



USP Convention Asia Pacific Regional Chapter Meeting Agenda
8th & 9th June 2022

Day 1 Wed, 08 June	https://nus-sg.zoom.us/meeting/register/tZ0ucOGsrD0qHNQFWUh9GNKCxmowdEVwKRRZ
Day 2 Thurs, 09 June	https://nus-sg.zoom.us/meeting/register/tZAkf-2trzgJHdN-B0wfAYutfriLjvvc0y-P

	Agenda discussion	Proposed speaker
1 15mins	Introduction (5mins) Opening remarks by Ron <i>(give a quick summary on supply chain subject to set stage for next panel discussion)</i>	John Lim Ron P. (sector series)
2 40mins	Taking from lessons learnt during pandemic, what can we do to be more prepared in ensuring greater supply chain resiliency before we face our next crisis? Proposed panel speakers (tbd) <ul style="list-style-type: none"> 1. Regulatory perspective (TGA, PFDA tbc) 2. Industry perspective (Roche, GSK tbc) 3. Distributor perspective (Zuellig) [Panel speakers from regulators, industry and distributor]	Moderator Questions to ask: <ol style="list-style-type: none"> 1. Can we identify any upstream supply chain risks to help avoid shortages? 2. What are current policies to increase diversity in ingredients and manufacturing? 3. How does supply chain diversity lead to medicines quality? 4. What are the efforts to ensure compliance to international standards, including good manufacturing practices and science-based public quality standards?
3 40mins	Impurities <ul style="list-style-type: none"> a. Nitrosamines Impurities <ul style="list-style-type: none"> • Nitrosamine Landscape (where we came from, and where we are heading) • The regulatory evolution of Nitrosamines Impurities • Compendial Resources and tools • USP ongoing work 	Confirmed: Naiffer (USP) - 30mins

	<ul style="list-style-type: none"> Nitrosamine Knowledge Hub <p>b. Vietnam experience (10mins) – pilot project</p> <p>c. Australian’s perspective on managing Nitrosamines Impurities</p>	<p>Dr Thuan Do Thi (Vietnam NIDQC)</p> <p>Dr Karen Loft (TGA) 10mins</p>
4 10mins	<p>Summary: Recap</p> <ul style="list-style-type: none"> Potential areas of collaboration 	

Day 2 – target audience is Developed markets e.g. Korea, Japan, Singapore

	Agenda – information sharing	Ruth & MK
1	Summary of Day 1 discussion - recap	USP – Anthony/Ruth
2	<p>1a. Advanced therapies</p> <ul style="list-style-type: none"> Scope/Definition of advanced therapies Advanced therapies regulatory landscape in APAC Cell and gene landscaping project overview USP ongoing work and resources <p>1b. Management of CGT & Biologics under Australian Advanced Therapy framework</p> <p>1c. Sharing of latest CGT developments in Singapore – E.g ACTRIS</p> <p>1. Vaccines – Latest developments</p> <ul style="list-style-type: none"> a. Sharing by Industry b. USP Vaccines Assessment Toolkit 	<p>Minkyung Kim (USP) 20mins</p> <p>Natasha Brockwell (TGA) 15mins</p> <p>Dr Sudipto Bari,ACTRIS 10mins</p> <p>Dr Christian Hong , Renhaim Therapeutics Inc 15mins</p> <p>John KoKai-Kun (USP) 20mins</p>
3 45mins	<p>Conclusion and Summary</p> <ul style="list-style-type: none"> Summary of key points moving forward 	