



# CHEMISTRY MANUFACTURING CONTROL

## STRATEGY MEETING USA

1st JUNE  
2020

*Le* MERIDIEN  
BOSTON CAMBRIDGE

### AGENDA

### INVESTORS TRACK

### SPONSORS

### HOTEL & TRAVEL

### OUR UNIQUE MEETING FORMAT

#### ● Roundtable Discussions

These interactive and informal discussion groups are the hallmark of the meeting. The brightest minds in the industry are brought together in 60-minute sessions that enable participants to share ideas, challenges and lessons learned.

#### ● Personalised Agenda

Each delegate receives a personalised agenda with the roundtable discussions that you choose. You only attend sessions and meetings that fit your challenges and interests, ensuring your time out of the office is focused and well-utilised.

#### ● One-to-one Meetings

The most effective and time efficient way to assess potential partners at a strategic level. Gain access to our exclusive networking app to identify the people that you need to meet. The app suggests a suitable time and place, all you need to do is grab the coffee.

#### ● Strategic Networking

Strategic networking opportunities form a key benefit of the meeting. Our proven format for building and strengthening alliances is underscored by a host of networking programmes, from a buffet breakfast through to evening drinks, make lasting connections that benefit you.

### CONTRIBUTORS TO THE AGENDA



**Nick Vrolijk**  
Vice President  
Fusion Pharma



**Stan Russell**  
Executive Director  
Alexion Pharmaceuticals



**James Stahl**  
Senior Director  
Promedior



**Qinghai Zhao**  
VP Technical Development  
& Manufacturing  
TG Therapeutics



**Cui Sheng**  
Executive Director  
Boston Pharmaceuticals



**Gregg Keany**  
VP Product Development  
Venture NewCo





**Rick Panicucci**  
SVP CMC  
QED Therapeutics



**Theodore Martinot**  
Head of Clinical Development  
Infinity Pharmaceuticals



	01	02	03	04	05	06
TRACK & ROOM	EMERGING BIOPHARMA	DRUG PRODUCT	TECHNOLOGY TRANSFER & ANALYTICAL	INTEGRATED DRUG DEVELOPMENT	PROCESS RESEARCH & SCALE-UP	INTERMEDIATE & API
08:00 - 08:30	REGISTRATION & BREAKFAST NETWORKING			REGISTRATION & BREAKFAST NETWORKING		
08:30 - 09:00	WELCOME SPEECH & INVESTOR'S PANEL DISCUSSION					
09:00 - 10:00	Comparitive analysis of available CDMOs - does more expensive always mean better?	Advances and Challenges in Nanomedicine and Nanotechnology	Ensuring clarity & communication of goals & expectations for successful technology transfer during drug development with your CDMO	Establishing a quality agreement with contracting partners to clearly define the quality system relationship	How to generate value for clinical stage companies with CMC strategy for commercial readiness	Rationale, Strategies and Execution for Developing API & Intermediate Supply
	Nick Vrolijk - Vice President Fusion Pharma	Zia Choudry - Director Med. Affairs Sanofi	Nick Dunwoody - Vice President Tetraphase Pharmaceuticals	Rick Panicucci - Sr. Vice President QED Therapeutics	Hemant Kumar - Sr. Vice President Rentschler	Stan Russell - Sr. Vice President Alexion
10:00 - 11:00	1 - 1 MEETING *10:00-10:20		NETWORKING BREAK	1 - 1 MEETING *10:20-10:40		1 - 1 MEETING *10:40-11:00
11:00 - 12:00	ROUNDTABLE TOPIC CONFIRMED FOR SPONSOR	ROUNDTABLE TOPIC CONFIRMED FOR SPONSOR	ROUNDTABLE TOPIC CONFIRMED FOR SPONSOR			ROUNDTABLE TOPIC CONFIRMED FOR SPONSOR
12:00 - 13:00	1 - 1 MEETING *12:00-12:20		1 - 1 MEETING *12:20-12:40		1 - 1 MEETING *12:40-13:00	
13:00 - 14:00	1 - 1 MEETING *13:00-13:20	3 COURSE NETWORKING LUNCH	1 - 1 MEETING *13:20-13:40	3 COURSE NETWORKING LUNCH	1 - 1 MEETING *13:40-14:00	3 COURSE NETWORKING LUNCH
14:00 - 14:30	KEYNOTE PRESENTATION		KEYNOTE PRESENTATION		KEYNOTE PRESENTATION	
14:30 - 15:30	Strategies to ensure strong CMC & in-house research for a successful approach to partnership with CMOs	Key Considerations for Intranasal Formulation Development	Using chromatography modelling software & computer assisted method development tools to maximise output of each experiment	Early stage CMC development strategy to speed IND	Scale-Out Biomanufacturing – A Paradigm Change to Scale Up	Addressing a wide range of API crystallization and early formulation challenges for drug development programs
	Gregg Keany - VP Atlas Venture NewCo	Padma Malyala - Exec. Director Verve Therapeutics	James Stahl - Sr. Director Analytical Promedior	Qinghai Zhao - Vice President Forty Seven Inc.	Cui Sheng - Exec. Director CMC Boston Pharmaceuticals	Jorge Ramos - Ext. Manuf. Lead Merck
15:30 - 15:40	AFTERNOON COFFEE BREAK			AFTERNOON COFFEE BREAK		
15:40 - 16:00	1 - 1 MEETING *20min		NETWORKING BREAK	1 - 1 MEETING *20min		1 - 1 MEETING *20min
16:00 - 17:00	Using “one-stop-shop” CDMOs against using suppliers best suited for each step of the process - advantages & disadvantages	Aseptic Manufacturing and Sterile Fill-Finish for Complex Drug Products	Maximising the value & impact of technology transfer package by facilitating the interplay between data, its integration into the knowledge base & decision making	Methods to drive new regulatory and drug pricing policies.	Selecting the right route to ensure fast development and scale-up across all the project phases and supporting the API projects requirements	Mitigating risks associated with API suppliers
	Alex Goraltchouk - VP Anika Therapeutics Inc.		Theodor Martinot - Head Infinity Pharmaceuticals	Heidi Reichert - Head of Quality Acceleron Pharma Inc.	Greg Liposky - SVP Athersys	Jim Stout - VP CMC Shattuck Labs
17:00 - 17:30	INVESTOR'S PANEL		INVESTOR'S PANEL		INVESTOR'S PANEL	
17:30 - 19:00	DRINKS & CANAPE RECEPTION		DRINKS & CANAPE RECEPTION		DRINKS & CANAPE RECEPTION	



CMC

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## INVESTMENTS & VENTURE CAPITAL

Introducing The New **‘Investment & Venture Capital’** Track - Proventa International’s latest evolutionary step in developing our signature Strategy Meetings. Now not only providing essential operational strategy solutions but also aiding in equally important fundraising and investment seeking strategy.

09:00 - 10:00	Allocating an adequate yet conservative CMC budget from investment fund, investor recommendations.	14:30 - 15:30	How a shared-risk partnership model can reduce the cost of outsourcing manufacturing - advantages and disadvantages
11:00 - 12:00	ROUNDTABLE TOPIC CONFIRMED FOR SPONSOR	16:00 - 17:00	Key considerations when approaching investors - investor insights

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