**ANNOUNCEMENT**

**APEC Life Sciences Innovation Forum – Regulatory Harmonization Steering Committee**

**USP-APEC Center of Excellence for Advanced Therapies**

**Pilot Virtual Workshop**

“Starting and Raw Materials for Advanced Therapies”

1, 3, 8, 9 March 2021 (Americas) / 2, 4, 9, 10 March 2021 (Asia)

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<th>Tuesday 2 March</th>
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<td>Bangkok Jakarta</td>
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<td>Washington Lima</td>
<td>8:00pm - 11:00pm (Monday, 1 March)</td>
<td>8:00pm - 11:00pm (Wednesday, 3 March)</td>
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The USP-APEC Center of Excellence for Advanced Therapies Pilot Virtual Workshop will convene government regulators from APEC member economies together with global academic and industry experts to share experiences on how to address the qualification of raw materials used in the manufacturing of advanced therapies. The sessions will include case studies using materials associated with the latest trends in cell and gene therapy products and tissue scaffolds. Session topics will include:

- Diversity of starting and raw materials used in manufacturing of advanced therapies – cells, plasmids, media, reagents, viral vectors
- Identification and selection of critical raw materials
- Risk-based approaches and categories of raw material used in manufacturing
- Lessons learned from biotherapeutics and other biological medicines
- Type of quality systems to have in place to assure the quality of raw materials
- Clarification of responsibilities between suppliers and end-users of raw materials

This workshop is part of the Advanced Therapy Priority Work Area under the APEC LSIF RHSC to promote prospective regulatory convergence for advanced therapy products, including cell and gene therapies. As a standard-setting body and active contributor to global scientific bodies, USP aims this workshop to serve as a platform to improve global health through public standards that ensure quality and safety of advanced therapies in collaboration with the APEC Harmonization Center (AHC).

If interested in attending the workshop, please complete the pre-registration form at [https://live.eventtia.com/en/usp-apec-coe](https://live.eventtia.com/en/usp-apec-coe) by Wednesday, 17 February. You will receive further details and instructions once your pre-registration has been approved. Please note that this workshop is open to regulators only. For questions, please contact Mr Michael Schmitz ([MSchmitz@crowell.com](mailto:MSchmitz@crowell.com)) or the APEC Harmonization Center ([apec-ahc@korea.kr](mailto:apec-ahc@korea.kr)).