ONLINE CHEMISTRY MANUFACTURING CONTROL STRATEGY MEETING 2020

29th October 2020, Thursday 1:00pm - 6:00pm UK | 9:00am - 2:00pm NY

CMC CHEMISTRYMANUFACTURINGCONTROL

Click here to find out what our clients think about our STRATEGY MEETINGS

OUR VISION

To be a platform for creating life-saving therapies and to facilitate the creation of a completely patient centric pharmaceutical industry.

OUR MISSION

By encouraging key leaders and their companies to put the patient at the very heart beat of every innovation. Sharing valuable insights and strategies to assist in the discovery, development and commercialisation of life saving therapies.

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.

Innovative Solutions
Whatever your challenge may be, let our official event partners find the solution. Gain access to our carefully selected solution providers and find your next strategic partner that will help take your business to the next level.

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

Melissa Seymour
Vice President,
Global Quality Control
Biogen

Stan Russell
Vice President,
Site Head of Quality
Sebela Pharmaceuticals

Nick Dunwoody
Vice President,
Pharmaceutical Development and Technical Operations
Tiburio Therapeutics

Thomas Sauer
VP, Head of Biologics Projects, CMC New Products Program
Sanofi

Ruby Casareno
Vice President,
Technical Operations
Allakos Inc

Qinghai Zhao
VP Technical Development and Manufacturing
Forty Seven Inc.

Praveen Prasanna
Senior Director, Technical Operations and Head of Biologics Development and Manufacturing
AVEO Oncology

Mukta Gupta
Quality Lead
Takeda

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Sai

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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.

JUBILANT BIOSYS

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Jubilant Biosys Limited (JBL) a subsidiary of Jubilant Life Sciences (a $1,293 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.

PRO-PARTNERS

R-PHARM Germany GmbH

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ANTARES HEALTH PRODUCTS, INC.

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AGENDA

ONLINE CHEMISTRY MANUFACTURING CONTROL STRATEGY MEETING 2020

CHEMISTRYMANUFACTURINGCONTROL

TRACK & ROOM		01 - INTERMEDIATES & API	02 - TECHNOLOGY TRANSFER & ANALYTICAL	03 - INTEGRATED DRUG DEVELOPMENT	04 - PROCESS RESEARCH & SCALE-UP	05 - DRUG PRODUCT & PATIENT DELIVERY	06 - OUTSOURCING
TIME (UK)	TIME (NY)						
1:00pm - 1:30pm UK	9:00am - 9:30am NY	KEYNOTE PRESENTATION **Stan Russell —** *Vice President, Site Head of Quality,* **Sebela Pharmaceuticals**					
1:30pm - 1:45pm UK	9:30am - 9:45am NY	BREAK					
1:45pm - 2:45pm UK	9:45am - 10:45am NY	Mitigating Risks Associated with API Suppliers **Stan Russell —** *Vice President, Site Head of Quality,* **Sebela Pharmaceuticals**	How much can we rely on the technology transfer from multiple sources in multiple locations to have the same QbD principles? **Thomas Sauer —** *VP, Head of Biologics Projects, CMC New Products Program,* **Sanofi**	Strategies to Accelerate CMC Development **Arul Joseph —** *Senior Director, Pharmaceutical Development and Clinical Supply Chain,* **Avanir Pharmaceuticals**	Best Strategies for Transitioning from Early-Phase to Late-Phase Manufacturing **Nick Dunwoody —** *Vice President, Pharmaceutical Development and Technical Operations,* **Tiburio Therapeutics**	Strategies to Monitor and Reduce Variability in Biologic Drug Products **Praveen Prasanna —** *Senior Director, Technical Operations and Head of Biologics Development and Manufacturing,* **AVEO Oncology**	Comparative Analysis of Available CDMOS - Does More Expensive Always Mean Better? **Qinghai Zhao —** *VP, Technical Development and Manufacturing,* **Forty Seven, Inc.**
2:45pm - 3:00pm UK	10:45am - 11:00am NY	BREAK					
3:00pm - 4:00pm UK	11:00am - 12:00pm NY				What is “Fit for Purpose” Process Research & Scale-Up of Small Molecule API? **Dean Edney —** *Global Head of Process R&D,* **Sai Life Sciences**		Speeding up Discovery with a right CRO Partner **Dr. Vikas Shirsath —** *Senior Vice President – Synthesis,* **Jubilant Biosys Limited**
4:00pm - 5:00pm UK	12:00pm - 1:00pm NY	BREAK					
5:00pm - 6:00pm UK	1:00pm - 2:00pm NY	Rationale, Strategies and Execution for Developing API & Intermediate Supply **Steve Wald —** *Vice President, Chemistry and Pharmaceutical Sciences,* **Rgenix**	Innovations in Quality Technology - What’s Worth Investing In and What Isn’t? **Melissa Seymour —** *Vice President, Global Quality Control,* **Biogen**	CMC Regulatory Challenges in Accelerated Product Development and Commercialization **George Chen —** *Executive Director, US/EU & Regional Regulatory Affairs-CMC,* **Daiichi Sankyo, Inc. &** **Uma Balasubramanian —** *Associate Director,* **Daiichi Sankyo, Inc.**	Manufacturing Process Scale-up of Natural Active Pharmaceutical Ingredient Complex Mixture’s from Clinical to Commercial phase **Jean-Pierre Metabanzoulou —** *Senior Director, CMC & RA,* **Acasti Pharma Inc.**	Key Considerations for Sterile Drug Product Development for the Marketplace **Mukta Gupta —** *Quality Lead,* **Takeda**	Using “One-Stop-Shop” CDMOs Compared to Using Providers Best Suited for Each Step of the Process - Advantages and Disadvantages **Ruby Casareno —** *Vice President, Technical Operations,* **Allakos Inc**
END							

KEYNOTE PRESENTATION

Stan Russell
Vice President,
Site Head of Quality
Sebela Pharmaceuticals

1ST KEYNOTE PRESENTATION

1:00pm - 1:30pm UK **9:00am - 9:30am NY**

- Conference Value Proposition
- Trends
- Lifecycle Management COVID-ized
- 2021 and Beyond-All New, No Normal?

Stan Russell
Vice President,
Site Head of Quality
Sebela Pharmaceuticals

1:45pm - 2:45pm UK | 9:45am - 10:45am NY

Mitigating Risks Associated with API Suppliers

- General quality and process knowledge
- Logistical challenges
- Alternate supplier compare/contrast

Steve Wald
Vice President, Chemistry and
Pharmaceutical Sciences
Rgenix

5:00pm - 6:00pm UK | 1:00pm - 2:00pm NY

Rationale, Strategies and Execution for Developing API & Intermediate Supply

- Intermediate sourcing with geographic diversity.
- Intermediate supplier control over their supply chains.
- API CMO strategy, including number of steps, location (price vs quality) and risk mitigation.

Thomas Sauer
VP, Head of Biologics Projects,
CMC New Products Program
Sanofi

1:45pm - 2:45pm UK | 9:45am - 10:45am NY

How much can we rely on the technology transfer from multiple sources in multiple locations to have the same QbD principles?

- Retrieving data through tech transfer typically adds knowledge in different formats with all relaxed Challenger. Will we ever reach a standardized and unified data format to allow for seamless tech transfer and allow a quick if not automated update of the accumulated product knowledge?
- While QbD starts already with entry in development, many projects face a change of ownership sometimes during development resulting in process transfers and potentially in development strategy breaks. Are QbD principles generally followed during tech transfer and if so Is there a smart way to adjust the received information to internal development philosophy during tech transfer already?
- Are QbD principles used to select required information for technology transfer packages and acceptance criteria? Will that improve the likelihood of a successful first run, e.g. by assessing comparability risks of process gaps with available design space information?

Melissa Seymour
Vice President,
Global Quality Control
Biogen

5:00pm - 6:00pm UK | 1:00pm - 2:00pm NY

Innovations in Quality Technology - What's Worth Investing In and What Isn't?

- Is Quality innovation driving to efficiency or better data and knowledge management?
- How important is ensuring compliance in driving innovation – where is risk acceptable?
- Does the cloud offer a unique opportunity for Quality?

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

1:45pm - 2:45pm UK | 9:45am - 10:45am NY

Strategies to Accelerate CMC Development

- Why are strategies needed to accelerate CMC development?
- What expectations need to be met for a drug product with accelerated development timelines
- What specific strategies and risk mitigation steps are used to accelerate CMC development?

George Chen
Executive Director, US/EU &
Regional Regulatory Affairs-CMC
Daiichi Sankyo, Inc.

Uma Balasubramanian
Associate Director
Daiichi Sankyo, Inc.

5:00pm - 6:00pm UK | 1:00pm - 2:00pm NY

CMC Regulatory Challenges in Accelerated Product Development and Commercialization

- What are the critical CMC issues that must be addressed to be able to truncate the development timeline to 2 years?
- What are successful strategies to address the need for sequential validation where the manufacture of multiple components and multiple manufacturing sites are required before drug product validation can be conducted - i.e., validation of ADCs?
- With transfer of analytical methods being rate limiting for manufacturing transfers, what validation strategies are best suited- i.e, transfer validation, co-validation, or independent validation? What criteria should be in place to select the validation strategy?
- For life-cycle maintenance, what are the successful strategies to implement comparability protocol? Are extended comparability protocols being accepted?

Nick Dunwoody
Vice President,
Pharmaceutical Development
and Technical Operations
Tiburio Therapeutics

1:45pm - 2:45pm UK | 9:45am - 10:45am NY

Best Strategies for Transitioning from Early-Phase to Late-Phase Manufacturing

- Technical capabilities/scalability and global presence
- Regulatory History
- CDMO versus CMO

Jean-Pierre Metabanzoulou
Senior Director,
CMC & RA
Acasti Pharma Inc.

5:00pm - 6:00pm UK | 1:00pm - 2:00pm NY

Manufacturing Process Scale-up of Natural Active Pharmaceutical Ingredient Complex Mixture's from Clinical to Commercial phase

- Physical and chemical characterisation as a fingerprint of the manufacturing process
- Continuous manufacturing process along with continuous QC as complementary imbedded QbD to yield high quality API
- For small biotech companies, R&D external collaboration with CDMO & Universities, a powerful resource to expand internal operational capacity and capability

Dean Edney
Global Head of Process R&D
Sai Life Sciences

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3:00pm - 4:00pm UK | 11:00am - 12:00pm NY

What is "Fit for Purpose" Process Research & Scale-Up of Small Molecule API?

Exploration of what is required for successful API scale-up, how to balance cost, speed and quality including what does "Fit for Purpose" really mean and how does it change.

- Important factors during API Process Research & Scale-Up and how to prioritise them.
- The advantages, downsides and pitfalls of focusing on a single goal (cost, speed, quality etc). How to manage the risks and minimise the impact of the downsides.
- Perspectives on the priority of various aspects of API process research & development dependent upon the goals of the sponsor and the phase of development.

Praveen Prasanna
Senior Director, Technical Operations and Head of Biologics Development and Manufacturing
AVEO Oncology

1:45pm - 2:45pm UK | 9:45am - 10:45am NY

Strategies to Monitor and Reduce Variability in Biologic Drug Products

- Discuss strategies for identifying sources of variability.
- Discuss variability reductions methods used.
- Identify methods of gaining alignment across the organization for these activities

Mukta Gupta
Quality Lead
Takeda

5:00pm - 6:00pm UK | 1:00pm - 2:00pm NY

Key Considerations for Sterile Drug Product Development for the Marketplace

- Identification of Critical Quality - Attributes
- Process Optimization
- Sterility Assurance

Qinghai Zhao
VP, Technical Development and Manufacturing
Forty Seven, Inc.

1:45pm - 2:45pm UK | 9:45am - 10:45am NY

Comparative Analysis of Available CDMOS - Does More Expensive Always Mean Better?

- Performance of CDMO service is likely linked to the price but be aware that is not always the case
- Understand your performance/quality needs at different stages of development and manufacturing
- Performance, Cost and Speed is a balance in outsourcing

Dr. Vikas Shirsath
Senior Vice President – Synthesis
Jubilant Biosys Limited

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3:00pm - 4:00pm UK | 11:00am - 12:00pm NY

Speeding up Discovery with a right CRO Partner

- Integrated Drug Discovery business
- IND and enabling business
- Medicinal chemistry and DMPK as key drivers in Discovery phase.

Ruby Casareno
Vice President, Technical Operations
Allakos Inc

5:00pm - 6:00pm UK | 1:00pm - 2:00pm NY

Using "One-Stop-Shop" CDMOs Compared to Using Providers Best Suited for Each Step of the Process - Advantages and Disadvantages

- Typical offerings of One Stop Shop CDMOs
- Advantages and Disadvantages
- Case studies shared by participants

2019 ATTENDEES

COMPANY	JOB TITLE
Abbott	Regional Manager in Regulatory Affairs
AbbVie	Director CMC Sciences
AbbVie	Director, Pharmaceutical Development
AbbVie	Director, Protein Analytics
AC Immune SA	Formulation and DP Development Lead
Access Vascular	Chief Executive Officer
Adaptimmune	Senior Director of Quality
Agenus Bio	Associate Director, CMC Management
Agenus Bio	Director Regulatory Strategy CMC
Agios	Associate Manager
Alexion Pharmaceuticals	Director Regulatory Strategy
Alexion Pharmaceuticals	Executive Director
Alexion Pharmaceuticals	Director Regulatory Affairs-CMC
Allakos Inc.	Director
Allakos Inc.	Director Upstream Process Development
Almirall	Head Drug Substance Development
Alnylam Pharmaceuticals	Associate Director
Amarin	Executive Director
Anika Therapeutics, Inc.	Vice President, Operations
Anokion	Chief Technical Officer
Anokion	Director of Manufacturing
AOP Orphan Pharmaceuticals AG	CMC Lead
Apellis Pharmaceuticals	Senior Director Global Regulatory Operations
Ardelyx	Senior Director
AstraZeneca	Director
Athenex	Director Cell Therapy Manufacturing/CMC
Atlas Venture NewCo	VP Product Development
Avanir	Senior Director Pharmaceutical Development & Clinical Supply
AVEO Oncology	Senior Director Technical Operations
AVROBIO	Quality GMP Operations/ Associate Director, Quality
Axanton Technology GmbH	Chief Executive Officer
Axcella Health Inc.	Vice President, Regulatory Affairs
Back Bay Group	Founder, President
Bayer	Lead Scientist MSAT
Bayer	Senior Director
Bayer	Senior Director, Cell and Gene Therapy Network Strategy & Supply Chain Management
Beam Therapeutics	Director, Program Management
BioCryst Pharmaceuticals	Executive Director Regulatory Affairs
Biogen	Associate Director Reg. Ops.
BioPharmX	Director of CMC
Black Diamond Therapeutics	Senior Director CMC
BlueRock Therapeutics	Senior Medical Director
BMS	Director, Cell therapy CMC development
BMS	Drug Product Development Team Leader
Boehringer Ingelheim	Director, QA
Boehringer Ingelheim	Executive Director CMC Biologics
Boehringer Ingelheim	Executive Director CMC Biologics
Boehringer Ingelheim	Head of Product Lifecycle Management
Boehringer Ingelheim	QA Senior Associate Director
Bolt Bio	Associate Director Manufacturing
Boston Pharmaceuticals	Executive Director CMC

COMPANY	JOB TITLE
BridgeBio Therapeutics	Senior Director of MFG
Celgene	Executive Medical Director Clinical R&D (Cell Therapy)
Celgene	Senior Director, Biopharmaceutical Development & MFG
Celyad	Global Head of Regulatory Affairs
Centrexion Therapeutics	Director of CMC
Chugai	Head of Regulatory Affairs
Collegium Pharmaceutical, Inc.	Senior Director, Pharmaceutical Development
Constellation Pharmaceuticals	Director, Regulatory Affairs
CSL Behring	Global Regulatory CTA Team Leader
CSL Behring	Head of Site Manufacturing Quality
CSL Behring	Senior Director CMC
Cyclerion, Inc.	CMC Regulatory Affairs, Director
Debiopharm	Head CMC
Evelo Biosciences	Director of Regulatory Affairs
FAST BioMedical	VP Regulatory Affairs and CMC
Forty Seven Inc	VP Technical Development and Manufacturing
Fresenius Kabi	Director CMC Regulatory Affairs
Fusion Pharma	Vice President
Glenmark (Inchos Sciences)	Head of Formulation, Analytical and Drug product development
Global Blood Therapeutics	Associate Director
Global Blood Therapeutics	Associate Director CMC Biologics
Gritstone Oncology	Director of Analytical Technologies
GSK	Director, Market Access & Pricing
Ikena Oncology	VP Therapeutics Development & Manufacturing
ImmunoGen	Associate Director Regulatory Affairs CMC
Infinity Pharmaceuticals	Head of Clinical Development
Insys Therapeutics Inc	Director
Intrommune Therapeutics	Chief Regulatory Officer
Janssen	Associate Director
Janssen	Global Regulatory Affairs Lead
Kinikska Pharmaceutical	Director of CMC Operations
Kite Pharma	Cell Therapy Account Manager
KLUS Pharma	Vice President
LogicBio Therapeutics	Director External Manufacturing and Supply Chain
Medac GMBH	Director Global Regulatory Affairs-Established Products
Medigene AG	VP Head of Innovation
Merck	Executive Director & Global Head - CMC Policy
Mersana Therapeutics	Associate Director
Mersana Therapeutics	Director Cell Line Development
Mersana Therapeutics	Principal Scientist
Merus	Executive Director Regulatory Affairs
Mylan	Head of Regulatory Affairs Germany
Mymetics SA	Head of Quality & Manufacturing
Navega Therapeutics	Chief Strategy Officer
NGM Biopharmaceuticals	Senior VP of Biologics Research and CMC
Northeastern University	Department Chair Quality Assurance, Regulatory Affairs and Advanced Manufacturing
Novartis	Director, Clinical Quality
Novartis	Executive Director, Sr GPRD
Novartis	Global Lead Regulatory Affairs, CMC (Cell and Gene)
Novartis	Head of Procurement Cell & Gene Therapies
Novartis	Senior Legal Counsel NTO Biologics, Cell and Gene

COMPANY	JOB TITLE
Novartis Pharma AG	Global RA CMC Senior Manager
Ocular Therapeutix	Senior Director Regulatory Affairs
Oncorus	VP Molecular Biology & Virology
Oragenics	Senior Director of Drug Development
Orbsen Therapeutics	Head of Analytical Development
Oyster Point Pharma	Executive Director, Regulatory CMC
Portola Pharmaceuticals	Associate Director Manufacturing
Progenics	Senior Director CMC
Promedior	Senior Director Analytical
Protagonist Therapeutics	SVP, Pharmaceutical Development
PTI	SVP of CMC
Rafael Pharmaceuticals	VP, MFG & CMC
Roche	Scientist
Roche	Senior Group Lead, Principal Scientist Cell Culture Development
Sanofi	Director MSAT
Sanofi	MSAT, Head
Sanofi	Principal Associate RA-CMC
Sanofi	Regulatory Affairs
Sanofi	Technical Lead Scientist
Sanofi Genzyme	Scientist II
Seres Therapeutics	Senior Vice President, Regulatory Affairs
Shattuck Labs	VP CMC
Sigilon	Senior Director Regulatory Affairs
Spark	Senior Director CMC Project Management
Stemline Therapeutics	Executive Director
Takeda	Associate Director Lead Rare Diseases
Takeda	Associate Director, Global Regulatory Affairs CMC
Takeda	Associate Director, Innovation Specialist
Takeda	CMC Lead
Takeda	Global Safety Lead - Medical Director
Takeda	GRA Compliance, QMS Lead, Global Regulatory Operations & Compliance R&D Development
Takeda	Head of CMC Commercial Submission Mgt.
Takeda	Manufacturing Sciences Site Head
Takeda	RA/QA/PV Head MCO EE
Takeda	Senior Manager GRA Emerging Markets/ Emerging Market Regulatory Lead
Takeda Pharmaceutical International AG	Head of MSci Innovation
Takeda VBU	Senior Director, Regulatory Operations
Tetraphase Pharmaceuticals	Associate Director, Regulatory Affairs
Tetraphase Pharmaceuticals	VP, CMC
Teva	Senior Director, Reg Affairs CMC
Transcenta	Senior Director DSP
Turnstone Biologics, Inc.	SVP, Technical Operations
VectivBio	Director Global CMC Operations
VectivBio	Head of CMC
Vertex Pharmaceuticals	Manager, Regulatory Affairs
Visterra	VP, Pharmaceutical Sciences & Technology
Waveray Capital	Partner (VC)
Xellia Pharmaceuticals	Manufacturing Science & Technology Director
Xencor	Senior Director, Bioanalytical Sciences (CMC Operations)