ONLINE CHEMISTRY MANUFACTURING CONTROL STRATEGY MEETING 2020

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

SPONSORS

AGENDA

KEYNOTE PRESENTATION

TRACK 1: **Intermediates & API**

TRACK 2: Technology Transfer & Analytical

TRACK 3: **Integrated Drug Development**

TRACK 4: **Process Research & Scale-up**

TRACK 5: **Drug Product & Patient Delivery**

TRACK 6: Outsourcing

2019 ATTENDEES





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.



GET IN TOUCH WITH US:





CONTRIBUTORS TO THE AGENDA

Stan Russell

Site Head of Quality

Pharmaceuticals

Vice President,

Sebela

CMC

STRATEGY MEETING

Melissa Seymour

Vice President. **Global Quality Control** Biogen





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**

Thomas Sauer

VP, Head of Biologics Projects, CMC New **Products Program** Sanofi



Nick Dunwoody

Pharmaceutical Development

Tiburio Therapeutics

and Technical Operations

Vice President,





Mukta Gupta Quality Lead Takeda











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CO-HOST SPONSORS



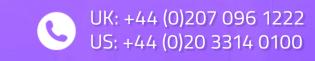
Sai Life Sciences provides services to our pharma innovator partners, which accelerate the discovery, development and manufacture of complex small molecule therapeutics. Our clients gain clear competitive advantages through shorter time to market and risk minimization using our integrated and high-quality 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 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:

- respiratory diseases.
- ADME-PK, in-vitro and in-vivo biology and IND enabling GLP toxicology.









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Target identification/target validation to lead optimization/preclinical candidate, for multiple therapeutic areas viz; oncology, metabolic disorders, CNS, pain, inflammation, fibrosis and

Functional services comprising of computational chemistry/ molecular modeling, medicinal chemistry, synthetic chemistry, scale-up (Non-GMP & GMP), structural biology,

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AGENDA

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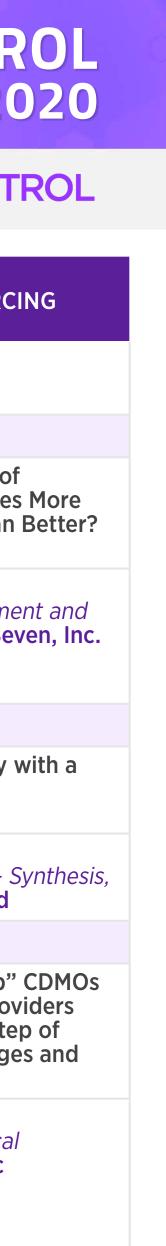
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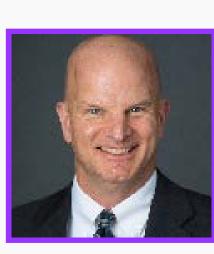
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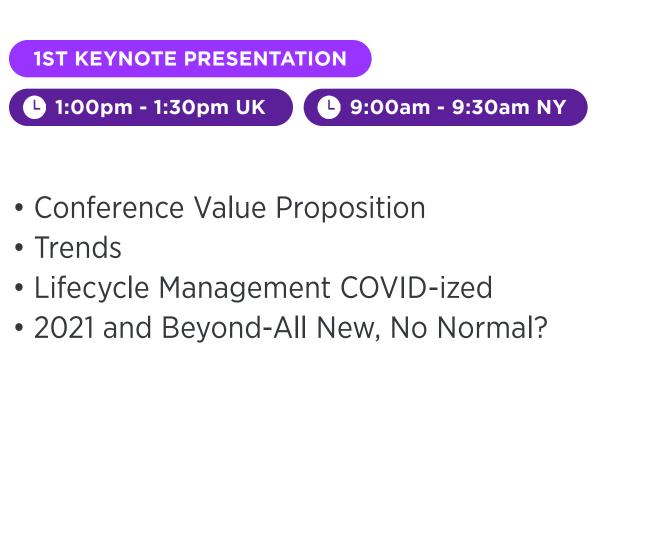




KEYNOTE PRESENTATION



Stan Russell Vice President, Site Head of Quality Sebela Pharmaceuticals







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TRACK 1 Intermediates & API



Stan Russell Vice President. Site Head of Quality Sebela Pharmaceuticals L 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









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Steve Wald Vice President, Chemistry and Pharmaceutical Sciences Rgenix

5:00pm - 6:00pm UK L 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.



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TRACK 2 **Technology Transfer** & Analytical



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?



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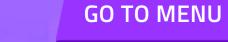


Melissa Seymour Vice President, **Global Quality Control** Biogen

L 1:00pm - 2:00pm NY **5:00pm - 6:00pm UK**

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?



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TRACK 3 Integrated Drug Development



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

Strategies to Accelerate CMC Development



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



Uma Balasubramanian Associate Director Daiichi Sankyo, Inc.





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L 1:45pm - 2:45pm UK

🕒 9:45am - 10:45am NY

• 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?

> L 1:00pm - 2:00pm NY 🕒 5:00pm - 6:00pm UK 🕽

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?
- 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?

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TRACK 4 Process Research & Scale-up



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.

L 1:00pm - 2:00pm NY 🕒 5:00pm - 6:00pm UK

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







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





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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.

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TRACK 5 Drug Product & Patient Delivery



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

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

Strategies to Monitor and Reduce Variability in **Biologic Drug Products**

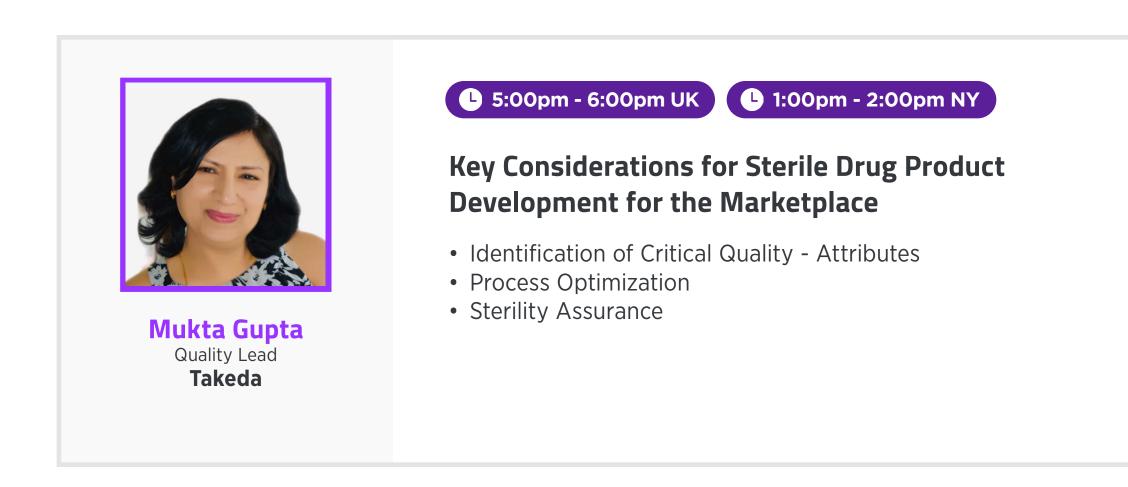
- Discuss strategies for identifying sources of variability.
- Discuss variability reductions methods used.
- Identify methods of gaining alignment across the organization for these activities

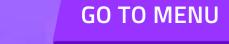




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TRACK 6 Outsourcing



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



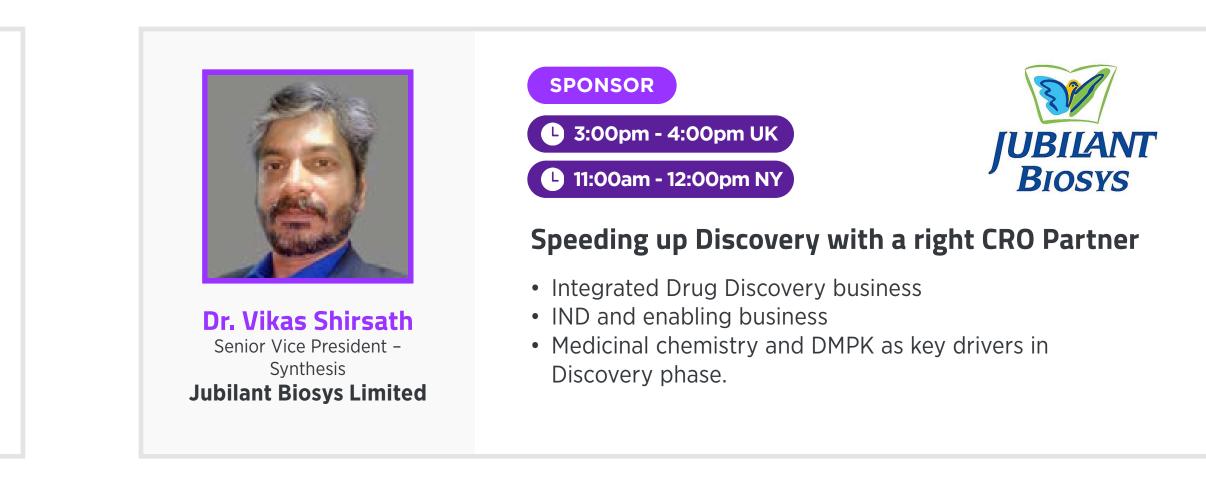
Ruby Casareno Vice President, Technical Operations Allakos Inc

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





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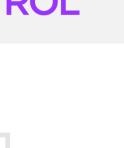
L 1:00pm - 2:00pm NY 🕒 5:00pm - 6:00pm UK

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

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2019 ATTENDEES

COMPANY

JOB TITLE

Abbott AbbVie AbbVie AbbVie AC Immune SA **Access Vascular Adaptimmune** Agenus Bio **Agenus Bio** Agios **Alexion Pharmaceuticals Alexion Pharmaceuticals Alexion Pharmaceuticals** Allakos Inc. Allakos Inc. Almirall **Alnylam Pharmaceuticals** Amarin Anika Therapeutics, Inc. Anokion Anokion **AOP Orphan Pharmaceuticals AG Apellis Pharmaceuticals** Ardelyx AstraZeneca Athenex Atlas Venture NewCo Avanir **AVEO Oncology AVROBIO Axanton Technology GmbH** Axcella Health Inc. Back Bay Group **Bayer Bayer Bayer**

Beam Therapeutics BioCryst Pharmaceuticals Biogen **BioPharmX** Black Diamond Therapeutics **BlueRock Therapeutics** BMS BMS **Boehringer Ingelheim** Boehringer Ingelheim **Boehringer Ingelheim Boehringer Ingelheim Boehringer Ingelheim** Bolt Bio **Boston Pharmaceuticals**

Regional Manager in Regulatory Affairs Director CMC Sciences Director, Pharmaceutical Development Director, Protein Analytics Formulation and DP Development Lead **Chief Executive Officer** Senior Director of Quality Associate Director, CMC Management Director Regulatory Strategy CMC Associate Manager Director Regulatory Strategy **Executive Director Director Regulatory Affairs-CMC** Director **Director Upstream Process Development** Head Drug Substance Development Associate Director **Executive Director** Vice President, Operations Chief Technical Officer Director of Manufacturing CMC Lead Senior Director Global Regulatory Operations Senior Director Director Director Cell Therapy Manufacturing/CMC **VP** Product Development Senior Director Pharmaceutical Development & Clinical Supply Senior Director Technical Operations Quality GMP Operations/ Associate Director, Quality **Chief Executive Officer** Vice President, Regulatory Affairs Founder, President Lead Scientist MSAT Senior Director Senior Director, Cell and Gene Therapy Network Strategy & Supply Chain Management **Director, Program Management Executive Director Regulatory Affairs** Associate Director Reg. Ops. Director of CMC Senior Director CMC Senior Medical Director Director, Cell therapy CMC development Drug Product Development Team Leader Director, QA **Executive Director CMC Biologics Executive Director CMC Biologics** Head of Product Lifecycle Management QA Senior Associate Director Associate Director Manufacturing **Executive Director CMC**

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



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JOB TITLE

COMPANY

Novartis Pharma AG **Ocular Therapeutix** Oncorus Oragenics **Orbsen Therapeutics Oyster Point Pharma Portola Pharmaceuticals Progenics** Promedior **Protagonist Therapeutics** PTI **Rafael Pharmaceuticals** Roche Roche Sanofi Sanofi Sanofi Sanofi Sanofi Sanofi Genzyme Seres Therapeutics Shattuck Labs Sigilon Spark **Stemline Therapeutics** Takeda Pharmaceutical International AG Takeda VBU **Tetraphase Pharmaceuticals Tetraphase Pharmaceuticals** Teva Transcenta **Turnstone Biologics, Inc. VectivBio** VectivBio **Vertex Pharmaceuticals** Visterra Waveray Capital **Xellia Pharmaceuticals** Xencor

JOB TITLE

Global RA CMC Senior Manager Senior Director Regulatory Affairs VP Molecular Biology & Virology Senior Director of Drug Development Head of Analytical Development **Executive Director, Regulatory CMC** Associate Director Manufacturing Senior Director CMC **Senior Director Analytical** SVP, Pharmaceutical Development SVP of CMC VP. MFG & CMC **Scientist** Senior Group Lead, Principal Scientist Cell Culture Development **Director MSAT** MSAT, Head **Principal Associate RA-CMC Regulatory Affairs Technical Lead Scientist** Scientist II Senior Vice President, Regulatory Affairs VP CMC Senior Director Regulatory Affairs Senior Director CMC Project Management **Executive Director** Associate Director Lead Rare Diseases Associate Director, Global Regulatory Affairs CMC Associate Director, Innovation Specialist CMC Lead **Global Safety Lead - Medical Director GRA Compliance, QMS Lead, Global Regulatory Operations & Compliance R&D Development** Head of CMC Commercial Submission Mgt. Manufacturing Sciences Site Head RA/QA/PV Head MCO EE Senior Manager GRA Emerging Markets/ Emerging Market **Regulatory Lead** Head of MSci Innovation Senior Director, Regulatory Operations Associate Director. Regulatory Affairs VP, CMC Senior Director. Reg Affairs CMC Senior Director DSP SVP, Technical Operations **Director Global CMC Operations** Head of CMC Manager, Regulatory Affairs **VP, Pharmaceutical Sciences & Technology** Partner (VC) Manufacturing Science & Technology Director

Senior Director, Bioanalytical Sciences (CMC Operations)

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