



Schedule	Sunday, 28th	Monday, 29th	Tuesday, 30th	Wednesday, 1ST	Thursday, 2ND	Friday, 3th	Saturday, 4th	
8:30-9:00	 HAVANA - VARADERO	Abdala vaccine, the first Latin American vaccine against COVID-19 Miladys LIMONTA Cuba	Lentiviral vector reference material Kelth CARSON USA (Recorded Lecture)	Elaboration of lipid nanoparticles for mRNA vaccines Carster LOSCH Germany	Scientific R&D is not the fairy-tale marketing wants you to believe Alistair HURST Germany	Cost of Quality: human error prevention and reduction, and history of the quality movement Willis THOMAS USA (Recorded Lecture)		
9:05-9:35		AICA. Enters into the world of biotechnology and vaccines. A growing partnership with CIGB Antonio VALLÍN Cuba	All molecular solutions under one roof is what HiGenoMB is all about Susanne FRASCH Germany	A low-molecular-weight leukocyte extract obtaining by ultrafiltration with immunomodulatory properties Eduardo SÁNCHEZ Cuba	Formulation development of a growth hormone releasing Hexapeptide: characterization insights Hector SANTANA Cuba	Updating of good manufacturing practices requirements in Cuba for biological products Blorkys YAÑEZ Cuba		
9:40-10:10		Fermentation process for production of the recombinant SARS CoV-2-Spike Receptor Binding Domain, on Pichia pastoris platform Juan MIGUEL Cuba	SARS-CoV-2 nucleocapsid protein elicits a diversified strong humoral response in COVID-19 convalescent patients Rodolfo VALDÉS Cuba	Vaccine technology in human and animal health María RODRÍGUEZ Cuba	Preformulation studies and real time stability of the Heberprovac for cancer prostate treatment Matilde LÓPEZ Cuba	Global regulatory requirements for anti COVID-19 vaccines Javier VÁZQUEZ Cuba		
10:15-10:45		Quality control of Cuban vaccine candidates against COVID-19, a battle against time Lourdes COSTA Cuba	<i>Nicotiana benthamiana</i> plants as bioreactor: SARS-CoV-2 RBD production as study case Abel HERNÁNDEZ Cuba	E2-CD154 vaccine candidate is safe and immunogenic in pregnant sows, and maternal derived neutralizing antibodies protect piglets from CSFV challenge Danny PÉREZ Cuba	Doses study of the CIGB550-E7 vaccine candidate with alum adjuvant in the TC-1 model Nadia RODRÍGUEZ Cuba	Analytical method validation: Overview and regulatory requirements expectations Luis RUIZ Spain		
10:50-11:05		COFFEE-BREAK						
11:10-11:40			Immunogenicity, antigenicity and molecular integrity tests of a vaccine candidate against SARS-CoV-2 infection Mabel IZQUIERDO Cuba	Characterization by mass spectrometry of the recombinant protein RBD obtained in different expression systems Ivan ANDUJAR Cuba	Technologies and products to support biotechnological product manufacturing Peter GURSKKE Germany	Cuba engineering activity in pharmaceutical industry: technological maintenance or effective support to processes? Study case Tania de la CRUZ Cuba	Raw material chemical analysis José ZARAZÚA Mexico	
11:45-12:15			Development and industrial scale up of the first vaccine against COVID-19 (Soberana 02) Darleys SANTANA Cuba	Analytical instrumentation and more for quality and process control Peter GURSKKE Germany	Peptide therapeutic drugs: The fastest way from research to production Hilda GARAY Cuba	Novel trends in Cuban biotechnology industry: Application of risk analysis to release active pharmaceutical ingredients Danells VELÁZQUEZ Cuba	CSA & QbD: new trends in computer system Validation. Critical Thinking & Effective Knowledge Management as pivotal concepts in the GMP arena Luca Giustini USA (Recorded Lecture)	
12:20-12:50			Technology transfer: Finlay Vaccine Institute approach in COVID-19 vaccines. Speaker. Yanell HERRERA Cuba	Determination of elemental impurities in pharmaceutical samples by ICP techniques Rodrigo MORETTO Brazil	Jusvinza, the first drug product of peptide origin obtained by CIGB Oscar CRUZ Cuba	Hydrogen peroxide surface disinfection: is automation the solution? Ignacio CABRERA Spain	Data privacy and Cybersecurity for life science industry in disruptive times Filipe DAL BELO Brazil (Recorded Lecture)	
12:55-14:25		LUNCH						
14:30-15:00			NasalFERON, formulation that contains Interferon alfa 2b for COVID-19 prophylactic treatment Ana AGUILERA Cuba	LC-MS/MS analyses for identification of conjugation sites, side reactions, and reproducibility evaluation in conjugate vaccines Luis GONZÁLEZ Cuba	BIOZEEN approach to enabling COVID vaccine manufacturing ramp up Sarin SIMON / (Daniel CARDOSO, Consultant CIH- Biozeen) India	Chromatographic methods applied to purification of biopharmaceuticals Ernesto URRUTIA Cuba	Software validation and data management Antonio CORTES Spain	
15:05-15:35		Production of recombinant human IFN-gamma and HeberFERON Gustavo FURRAZOLA Cuba	Mass spectrometric characterization of low-abundance species in active pharmaceutical ingredient of synthetic peptides Vladimir BESADA Cuba	Aliam: automation integral solutions Miguel CAPDEVILLA Switzerland	High performance electrophoresis applied as 2D PAGE and Western blotting in HCP analysis Peter GURSKKE Germany	The cocoon of transgenic silkworms as a suitable system for obtaining heterologous proteins of pharmaceutical interest Lianet RODRÍGUEZ Cuba	 VARADERO - HAVANA	
15:40-16:10		HeberFERON. From desktop to medical practices Iraido BELLO Cuba	BIACORE experiments in physicochemical characterization of drug substances that involve protein-protein interaction in their biological activity Ania CABRALES Cuba	Nucleation in Lyophilization process Ignacio CABRERA Spain	Aseptic process validation. Media fill design in a multiproduct plant. A real case study Raúl FERNANDEZ Spain	Heberprot-P Technological details, a therapy to treat diabetic foot ulcers (DFU), and its use in the Cuban integral care program for patients with DFU Manuel RAICES Cuba		
17:00-17:30	Venue Information Program Presentation Rodolfo VALDÉS Cuba							
17:35-18:35	Building Biotech Products Key Lecture Jorge VEGA Cuba							
18:35-19:10	Special Cultural Moment							
22:00-22:30						Biomanufacturing 2021 Closing Biomanufacturing 2023 Launching Rodolfo VALDÉS Cuba		

SCHEDULE	RECORDED PRESENTATION (TV-1)	RECORDED PRESENTATION (TV-2)	RECORDED PRESENTATION (TV-3)	RECORDED PRESENTATION (TV-4)	
MONDAY, 29TH TUESDAY, 30TH WEDNESDAY, 1ST THURSDAY, 2ND	8:30 - 8:45	Monoclonal and polyclonal antibodies as biological reagents for SARS-CoV-2 diagnosis through nucleocapsid protein detection Daily HERNÁNDEZ Cuba	Production of bacterially-expressed CIGB-247 recombinant antigen for the HEBERSaVax VEGF active immunotherapy Anlurka PANFET Cuba	Recombinant human epidermal growth factor (Heberprot-P®). Lyophilized pharmaceutical product for intralesional injection that has demonstrated its high production Vivian PUJOL Cuba	Certification by CECMED of the CIGB-814 peptide reference material used in Jusvinza analytical release Cristina RODRÍGUEZ Cuba
	8:50 - 9:05	Comparison between convalescent plasma and purified immunoglobulins to recognize SARS-CoV-2 S-protein linear peptides Sigifredo PADILLA Cuba	Implementation of a purification method for an antigen of an immune checkpoint molecule-based cancer therapeutic vaccine Camila CANÁAN Cuba	Validation of Heberprot-P active pharmaceutical ingredient by the HPLC-RP analytical technique Jennifer ROJAS Cuba	Trend analysis of environmental microbiological control of a biopharmaceutical plant in its three operational conditions Blunayki REYES Cuba
	9:10 - 9:25	Recombinant protein expression in HEK293 cells to obtain a vaccine candidate against SARS-CoV-2 based on the N-protein Thalín La O Cuba	Immunogenicity and thermal stability of the Porvac® protein subunit vaccine formulation stored at 25 Celsius degrees for twelve months Yusmel SORDO Cuba	Elimination and exchange of trifluoroacetate counterion in a cationic peptide: improvements in the process Ever PÉREZ Cuba	Methodology based on risk analysis to turn a dedicated plant into a multi-product plant Milda PÉREZ Cuba
	9:30 - 9:45	Preformulation study of the vaccine candidate CIGB-66 against SARS-CoV-2 virus by parenteral route Margarita COBA Cuba	Mass balance in the quality control of synthetic peptides. An useful tool for consistency of the process José MARCELO Cuba	Characterization of polyribosylribitol phosphate by high efficiency size-exclusion chromatography with ultraviolet detection Yaneylis MÉNDEZ Cuba	Methodology for equipment cleaning validation and continuous verification on the Epidermal Growth Factor production process Rebeca BOUYÓN Cuba
	9:50 - 10:05	Study of adsorption of the RBD-Ppa protein to the IMAC-Cu matrix Juliet PADRÓN Cuba	Drinking water as raw material for biomanufacturing: analysis of physicochemical parameters to evaluate its quality Rebeca VIZCAÍNO Cuba	Risk assessment establishment of the P64Kr production process Dania BACARDÍ Cuba	Determination of critical process parameters in HBsAg manufacturing used as API in vaccine production Yeny DE LA TORRE Cuba
	10:10 - 10:25	Design and optimization of the lyophilization process of the Active Pharmaceutical Ingredient of immunomodulatory peptide Jusvinza® Eliane BLANCO Cuba	Design of a process validation test in fermenters. Comparison with fermenter sterility test conducted during performance qualification Wilnot FERRERO Cuba	Design of risk management matrices to validate aseptic process of the sterilizing filtration in a multi-product facility Yaneylis ÁLVAREZ Cuba	Some regulatory analysis applied to the manufacture of biologicals in a CIGB multiproduct facility Natacha PÉREZ Cuba
	10:30 - 10:45	Establishment by RP-HPLC of the purity test, for the analysis of the IFA of RBD, vaccine candidate against COVID-19 Maylín La O Cuba	N-Terminal sequencing by Edman degradation implementation for the Identification of the pharmaceutical peptide CIGB-258 Galina MOYA Cuba	Consistency analysis of the CB.Hep-1 immunosorbent large scale manufacturing process Andrés TAMAYO Cuba	Quality by Design: Reality or Utopia? David DIAGO Cuba
	10:50 - 11:05	Determination of RBD reference material isoelectric point used to release COVID-19 vaccine candidate API samples Raydan LEMUS Cuba	Building automation systems, a new horizon for the Cuban biotechnology industry David GOITZOLO Cuba	New <i>in vitro</i> bioassay as part of the new trends in the quality control of biotechnological products: Heberprot-P® Luisa GLENDA Cuba	Use of risk analysis in manage changes in the biotechnological productions Ivonne RODRÍGUEZ Cuba
	11:10 - 11:25	Scaling-up of <i>Escherichia coli</i> fermentation process for recombinant P64k protein production Denis ÁLVAREZ Cuba	Fermenter requalification strategy based on risk analysis Carlos MARTÍNEZ Cuba	Synthesis and LC-MS/MS characterization of two vaccine candidates against ticks Satomy POUSA Cuba	Satisfactory execution of international simulation of product withdrawal from market with exported product together with the company Liof-Pharma Kenia VÁZQUEZ Cuba
	11:30 - 11:45	State of art of plantibody purification from transgenic plant. Plantibody HB-01 purification process as study case Leonardo GÓMEZ Cuba	Validation of peptide CIGB500 determination by 280 nm spectrophotometric method Rubén LÓPEZ Cuba	Qualification and continuous validation of the compressed air system of a production plant Adonis SENRA Cuba	Microbiological evaluation of environment and proposal of an environmental monitoring program for introduction of a new product Caridad SUÁREZ Cuba
	11:50 - 12:05	Comparison of two systems for the plantibody HB-01 purification from transgenic tobacco plant leaves Williams FERRO Cuba	A liquid chromatographic method for Thiomersal quantitation in raw materials and multidosed vaccine formulation Susette PALACIO Cuba	Establishment of a chemically defined medium for the expression of P64Kr in <i>Escherichia coli</i> Laura VARAS Cuba	New flow of operations in the production plant of CIGB to improve good manufacturing practices María TUÑÓN Cuba
	12:10 - 12:25	Characterization of Sodium Periodate-Zetarese-CL4B in the Hepatitis B Surface Antigen Immunopurification Alreia LLAMO Cuba	Improvement of an alternative system for the expression of recombinant human Interferon alpha in <i>Escherichia coli</i> Yallín BARBÓN Cuba	Study on the separation by SDS-PAGE of IFN gamma with the conditions of the European Pharmacopoeia Osniel CABRERA Cuba	Application of the risk analysis to the production of the recombinant protein HBsAg expressed in <i>Pichia pastoris</i> Rafael FERNÁNDEZ Cuba
	12:30 - 12:45	Mouse hybridoma cell continuous culture in the Lambda-MINIFOR bioreactor using protein free media in hundred days Hasel ARAGÓN Cuba	Updating vaccines Soberana development & manufacturing program Roselyn MARTÍNEZ Cuba	Qualification of a system that allows samples to be transported María DENIS Cuba	Establishment of the expanded bed chromatography technology for recovery stage the new vaccine production Yadira VICENTE Cuba
	12:50 - 13:05	Evaluation of an alternative activation and immobilization method for CB.Hep-1 mAb immunosorbent using Zetarese CL4B Mayté QUINTANA Cuba		Multilayer filtration as clarification step in VLP purification protocol Elias NELSON Cuba	Determination of absolute protein concentration by amino acid analysis of recombinant protein reference materials Yanet TAMBARA Cuba
	13:10 - 13:25	Jusvinza, a peptide ligand against hyper-inflammation induced by SARS-CoV-2 is safe in <i>Macaca fascicularis</i> Jorge CASTRO Cuba		Soberana productive system: an alliance among Biocubafarma centers Mariela NARANJO Cuba	Trend analysis of the environmental microbiological control of a final filtration area of active pharmaceutical ingredient Eulalia RIVERA Cuba
15:30 - 16:10	POSTER PRESENTATION IN DIGITAL FORMAT FOR TRADE FIRMS				
16:15 - 17:00	EXCHANGES WITH SPEAKERS OF RECORDED PRESENTATIONS				