

Biosimilars Latam - Colombia 2021 23rd, 24th & 25th June Online Forum





Speaker Panel



Chairman Dechea

Fernando Goicoechea Recordati Rare Diseases, Mexico General Manager



Iván Darío Agudelo Zapata Senate, Colombia Senator of the Republic



Cristina Ausin FDA, USA Scientific Reviewer



Angela Caro Asociación Colombiana de Farmacovigilancia, Colombia President



Sean McGowan Amerisource Bergen, USA Biosimilars, Pharmaceutical Commercialization



Patricia Socualaya Sotomayor Ministry of Health - DIGEMID, Peru Chief Officer at Biological Product Unit



Alvaro León Torres Dempos, Colombia Director of Pharmaceutical Care



Ricardo Castro Neolpharma, Mexico Biotechnology Manager



Diana Bernal Universidad del Rosario, Colombia Associate Professor



Gilberto Castañeda Cinvestav, Mexico Senior Investigator



Nicolas Estrada Merck, Mexico Single-Use customer applications



Guillermo Pardo Laboratorios Legrand, Colombia VP Operations & COO



Mauricio Rubio Grupo Indukern, Colombia Manager Pharmacy and Animal Health Division



Fernando Carmona Cytiva, Argentina Upstream Technical Sales Specialist



Julio César Vega Laboratorio Pablo Cassará, Argentina R&D Manager



Eart Cruz Teva Pharmaceuticals, Peru Senior Manager Regulatory Affairs

Speaker Panel



Jane Finzi Waters, Brazil Market Development Lead



Luis Reyes LEI, Mexico Head of Quality Assurance Preclinical Unit



Giancarlo Videla Yarlequé Marken, Peru Senior Specialist in Clinical and Pharmaceutical Logistic Operations



Nicolas Alberto Costa Sandoz, Argentina Head Medical Affairs - Argentina, Chile, Uruguay & Paraguay



Carlos Felipe Escobar Roa INNOS, Colombia Director



Enrique Alvarez Basurto Sartorius, Mexico Central America, Caribbean & VECO Sub Region Manager



Paola Fletscher Amgen, Colombia Compliance Senior Manager



Ximena Bonilla IDCBIS, Colombia Specialized researcher



Julian Molina CEDSS, Colombia Scientific Director



Carlos Dominguez Synthon, Mexico General Manager



John E. Feliciano Alfonso National University of Colombia, Colombia Clinical Pharmacologist and Clinical Epidemiologist, University Professor



Carlos Ochoa Previs IPS, Colombia Laboratory Lead Microbiologist



Fabio Aristizabal Universidad Nacional de Colombia, Colombia Senior Associate Professor

JackLeckerman³⁴



08:00 Opening Ceremony

08:10 Looking Back to Biosimilars in FDA



Cristina Ausin FDA, USA Scientific Reviewer

08:40 Private Initiatives for Biosimilars Development



Guillermo Pardo Laboratorios Legrand, Colombia VP Operations & COO

Julian Molina CEDSS, Colombia Scientific Director

Moderator



Fernando Goicoechea Recordati Rare Diseases, Mexico General Manager

09:25 Pharmacokinetic and Pharmacodynamic Considerations for Biosimilars Development



John E. Feliciano Alfonso National University of Colombia, Colombia Clinical Pharmacologist and Clinical Epidemiologist, University Professor

09:55 Biosimilars Administration in Colombia



Alvaro León Torres Dempos, Colombia Director of Pharmaceutical Care

10:25 Inclusive Collaboration Model in Biotherapeutics Production Ecosystems in Colombia.



Enrique Alvarez Basurto Sartorius, Mexico Central America, Caribbean & VECO Sub Region Manager

10:55 Virtual Networking Break

11:25 Challenges for Innovation

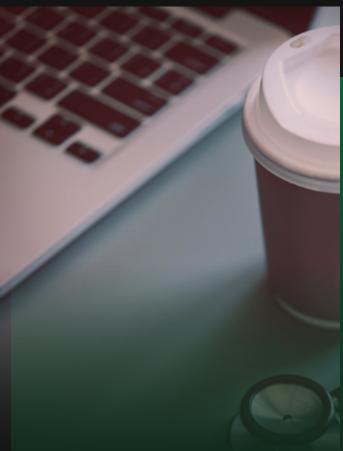


Carlos Felipe Escobar Roa INNOS, Colombia Director

<u>Chairman</u>



Fernando Goicoechea Recordati Rare Diseases, Mexico General Manager



08:40

Private Initiatives for Biosimilars Development

11:55 Proper Communication between Companies, Healthcare Professionals and Patients



Angela Caro Asociación Colombiana de Farmacovigilancia, Colombia President



Eart Cruz Teva Pharmaceuticals, Peru Senior Manager Regulatory Affairs

Moderator



Mauricio Rubio Grupo Indukern, Colombia Manager Pharmacy and Animal Health Division

12:40 Wrap up

Program Day 2 24th June

<u>Chairman</u>



Fernando Goicoechea Recordati Rare Diseases, Mexico General Manager

09:00 Welcome and 1st day's Summary

09:10 Biosimilars Success Stories



Julio César Vega Laboratorio Pablo Cassará, Argentina R&D Manager



Sean McGowan Amerisource Bergen, USA Biosimilars, Pharmaceutical Commercialization

Moderator



Diana Bernal Universidad del Rosario, Colombia Associate Professor

09:55 Public Initiatives



Iván Darío Agudelo Zapata Senate, Colombia Senator of the Republic

10:25 Virtual Networking Break

10:55 Unlocking the Potential for Scalability of mAbs - from Process Development to Manufacturing



Fernando Carmona Cytiva, Argentina Upstream Technical Sales Specialist

11:25 Communication of Regulatory Agencies in Latam



Patricia Socualaya Sotomayor Ministry of Health - DIGEMID, Peru Chief Officer at Biological Product Unit

Moderator



Fabio Aristizabal Universidad Nacional de Colombia Senior Associate Professor

12:10 Wrap up

09:55 Public Initiatives



08:00 Welcome and 2nd day's Summary

08:10 Leading Solutions



Jane Finzi Waters, Brazil Market Development Lead



Luis Reyes LEI, Mexico Head of Quality Assurance Preclinical Unit

Moderator



Carlos Ochoa Previs IPS, Colombia Laboratory Lead Microbiologist

08:55 The Academy Partnering Up with the Industry in Colombia



Ximena Bonilla IDCBIS, Colombia Specialized researcher

09:25 Pharmaceutical Safety

Paola Fletscher Amgen, Colombia Compliance Senior Manager

09:55 Biotechnology Quality Control



Ricardo Castro Neolpharma, Mexico Biotechnology Manager

10:25 Virtual Networking Break

10:55 Logistics of Biological Medicines



Giancarlo Videla Yarlequé Marken, Peru Senior Specialist in Clinical and Pharmaceutical Logistic Operations

11:25 Single-Use Technology Drives Flexible Manufacturing Plants



Nicolas Estrada Merck, Mexico Single-Use customer applications

<u>Chairman</u>



Fernando Goicoechea Recordati Rare Diseases, Mexico General Manager



Biosimilars post-Pandemic

11:55 Biosimilars Post-Pandemic



Carlos Dominguez Synthon, Mexico General Manager



Nicolas Alberto Costa Sandoz, Argentina Head Medical Affairs - Argentina, Chile, Uruguay & Paraguay



Gilberto Castañeda Cinvestav, Mexico Senior Investigator

12:40 Closure



safe and efficient Fluid Management

Mobius® 2D and 3D Assemblies, Storage and transportation solutions are key components for efficient, ergonomic and scalable fluid management, from media and buffer prep to final fill applications.

Applications

Sterile filtration and transfer

HOB

 Storage of buffers, media and bulk intermediates

Millipore

Preparation, Separation, Filtration & Monitoring Products



Biographies



Fernando Goicoechea Recordati Rare Diseases, Mexico

By creating new cross-functional teams maximize profits for the pharmaceutical industry based on finding new marketing and sales initiatives that can bring access to more patients, but always respecting the local and external regulations.

Specialties: Sales & Marketing for Latin America Region and Mexico for Biotech & Medical Device Industry.



Cristina Ausin FDA, USA

Cristina Ausin received her Bachelor's in chemistry and her Masters in chemical engineering from University Ramon Llull in Spain and her Ph.D. in chemistry from the University of Barcelona in Spain She arrived to the Office of Biotechnology Products in the Food and Drug Administration (FDA) as a post-doctoral fellow in 2004 and spent four years doing research in the oligonucleotide synthesis field. In 2008 she became a researcher reviewer, a full-time reviewer in 2013, and a team lead in 2015. Dr. Ausin joined the Office of Therapeutic Biologics and Biosimilars (OTBB) in FDA in 2018 as a scientific reviewer.



Guillermo Pardo Laboratorios Legrand, Colombia

Business Administration graduate with an emphasis in C level management for the Oil and Gas industry. Additional degrees in Energy Economics and Taxes. Over 15 years of experience in management of multinational companies in various sectors: hydrocarbon, mining, pharmaceuticals and energy consumption with roles including Vice President, General Manager, and Director of Administration and Finance.

In my professional development, I have had the opportunity to lead and be part of teams in areas of budget, trade policy, planning and logistics, material and supply costs, cash flows, financial statements, financial negotiation with financial institutions, and reports to headquarters. I have been directly responsible for the management of accounting, treasury, portfolio, human resources, payroll, logistics and internal control. I have served as company spokesperson to the media and public and private institutions.



Julian Molina CEDSS, Colombia

Julián Andrés Molina Menjura. Pharmaceutical Chemist. Scientific Director and CEDSS Consultancy Specializing in Drugs, Health & Society. Consultant and Researcher in the area of Regulatory Affairs, Industrial Property and Technology and Innovation Management for the Pharmaceutical and Biomedical Industry and the Public Health Sector.



John E. Feliciano Alfonso National University of Colombia

Surgeon with a Master's Degree in Clinical Epidemiology, with ten years of experience in the clinical care of patients with chronic non-communicable diseases.

Medical-surgical specialization in Clinical Pharmacology. Undergraduate and graduate university professor for the subjects of Physiology, Biochemistry, Pharmacology, Epidemiology, Biostatistics and Internal Medicine.

More than seven years of experience in clinical and applied research carrying out coordination and execution of projects such as the preparation of health technology evaluations, systematic reviews and meta-analysis in internal medicine; development of clinical practice guidelines and clinical protocols in oncology, and development of risk management systems analysis (reagent and technovigilance). Researcher controlled clinical trials of bioequivalence and bioavailability.



Alvaro León Torres Dempos, Colombia

Pharmacist from Universidad de Antioquia. Alvaro has experience in several areas of pharmacy and healthcare services, leadership, project management, intra-company innovation and entrepreneurship, problem solving, risk and opportunities management, quality assessment, and pharmacy services modeling skills.



Enrique Alvarez Basurto Sartorius, Mexico

Central America, Caribbean & VECO Sub

Region Manager.

Electrical Mechanical Engineer from the National Autonomous University of Mexico with more than 12 years of experience in the development of International Markets and 8 years of experience in the development of distribution chains for Sartorius de México. Strategic leader for the development of Business Units in Bio Processes & Laboratory Products in the Region. Currently with active participation in the Development and Implementation of Biopharmaceutical and Biotherapeutic Product Platforms for Colombia, Ecuador, & Costa Rica.

Central America, Caribbean & VECO Sub Region Manager. Ingeniero Mecánico Eléctrico por la Universidad Nacional Autónoma de México con más de 12 años de experiencia en desarrollo de Mercados Internacionales y experiencia de 8 años en desarrollo de cadenas de distribución para Sartorius de México. Líder estratégico para el desarrollo de las Unidades negocio en Bio Procesos & Productos de Laboratorio en la Región.

Actualmente con participación activa en el Desarrollo e Implementación para Plataformas de productos Biofarmacéuticos y Bio terapéuticos para Colombia, Ecuador, & Costa Rica.



Carlos Felipe Escobar Roa INNOS, Colombia

With nearly 15 years of experience in Educational Management, Carlos has led and implemented improvement, change and innovation processes. As an independent consultant, he led the team that prepared the start of activities of ELITE - Latin American School of Engineers, Technologists and Entrepreneurs. The Institution opened its doors in Bogotá, in August 2014; Carlos currently serve as its Rector. Previously, he led the growth and improvement process of El Bosque University as Rector and Administrative Vice-Rector, doubling its size, starting its second campus and directing the institutional planning and self-evaluation processes. As a leader in Higher Education, Carlos got involved in the work tables for the construction of the Agreement for the Higher. His experience and permanent training in Educational Management and Innovation allows him to contribute to its improvement and transformation at a National and International level.



Angela Caro Asociación Colombiana de Farmacovigilancia, Colombia

Pharmacist, Epidemiologist, Ms Pharmaceutical Care, Msc Education. 15 years experience in Patient Safety, Medication safe use, medical devices safety. Speaker, teacher and Consultant in the same topics and Leadership (communication, teamwork, empathy).



Eart Cruz Teva Pharmaceuticals, Peru

RAC Certification holder (Global Scope)

with 15 years of extensive experience and demonstrated success in international (LATAM) regulatory/quality projects (new registrations, renewals, CMC changes, labelling, etc) of pharmaceutical (drug product) /biotechnological products in Multinational Pharmaceutical Companies; Licensed pharmacist holding a diploma in Business Administration and Project Management.



Mauricio Rubio

Grupo Indukern, Colombia Bilingual Life Sciences and Pharmaceutical

Business Development, Sales & Marketing Executive in Latin America, with extensive experience performing Business Development and Sales to boost the Life Science and pharmaceutical product development & commercialisation lifecycle. Mauricio has proven skills in the pharmaceutical and healthcare sector analysis and abilities of negotiation with key accounts, government, customers, licensors, and suppliers for products and services.



Julio César Vega Laboratorio Pablo Cassará, Argentina

Julio C. Vega has graduated in Chemistry at the University of Buenos Aires. He holds a degree as Master of Industrial Business Administration from Escuela de Organización Industrial de Madrid and a postgraduate degree in Industrial Business Administration from Universidad Católica Argentina. He is R&D Manager at Laboratorio Pablo Cassará S.R.L., a pharmaceutical company in Argentina. He is author and co-author of patents related to pharmaceutical formulations and pharmaceutical primary packaging materials. He is co-author of an article on melanoma cells cryopreservation.



Sean McGowan

Amerisource Bergen, USA

As the Senior Director of Biosimilars, Sean McGowan is responsible for leading strategy and business development initiatives for the Biosimilar product category at AmerisourceBergen. As the Biosimilar market continues to expand, Sean partners with Biosimilar manufacturers in the pre-commercial, launch and post-launch phases to ensure the successful launch and growth of these products. Additionally, he leads the internal collaboration with AmerisourceBergen's customer groups to guarantee open access to Biosimilar products for the organization's customers and patients.

Sean has over a decade of experience in the healthcare industry, including the pharmaceutical, specialty pharmaceutical and patient services areas of focus. He joined AmerisourceBergen in 2017 as part of the organization's Strategic Global Sourcing team, focusing on brand and specialty pharmaceutical distribution initiatives. Prior to joining AmerisourceBergen, Sean held commercial, strategic account management and business development positions at AstraZeneca, Endo Pharmaceuticals and Accolade, Inc.

Sean graduated from the Fox School of Business at Temple University with a Master of Business Administration degree and received his undergraduate degree from Dickinson College.



Diana Bernal

Universidad del Rosario, Colombia

Diana Rocío Bernal-Camargo. Senior professor and researcher of the Faculty of Law at Universidad del Rosario (Bogotá, Colombia). She has a Ph.D. in Bioethics and Biolaw – Unesco Chair and Rey Juan Carlos University. Diana's research focuses on bioethics, biolaw, human rights, health and access to medicines. She is currently co-director of the Medical Law Specialization at the Faculty of Law – Universidad del Rosario. Diana is a member of the National Bioethics Council in Colombia and a consultant for law firms in Bogotá.



Iván Darío Agudelo Zapata Senate, Colombia

Senator of the Republic 2018-2022

Representative to the House of Representatives for Antioquia in the 2010-2014 and 2014-2018 periods, he was previously a deputy of the Assembly of Antioquia 2008-2009 being president of the same and Vice President of the National Federation of Deputies. His legislative work in favor of Science, Technology and Innovation stands out being author and rapporteur of important laws such as the one that creates the Ministry of Science, the Spin off Law that allows the creation of knowledge-based companies, coordinating rapporteur of the Law that restores the mandatory teaching of history and author of the recent law of amnesty of traffic fines, as well as of the propositions that have managed to maintain resources for public education in terms of royalties, the most recent being the one incorporated in Law 2056 of 2020 which establishes that 5% of the royalties of direct allocation must be destined to the Public IES to improve infrastructure, coverage and quality, which has earned him the recognition by the portal la silla vacía as one of the "Indispensable" of Science in Colombia, and recently recognized as Member of the Colombian Academy of Exact, Physical and Natural Sciences in the category Friend of the Academy, being the first politician to have such a dignity.

He is currently working on the construction of 3 bills to ensure pharmaceutical, energy and food security for Colombia, seeking in all his legislative work, to build consensus on the essentials.



Fernando Carmona Cytiva, Argentina

I'm a Biotechnologist who made his studies at the University of San Martin in Argentina and my thesis was based on cell adhesion

I began my professional career serving as a scientific assessor. Then my career followed in the human and animal pharmaceutical industry in cell culture area, protein purification and process development. I was able to acquire knowledge about equipment and application techniques. This previous works allowed me to understand the whole biotechnology flow path which now I'm using in my daily work on Cytiva



Patricia Socualaya Sotomayor Ministry of Health - DIGEMID, Peru

Graduated of Clinical Epidemiology Master and Management Health Master from Cayetano Heredia Peruvian University (UPCH). She is currently teacher's assistant in the Undergraduate Program of Clinical Epidemiology Unit from UPCH, member of the Research and Innovation Committee of the Medical College of Peru, and Chief Officer at Biological Product Unit at DIGEMID.



Fabio Aristizabal

Universidad Nacional de Colombia

Senior Associate Professor



Jane Finzi Waters, Brazil

Experienced Business developer with a demonstrated history of working in the research industry. Strong sales professional skilled in Good Laboratory Practice (GLP), Liquid Chromatography-Mass Spectrometry (LC-MS), Protein Chemistry, Validation, and GC-MS. LC-MS Hardware knowledge and field service experience.



Luis Reyes

LEI, Mexico

Biologist Pharmaceutical Chemist with a Master's degree in Industrial Administration. Specialist in the development and validation of analytical methods for the physicochemical and biological characterization of biopharmaceuticals products. With experience in technology transfer of analytical methods and development of quality management systems. He has developed different multidisciplinary teams focused on the analysis of biotechnological drugs that have been characterized by their leadership and global business focus.



Carlos Ochoa

Previs IPS, Colombia

Carlos Eduardo Ochoa Gamboa, Born in Pamplona, Norte de Santander, Microbiologist graduated from the University of Pamplona in 2013. Carlos did his postgraduate studies in the Autonomous City of Buenos Aires Argentina, obtaining a Msc degree in Molecular Microbiology at UNSAM together with the National Institute of Microbiology and a diploma in Comprehensive Quality Management from the National Technology University of Buenos Aires (UTN). Hisprofessional career has been multidisciplinary starting with Industrial Microbiology, Food Microbiology, sanitary inspection, teaching, microbiological tests for the pharmaceutical industry and mainly in research and development in Molecular Microbiology.



Ximena Bonilla IDCBIS, Colombia

Ximena Marcela Bonilla Forero, Pharm PhD. In 2006 Dr. Bonilla obtained a Pharmacy Bachelor's Degree at the National University of Colombia. In 2014 finished doctoral studies in Cellular and Molecular Pharmacology at the Comprehensive Cancer Research Center of Salamanca (Spain). On the same year obtained a Postdoctoral Fellowship for the Colombian government to investigate the role of stem cells in leukemia development. Since 2017 Dr. Bonilla is working at the "Instituto Distrital de Ciencia, Biotecnología e Innovación en Salud (IDCBIS)" as a specialized researcher at the cord blood bank research group developing new stem cell-based therapies for treatment of hematopoietic and metabolic malignancies.



Paola Fletscher

Amgen, Colombia

Paola Marcela Fletscher Covaleda

Education: Pharmacist

MSc Pharmacology

Master in Pharmacovigilance and Pharmacoepidemiology Specialist in Health Audit

MSc (c) Clinical Effectiveness with emphasis on Health Technology Assessment and Pharmacoeconomics Professional experience:

Senior Manager of PV Compliance at Amgen, previously Pharmacovigilance Manager for Amgen Colombia, with 12 years of experience in patient safety programs, pharmacovigilance, medication errors, technovigilance and pharmaceutical care for different actors of the Colombian health system, such as logistics operators, hospitals, health institutions and national and multinational pharmaceutical industry. Solid experience in the management of drug information systems, generation of metrics, auditing processes and national and international regulations.



Ricardo Castro Neolpharma, Mexico

Biochemical engineer with an M.Sc. and PhD in Biochemical Sciences. Experience in upstream and downstream processes for vaccine and biotherapeutics production -Expert in the production of virus-like particles, its purification, and assembly, including the development of analytical methods for CQa and characterization process -including capillary electrophoresis, high and ultra-performance liquid chromatography, spectroscopy, spectrofluorimetry, ELISA cell-based potency assays.



Giancarlo Videla Yarlequé Marken, Peru

Professional Pharmaceutical Chemistry qualified and enabled, graduated from the Faculty of Pharmacy and Biochemistry, of Universidad Nacional Mayor de San Marcos. Eight years of experience in pharmaceutical, cosmetic, food, veterinary, mass consumption and medical device industries ; with solid knowledge in Good Manufacturing Practices, Good Laboratory Practices, Good Documentary Practices, Good Storage Practices, Transport and Distribution, HACCP, Cold chain, Healthcare and Pharmaceutical Logistics, First, Second, and Third-party audits, Regulatory Affairs Management in products: Pharmaceutical (Category I, II and III), Herbal health, Natural, Dietary supplements, Galenic), Biologics and Biosimilars, Medical devices and equipment (Class I, II, III and IV), Sanitary Products (Cosmetics, sanitary articles and home hygiene products), Qualification of suppliers, Validation of manufacturing processes, cleaning and sanitizing, packaging units for refrigerated products, and analytical techniques; Ratings for critical support systems, areas and premises, equipment and machines. Additionally, I possess higher studies in Project Management, Integrated Quality Management Systems: ISO 9001, ISO 14001, OHSAS 18001, ISO 22000, 21 CFR, ICH Q7, Q8, Q9, Q10 and International Trade.

rimetry, ELISA cell-based potency assays.



Giancarlo Videla Yarlequé Marken, Peru

Nicolás Estrada joined Merck Millipore in 2016 as a Single-Use Sales Development Specialist LATAM. He has worked for more than 15 years in the pharmaceutical industry and has extensive experience in the management of injection product manufacturing areas (aseptic processes). In the commercial and technical approach, he has more than 15 years of experience in filtration and Single-Use technologies.

Nicolás received his bachelor's degree as a Bachelor of Pharmaceutical Chemical Biologist from the Autonomous Metropolitan University in Mexico City. He is currently one of the main references of the application, use and implementation of Single-Use technologies in the industry.



Carlos Dominguez

Synthon, Mexico

Carlos Dominguez is a Professional with extensive and proven experience of 20 years, contributing

in the Pharmaceutical Industry in the management and administration of business strategies (Marketing&Sales), Push&Pull: in Retail & non Retail segments, with Patented and Generic products (BGx GG) in therapeutic areas as; Neurosciences, Cardiology, Respiratory, High Specialty (Multiple Sclerosis, Spinal Muscular Athrophy, Oncology, Nefrology Transplants, Parkinson's disease, Cardiology, Respiratory WH and Dermatology diseases), in the upcoming months Alzheimers disease.

Carlos is able to design, launch, and implement startups such as: Being part of the executive team which it's been responsible to establish the Biogen's Mexican Affiliate. Also had the opportunity to launch the first Aesthetic business in join venture with LG life Sciences and Daewoong (Korea).

Being able to identify by means of market analysis and studies, opportunities of development and growth for the company's business implementing programs, strategies and Marketing actions to assure sales and profit objectives. Carlos has developed executive skills such as strategic/ analytical thinking and organizational re-engineering, leadership such as training and coordination of high-performance teams, Coaching, Communicating and negotiating, which have allowed him to achieve balance in a high focus environment on results, human factor development and business ethics.

MBA Focus in strategic marketing and trade.



Nicolas Alberto Costa Sandoz, Argentina

Nicolas Costa is a cardiologist with 15 years of experience in cardiovascular diseases, with special interest in heart failure, coronary heart disease, hypertension, and dyslipidemia. He is also Medical affairs Head for Sandoz South Latam (Argentina, Chile, Uruguay & amp; Paraguay), with almost 10 years of experience in generics & biosimilars in the region.



Gilberto Castañeda Cinvestav, Mexico

Gilberto Castañeda-Hernández is a main researcher at the Pharmacology Department of the Center for Research and Advanced Studies of the National Polytechnic Institute in Mexico City. Professor Castañeda-Hernández has published 190 articles in international journals in the area of Pharmacology and has supervised several, 29 doctoral and 61 masters, thesis in this discipline. Currently, he is editor-in-chief of the Latin American Journal of Clinical Sciences and Medical Technology.