2019 APEC Harmonization Center Biotherapeutics Workshop

Biotherapeutics Roadmap 2012-2019: Gap Analysis and Assessment of Progress Made Towards Convergence

DRAFT v. Agust 13, 2019

September 3-4, 2019 (COEX Conference Room 300) | Seoul, Republic of Korea

The Biotherapeutics Roadmap was developed in 2012 with a goal to bringing into convergence the regulatory systems of APEC economies in the biotherapeutics space by 2020. Over the past 7 years, the APEC RHSC at the recommendations set forth in the Roadmap, hosted several workshops to assess the biotherapeutics regulatory gaps in the region; identified guidances that if implemented, would minimize these gaps; developed a curriculum for biotherapeutics; identified a Center of Excellence to train regulators; and developed key performance indicators to assess convergence. Now, in 2019, just one year away from the target goal of 2020, the APEC RHSC will recap the region's progress towards that goal and envision the Roadmap beyond 2020

Time	Topic	
[Day 1] September 3, 2019		
09:00-09:30	Arrival, Registration, and Networking	
Welcome and Introduction		
09:30-09:40	Opening Remarks	AHC Director(NIFDS)
	Welcoming Remarks	Roadmap Champion (MFDS)
Introductory: APEC RHSC 2020 Vision and the Accomplishment Overview of APEC RHSC 2020 Vision and the Strategic Approaches; Share the results of the joint AHC-LSIF project to track key performance indicators (KPIs) measuring progress towards regulatory convergence in APEC region.		
09:40-10:10	**APEC RHSC 2020 Vision and the Strategic Approaches**	RHSC
10:10-10:40	**APEC Progress Towards Regulatory Convergence** Results from tracking the Key Performance Indicator(KPIs) and measuring progress towards regulatory convergence among APEC economies.	AHC
10:40-11:00	Group Photo & Break	
Session I: APEC RHSC Biotherapeutics Roadmap Overview of the Biotherapeutics roadmap; Highlight major outcomes from the past 7 years' of roadmap activities including CoEs		
11:00-11:30	**Overview and History of the Biotherapeutic Roadmap** Roadmap Vision 2020, highlight the roadmap activities in the past	MFDS
11:30-12:00	**Center of Excellence (CoE)** Practical approach to build capacity in real world, sucessess and lessons learned	NEU

12:00-13:30	Lunch	
Session II: Global Impacts of the APEC RHSC Biotherapeutics Roadmap The impact from the work of Biotherapeutics Roadmap in development and adaptation of the global guidelines as well as leveraging initial concept of regulatory capacity-building **Chair: Jared Auclair (NEU)**		
13:30-16:50	- WHO guideline of the Life Cycle Management for the Biologics - ICH guideline Industry perspectives of how convergence and alignment to ICH guidelines has progressed in the past 10 years - Other global outreach efforts	- Il Ung Oh (NIFDS) - Inhwa Choi (Roche) -NEU
16:50-17:00	Wrap Up for Day1	
[Day 2] September 4, 2019		
Session III, Part A: Evolving the APEC Biotherapeutics Roadmap Considerations for broadening scope of work areas in Biotherapeutics and Innovated Technologies for Manufacturing Biotherapeutics **Chair: Industry**		
09:30-10:05	- Antibody-Drug Conjugates	Tae kyo Park (IntoCell)
10:05-10:40	- Precision Medicine	
10:40-11:00	Break	
11:00-11:30	- Cancer metabolism Drug (Targeting metabolism for cancer therapy)	
11:30-12:00	- medical device coated with drug/biologicals	
12:00-13:30	Lunch	
Session III, Part B: Evolution of the APEC Biotherapeutics Roadmap Working together with other PWAs and initiatives and navigating the synergy **Chair: Yoo-kyoung Lee**		
Session IV: [Panel Discussion] Pre-assessment of the APEC regulatory convergence in Biotherpaeutics **Moderator: AHC (with Romi Singh)**		
15:00-16:00	[Panel Discussion] Real-time survey on Biotherapeutics regulatory status with the APEC regulatory authorities	
16:00-16:20	Wrap up: Highlight of the workshop and next steps	
16:30-16:45	Closing Remark	AHC Director