

Life Science Regulatory Summit 2026: Navigating Risk & Change

July 7 – July 9, 2026 4hr. session/day

Live: 14:00 - 18:00 JP/KR Time



- 12 expert-led sessions | 12 critical challenges | Free access
- 3 days virtual seminar to explore Life Science Regulatory insights
- Register Once to access Live and On-Demand

Day 1

Sessions



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Time	Title	Speakers	Moderators
Advancing Regulatory Excellence in Excipient Quality and Single-Use Systems for Pharma Manufacturing			
14:00 – 14:05	Opening Remarks		Manisha Chaudhari <i>Head of Customer Applications-Excipient, APeC</i>
14:05 - 14:55	Excipient for Drug Product in China - Refresh and Update	Cloris Tian <i>Senior Regulatory Expert Shanghai, China</i>	Manisha Chaudhari <i>Head of Customer Applications-Excipient, APeC</i>
Break			
15:00 - 15:50	Excipients in Nitrosamine Risk Mitigation: Nitrite Control and Formulation Strategies	Dr. Ulrich Reichert, M.D.R.A. <i>Head of CDMO and Bioprocess Materials Darmstadt, Germany</i>	Kyung-Min Shin <i>Technical Application Expert, Formulation, South Korea</i>
Break			
16:00-16:50	Update of Regulatory Requirements for EG/DEG in Pharmaceutical Products	Yuwei Heinzel <i>Head of Pharma Registration Darmstadt, Germany</i>	Manisha Chaudhari <i>Head of Customer Applications-Excipient, APeC</i>
Break			
17:00-17:55	Single-Use Systems for Aseptic Manufacturing – Balancing Risks and Benefits	Dr. Simone Biel <i>Senior Regulatory Expert Darmstadt, Germany</i>	Bennett Tan <i>Regional Strategy Execution Manager, SU&IPS APeC</i>
	Closing		

Day 2

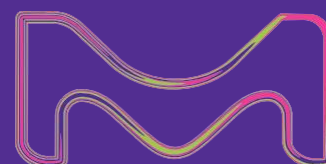
Sessions

Time	Title	Speakers	Moderators
Advancing Biologics Regulation: ADC, ATMP Comparability, and Raw Material/Excipient Management			
14:00 – 14:05	Opening Remarks		June Hwang <i>Senior Modality Leader, Advanced Antibodies, Strategic Modality, Asia Pacific excluding China</i>
14:05 - 14:55	Regulatory Considerations for Antibody–Drug Conjugates and their components	Mandy Balleine <i>Senior Regulatory Affairs Expert (CDMO) Madison, USA</i>	June Hwang <i>Senior Modality Leader, Advanced Antibodies, Strategic Modality, Asia Pacific excluding China</i>
Break			
15:00 - 15:50	A Regulatory Framework for Raw Materials Used in Biologic Drug Manufacturing	Dr. Janmeet Anant <i>Senior Regulatory Consultant Burlington, USA</i>	Jeong-Hoon Lee <i>Regulatory Management Specialist, South Korea</i>
Break			
16:00-16:50	ATMP Comparability Study: Regulatory Requirements for Critical Changes - A Case Study	Houda Beltaief <i>Head of Biopharma Regulatory Experts Pessac, France</i>	Rain Lee <i>Regional Strategy Execution Manager Upstream APeC</i>
Break			
17:00-17:55	Excipient Excellence: Understanding GMP and GDP Guidelines	Mike Polito <i>Regulatory Expert, Pharma Materials Burlington, USA</i>	Dr. Saroj Varavadekar <i>Head of Regulatory Management, India</i>
Closing			



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Day 3

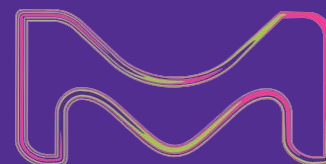
Sessions

Time	Title	Speakers	Moderators
Global Regulatory Updates: Strategic Insights into Annex 1, MAT, RMM, and ABP Compliance			
14:00 – 14:05	Opening Remarks		Parag Vachhani <i>Sr. Expert, Regional Commercial Applications APAC</i>
14:05 - 14:55	EU GMP Annex 1 Compliant Air Monitoring: Choosing the Right Equipment and Key Features for Effective Microbial Sampling	Kenny Tay <i>Head of Commercial Applications, APAC, Singapore</i>	Parag Vachhani <i>Sr. Expert, Regional Commercial Applications APAC</i>
Break			
15:00 - 15:50	Monocyte Activation Test (MAT) in India: Bridging Regulatory Frameworks and Industrial Adoption	Dr. Rohit Bisht <i>Senior Scientist-Regulatory Testing (Pharm & Med Devices), PETA India</i>	Parag Vachhani <i>Sr. Expert, Regional Commercial Applications APAC</i>
Break			
16:00-16:50	Update on the Regulatory Landscape and Technical Application of Rapid Microbiological Methods	Dr. Sha Zhu <i>Senior Regulatory Marketing Expert, BioMonitoring Darmstadt, Germany</i>	Parag Vachhani <i>Sr. Expert, Regional Commercial Applications APAC</i>
Break			
17:00-17:55	Animal By-Product Regulations, Implications to Global Trade	Dr. Tobias Hertzig <i>Regulatory Affairs Expert Darmstadt, Germany</i>	Parag Vachhani <i>Sr. Expert, Regional Commercial Applications APAC</i>
Closing			



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Meet the Experts

Speakers:



Cloris Tian
Senior Regulatory
Expert
Shanghai, China



Mandy Balleine
Senior
Regulatory Affairs
Expert (CDMO)
Madison, USA



Kenny Tay
Head of Commercial
Applications,
APAC, Singapore



**Dr. Ulrich
Reichert,
M.D.R.A.**
Head of CDMO and
Bioprocess Materials
Darmstadt, Germany



**Dr. Janmeet
Anant**
Senior Regulatory
Consultant
Burlington, USA



Dr. Rohit Bisht
Senior Scientist-
Regulatory Testing
(Pharm & Med Devices),
PETA India



Yuwei Heinzel
Head of
Pharma Registration
Darmstadt, Germany



Houda Beltaief
Head of Biopharma
Regulatory Experts
Pessac, France



Dr. Sha Zhu
Senior Regulatory
Marketing
Expert, BioMonitoring
Darmstadt, Germany



Dr. Simone Biel
Senior Regulatory
Expert
Darmstadt, Germany



Mike Polito
Regulatory Expert,
Pharma Materials
Burlington, USA



Dr. Tobias Hertzig
Regulatory
Affairs Expert
Darmstadt, Germany

Moderators:



Manisha Chaudhari
Head of Customer
Applications-Excipient,
APeC



June Hwang
Senior Modality Leader,
Advanced Antibodies,
Strategic Modality, Asia
Pacific excluding China



Parag Vachhani
Sr. Expert, Regional
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Kyung-Min Shin
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Jeong-Hoon Lee
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Management
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South Korea



Bennett Tan
Regional Strategy
Execution Manager,
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Rain Lee
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Execution Manager
Upstream APeC



**Dr. Saroj
Varavadekar**
Head of Regulatory
Management, India



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