketing and reimbursement perspective of drug development. Very useful."*

*"The need to understand target product profile and the druggability and consideration and not just efficacy and toxicity."*

*"Well laid out."*

*"Commercial decisions are based on very detailed financial calculations (ROI). This seems like it should be obvious, but on the discovery we don't often get to see the math behind the decisions reflected in our companies' press releases."*

## Feedback on the Global and Strategic Regulatory Affairs Session

*"Interesting insights into Priority Review Voucher."*

*"Very informative to delineate the differences between the IND/CTA."*

*Very important to understand the 7 Mistakes. Helpful to be told this."*

*"I will Keep the 7 most common mistakes listed on my mind throughout the programme development."*

*"Carlos was great."*

*"Keep the 7 most common mistakes listed on my mind throughout the programme development."*

*"I liked the idea of a strong plot for development of CTD/regulatory strategy."*

*"Be the expert on your drug."*

*"I learned about the difference between plan and strategy."*

*"Importance of creating a regulatory strategy early with review often."*

*"7 Mistakes to avoid for IND/.CTA - failure to develop a TPP etc."*

*"As this impacts many other development disciplines as well, one could put more emphasis on this topic."*

*"7 Mistakes in Regulatory Affairs."*

*"Things I haven't even considered before - good perspectives."*

*"Learnt how important it is to have a comprehensive regulatory strategy."*

*"Plan your TPP so you can determine key Go/No Go details early. Don't rush talk with FDA. Open a dialogue."*

*"7 Mistakes was a nice reminder. Don't let questions become justifications."*

*"The 7 Mistakes. Will print this out and keep on my desk."*

*"Importance of the Target Product Profile."*

*"Importance of TPP."*

*"Very informative session."*

*"To design proper studies that will define the TPP."*

*"This session gave a thorough understanding on the IND/CTA application and about registration of drugs."*

*"Terminology relevant for various regulatory requirements (CTA, etc.)."*

*"Developing relationships with FDA."*

## Feedback on the Preclinical Efficacy Session

*"Good oveview of PK/PD essentials."*

*"Very interesting discussion on delayed effects."*

*"Information and content was clear even though the topic is foreign and distant for me."*

*"The mathematical modeling to determine dosing was very relevant. The exercise we were given was extremely useful."*

*"This was an excellent session. How PK relates to PD using the applied math software."*

*"The Workshop questions were great and really reinforced the learnings."*

*"Mathematical modeling is fun."*

*"I now understand PK/PD data and how to interpret the data."*

*"The bath tub model is a great way to conceptualize PK model."*

*"Stronger appreciation for the importance of PK/PD relationship for clinical trial progression."*

*"Information and content was clear even though the topic is foreign and distant for me."*

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*"This was an excellent session. How PK relates to PD using the applied math software."*

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*"Mathematical modeling is fun."*

*"The bath tub model is a great way to conceptualize PK model."*

*"PK/PD models can help us make predictions about as yet unstudied scenarios."*

*"Much better understanding of PK/PD"*

*"Great introduction to PK/PD. Modeling helps."*

*"Modeling - is this something I can discuss with my sponsors? Yes! This will help me understand the evaluation they have gone through. Great presentation! Learnt a lot."*

*"Ability to understand the importance and utility of PK/PD data."*

*"The bathtub analogy for PK/PD is fantastic."*

*"Very interested in computerized model for planning.*

*Ability to model different dosage levels/schedules."*

*"Super helpful for me. Good charts for cross species."*

*"Interesting to see how physiology affects PK/PD."*

*Fast! But good overview of preclinical. Would like to hear more about preclinical R&D and tox and MABEL approach to FIH biologics."*

*"PK/PD modeling and the Workshop were very helpful and I really learned a lot."*

*"Really interesting modeling workshop. Good speakers."*

*"Very good"*

*"Use of the pharmacology software was a great way to apply the information offered during the lecture part."*

*"PK/PD software is great."*

*"PK/PD modeling is very very useful."*

*"Enjoyed the session."*

*"So far I have only been thinking about primary PD. This session gave me thoughts on secondary PD.*
*using the software to model PK/PD was eye opening. I had seen similar graphs before but really felt like I grasped the concepts better after the simulation."*

*"Simple definition of PK."*

## Feedback on the Toxicology Session

*"Very good overview of what is needed to start the different clinical development stages."*

*"Very good Workshop feedback on how to carefully interpret toxicology findings."*

*"I found this well structured and very informative. Scott Boley did a fantastic job on toxicology."*

*"Great material. Well presented. The Workshop exemplified how to determine dosage. Too tired to get the most out of this session."*

*"Another excellent session and Workshop exercise."*

*"This will definitely change the way I look at risk mitigation strategy prior to the FIH studies."*

*Case studies very helpful to understand principles."*

*"I found this well structured and very informative. Scott Boley did a fantastic job on toxicology."*

*"Great material. Well presented. The Workshop exemplified how to determine dosage. Too tired to get the most out of this session."*

*"Another excellent session and Workshop exercise."*

*"This will definitely change the way I look at risk mitigation strategy prior to the FIH studies."*

*"How to calculate the starting dose in Phase 1."*

*"Scott was great."*

*"Greater understanding of how doses are determined for early phase trials."*

*"It was helpful to learn how type of compound affects tox development path."*

*"Would like to hear more about toxicology of bio layer molecules."*

*"Best lecture of the first day. Liked simple rules for FIH dose. Complex issues made simple so those outside expertise have some framework."*

*"Enjoyed the review of how to develop development plan."*

*"Very good overview of small molecule vs biologic - learned a lot about small molecule development. Also good overview of differences for "chronic non life threatening" vs acute life threatening approaches."*

*"Interesting review of tox for biopharmaceuticals."*

*"The human equivalence dose calculation table with be a tool I can refer back to again and again."*

*"The key differences between small molecules, biologics, and life threatening vs non life threatening diseases."*

*"Good session"*

*"Great session! Really enjoyed the toxicology workshop."*

*"The conversion formulas for animals to human."*

*"How to design toxicology studies from previous data."*

*"Very interesting session!"*

*"Toxicology session and workshop - thoroughly enjoyed."*

*"Very interesting session."*

*"How to design toxicology studies relevant to or leading to IND/CTA Phase 1/2."*

*"Very well laid out. Can use this as a checklist for myself."*

*"I really appreciated hearing about which tox studies are required in which situations. I feel like I can understand my tox colleagues efforts much better."*

*"Dose selection strategies and conversion tables."*

## Feedback on the Chemistry Manufacturing Controls Session

*"Good overview and introduction of quality by design (QbD) -- also the importance of QTPP."*

*"It was great to hear mistakes not to make."*

*"Understood the increased amount of variability for biologics. Relly liked the "scaling up" challenges description by Seshu: Building/Country/Org."*

*"Great session, positioned importance clearly and in a digestible manner."*

*"Key points and how to avoid mistakes."*

*"Good session."*

*"Fabulous! Brought great key messages for me to use."*

*"That CMC can be quite fun. Excellent Faculty."*

*"I have a better appreciation for the variety of challenges respect to manufacturing - particularly the academia - industry transition."*

*"Good session."*

*"An excellent, engaging session."*

*"Liked very much Biologics section."*

*"Very informative."*

*"Education of CMC tasks, challenges, time needed, and complexity is very much needed by all the personnel involved in drug development."*

*"Very good coverage of a complex topic."*

*"Could be a bit less detailed to allow other sessions to have more time. This was excellent though!"*

*"Very nice presentations!"*

*"Increased appreciation for this function."*

*"Very informative session."*

*"Both CMC sessions were great."*

*"Now I know why my Chemistry colleagues get so excited about process improvements!"*

## Feedback on the Clinical Session

*"Workshop with statistical modeling was good."*

*"I learnt about the use of appropriate designs!"*

*I'll consider adaptive design for upcoming Phase 2 study."*

*"I liked the format."*

*"Think, rethink and challenge myself / others to design "smart clinical trials."*

*"Use of the stats software was great. Should have spent more time on it."*

*"Dr. Chang's statistic program for Adaptive design was exceptionally useful for clinical designs."*

*"I have developed a much more comprehensive understanding of clinical trial design in conjunction with process development. All of this will enable me to make better decisions and ask the right questions."*

*"Very good explanation / examples of Trial Designs (Adaptive)."*

*"Interesting to learn how clinical trials are designed."*

*"Use of adaptive design. Better understanding of how to better design clinical trials."*

## Feedback on the Day 2 Afternoon Workshop Session

*"This was so helpful in bringing all of our learnings together - great session!"*

*"A strategic perspective of how to incorporate all aspects in a full program."*

*"Very interesting case."*

*"This activity was excellent."*

*"The real-world development story is stirring. I am so impressed!"*

*"Even with limited CMC CMC expertise we could make useful comments."*

*"Good collaborative team work."*

*"An understanding of the challenges in the preclinical lead optimization phase."*

*"During the final reporting back was great to see the actual development unfold. Very well structured."*

*"Very good case! Very interesting to see the real-life story."*

*"A little bit of a struggle, but very productive."*

## Feedback on Final Session: *Sending Out the Special Forces!*

*"The economic framework and holistic picture on the industry are crical for participants to understand drivers behind drug development trends."*

*"Understanding the major cost driver is clinical trial cost (Tuft's analysis)."*

*"The economic framework and holistic picture on the industry are critical for participants to understand drivers behind drug development trends."*

*Need for efficiency in our industry due to the cost of bringing a drug to market.*

*The key major take home message is "Think out of the box."*

*The figures were revealing about the trends - certainly delivering programs is getting tougher, competition for patients is driving up costs and timelines.*

*Great insight into the driving forces around the future directions of the industry.*
*"Interesting look at costs and collaborative opportunities. Adequate scope of due diligence and consequences of decisions."*

*"Tufts data provides nice call to action to plan to increase productivity."*

*"Great presenters"*

*"Very interesting. Right tempo."*

*"Interesting to have broad view of the industry."*

*"This session really completes our learning on drug development."*

*"Very informative session."*

*"The follow-on timings for "me-toos" was a new datapoint for me. Will use in financial modeling."*

# Outline Agenda

| Day 1<br>Start at 7:00 am EST<br>Breakfast available at 6:30 am | Day 2<br>Start at 7:00 am EST<br>Breakfast available at 6:30 am | Special Features |
|---|---|---|
| **COMMERCIAL SESSION**<br>**Drug Discovery to Product Candidate**<br>The criteria for selecting the lead candidate will be explored. | **CHEMISTRY MANUFACTURING CONTROLS (CMC)**<br>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.<br><br>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.<br><br>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.<br><br>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.<br><br>The Drug Development Boot Camp® is extremely interactive. It is taught by expert drug developers. The Faculty are experts in their fields.<br><br>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.<br><br>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**<br>The Target Product Profile and Development of the Regulatory Strategy<br><br>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.<br><br>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**<br>The four phases of clinical development, the goals of each, and the potential issues to be managed will be identified and explored in detail.<br><br>Clinical strategy will be covered in a lot of detail.<br><br>A clinical Workshop featuring a real case study will be presented. | |
| **PRECLINICAL DEVELOPMENT**<br>Preclinical Efficacy<br>Different methods for demonstrating proof of concept during the preclinical phase will be presented and considered in detail.<br><br>Scale up of the data obtained to preclinical toxicology studies will be considered.<br><br>An interactive workshop on PK/PD will be presented. | **WORKSHOPS - AFTERNOON OF DAY 2**<br><br>Participants will be divided into project teams according to their levels of previous drug development experience, skills, and their objectives stated on a questionnaire.<br><br>The Project Teams will work on drug development case studies.<br><br>Each project team will report back to the whole group regarding how their case studies.<br><br>The Faculty will present the responses. This is a time to consolidate all that has been learnt during the Boot Camp. | |

| Day 1<br>Start at 7:00 am EST<br>Breakfast available at 6:30 am | Day 2<br>Start at 7:00 am EST<br>Breakfast available at 6:30 am | Special Features |
|---|---|---|
| **PRECLINICAL TOXICOLOGY**<br>**Clinical Development and the inter-relationship with toxicological evaluation up to registration**<br><br>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**<br>Consideration will be given to how those who have completed the Drug Development Boot Camp® can make a strategic contribution. | |
| **Reception and Networking - optional**<br><br>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.<br><br>Background reading will be provided for overnight reading, in preparation for Day 2. | **PANEL Q&A AND DISCUSSION**<br>**Your opportunity to ask remaining questions, discuss your individual project challenges, etc.**<br><br>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 finish the complete two day intensive training.<br><br>Day 2 will end at about 6:00 pm EST. The coveted **Certificates of Completion** can only be provided to those who remain to the end of the Boot Camp. We regret that exceptions cannot be made for any reason. |

## Laptops and iPads

Participants will be provided the Briefing Book in an electronic format. The electronic Briefing Book will also be available on a server 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. Early registration is encouraged to allow participants to begin the preparation process. Access will be granted to registrants to a password protected Server with specially prepared Pre-Boot Camp preparatory materials. Please register as soon as possible to start the preparation process.

## Last Date for Registrations

The last date for registration is the 31st of October 2019. Please register as early as possible to gain the benefit of the Pre- Boot Camp preparation process.

## Refunds and Cancellations

We regret that refunds will not be given to anyone, for any reason, after registration. A substitution can be made up to twice, for a single registration, up to the end of the 31st of October. After the 31st of October, no substitutions will be possible, for any reason.

# Founder and Chair

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

Lorna Speid, B.Pharm.(Hons). M.R.Pharm.S., Ph.D., RAC is President of Speid & Associates, Inc. a global regulatory affairs and drug development consultancy based in San Diego, California. She 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 by her peers. She has experience with many therapeutic areas including oncology (solid tumors 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. She has secured marketing approvals in all regulatory and health authority jurisdictions.

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.* The research that she conducted was used by the International Conference of Harmonization to amend the long term toxicological requirements.

Dr. Speid 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.

Lorna 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.

# Speakers and Panel Members: Faculty

The following Faculty are representative for the 2019 Drug Development Boot Camp®. Changes may be necessary due to scheduling and personal conflicts nearer the Boot Camp.

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

Areas to be covered: Preclinical Development and Toxicology

Scott E. Boley, Ph.D., DABT, joined MPI Research in August 2005 as a study director in general toxicology. He received his doctorate in biochemistry and environmental toxicology from Michigan State University, where his research focused on the malignant transformation of human cells using tissue culture. His postdoctoral work, conducted over three years 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. He then went to Eli Lilly and Company as a research scientist in nonclinical safety assessment, where he developed the nonclinical strategy for novel oncological and neurological compounds. 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. He now serves as Senior Director of General Toxicology and Infusion Toxicology at MPI Research.

### 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 the Drug Information Journal, and has served on the editorial boards of the Journal of Research in Pharmaceutical Economics, and the Journal of Pharmaceutical Finance, Economics & Policy. He currently is the Guest Editor of a special issue of the International Journal of Environmental Research and Public Health. 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, Senior Development Operations Project 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 Roche Diagnostics in their Near Patient Testing Product Management team.

**Carlos R. Langezaal, Ph.D., Senior Director Global Regulatory Affairs, Celgene** Areas to be covered: Regulatory Affairs

Carlos R. Langezaal, Ph.D., Senior Director, Global Regulatory Affairs, is currently involved with development projects in the Oncology franchise at Celgene. Previously, he worked at Eisai, Sanofi-Aventis, J&J PRD, Schering-Plough, Core Technologies, Eli Lilly and Baxter in various therapeutic areas, including 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 been a member of the Board of Directors for 6 years, and a member of the Annual Symposium Working Party for 5 years.

**John Moscariello, Ph.D., Senior Director, Viral Vector and Gene Editing Process Development, Juno Therapeutics, a Celgene Company**

Areas to be covered: Chemistry Manufacturing Controls, Biologics and Cellular Therapies

John Moscariello currently serves as Senior Director of Viral Vector and Gene Editing Process Development at Juno Therapeutics, a Celgene Company. Prior to that, he was the Vice President of Process Development at AGC Biologics (formerly CMC Biologics) where his team was responsible cell line development, upstream and downstream process development, analytical and formulation development, and technical support for AGC Biologic's commercial manufacturing facility and supported development activities from generating processes for Toxicology/Phase 1 supply up to and including commercialization and post-approval process support. John is very active in the biotechnology community. He is on the Scientific Advisory Board for various conferences, including the BioProcess International conference series, and the CBI conference series on achieving efficient facilities and the next frontier of single-use technologies. John obtained his Ph.D. in Chemical and Biological Engineering from the University of Wisconsin-Madison, and his B.Eng. in Chemical Engineering from the University of Delaware.

**Tom J. Parry, Ph.D., M.B.A., BCMAS Assoc. VP Pharmacology and Toxicology, Ovid Therapeutics**

Areas to be covered: Preclinical Efficacy and Toxicology, Case Studies

Tom J. Parry, PhD, MBA, BCMAS is Assoc. VP of Pharmacology and Safety at Ovid Therapeutics, joining the company in April 2018. Tom is also Founder and Principal of Skyline Biopharma, LLC, a biopharmaceutical development consulting group, established in 2017. Prior to his roles at Ovid Therapeutics and Skyline Biopharma, Tom was Sr. Director of Pharmacology and Safety at Acorda Therapeutics, supporting nonclinical and business 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 (acquired by GSK), where he supported drug discovery and development including helping to file multiple IND’s. Dr. Parry also served as a Principal Scientist at Johnson and Johnson where he worked on multiple products including drug-eluting stents, cardiovascular and metabolic disease and led a small group supporting cardiovascular safety screening. Over his 20+ year biopharmaceutical career, Dr. Parry has obtained research grants, patents, authored/co-authored numerous peer-reviewed publications and serves on multiple NIH SBIR study sections. 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 regularly 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 and Program Committee and is Secretary/Treasurer-elect of the Division of Drug Discovery and Development 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 30 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 is currently President of JJPiwinski Pharma Consulting, LLC in Lebanon, New Jersey and consults in the areas of medicinal chemistry and drug discovery, including small molecule lead discovery and optimization. He has presented numerous talks at scientific meetings and has approximately 130 published research papers, abstracts and approved U.S. patents. He has been a member of the American Chemical Society since 1975 and serves as a member for the Institute of Chemical Biology & Drug Discovery Advisory Board at Stony Brook University.

## Tony Sarraino, Executive Director, Global Commercial Development for Anti-Infectives, Pfizer

Areas to be covered: Commercial

Tony Sarraino is Executive Director, Global Commercial Development for Anti-Infectives at Pfizer responsible for both management of the Global Asset Teams for marketed brands as well as the new product development portfolio. He has more than 25 years of industry experience in Sales, Marketing and Business Development in a variety of therapeutic areas including antibacterials, antivirals, transplant and metabolic diseases. Tony brings a unique perspective to product development with his experience in successfully launching/marketing products in Canada, US and Globally to provide insights on drivers to success in building successful brands. He obtained his B. Commerce (Honors) in Finance from the University of Manitoba and a license from the Canadian Securities Institute.

### 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 Chair of the Drug Development Boot Camp®.

See above for Bio

**Weiwei Tan, Ph.D., Director, Clinical Pharmacology, Global Product Development, Pfizer, Inc.**

Areas to be covered: Clinical Strategic, Crizotinib Approval Experience

Weiwei Tan, Ph.D., an employee at Pfizer since 2000, is currently a Director for Clinical Pharmacology, Global Product Development. Dr. Tan has 15+ year industry experience in pharmacokinetics/pharmacodynamics from preclinical to clinical. She has been a clinical pharmacologist for 8 oncology drug discovery and development projects, including one global NDA approval and 3 IND submissions. She is in charge of global development for the clinical pharmacology aspects of Xalkori®, which is the first-in-class drug to treat patients with ALK-positive non-small cell lung cancer.

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The Massachusetts Life Sciences Center is a quasi-public agency tasked with implementing the Massachusetts Life Sciences Act, a ten-year, $1 billion initiative that was signed into law 2008.

MassBio, a not-for-profit organization that represents and provides services and support for the Massachusetts biotechnology industry, is committed to advancing the development of critical new science, technology and medicines for patients worldwide.

The Biotechnology Association of Alabama exists to promote biotechnology innovation by creating a favorable scientific, business and legislative environment that will facilitate the growth of emerging and existing companies while attracting new biotechnology opportunities to Alabama.

Since 1994, Iowa Biotechnology Association has provided benefits and services to promote the interests and growth of the life sciences industries in Iowa.

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As principal of Speid & Associates, Lorna provides strategic global regulatory affairs support to companies, and institutions working at the cutting edge of drug development. Her expertise includes working in appeal situations when applications have been rejected by major regulatory authorities. She has a track record of success in these situations, although her mantra is that *it is better to get it right first time*.

Speid & Associates is a global and strategic regulatory affairs and drug development consultancy. The company has expertise in global, international, EU and US regulatory affairs, and drug development. Although Lorna is the main consultant, she works with other experts from the US and abroad, as needed, including former health authority reviewers and experts.

The firm provides regulatory affairs and drug development consulting services to companies at all stages of the drug development pathway, on all indications, and types of therapeutics, including small and large molecules, gene therapy, combination products, diagnostic and therapeutic combinations, and cellular therapies. Contact her by emailing LSPEID@SNDTM.COM or by telephoning her at +1 858 531 6640.