Day 1: Understanding and De-risking 505(b)(2) Product Development

Day 1 (All Disciplines): Strategic 505(b)(2) Product Development from Concept to Post-Approval	
Time	**Event/Title**
7:30 am – 10:00 am	Registration
10:00 am – 10:15 am	Introduction to SAAMnow and The 505(b)(2)-Platform Organizations and Program Committee Chair
10:15 am – 11:00 am	Workshop Keynote Address
	Successful Pillars for 505(b)(2) Drug Development: Science, Regulatory, Medical, Legal, & Commercial Assessment
11:00 am – 11:45 am	505(b)(2) Value by Design; Product Value Drives Everything
11:45 am – 12:30 pm	Preclinical Evidence; What, When, Why and How Much?
12:30 pm – 1:45 pm	Lunch & Networking
1:45 pm – 2:30 pm	Clinical Program Features Peculiar to 505(b)(2)s; Bridging Studies, the Safety/Efficacy Paradox, and more.
2:30 pm – 3:15 pm	How 505(b)(2) Clinical Pharmacology Programs Differ From Those of 505(j)/ANDAs
3:15 pm – 4:00 pm	Adaptive vs Non-inferiority vs Traditional Clinical Study Designs (Phases 2 – 4) for 505(b)(2)s
4:00 pm – 4:30 pm	Networking Coffee Break
4:30 pm – 5:00 pm	PREA (Pediatric Research Equity Act); What You Really Should Know….
5:00 pm – 6:00 pm	Panel Discussion on 505(b)(2) Product Development
6:00 pm – 7:00 pm	Networking Cocktail Reception

Day 2: Regulatory, Legal, Business, and Financial Strategies - Parallel Tracks

Day 2 Track A (Regulatory Focus): A Deep Dive into 505(b)(2) Regulatory Strategy	
Time	**Event/Title**
7:15 am – 8:15 am	Breakfast & Registration
8:15 am – 8:30 am	Recap Day 1 and Introduction to Day 2 (both tracks)
8:30 am – 9:00 am	Compare & Contrast the 505(b)(1) – 505(b)(2) and 505(j) Pathways
9:00 am – 9:30 am	Rely/Reliance: What does this mean and how is this defined for 505(b)(2) Product Development?
9:30 am – 10:00 am	FDA's Expedited Review/Approval Programs
10:00 am – 10:30 am	Networking Coffee Break (both tracks)
10:30 am – 11:00 am	Enhancing Product Exclusivity; 505(b)(2) Designations: Orphan Drug/QIDP/LPAD/RPDV
11:00 am – 11:30 am	FDA Meetings and Communications – FDA Perspective
11:30 pm – 12:00 pm	FDA Meetings and Communications –Industry Perspective
12:00 pm – 1:15 pm	Lunch & Networking (both tracks)
1:15 pm – 2:00 pm	Panel Discussion 1 – Comparing & Contrasting Small Molecule 505(b)(1), 505(b)(2), and 505(j) Pathways – FDA Programs,
2:00 pm – 2:30 pm	505(b)(2) Regulatory Question - Is an AB rating attainable?
2:30 pm – 3:00 pm	505(b)(2) Regulatory Question – Can you repurpose a failed 505(j)?
3:00 pm – 3:30 pm	505(b)(2) Regulatory Development – Combination Drug-Device Products
3:30 pm – 4:00 pm	Networking Coffee Break (track A only)
4:00 pm – 4:30 pm	Regulatory Question – How do you streamline taking a 505(b)(2) product and/or an orphan 505(b)(2) product to EU?
4:30 pm – 5:30 pm	Panel 2 Discussion; Specific Regulatory Questions for 505(b)(2)s
5:30 pm – 6:30 pm	Networking Cocktail Reception (both tracks)

Day 2 Track B (Legal/Business/Financial Focus): Successfully Navigating the 505(b)(2) Legal, Business, and Financial Landscapes	
Time	**Event/Title**
7:30 am – 8:30 am	Breakfast & Registration
8:15 am – 8:30 am	Recap Day 1 and Introduction to Day 2 (both tracks)
8:30 am – 9:00 am	Creating Product Value, Identifying Value Drivers and Integrating into Product Development
9:00 am – 9:30 am	Globalization of Value-Added Medicines
9:30 am – 10:00 am	Realistic Financial Planning for 505(b)(2) Development & Commercialization
10:00 am – 10:30 am	Networking Coffee Break (both tracks)
10:30 am – 11:00 am	505(b)(2) Product Valuation – Business Development Perspective
11:00 am – 11:30 am	505(b)(2) Product Valuation – Commercialization Perspective
11:30 pm – 12:00 pm	FDA Meetings and Communications –Industry Perspective
12:00 pm – 1:15 pm	Lunch & Networking (both tracks)
1:15 pm – 1:45 pm	Making the Most of FDA's Small Business Office
1:45 pm – 2:15 pm	Intellectual Property Issues I: Navigating the Existing IP Landscape
2:45 pm – 3:45 pm	Intellectual Property Issues II: Creating Your Own IP
3:45 pm – 4:15 pm	505(b)(2) Legislative Initiatives and Unmet Needs
4:15 pm – 5:00 pm	Panel Discussion on Legal, Business, and Financial Opportunities & Challenges
5:00 pm -5:30 pm	Legal/Business/Finance Meetings: (opportunity for 505(b)(2) developers/sponsors to meet with lawyers, investors, service providers, etc.)
5:30 pm – 6:30 pm	Networking Cocktail Reception (both tracks)

Day 3: 505(b)(2) Case Studies

Day 3: (All Disciplines): Putting Theory into Practice – 505(b)(2) Case Studies	
Multiple case studies will be selected to illustrate all disciplines (scientific, regulatory, financial, legal and commercial) focusing on practical issues; This will provide attendees an outstanding opportunity to see how the the knowledge gained in Days 1 and 2 is actually applied in the real world.	
Time	**Event/Title**
7:30am – 8:30am	Breakfast & Registration
8:30am – 1:00pm	505(b)(2) Case Studies
1:00pm	Workshop adjourns