



# CHEMISTRY MANUFACTURING CONTROL

## STRATEGY MEETING USA

1st JUNE  
2020

Le MERIDIEN  
BOSTON CAMBRIDGE

### OUR UNIQUE MEETING FORMAT

#### AGENDA

TRACK 1  
EMERGING BIOPHARMA

TRACK 2  
DRUG PRODUCT

TRACK 3  
TECHNOLOGY TRANSFER & ANALYTICAL

TRACK 4  
INTEGRATED DRUG DEVELOPMENT

TRACK 5  
PROCESS RESEARCH & SCALE-UP

TRACK 6  
INTERMEDIATES & API

TRACK 7  
INVESTMENT & VENTURE CAPITAL

SPONSORS

HOTEL & TRAVEL

- **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



**Praveen Prasanna**  
Sr. Director Technical Operations  
AVEO Oncology





**Padma Malyala**  
Executive Director  
Verve Therapeutics



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





TRACK & ROOM	01 EMERGING BIOPHARMA	02 DRUG PRODUCT	03 TECHNOLOGY TRANSFER & ANALYTICAL	04 INTEGRATED DRUG DEVELOPMENT	05 PROCESS RESEARCH & SCALE-UP	06 INTERMEDIATE & API
8:00 - 8:30 a.m.	REGISTRATION & BREAKFAST NETWORKING			REGISTRATION & BREAKFAST NETWORKING		
8:30 - 9:00 a.m.	WELCOME SPEECH & INVESTOR'S PANEL DISCUSSION					
9:00 - 10:00 a.m.	Comparative analysis of available CDMOs - does more expensive always mean better?  Nick Vrolijk - Vice President Fusion Pharma	Advances and Challenges in Nanomedicine and Nanotechnology  Zia Choudry - Director Med. Affairs Sanofi	Ensuring clarity & communication of goals & expectations for successful technology transfer during drug development with your CDMO  Nick Dunwoody - Vice President Tetraphase Pharmaceuticals	Establishing a quality agreement with contracting partners to clearly define the quality system relationship  Rick Panicucci - Sr. Vice President QED Therapeutics	How to generate value for clinical stage companies with CMC strategy for commercial readiness  Hemant Kumar - Sr. Vice President Rentschler	Rationale, Strategies and Execution for Developing API & Intermediate Supply  Stan Russell - Sr. Vice President Alexion
10:00 - 11:00 a.m.	1-1 MEETING *10:00-10:20		NETWORKING BREAK	1-1 MEETING *10:20-10:40		NETWORKING BREAK
11:00 - 12:00 a.m.	ROUNDTABLE TOPIC CONFIRMED FOR SPONSOR	ROUNDTABLE TOPIC CONFIRMED FOR SPONSOR	ROUNDTABLE TOPIC CONFIRMED FOR SPONSOR			ROUNDTABLE TOPIC CONFIRMED FOR SPONSOR
12:00 - 1:00 p.m.	1-1 MEETING *12:00-12:20		1-1 MEETING *12:20-12:40		1-1 MEETING *12:40-13:00	
1:00 - 2:00 p.m.	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
2:00 - 2:30 p.m.	KEYNOTE PRESENTATION		KEYNOTE PRESENTATION		KEYNOTE PRESENTATION	
2:30 - 3:30 p.m.	Strategies to ensure strong CMC & in-house research for a successful approach to partnership with CMOs  Gregg Keany - VP Atlas Venture NewCo	Key Considerations for Intranasal Formulation Development  Padma Malyala - Exec. Director Verve Therapeutics	Using chromatography modelling software & computer assisted method development tools to maximise output of each experiment  James Stahl - Sr. Director Analytical Promedior	Early stage CMC development strategy to speed IND  Qinghai Zhao - Vice President Forty Seven Inc.	Scale-Out Biomanufacturing - A Paradigm Change to Scale Up  Cui Sheng - Exec. Director CMC Boston Pharmaceuticals	Addressing a wide range of API crystallization and early formulation challenges for drug development programs  Jorge Ramos - Ext. Manuf. Lead Merck
3:30 - 3:40 p.m.	AFTERNOON COFFEE BREAK			AFTERNOON COFFEE BREAK		
3:40 - 4:00 p.m.	1-1 MEETING *20min		NETWORKING BREAK	1-1 MEETING *20min		NETWORKING BREAK
4:00 - 5:00 p.m.	Using "one-stop-shop" CDMOs against using suppliers best suited for each step of the process - advantages & disadvantages  Alex Goraltchouk - VP Anika Therapeutics Inc.	Aseptic Manufacturing and Sterile Fill-Finish for Complex Drug Products  Praveen Prasanna - Sr. Director AVEO Oncology	Maximising the value & impact of technology transfer package by facilitating the interplay between data, its integration into the knowledge base & decision making  Theodor Martinot - Head Infinity Pharmaceuticals	Methods to drive new regulatory and drug pricing policies.  Heidi Reichert - Head of Quality Acceleron Pharma Inc.	Selecting the right route to ensure fast development and scale-up across all the project phases and supporting the API projects requirements  Greg Liposky - SVP Athersys	Mitigating risks associated with API suppliers  Jim Stout - VP CMC Shattuck Labs
5:00 - 5:30 p.m.	INVESTOR'S PANEL		INVESTOR'S PANEL		INVESTOR'S PANEL	
5:30 - 7:00 p.m.	DRINKS & CANAPE RECEPTION			DRINKS & CANAPE RECEPTION		





**Nick Vrolijk**  
Vice President  
Fusion **Pharma**

### ROUNDTABLE TOPIC

Comparitive analysis of available CDMOs - does more expensive always mean better?

### TIME SLOT

9:00 - 10:00 a.m.



**SPEAKER TBC**  
TBC  
TBC

### SPONSOR ROUNDTABLE TOPIC

TOPIC TBC

### TIME SLOT

11:00 - 12:00 a.m.



**Gregg Keany**  
V.P. Product Development  
Venture **NewCo**

### ROUNDTABLE TOPIC

Strategies to Ensure Strong and Efficient CMC Function at Startup Biotechs.

### TIME SLOT

2:30 - 3:30 p.m.



**Alex Goraltchouk**  
V.P. Operations  
**Anika Therapeutics Inc.**

### ROUNDTABLE TOPIC

Using “one-stop-shop” CDMOs compared to using suppliers best suited for each step of the process - advantages and disadvantages.

### TIME SLOT

4:00 - 5:00 p.m.

[+ INFO ABOUT OUR SPEAKERS](#)

[PREVIOUS PAGE](#)

[GO TO MENU](#)

[NEXT PAGE](#)





**Zia Choudhry**  
Director Medical Affairs  
Sanofi

### ROUNDTABLE TOPIC

Advances and Challenges in Nanomedicine and Nanotechnology.

### TIME SLOT

9:00 - 10:00 a.m.



**SPEAKER TBC**  
TBC  
TBC

### SPONSOR ROUNDTABLE TOPIC

TOPIC TBC

### TIME SLOT

11:00 - 12:00 a.m.



**Padma Malyala**  
Executive Director  
Verve Therapeutics

### ROUNDTABLE TOPIC

Key Considerations for Intranasal Formulation Development.

### TIME SLOT

2:30 - 3:30 p.m.



**Praveen Prasanna**  
Sr. Director Technical Ops  
AVEO Oncology

### ROUNDTABLE TOPIC

Aseptic Manufacturing and Sterile Fill-Finish for Complex Drug Products.

### TIME SLOT

4:00 - 5:00 p.m.

[+ INFO ABOUT OUR SPEAKERS](#)

[PREVIOUS PAGE](#)

[GO TO MENU](#)

[NEXT PAGE](#)





**Nick Dunwoody**  
VP CMC  
Tetraphase Pharmaceuticals

### ROUNDTABLE TOPIC

How to ensure clarity and communication of goals and expectations for successful technology transfer during drug development with your CDMO

### TIME SLOT

9:00 - 10:00 a.m.



**SPEAKER TBC**  
TBC  
TBC

### SPONSOR ROUNDTABLE TOPIC

TOPIC TBC

### TIME SLOT

11:00 - 12:00 a.m.



**James Stahl**  
Sr. Director, Analytical  
Promedior

### ROUNDTABLE TOPIC

Using chromatography modelling software and computer assisted method development tools to maximise output of each experiment

### TIME SLOT

2:30 - 3:30 p.m.



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

### ROUNDTABLE TOPIC

Maximising the value and impact of a technology transfer package by facilitating the interplay between data, its integration into the knowledge base, decision making based on said knowledge based and ensuring data integrity

### TIME SLOT

4:00 - 5:00 p.m.

[+ INFO ABOUT OUR SPEAKERS](#)

[PREVIOUS PAGE](#)

[GO TO MENU](#)

[NEXT PAGE](#)





**Rick Panicucci**  
SVP CMC  
QED Therapeutics

### ROUNDTABLE TOPIC

Establishing a quality agreement with contracting partners to clearly define the quality system relationship

### TIME SLOT

9:00 - 10:00 a.m.



**SPEAKER TBC**  
TBC  
Sai

### SPONSOR ROUNDTABLE TOPIC

TOPIC TBC

### TIME SLOT

11:00 - 12:00 a.m.



**Qinghai Zhao**  
V.P. Technical Development  
& Manufacturing  
Forty Seven Inc.

### ROUNDTABLE TOPIC

Early stage CMC development strategy to speed IND.

### TIME SLOT

2:30 - 3:30 p.m.



**Heidi Reichert**  
Head of Quality & Regulatory  
Affairs CMC  
Accelaron Pharma Inc.

### ROUNDTABLE TOPIC

Methods to drive new regulatory and drug pricing policies.

### TIME SLOT

4:00 - 5:00 p.m.

[+ INFO ABOUT OUR SPEAKERS](#)

[PREVIOUS PAGE](#)

[GO TO MENU](#)

[NEXT PAGE](#)





**Hemant Kumar**  
SVP Technical Development  
& Manufacturing Ops.  
**Rentschler**

### ROUNDTABLE TOPIC

How to generate value for clinical stage companies with CMC strategy for commercial readiness

### TIME SLOT

9:00 - 10:00 a.m.



**SPEAKER TBC**  
TBC  
**BirdoTech**

### SPONSOR ROUNDTABLE TOPIC

Topic TBC

### TIME SLOT

11:00 - 12:00 a.m.



**Cui Sheng**  
Executive Director CMC  
**Boston Pharmaceuticals**

### ROUNDTABLE TOPIC

Scale-Out Biomanufacturing – A Paradigm Change to Scale Up.

### TIME SLOT

2:30 - 3:30 p.m.



**Greg Liposky**  
SVP Commercial Manufacturing  
**Athersys**

### ROUNDTABLE TOPIC

Selecting the right route to ensure fast development and scale-up across all the project phases and supporting the API projects requirements

### TIME SLOT

4:00 - 5:00 p.m.

[+ INFO ABOUT OUR SPEAKERS](#)

[PREVIOUS PAGE](#)

[GO TO MENU](#)

[NEXT PAGE](#)





**Stan Russell**  
Executive Director  
Alexion

### ROUNDTABLE TOPIC

Rationale, Strategies and Execution for Developing API & Intermediate Supply.

### TIME SLOT

9:00 - 10:00 a.m.



**SPEAKER TBC**  
TBC  
TBC

### SPONSOR ROUNDTABLE TOPIC

Optimizing and adopting use of RBM data for predictive analytics and clinical ops decision-making.

### TIME SLOT

11:00 - 12:00 a.m.



**Jorge Ramos**  
External Manufacturing Lead  
API  
Merck

### ROUNDTABLE TOPIC

Addressing a wide range of API crystallization and early formulation challenges for drug development programs

### TIME SLOT

2:30 - 3:30 p.m.



**Jim Stout**  
VP CMC  
Shattuck Labs

### ROUNDTABLE TOPIC

Mitigating risks associated with API suppliers.

### TIME SLOT

4:00 - 5:00 p.m.

[+ INFO ABOUT OUR SPEAKERS](#)

[PREVIOUS PAGE](#)

[GO TO MENU](#)

[NEXT PAGE](#)



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 fund raising and investment seeking strategy.



**Speaker TBC**  
TBC  
TBC

### ROUNDTABLE TOPIC

Allocating an adequate yet conservative CMC budget from investment fund, investor recommendations.

TIME SLOT

9:00 - 10:00 a.m.



**SPEAKER TBC**  
TBC  
TBC

### SPONSOR ROUNDTABLE TOPIC TOPIC TBC

TIME SLOT

11:00 - 12:00 a.m.



**SPEAKER TBC**  
TBC  
TBC

### ROUNDTABLE TOPIC

How a shared-risk partnership model can reduce the cost of outsourcing manufacturing - advantages and disadvantages.

TIME SLOT

2:30 - 3:30 p.m.



**SPEAKER TBC**  
TBC  
TBC

### ROUNDTABLE TOPIC

Key considerations when approaching investors - investor insights.

TIME SLOT

4:00 - 5:00 p.m.

[+ INFO ABOUT OUR SPEAKERS](#)

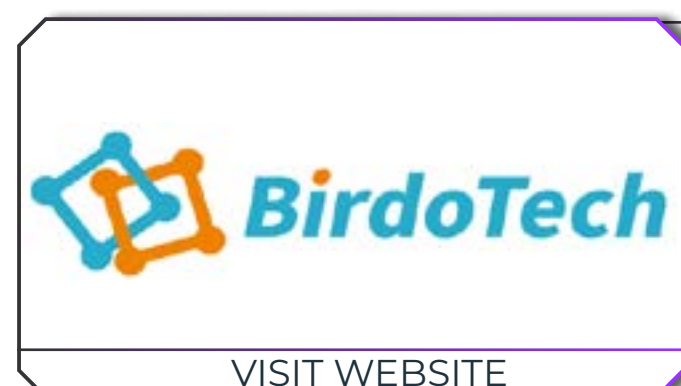
[PREVIOUS PAGE](#)

[GO TO MENU](#)

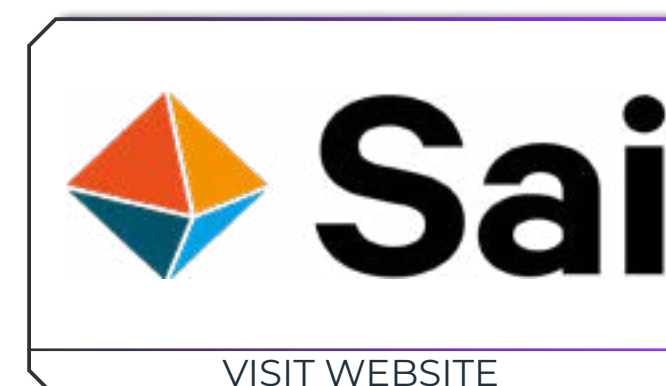
[NEXT PAGE](#)



### CO-HOST



**BirdoTech** is a chemistry services CRO headquartered in Shanghai China. With clients across North America, Europe, and Asia, BirdoTech delivers quality products with utmost stringent criteria while meeting demanding timelines. Our laboratories are equipped with the latest in advanced instrumentations to provide reliable data that are critical for decision-making. To meet our clients' demand, we employ >100 scientists and expanded our R&D labs in Shanghai and Xi'an to 4,000 m<sup>2</sup>. Further expansion with pilot plants are in Baiyin, Gansu and Jining, Shandong.



**Sai Life Sciences** provides services to our pharma innovator partners, which accelerate the discovery, development and manufacture of complex small molecule therapeutics. Our clients gain clear competitive advantages through shorter time to market and risk minimization using our integrated and high-quality scientific services. Established in 1999, Sai has ;2,000 employees located at 4 R&D and manufacturing sites in India. Sai has focused on building expert core capabilities in all areas of chemistry from hit discovery to GMP manufacturing. Sai also provides high-value integrated services in pharmacology, DMPK, toxicology and formulation development to better support the increasing needs of our customers.

### EXHIBITOR







# CHEMISTRY MANUFACTURING CONTROL

# HOTEL & TRAVEL

Le MERIDIEN

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PREVIOUS PAGE

GO TO MENU

