CHEMISTRYMANUFACTURINGCONTROL

REGULATORYAFFAIRS

ONLINE STRATEGY MEETING 2nd JUNE 2020

Click here to find out what our clients think about our Strategy Meetings

OUR UNIQUE ONLINE 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 from all over the world 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 spent on the online platform 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 will allow for instant and direct messaging to organise online meetings during the dedicated time to most benefit you.

Strategic Networking

Strategic networking opportunities form a key benefit of the meeting. Our new online format for building and strengthening alliances to make lasting connections that benefit you.

CONTRIBUTORS TO THE AGENDA

Gregg Keaney
VP Product Development
Atlas Venture NewCo

Karin McIntosh
Executive Director
Stemline Therapeutics

Stan Russell
Vice President
Sebela Pharmaceuticals

Daniela Drago
Senior Director Regulatory Sciences
Biogen

Art Faulkner
Vice President, Regulatory CMC
TG Therapeutics

Trey Putnam
Vice President, Regulatory Affairs and CMC
FAST BioMedical, Inc.

Qinghai Zhao
VP Technical Development and Manufacturing
Forty Seven Inc.

Praveen Prasanna
Senior Director Technical Operations
AVEO Oncology

Fernando Aleman
Chief Scientific Officer
Navega Therapeutics

Nick Dunwoody
Vice President CMC
Tetraphase Pharmaceuticals

PROVENTA INTERNATIONAL

SPONSORS

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 m2. Further expansion with pilot plants are in Baiyin, Gansu and Jining, Shandong.

VISIT WEBSITE

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.

VISIT WEBSITE

MercachemSyncom has a 30 year track record in assisting leading pharma and biotechnology companies with medicinal chemistry programs. Starting as a chemistry service provider, MercachemSyncom has transformed into an integrated drug discovery CRO offering chemistry services, in vitro screening, ADME studies, pharmacokinetics and in vivo pharmacology. Primary chemistry activities include medicinal chemistry services, hit-to-lead optimization programs, synthesis of key building blocks, library synthesis, route scouting services, process research activities, scale up, and cGMP manufacturing. On a custom basis, we also synthesize metabolites, impurities, reference standards and stable labelled compounds. Our services are backed by state-of-the-art analytical technologies such as SFC, HPLC, GC, LC-MS, GC-MS and NMR. MercachemSyncom is based in Europe (The Netherlands and Czech Republic) and employs around 300 chemists.

VISIT WEBSITE

At **Proventa Talent**, we always look ahead to ensure that the service we deliver to you is second to none, both now and in the future. Proventa Talent based around our three key principles of commitment, intelligence and partnership ensures an unparalleled recruitment solution in the industry. We work with the leading talent in the field to offer a service of high quality, efficiency and transparency. In addition to this, our relationship with many organisations across the Life Sciences sector means that we are constantly developing our recruitment services to offer market-leading solutions including Contingency, Executive Search, Contract and fully integrated Recruitment Process Outsourcing to suit your short, medium and long term needs.

VISIT WEBSITE

Asphalion is an International Scientific and Regulatory Affairs consultancy, with offices in Barcelona, Madrid, Munich, Amsterdam and London. Our team now has over 100 professional consultants offering comprehensive support for Drug Development and Regulatory Affairs to Pharma, Biotech and Medical Devices companies. We assist our clients in phases ranging from early development, throughout registration, until marketing and post- commercialization. Our consultants are experts in their field and are in direct contact with EU agencies (EMA and NCAs) for the development and implementation of new regulatory standards.

VISIT WEBSITE

Jubilant Biosys Limited (JBL) a subsidiary of Jubilant Life Sciences (a $1,310 MM Sales Corporation) providing innovative drug discovery services to the global life sciences, agro-chemicals and specialty chemicals industry through its research centers in India. Jubilant's services in discovery research includes:

- Target identification/ target validation to lead optimization/ preclinical candidate, for multiple therapeutic areas viz; oncology, metabolic disorders, CNS, pain, inflammation, fibrosis and respiratory diseases.
- Functional services comprising of computational chemistry/ molecular modeling, medicinal chemistry, synthetic chemistry, scale-up (Non-GMP & GMP), structural biology, ADME-PK, in-vitro and in-vivo biology and IND enabling GLP toxicology.

VISIT WEBSITE

A leading global provider of technology and services to life sciences customers, IQVIA offers a new, transformative vision for regulatory. We bring together innovative technologies, decades of life sciences experience and advanced analytics— including AI—to fundamentally change how you can better execute and manage regulatory compliance, integrating with safety and quality in the cloud. The result—a more intelligent, efficient approach providing insight and visibility into the complete regulatory landscape, enabling fast response and predictive planning across the product lifecycle. IQVIA customers have a choice of delivery models, from SaaS-based RIM Smart to managed services. Learn more at www.iqvia.com/regulatorycompliance.

VISIT WEBSITE

As an independent globally operating consultancy, **knoell's** international team of medical device experts includes specialists in biomedical engineering, software engineering, medical sciences and medical writing, pharmacology, toxicology, chemistry and biochemistry. We support manufacturers of medical devices and in vitro diagnostic medical devices (IVD) with our extensive expertise at every point of the product life cycle. Our medical device experts support you in gaining access to global key markets like Europe, North & South America and Asia. Together with our clients we build a sound market access strategy by identifying the most efficient route to place your products on the desired market.

VISIT WEBSITE

PRO-PARTNER

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AGENDA

TRACK & ROOM (*TIME - B.S.T.)	TRACK & ROOM (*TIME - E.T.)	01 EMERGING BIOPHARMA	02 DRUG PRODUCT	03 TECHNOLOGY TRANSFER & ANALYTICAL	04 INTEGRATED DRUG DEVELOPMENT	05 PROCESS RESEARCH & SCALE-UP	06 INTERMEDIATE & API
13:00 - 13:30	08:00 - 08:30	KEYNOTE PRESENTATION		KEYNOTE PRESENTATION	KEYNOTE PRESENTATION	KEYNOTE PRESENTATION	
13:30 - 14:30	08:30 - 09:30	Comparative analysis of available CDMOs - does more expensive always mean better? **Yuyi Shen - Associate Director Bolt Biotherapeutics**		How to ensure clarity and communication of goals and expectations for successful technology transfer during drug development with your CDMO **Nick Dunwoody - Vice President, CMC Tetraphase Pharmaceuticals, Inc.**		How to generate value for clinical stage companies with CMC strategy for commercial readiness **Daniel Hogan - Associate Director Tech Transfer and Manufacturing Portola Pharmaecuticals**	
14:30 - 15:30	09:30 - 10:30	1 - 1 MEETING *09:30-09:50 E.T.	NETWORKING BREAK	1 - 1 MEETING *09:50-10:10 E.T.	NETWORKING BREAK	1 - 1 MEETING *10:10-10:30 E.T.	
15:30 - 16:30	10:30 - 11:30	JUBILANT BIOSYS **Marcel J. Velterop - President**			Sai **Dean Edney - Head of Process Res. & Dev.**	BirdoTech **Branden Lee - Director Business Dev.**	MercachemSyncom **Roger McDonald - Bus. Dev. - CMC Services**
16:30 - 18:30	11:30 - 13:30	1 - 1 MEETING *11:30-11:50 E.T.	1 - 1 MEETING *11:50-12:10 E.T.	1 - 1 MEETING *12:10-12:30 E.T.	1 - 1 MEETING *12:30-12:50 E.T.	1 - 1 MEETING *12:50-13:10 E.T.	1 - 1 MEETING *13:10-13:30 E.T.
18:30 - 19:30	13:30 - 14:30	Strategies to Ensure Strong and Efficient CMC Function at Startup Biotechs **Gregg Keaney - VP Atlas Venture NewCo**	Key considerations for sterile drug product development for the marketplace **Nick Dunwoody - Vice President Tetraphase Pharmaceuticals**	Development and Transfer of Analytical Assays for Polysorbate Excipients in your Drug Product **James Stahl - Sr. Director Analytica Promedior**	Early stage CMC development strategy to speed IND **Qinghai Zhao - Vice President Forty Seven Inc.**		Rationale, Strategies and Execution for Developing API & Intermediate Supply **Stan Russell - Vice President Sebela Pharmaceuticals**
19:30 - 19:50	14:30 - 14:50	1 - 1 MEETING *14:30-14:50 E.T.					
19:50 - 20:50	14:50 - 15:50	Using “one-stop-shop” CDMOs compared to using providers best suited for each step of the process - advantages and disadvantages **Alex Goraltchouk - VP Anika Therapeutics Inc.**	Preparation and Process Validation Practices for Drug Product Development & Manufacturing and Concerns Surrounding Outsourcing Partners **Praveen Prasanna - Senior Director AVEO Oncology**	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 **Theodore Martinot - Head of Chemical Dev. Infinity Pharmaceuticals**	Lifecycle Approach to Process Validation **Arul Joseph - Senior Director Avanir Pharmaceuticals**	Implementation of Continuous Upstream and Downstream Operations in Clinical Manufacturing **Van Leang - Senior Director HJB Bio**	Mitigating risks associated with API suppliers **Jim Stout - VP CMC Shattuck Labs**

AGENDA

TRACK & ROOM (*TIME - B.S.T.)	TRACK & ROOM (*TIME - E.T.)	07 RIM AND DATA MANAGEMENT	08 REGULATORY OPERATIONS/ REGULATORY STRATEGY	09 CHANGE CONTROL	10 MEDICAL DEVICES	11 LABELLING	12 REGULATORY SUBMISSIONS
13:00 - 13:30	08:00 - 08:30	KEYNOTE PRESENTATION		KEYNOTE PRESENTATION	KEYNOTE PRESENTATION	KEYNOTE PRESENTATION	
13:30 - 14:30	08:30 - 09:30		Regulatory Challenges and Opportunities for the Global Development of Gene Therapies **Daniela Drago - Senior Director Biogen**	Green/Brown fields - managing quality, regulatory and supply chain aspects for chemical raw materials and consumables during tech transfer **Ramzan Tabasum - Head of Manu. Qua. CSL Behring, Lengnau, Switzerland**			Strategies to manage differing country-specific requirements for submissions **Art Faulkner - VP, Regulatory CMC TG Therapeutics**
14:30 - 15:30	09:30 - 10:30	1 - 1 MEETING *09:30-09:50 E.T.	NETWORKING BREAK	1 - 1 MEETING *09:50-10:10 E.T.	NETWORKING BREAK	1 - 1 MEETING *10:10-10:30 E.T.	
15:30 - 16:30	10:30 - 11:30	ASPHALION **Marcos Fernández - Assoc. Director**	IQVIA™ **Cecile Riboud - Senior Director Europe**		knoell worldwide registration **Dr. Isabelle Lang-Zwosta - GRA Manager**		
16:30 - 18:30	11:30 - 13:30	1 - 1 MEETING *11:30-11:50 E.T.	1 - 1 MEETING *11:50-12:10 E.T.	1 - 1 MEETING *12:10-12:30 E.T.	1 - 1 MEETING *12:30-12:50 E.T.	1 - 1 MEETING *12:50-13:10 E.T.	1 - 1 MEETING *13:10-13:30 E.T.
18:30 - 19:30	13:30 - 14:30		Early communication with regulatory agencies for gene therapy products: INTERACT and ITF meetings **Fernando Aleman - CSO Navega Therapeutics**	Implementing change control in a newly commercialised company **Karin McIntosh - Executive Director Stemline Therapeutics**			Development to Registration – challenges for Regulatory Affairs in global environments **Subhadip Jana - Emerging Market Reg. Lead Takeda Pharmaceutical Company**
19:30 - 19:50	14:30 - 14:50	1 - 1 MEETING *14:30-14:50 E.T.					
19:50 - 20:50	14:50 - 15:50		Effectively preparing for late phase development and mitigation of risk associated **Trey Putnam - Vice President, RA & CMC FAST BioMedical, Inc.**		Drug-Device Combination Treatments & Diagnostics **Angela N. Johnson - Senior Director Sigilon Therapeutics**	Regulatory Partnerships on Human Factor/BLA/NDA Labeling **Lisa Kelse - Head of Com. Labeling Genentech, Inc.**	Knowledge based CQA assessment for BLA submission **Weijun Li - Director Allakos Inc.**

TRACK 1
EMERGING BIOPHARMA

Yuyi Shen
Associate Director
Bolt Biotherapeutics

ROUNDTABLE TOPIC

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

- What do you need to prepare for selecting CDMO that suits your needs?
- CDMO selection criteria, what are the most important factors?
- Fair comparison? apple to apple analysis of CDMO's proposal

TIME SLOT (*E.T.)

08:30 - 9:30

Marcel J. Velterop
President – Drug Discovery Services & CDMO
Jubilant Biosys Limited

SPONSOR ROUNDTABLE TOPIC

Difficulties in Development - From MedChem to first GMP supplies

- Speed Vs. Price when scaling up- What would you choose and why?
- MedChem route Vs. Process Research and Development- where to strike a balance?
- Analytical Method Development & Validation- Must haves and good to haves
- A CDMO's role in managing project costs & timelines
- Sourcing of KSMs- importance of de-risking your supply-chain

TIME SLOT (*E.T.)

10:30 - 11:30

Gregg Keaney
VP Product Development
Atlas Venture NewCo

ROUNDTABLE TOPIC

Strategies to Ensure Strong and Efficient CMC Function at Startup Biotechs

- Project leadership of Drug Substance campaigns from a distance: opportunities and challenges with a virtual biotech model
- Project leadership of Drug Product campaigns from a distance: opportunities and challenges with a virtual biotech model
- Leveraging consultants effectively and cost-effectively

TIME SLOT (*E.T.)

13:30 - 14:30

Alex Goraltchouk
Vice President, Operations
Anika Therapeutics Inc.

ROUNDTABLE TOPIC

Using "one-stop-shop" CDMOs compared to using providers best suited for each step of the process - advantages and disadvantages

- Focused Plants are the role model of efficiency, but a One-Stop-Shop CDMO can offer cohesive value across a broad range of technical disciplines. The risk / benefit ratio for the customer is highly dependent on the molecule and development program.
- With the advent of gene and cell therapy, the number of technical disciplines involved in manufacturing a product has broadened. As One-Stop-Shop CDMOs stretch to fill the spectrum, the once Focused CDMOs expand their product portfolios – blending the lines.
- Real-time, easily accessible, user friendly Data is becoming increasing critical to decision-making; from the Quality of a batch, to the Efficiency of an entire Supply Chain. CDMO model decisions can have significant impact on data availability, from early development to full-scale global distribution.

TIME SLOT (*E.T.)

14:50 - 15:50

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TRACK 2
DRUG PRODUCT

Nick Dunwoody
VP CMC
Tetraphase Pharmaceuticals

ROUNDTABLE TOPIC

Key considerations for sterile drug product development for the marketplace

- The necessity for cross functional interaction/ communication, (i.e., development, commercial, medication affairs)
- Leverage of clinical and pre-clinical development data
- Packaging studies and factors to consider

TIME SLOT (*E.T.)

13:30 - 14:30

Praveen Prasanna
Senior Director Technical Operations
AVEO Oncology

ROUNDTABLE TOPIC

Preparation and Process Validation Practices for Drug Product Development & Manufacturing and Concerns Surrounding Outsourcing Partners

- Key factors to prepare for drug product manufacturing
- Process validations practices for drug product development and manufacturing
- Issues and concerns with working with external manufacturing partners

TIME SLOT (*E.T.)

14:50 - 15:50

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TRACK 3
TECHNOLOGY TRANSFER & ANALYTICAL

Nick Dunwoody
Vice President, CMC
Tetraphase Pharmaceuticals, Inc.

ROUNDTABLE TOPIC

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

- Identification of key stake holders at the sending and receiving laboratory
- Clear (transparent), constant communication (i.e., don't just throw it over the fence!!)
- Risk mitigation strategies (i.e., pre tech transfer exercises);
  - Laboratory appraisal (Staff, schedule, equipment, etc
  - Limitations of receiving lab

TIME SLOT (*E.T.)

08:30 - 9:30

James Stahl
Senior Director, Analytical
Promedior

ROUNDTABLE TOPIC

Development and Transfer of Analytical Assays for Polysorbate Excipients in your Drug Product

- The Agencies are starting to ask for assays to confirm concentration and quality of excipients in drug products and confirm that degradation of these excipient do not have any negative impact on the drug product.
- What approaches are people using to accommodate these requests. – Techniques, assays, detection methodologies – pros and cons of each?
- What assays are needed? All-in-one assays or different assays for different aspects?
- What are people's experiences in validating and transferring these methods within or between research/QC/CRO laboratories.

TIME SLOT (*E.T.)

13:30 - 14:30

Theodore Martinot
Head of Chemical 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

- In an increasingly virtual research environment, CROs/CMOs become strategic partners: Engaging them and empowering them with information and data is key to success and speed.
- How do we facilitate an interplay between partner and sponsor to allow for the seamless integration of data in real time?
- Best practices to structure CMC data to enable knowledge-building: Machine-Learning and beyond.

TIME SLOT (*E.T.)

14:50 - 15:50

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TRACK 4
INTEGRATED DRUG DEVELOPMENT

Dean Edney
Head of Process Research & Development (API)
Sai Life Sciences Ltd.

SPONSOR ROUNDTABLE TOPIC

CMC Complexities & Challenges in Drug Development

- Key deliverables (potentially by phase of development) and what technical expertise is required for these
- Priorities of each of these CMC functions, of these what is critical? What is nice to have?
- Level of integration/teamwork across the CMC Technical Team/ Disciplines, where is this most important? Tips on how to enhance this.

Sai

TIME SLOT (*E.T.)

10:30 - 11:30

Qinghai Zhao
VP Technical Development and Manufacturing
Forty Seven Inc.

ROUNDTABLE TOPIC

Early stage CMC development strategy to speed IND

- Use one-stop shop service for speed
- Use platform technology for risk mitigation
- Ensure critical developments aligned with late stage commercialization

TIME SLOT (*E.T.)

13:30 - 14:30

Arul Joseph
Senior Director, Pharmaceutical Development and Clinical Supply Chain
Avanir Pharmaceuticals

ROUNDTABLE TOPIC

Lifecycle Approach to Process Validation

- Design Development Phase
- Process Performance Qualification
- Continued Process Verification

TIME SLOT (*E.T.)

14:50 - 15:50

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TRACK 5
PROCESS RESEARCH & SCALE-UP

Daniel Hogan
Associate Director Tech Transfer and Manufacturing
Portola Pharmaecuticals

ROUNDTABLE TOPIC

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

- Choosing the right CDMO for your compound/product. Does size matter?
- Selecting the correct scale to provide the best quality and commercial success.
- The CDMO relationship: How to setup a viable working relationship with your CDMO to ensure that you get the best quality and value for your product.

TIME SLOT (*E.T.)

08:30 - 9:30

Branden Lee
Director Business Development
BirdoTech

SPONSOR ROUNDTABLE TOPIC

It is not enough to have the best chemistry – working well with upstream and downstream partners makes for seamless collaboration

- Continuous process R&D support into manufacturing
- Pro-active anticipating – see around the corners
- Resilient supply chain

BirdoTech

TIME SLOT (*E.T.)

10:30 - 11:30

Van Leang
Senior Director
Global CMC Operations
HJB Bio

ROUNDTABLE TOPIC

Implementation of Continuous Upstream and Downstream Operations in Clinical Manufacturing

- Can perfusion replace fed batch as the default bioreactor?
- Automation in downstream is key to continuous operations
- Single Use vs Stainless steel for continuous operations

TIME SLOT (*E.T.)

14:50 - 15:50

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TRACK 6
INTERMIDIATES & API

Roger McDonald
Business Development – CMC services
MercachemSyncom

SPONSOR ROUNDTABLE TOPIC

Appropriate Development: why, what and when...

- An early process research effort will pay back many times over
- An early understanding of physicochemical properties may impact candidate selection
- And it's not only API – "starting materials" are frequently more complex to make than the API itself

MercachemSyncom
UNLOCKING NEW POTENTIAL

TIME SLOT (*E.T.)

10:30 - 11:30

Stan Russell
Vice President
Sebela Pharmaceuticals

ROUNDTABLE TOPIC

Rationale, Strategies and Execution for Developing API & Intermediate Supply

- Risk/Reward or Cost/Benefit Analysis Factors
- CMC Module Impact and Change Control Guidance
- Timing

TIME SLOT (*E.T.)

13:30 - 14:30

Jim Stout
VP CMC
Shattuck Labs

ROUNDTABLE TOPIC

Mitigating risks associated with API suppliers

- Timelines, Transparency & Communication
- Product Quality & Yield
- Investigations & Issue Resolution
- Shortage of Expertise

TIME SLOT (*E.T.)

14:50 - 15:50

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TRACK 7
RIM AND DATA MANAGEMENT

Marcos Fernández
Regulatory Affairs
Associate Director
Asphalion

SPONSOR ROUNDTABLE TOPIC

IDMP and the impact in regulatory affairs

- How IDMP is going to impact Regulatory Affairs
- RIMs: implementation and data activities
- Data processes between departments

ASPHALION

TIME SLOT (*E.T.)

10:30 - 11:30

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TRACK 8
REGULATORY OPERATIONS/REGULATORY STRATEGY

Daniela Drago
Senior Director
Regulatory Sciences
Biogen

ROUNDTABLE TOPIC

Regulatory Challenges and Opportunities for the Global Development of Gene Therapies

- Regulatory requirements and scientific advice for gene therapies often vary across regions (e.g., trial design, endpoints, long term follow-up, and CMC expectations). Are there opportunities for regulatory convergence across different jurisdictions?
- The accelerated nature of gene therapy programs creates a situation for aggressive development progression and compressed timelines. What are some common challenges from an industry perspective, and what strategies can be applied to overcome them?
- Several stakeholders advocate that regulatory frameworks for gene therapies might benefit from modifications (e.g., exempting clinical research in gene therapy from the EU GMO legislation, and increasing early dialogue between regulators). What are some high-impact regulatory policy areas that should be highlighted, and what can be done to improve collaboration and partnership across stakeholders?

TIME SLOT (*E.T.)

08:30 - 9:30

Cecile Riboud
Senior Director Europe, Integrated
Technology and Compliance Solutions
IQVIA

SPONSOR ROUNDTABLE TOPIC

Ensuring Business Continuity during Mergers & Acquisitions, Divestments and Portfolio Swaps

- Asset due diligence
- Data rooms and the Q&A phase
- Regulatory and safety asset transfers, key considerations
- Technology, systems and data transfers

TIME SLOT (*E.T.)

10:30 - 11:30

Fernando Aleman
Chief Scientific Officer
Navega Therapeutics

ROUNDTABLE TOPIC

Early communication with regulatory agencies for gene therapy products: INTERACT and ITF meetings

- When is the right time to start the communication process?
- What do I need to get there and should I look for help outside my organization?
- Considerations for different types of gene therapy products and cell therapie

TIME SLOT (*E.T.)

13:30 - 14:30

Trey Putnam
Vice President,
Regulatory Affairs and CMC
FAST BioMedical, Inc.

ROUNDTABLE TOPIC

Effectively preparing for late phase development and mitigation of risk associated

- Technology transfer (manufacturing and analytical) - planning for commercialization
- Impurities – risk evaluation and mitigation strategies
- Scale up issues
- NDA/BLA-focused development

TIME SLOT (*E.T.)

14:50 - 15:50

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TRACK 9
CHANGE CONTROL

Ramzan Tabasum
Head of Manufacturing Quality
CSL Behring, Lengnau, Switzerland

ROUNDTABLE TOPIC

Green/Brown fields - managing quality, regulatory and supply chain aspects for chemical raw materials and consumables during tech transfer

- How to integrate the quality updates concerning materials testing
- What aspects should be considered related to supply chain and business continuity
- Which aspects need consideration while filing new manufacturing units/sites

TIME SLOT (*E.T.)

08:30 - 9:30

Karin McIntosh
Executive Director
Stemline Therapeutics

ROUNDTABLE TOPIC

Implementing change control in a newly commercialised company

- The necessity of a well implemented process to manage and track change controls from a Reg CMC point of view.
- How to identify change types per market and where to find necessary regulatory information.
- Change control obstacles on commercialization.

TIME SLOT (*E.T.)

13:30 - 14:30

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TRACK 10
MEDICAL DEVICES

Dr. Isabelle Lang-Zwosta
Global Regulatory Affairs Manager
knoell

SPONSOR ROUNDTABLE TOPIC

When regulatory strategy planning becomes a benefit in global submissions

- How to strategically leverage existing regulatory approvals in order to enter new markets for medical devices quickly and effectively.
- Practical examples for Europe, the United States and Brazil will be given and used as starting point for discussions.

knoell worldwide registration

TIME SLOT (*E.T.)

10:30 - 11:30

Angela N. Johnson
Senior Director Regulatory Affairs
Sigilon Therapeutics

ROUNDTABLE TOPIC

Drug-Device Combination Treatments & Diagnostics

- Explore the dynamic landscape for global classification and pathway selection for drug-, device-, and biologics-led combo products.
- Optimize your Companion Diagnostic strategy during drug and biologics development.
- Assess impact on drug development of new technologies in digital therapeutics, connected devices, and advanced materials.

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14:50 - 15:50

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TRACK 11
LABELLING

Lisa Kelsey
Head of Commercial Labeling
Genentech, Inc.

ROUNDTABLE TOPIC

Regulatory Partnerships on Human Factor/ BLA/NDA Labeling

- Human Factor study labeling, key factors, watch outs and lessons learned
- New Product/New Configurations labeling, key factors, watch outs and lessons learned
- Labeling Changes/Equipment/Packaging line changes, key factors, watch outs and lessons learned

TIME SLOT (*E.T.)

14:50 - 15:50

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TRACK 12
REGULATORY SUBMISSIONS

Art Faulkner
Vice President,
Regulatory CMC
TG Therapeutics

ROUNDTABLE TOPIC

Strategies to manage differing country-specific requirements for submissions

- Discuss options to manage country specific regulatory CMC requirements.
- Options to maintain a core dossier and manage exceptions.
- Central versus local mechanism to manage administrative documents.

TIME SLOT (*E.T.)

08:30 - 9:30

Subhadip Jana
Emerging Market Regulatory Lead, Global Regulatory Affairs
Takeda Pharmaceutical Company

ROUNDTABLE TOPIC

Development to Registration – challenges for Regulatory Affairs in global environments

- Consideration of different regulatory requirements / guidance of different countries during development.
- Evaluation of available regulatory pathways and options in different countries for registrations.
- Interactions with different Health Authorities for successful outcomes.

TIME SLOT (*E.T.)

13:30 - 14:30

Weijun Li
Director, Analytical Development and Quality Control
Allakos Inc.

ROUNDTABLE TOPIC

Knowledge based CQA assessment for BLA submission

- Regulatory expectations for CQA assessment
- Prior/platform vs. product-specific knowledge for CQA assessment
- How to present CQA assessment in the BLA eCTD

TIME SLOT (*E.T.)

14:50 - 15:50

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COMPANY	JOB TITLE
AB-Science	Head of Computational chemistry
ABAC Therapeutics	Chief Executive Officer & Founder
Abbvie	Senior Director, Discovery Platform Technologies
Abbvie	Head of Discovery Chemistry and Screening biology
Abbvie	Vice President and Distinguished Research Fellow, Discovery
Almirall	Chemistry and Technology
Amcure	Section Head Medicinal Chemistry II
Annexin Pharmaceutical	Chief Executive Officer
AstraZeneca	Chief Scientific Officer and Chief Medical Officer
AstraZeneca	Vice President, Global Head of Structure, Biophysics & Frag-
Astrazeneca	ment-Based lead Generation
Astrazeneca	Global Head Oncology Safety
Astrazeneca	Executive Director
Astrazeneca	Associate Principal Scientist
Astrazeneca	Associate Director
AstraZeneca	Lead Scientist
Astrazeneca	Senior Scientist/Lead Scientist
Astrazeneca	Senior Director, Medicinal Chemistry
Barts Clinical Trials Unit,	Director, Medicinal Chemistry
Queen Mary University of Lon-	Head of Hit Discovery
don	Director
Bayer	Vice President, Head Research Pharmacokinetics
Bayer	Director, Medicinal Chemistry
Bergenbio	CSO
Biogen	Head of Computational Chemistry
Boehringer Ingelheim RCV	Scientific Director – Group Leader
GmbH & Co KG	Director/CEO
Bridge Biotec	CEO/Director
Bridge Biotech	Head of Department of Life Sciences
Brunel University London	CSO
C4X Discovery Ltd.	VP Structural Design & Medicinal Chemistry
C4X Discovery Ltd.	VP Medicinal Chemistry
C4X Discovery Ltd.	Head of Chemistry
Centauri Therapeutics	Professor of Biomedical Science, and Head of Biomedical
De Montfort University	and Environmental Health Research
E Therapeutics Plc	Business Development & Programme Manager
E-Therapeutics	Principal Data Scientist
E-Therapeutics	Head of Discovery Informatics

COMPANY	JOB TITLE
Elasmogen	Chief Executive Officer and Chief Scientific Officer
Eli Lilly	Director, Emerging Technologies and Innovation
Eli Lilly	Senior Research Scientist
Forendo Pharma	Head of Drug Discovery
Geneuro	Senior Vice President, Head of Preclinical Development
GlaxoSmithKline	Senior MetaData Manager
GSK	Research Director
GSk	UK Director Structural Biology & Biophysics
GSK	VP, Mechanistic Safety
GSK	Scientific Project Leadership
GSK	Big Data Analyst
GSk	Scientific Leader
GSK	Research Director/ Sr. Fellow
GSK	Research Director
GSK	Scientific Leader
GSK	Director, Medicinal Chemistry
Idorsia	Computational Chemist
Idorsia	Discovery Scientist & Head of Laboratory
Imperial College London	Professor of Cancer Biology
Inventiva	Head of Chemistry
Ipsen	Director – Toxins In Vitro
Ipsen	Principal Scientist
Janssen	Head, Computational Chemistry
Janssen Pharmaceutica	Computational Chemist
Johnson Johnson	Senior Director – New Ventures and Transactions
KalVista Pharmaceuticals	Director of Medicinal Chemistry
Karus Therapeutics	Chief Operations Officer & Chief Scientific Officer
Leo Pharma	Vice President of Research
LifeArc	Head of Chemistry
LifeArc	Principal Scientist
Lundbeck	Director and Head of Medicinal Chemistry
Merck	Executive Director, Global Head Quantitative Pharmacology
Merck	Director, Global Head of Search & Evaluation Discovery Technologies
Merck KGaA	Associate Director
Merck Serono	Director Discovery DMPK
Merck Sharp and Dohme	Executive Director
Mirzyme Therapeutics	ECO
MirZyme Therapeutics	Director for R&D
MirZyme Therapeutics	Senior scientist/Research Fellow

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COMPANY	JOB TITLE
Novartis	Senior Investigator I
Novartis	Investigator III / Lab Head Screening Sciences
Novartis	Global Head, External Science & Drug Discovery, Global Discovery Chemistry
Novo Nordisk	Director
Novo Nordisk	Principal Data Scientist
Orion Pharma	Director, Global Medicine Design
Redx Pharma	Principal Scientist
Roche	Global Head Strategic Alliances, pRED Informatics
Roche	Head of Medicinal Chemistry
Roche Innovation Center	Large Molecule Research Digital Lead
Sanofi	Vice President, Head of North America Diabetes and Cardiovascular Scientific Communications, North America Medical Affairs
Sanofi	Director Integrated Drug Discovery Outsourcing
Sanofi	Director, External Innovation in Drug Discovery
Sanofi	Section Head Small Molecular Design
Sanofi	Head External Innovation Drug Discovery
Sentinel Oncology	Director of Chemistry
Sentinel Oncology Ltd	Director of Chemistry
Silence Therapeutics	VP, Head of Technology Innovation
Sosei Heptares	Medicinal Chemistry Director
Summit Therapeutics	Director, Chemistry
Topadur Pharma	Chief Operating Officer
Topivert Pharma	Head of Biology

COMPANY	JOB TITLE
UCB	Director, Structural Biology & Biophysics
UCB	Director (Structural Biology and New Modalities)
UCB	Principal Scientist Crystallographer
UCL	Senior Research Associate/ Lead Biologist
University of Bradford	Head of Medicinal Chemistry
University of Bristol	Professor of Organic Chemistry
University of Central Lancashire	Chairman in Biosciences
University of Geneva	Professor and Director
University of Glasgow	Professor of Chemical Biology
University of Nottingham	Professor of Developmental Physiology
University of Oxford	Medicinal Chemistry Advisor
University of Southampton	Professor, Director of Research
University of Surrey	Professor of RNA Biology
Vernalis	Research Director
Vertex	Principal Research Fellow/ Head Biological Sciences
Vertex	Head of Chemistry, UK
Vifor Pharma	Director and Head of Toxicology
Vifor Pharma	Head of Chemical and Preclinical