Time	DAY 1 (2 Oct 2018)	DAY 2 (3 Oct 2018)		DAY 3 (4 Oct 2018)
		Pharmaceutical/ Biological Track	TMHS / Veterinary Track	
7.30am – 9.00am	REGISTRATION			
9.00am – 9.10am 9.10am – 9.30am	**Welcoming Remarks** *Senior Director of Pharmaceutical Services MOH* **Opening Ceremony** *YB Minister of Health*	**Topic 1** - Process Validation Inspection and General Updates (*NPRA*)	**Topic 1** - Malaysian Variation Guidelines for TMHS (*NPRA*)	**Regulatory Updates 1** – Updates on Guidelines / Directives (*NPRA*)
9.30am – 10.00am	**Key Note Address** *Director General of Health, MOH*	**Topic 2** - Bioinformatics – Drug Delivery (*Sengenics*)	**Topic 2** – Quality & Safety of TMHS Material (TBC)	**Regulatory Updates 2** – Compounding Guidelines / Medical Device Drug Combination (*NPRA*)
10.00am – 10.30am	COFFEE BREAK			
10.30am – 11.15am	**Plenary 1** – Regulatory Review System Strengthening Industry Perspective (*Pfizer*)	**Topic 3** - Guideline on Regulatory Control of Active Pharmaceutical Ingredients (*Dr. Parvis, Swedish Medical Products Agency*)	**Topic 3** - Clinical Trials Requirements for TMHS (*Quintiles*)	**Regulatory Updates 3** – Cell & Gene Therapy Products Guidelines (*NPRA*)
11.15am– 12.00pm	**Plenary 2** – Regulatory Approval for Innovative Medicine – Regulatory Authority perspective (*Japan PMDA*)	**Topic 4** – Cell & Gene Therapy Products (*Taiwan FDA*)	**Topic 4** - TMHS in term on Therapeutic Claims (TBC)	**Regulatory Updates 4** – Phase I Unit Inspection Guidelines (*NPRA*)
12.00pm – 12.30pm	**Plenary 3** – Topic TBD (*SIRIM*)	Q & A	Q & A	Q & A
12.30pm – 2.00pm	LUNCH			12.30 – 12.45 pm Closing 12.45pm Adjourned & Lunch
2.00pm – 2.45pm	**Plenary 4** – Good Manufacturing Practice Desktop Audit (*ISPE*)	**Topic 5** - Medical Device Interphase Implementation (*MDA / SIRIM*)	**Topic 5** - Procedure for Obtaining Halal Certification for Local & Imported TMHS Products (*JAKIM*)	
2.45pm – 3.30pm	**Plenary 5** – Pharmacovigilance (TBC)	**Topic 6** – Facilitated Registration Pathway (TBC)	**Topic 6** - Registration Requirements for Veterinary Innovator/NCE Products (*Eli-Lily*)	
3.30pm – 4.00pm	COFFEE BREAK			
4.00pm – 4.30pm 4.30pm – 5.00pm	**Forum Discussion :** Trade & Patent issues (CL) / The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) / Access to Medicines	**Topic 7** - Orphan Drug Designation and Guidelines (TBC) Q & A	**Topic 7** – Herbal Monograph (*NPRA*) Q & A	
5.00pm	ADJOURNED			