



FLAB 2017

Latin American Forum on Biosimilars

*7TH LATIN AMERICAN FORUM ON BIOSIMILARS AND
8TH BRAZILIAN FORUM ON BIOSIMILARS*

28 and 29 June, 2017

Brasil 21, Centro de eventos e convenções

Brasília - DF





DEAR FRIENDS

It is with great pleasure that we present the seventh Latin American Forum on Biosimilars (FLAB 2017), and the eighth Brazilian Forum on Biosimilars. This event on 28 and 29 June will bring us together in Brasília once again and feature a comprehensive schedule covering the main topics related to the future of biosimilar drugs in Latin America.

Over 500 local and international visitors are scheduled to attend the forum, including health professionals, researchers, and representatives of patient associations, government agencies, the pharmaceutical industry, and regulating bodies from Brazil and Latin America, among others.

Since its first edition, FLAB has promoted debates, basic and clinical education, and the creation of new perspectives on biosimilars. For 2017, the scientific commission has organized a thoroughly structured program around current and highly relevant topics. The organizing team itself was restructured, and now enjoys support from new and important specialists in the area.

There is no doubt that the commercialization of new biosimilar drugs gives rise to broad regulatory, scientific, and marketing debates, as well as educational ones. Pharmacovigilance of Biosimilars in Latin America.

Hard work on the part of the organizers since the first editions of the event has granted a maturity to FLAB, which in its 2017 edition has attained unquestionable status as the largest and most important Latin American event on biosimilars. Attendees have been witnesses to the progress seen on both organizational and program quality levels.

We hope that all participants will actively take advantage of all this event has to offer. FLAB 2017 was especially designed for you to initiate or expand your knowledge on this subject while strengthening your network.

Best regards and welcome to FLAB 2017!

The Organizing Committee, FLAB 2017



FLAB 2017

Latin American Forum on Biosimilars

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ORGANIZING COMMITTEE

Valderilio Feijó Azevedo

Fabio Vieira Teixeira

Renato Murillo

Regina Abreu

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FACULTY



ADALTON GUIMARÃES RIBEIRO

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Farmaceutical-biochemical, graduate from FCF-USP, MBA in Economics and ATS and Specialist in Health Surveillance Management.

Currently Technical Director of Pharmacovigilance at CVS-SP.



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Endocrinologist Doctor with practice in São Paulo since 1976.

Director of the Brazilian Society of Diabetes in the administrations of 2000 to the present.



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Medical Auditor and Medical Expert of the Curitiba Health Institute - Curitiba City Hall / PR.

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EVA MARIA RUIZ DE CASTILLA

Miami/EUA

Director of the ESPERANTRA NGO since 2006, in charge of Cancer Control Programs and Patient Advocacy IAPO Governing Board Member.



FÁBIO VIEIRA TEIXEIRA

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Coloproctologist Surgeon — Marília — São Paulo.

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Member of Dannemann Siemsen since 1999 and member of the executive committee of the law firm Dannemann Siemsen lawyers and of the industrial property office Dannemann, Diemsen, Bigler Ipanema Moreira, electronic engineer and lawyer, with specialization in intellectual property in the Franklin Pierce Law Center USA). Professor of the post-graduation program lato sensu of the law SP (GV LAW), FGV



GUSTAVO DE PAIVA COSTA

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HARRY L. GEWANTER

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IGNÁCIO MAGLIO

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Maglio & Associates Law Firm

Professor of the postgraduate department of the Faculty of Law of UBA.

Professor of regulations at the Master of Research Pharmacopoeia UAI.



IVAN RICARDO ZIMMERMANN

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Substitute Director of the Management and Incorporation Department of Technologies in Health (DGITS / SCTIE), Representative of the Science, Technology and Strategic Inputs Secretariat.



JOÃO GONÇALVES

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Pharmacologist, Professor and Researcher of the Pharmacy Faculty of the Lisbon University.





JORGE VENÂNCIO

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Coordinator of the National Commission of Ethics in Research (CONEP)
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Secretary of Worker Health of the Workers Central General of Brazil - CGTB,
Doctor graduated from the Federal University of Rio de Janeiro UFRJ.



LUTZ HEINEMANN

Germany

Process Engineer and Biologist
Founder of the Profil Institute for Metabolic Research in Neuss, Germany
Part owner of the profil Institute for Clinical Research in San Diego, USA
Scientific Researches Focused on Insulin Pharmacology and Diabetes Technology
Managing Editor of the Journal of Diabetes Science and Technology
Member of the German Diabetes Association (DDG), the European Association for the Study of Diabetes (EASD) and the American Diabetes Association (ADA).



MANOEL CARLOS SANTOS

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General Medical Intensivist Surgeon, Forensic Doctor; Medical Audit
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MARCELO NITA

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Doctor and Residency in Digestive Surgery, Hospital das Clínicas, FMUSP
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MAURO SCHARF PINTO

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Vice-president of Brazilian Society of Diabetes.
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Clinical researcher at the Curitiba Diabetes Center.



MORTON AARON SCHEINBERG

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Physician at Hospital Israelita Albert Einstein - HIAE and Scientific Director of Abreu Sodré Hospital - AACD (Hospital Unit Specialized in Musculoskeletal Diseases).



OTÁVIO CLARK

Campinas/SP

Oncologist, Doctor of Medicine, Ceo Kantar Health.





PABLO MATAR

Rosário/Argentina

Doctor In Biochemistry From the National University of Rosario (UNR-ARGENTINA) and Postdoctor By Vall D´ Hebron University Hospital, Barcelona (SPAIN) With Focus on Oncology and Thesis In targeted therapies for cancer.

Research Associate of the National Council of Scientific and Technical Research (CONICET), Argentina. Professor of Medical Genetics for the Course of Medicine and Oncology and Genetics For PH.D.



PAULA SUE

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Coordinator of the lawsuits in Health of the State of São Paulo.

Specialist in Public Administration and Sanitary Law.

Member Representative on the Technical Committee on Health Judicialization of CONASS.



PRISCILA TORRES DA SILVA

Itaquecetuba/SP

Chairman of the Find Group, Vice-Chairman Group-RP.

Social Entrepreneur in Health Bloggers, blogger in the rheumatoid arthritis blog.

Author of the tweet campaign of social mobilization in social network, to update the clinical protocol and therapeutic guidelines of rheumatoid arthritis in the ministry of health.

Nursing technique, with specialization in hospital quality management.



REGINA ABREU

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Pediatrician.

Medical Auditor.

MBA in Political Science and Public Administration.

Masters Degree in Auditing and Medical Expertise.

Former President of the Society of Medical Auditors of the State of Paraná.



RENATO MURILLO

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Professor at the University of Costa Rica.



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ROSIANE FOLLADOR ROCHA EGG

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Master in Education - Tuiuti University of Paraná. Qualification in mediation and conciliation of conflicts by the Institute of Mediation of Paraná and Court of Justice of Paraná.

Lawyer with experience in conflict resolution in the consumer law area.



SÉRGIO KOWALSKI

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Rheumatologist, Adjunct Professor of Rheumatology at UFPR.

Member of the Grade Working Group Grading of Recommendations Assessment, Development and Evaluation) and Cochrane Grade Group.



THOMAS SCHREITMULLER

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PHD in biochemistry from the University of Munich (Max Planck Institute for biochemistry, Munich, Martinsried and Institute for Clinical Chemistry and Clinical Biochemistry University of Munich).

The Global Lead For Technical Regulatory Policy And Strategy For Biologics Within Roche.



VALDAIR PINTO

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Executive of the Pharmaceutical Sector and Independent Consulting in Pharmaceutical Medicine Area in Brazil.



VALDERÍLIO FEIJÓ AZEVEDO

Curitiba/PR

Adjunct Professor in Rheumatology, UFPR Executive Committee Member of GRAPPA. Group of Research and Assessment of Psoriasis and Psoriatic arthritis.

ASAS Member, International Society of Spond.



WILLIAM LAMANNA

Curitiba/PR

PHD

Global Scientific Affairs Manager SANDOZ Biopharmaceuticals






28.JUNE.WEDNESDAY

MORNING

08:15

Openings


-  VALDERILIO FEIJÓ AZEVEDO (BR)
-  FABIO VIEIRA TEIXEIRA (BR)
-  PABLO MATAR (ARGENTINA)

08:30 – 10:15


BIOSIMILARS: THE IMPORTANCE OF TOTALITY OF EVIDENCE

MODERATOR:  MORTON SCHEIBERG (BR)
 FELIPE PINHO (BR)


08:30

Analytical Techniques for Biosimilars – The role of MRI
 RENATO MURILLO (COSTA RICA)

09:00

Biosimilars: Clinical equivalence through totality of evidence
 WILLIAM LAMANNA (USA)

09:30

Remsima: The First Biosimilar approved in Brazil
 JOÃO GONÇALVES (PORTUGAL)

10:00

Discussion

10:15


Coffee Break

10:30 – 12:15

CHALLENGES FOR INSULIN BIOSIMILARS

CHAIRMAN AND MODERATOR:
 VALDERILIO FEIJÓ AZEVEDO (BR)

10:30

Diabetes: Importance of Control and Personalized Treatment
 DOMINGOS MALERBI (BR)

10:50

Complexity of Insulinization
 ANTONIO CARLOS PIRES (BR)

11:10

Endocrinology Experience With Biosimilars
 MAURO SCHARF (BR)



11:30 Insulin Biosimilars Worldwide - what is going on – International
 LUTZ HEINEMANN (GERMANY)

12:00 Discussion: What to Expect for Brazil

AFTERNOON

14:00 – 16:20 INTERCHANGEABILITY AND NON-MEDICAL SWITCH – CURRENT DATA IN BRAZIL

MODERATOR:  DANIELA CERQUEIRA (DF)
 VALDAIR PINTO (SP)
 JOÃO GONÇALVES (PORTUGAL)

14:00 The Impact of Non-Medical-Switch in the patient's Journey in
the Gastroenterology

 FÁBIO VIEIRA TEIXEIRA (SP)

14:20 The Impact of Non-Medical-Switch in the patient's Journey in
the Rheumatology

 RICARDO XAVIER (RS)

14:40 Interchangeability to the Public Health Manager

 PAULA SUE (SP)

15:00 Interchangeability: Anvisa's perspective

15:20 Interchangeability: The Patient's Point of View

 EVA MARIA RUIZ DE CASTILLO (USA)

15:40 Multidisciplinary Discussion: Medical, Law, Manager and
Regulator perspectives







16:20 Coffee Break

16:40 CONFERENCE: NEW DATA ON BIOSIMILARS

SPEAKER:  HARRY GEWANTER (USA)



28.JUNE.WEDNESDAY

- 17:10 **ACCESS TO BIOSIMILARS IN THE PUBLIC AND PRIVATE HEALTH CARE SYSTEMS**
MODERATOR:  ELIO TANAKA (PR)
 REGINA ABREU (PR)
 MANOEL CARLOS SANTOS (SP)
- 17:10 Cost Reduction X Cost Effectiveness for Biosimilars.
 SERGIO KOWALSKI (PR)
- 17:30 Multiple Criteria Decision Analysis (MCDA). How is it Useful to Biosimilars?
 MARCELO NITA (SP)
- 17:50 Challenges to the Incorporation of Biosimilars in the Brazilian Public Health Care System (SUS)
 IVAN RICARDO ZIMMERMAN (DGITS/SCTIE)
- 18:10 Discussion



08:15

CHALLENGES: MANAGEMENT AND PHARMACOVIGILANCE OF BIOSIMILARS

MODERATOR:



ADALTON G. RIBEIRO (SP)



PABLO MATAR (ARGENTINA)



VALDERILIO AZEVEDO (PR)

08:15

Pharmacovigilance in oncology

08:35

Biosimilars X Quality Management in University Hospitals



HELAINÉ CAPUCHO (DF)

09:55

Strategies of Pharmacovigilance to Biosimilars



ADALTON G. RIBEIRO (SP)

09:15

How Similar Is Similar and How to Manage Residual Risks?



THOMAS SCHREITMÜLLER (GERMANY)

09:45

DISCUSSION

10:15

Coffee Break

10:30

Conep and the evaluation of biosimilar trial



JORGE VENANCIO (SP)

11:00

Update on Pdps in Brazil



GUSTAVO DE FREITAS MORAIS (SP)

11:30

Ethics and legal responsibility in reports of adverse events reports



IGNACIO MAGLIO (ARGENTINA)

AFTERNOON

14:00

INTERCHANGEABILITY X PHARMACOVIGILANCE

MODERATOR:



FÁBIO TEIXEIRA (SP)



IGNACIO MAGLIO (ARGENTINA)

14:00


Global trends on interchangeability of Biosimilar molecules



VALDERILIO AZEVEDO (PR)



29.JUNE.THURSDAY

- 14:30 Clinical Trials design
 FREDDY FACCIN (USA)
- 15:00 Biosimilarity is not transitivity. Implications in interchangeability, nomenclature and pharmacovigilance
 PABLO MATAR (ARGENTINA)
- 15:30 Discussion
- 16:00 Coffee Break
- 16:20 MEDICAL EDUCATION STRATEGIES FOR BIOSIMILARS**
MODERATOR:  ROSIANE EGG (PR)
 GUSTAVO DE PAIVA COSTA (DF)
 HARRY GEWANTER (USA)
- 16:20 Patient Education: the role of Non-Governmental Organizations (NGOs)
 PRISCILA TORRES (SP)
- 16:50 Continued education of managers and auditors
 OTAVIO CLARK (SP)
- 17:10 Medical education: who is responsible for it? The role of medical schools and specialty societies
- 17:40 Discussion
- 18:00 Highlights and Closure
 FABIO VIEIRA TEIXEIRA (SP)
 PABLO MATAR (ARGENTINA)
 VALDERÍLIO FEIJÓ AZEVEDO (PR)



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