## conferenceseries.com

14<sup>TH</sup> INTERNATIONAL CONFERENCE ON **GENERIC DRUGS AND** BIOSIMILARS ovember 15-16, 2018 Berlin, Germany

# 14th International Conference on Generic Drugs and Biosimilars

10+ B<sub>2</sub>B Meetings 10+ Keynote **Exhibitors** Lectures 30+ Supporting Journals

Journal Of Developing Drugs

Generic Drugs, Generic Pills and Generic Medication

**Biologics & Biosimilars** 

Pharmacovigilance & Safety of Biosimilars

Biosimilars Uptake & Patient Safety

Developing Biosimilars And Biobetters

Protein Biotherapeutics & biosimilars

Chronicles of a Biosimilar Production Facility

Biosimilar development challenges

Pharmacology and Drug Developement

Global Generic Trends & Global Pharma Market

Pharma Pricing & Market Access

Patent Access& Intellectual property & FDA Regulations

### Berlin, Germany

Drug Designing: Open Access

November 15-16, 2018 genericpharma@pharmaceuticalconferences.org

Journal of Bioequivalence &

Bioavailability



### Invitation

Dear Attendees,

We are glad to announce the 14<sup>th</sup> International Conference on Generic Drugs and Biosimilars to be held in Berlin, Germany on November 15-16, 2018 organized by Conference Series, UK in collaboration with generous support and cooperation from enthusiastic academicians and editorial Board Members.

Generic Biosimilars 2018 is a specially designed cluster conference. The main theme of the conference is "A new Era in Biosimilars Industry –Biosimilars & Generics" which covers a wide range of critically important sessions. The biggest conference gathering of the global generic industry, attracting attendees from around the globe. The program agenda provides a unique forum for generic pharmaceutical executives from around the world to network and hear world-renowned experts discussing the latest insight into the international commercial, legal, and regulatory developments concerning the generic pharmaceutical sector

Generic Biosimilars 2018 anticipates participants around the globe with thought provoking Keynote lectures, Workshops, Oral and Poster Presentations. The attending delegates include Editorial Board Members of related International Journals. This is an excellent opportunity for the delegates from Universities and Institutes to interact with the world class professionals and scientists. The intending participants can confirm their participation by registering for the conference along with your colleagues.

Life is full of give and take. Make it count in your professional life. Attend the Pharma Industry Conference to network with your peers, exchange expertise and experiences, and arm yourself with the latest information to take your department to the next level.

Sincerely,
Generic Biosimilars 2018
Organizing Committee

# Welcome Message



### **Dear Colleagues**

On Behalf of the Organizing Committee I personally welcome all the Pharmaceutical professionals to the Leading Pharmaceutical event 14<sup>th</sup> International Conference on Generic Drugs and Biosimilars historic Berlin, Germany on November 15-16, 2018 Generics and Biosimilars are an important driver in the market for urgently needed drugs. The path to new Generics and Biosimilars is a story of appreciation and innovation. Pharmaceutical products which have a proven demand in the market are selected as models for Generics and Biosimilars and significant innovation is required before a Generic or Biosimilar can be made available to the doctors, patients and payers.

The excellent program and networking at this meeting in the historic city of Rome will provide new insights and opportunities for new lasting collaborations for all attendees.

I'd like to add my best wishes for great success for the conference.

See You soon in Rome, Italy.

**Dr. Anka G. Ehrhardt**Director Clinical Cytometry
Bristol-Myers Squibb Co, USA



# Organizing Committee @ Generic-Biosimilars 2018



Emmanuel O. Akala Professor Howard University USA



Kurt R. Karst
Director
Hyman, Phelps & McNamara



Anka G. Ehrhardt
Director
Bristol-Myers Squibb Co
USA



Christoph Volpers
Senior Patent Consultant
Michalski Hüttermann & Partners,
Germany



Anna Szemik-Hojniak
Director
INWES Education and Research
Institute
USA



Pillhun Son
Projects Coordination Manager
American Chemical Society
USA



Christopher Tirotta
Director
Nicklaus Children's Hospital
USA



**Dipti Gulati**President
PJI Biotech
USA



George Perry
Dean
University of Texas
USA



Sophia Zi Gu
Professor
University of New South Wales
Australia

# Organizing Committee @ Generic-Biosimilars 2018



Adam Le Gresley
Professor
Kingston University
United Kingdom



**Igor Klepikov**Professor
Tel Aviv University
USA



Andrea Nicolini Professor University of Pisa Italy



Kamali Chance Chief Regulatory Officer BioSciencesCorp USA



**Dieter Heber**Professor
University of Kiel
Germany



George Schroeder
Executive Director
American Academy of Urgent
Care Medicine
USA



Pierre A. Morgon CEO MRGN Advisors, Geneva Switzerland



Zeeshan Ahmad Professor De Montfort University United Kingdom



Adnan Sabir
Principal Consultant & Founder
Pharma Consulting Services
USA

# Previous Speakers @ Generic-Biosimilars 2017



Raymond A Huml Quintiles, USA



**Nigel J Rulewski** Quintiles, Inc, USA



James Harris Healthcare Economics LLC, USA



Ronald A Rader Biotechnology Information Institute, USA



András Guttman University of Pannonia, Hungary SCIEX, USA



**Sumant Chaubey**Bills Biotech, India



Tom Carver
Wragge Lawrence Graham & Co



**Andreu Soldevila** CEO LeanBioPro, Spain



**Sarfaraz K. Niazi** TheraProteins, USA



**Christoph Volpers** Senior Patent Consultant at Michalski & Hüttermann, Germany



**Wolfgang A. Rehmann** Taylor Wessing, Germany



Marcus Mreyen
Protagen Protein Services GmbH
Germany



Min Zhang
Fujifilm Diosynth Biotechnologies
USA



**Fiona M Greer** SGS Life Sciences, Switzerland



**Volker Schellenberger** Amunix Operating Inc., USA



**Alan L. Epstein**USC Keck School of Medicine
USA



**Upendra Nagaich** Amity Institute of Pharmacy, India



Gene M. Ransom, III
University of Maryland and
University of Baltimore School of
Law, USA



**Gordon T. Bolger** Nucro-Technics, Canada



**Adetunji Olawale** Osun State Polytechnic, Nigeria



**Angela Furlanetto** Dimock Stratton LLP, Canada

# Previous Speakers @ Generic-Biosimilars 2017



**Afshin Safavi** BioAgilytix , USA



Mariana Babayeva Touro College Of Pharmacy, USA



**Andy Upsall**BioOutsource, UK



Samantha Little Covance Laboratories Ltd, UK



**Kamali Chance**Quintiles Inc., USA



Mario DiPaola Blue Stream Laboratories, USA



**Francesco Marchesi** Regina Elena National Cancer Institute , Italy



**Candida Fratazzi** BBCR Consulting, USA



**Krishna Menon** USA



**Daniel Galbraith**BioOutsource Ltd, UK



**Siddhartha Roy** CSIR - Indian Institute of Chemical Biology, India



**Noelle Sunstrom** Neuclone PTY LTD, Australia



**Dipti Gulati** PJI Biotech, USA



**Alexander Pitters**Kaiser Optical Systems, France



**Laszlo Endrenyi** University of Toronto, Canada



Michael G Tovey INSERM , France



**Christina Vessely**Biologics Consulting , USA



Ruideger Janwosky Cinfa Biotech GmbH, Germany



**Christelle Dagoneau**Catalent Biologics, USA



**Aparna Kasinath** Syngene International , India



**Denise M Kettelberger**Sunstein Kann Murphy & Timbers
LLP

### Glimpses @ Generic Biosimilars 2017































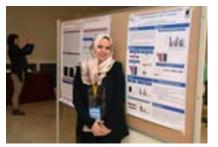


### Glimpses @ Generic Biosimilars 2017

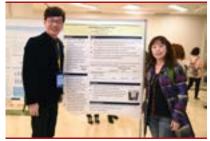
































# Speaker Representations @ Generic Biosimilars 2017



















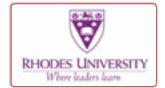


















# Supporters















# **Testimonials**



Alistair Coates, Oviya MedSafe, UK

"Very well arranged Generic Biosimilars 2017, nice experience for me as I got to meet people from a variety of backgrounds like industries and academia. Various topics are being discussed. It is very useful to someone who wants to learn more about biologics and biosimilars. Great experience at Rome. I congratulate the organizing team for a very well arranged conference".



#### Andreu Soldevila, LeanBioPro, Spain

"Generic Biosimilars 2017 is an excellent forum to exchange your ideas & views, get new information and interact with different people from industries and academia. This conference has a great value for the people participants. I hope conferenceseries will arrange for similar conferences in future as well."



#### Andras Guttman, University of Pannonia, Hungary SCIEX, USA

"I found Generic Biosimilars 2017 very impactful. We have very good keynote speakers each day and met a lot of speakers that basically talk about their background and have a very good size of audience with free flow of information. The best thing is we were able to use the opportunity to network after the meeting. So if you haven't yet come to the Generic Biosimilars conference, I would recommend attending the next one as it is very impactful".



#### **Christina Vessely, Biologics Consulting, USA**

"Generic Biosimilars 2017 has been an activity packed 2 days. Good speakers with very good content. I have learnt something new and shared experiences as well. Great 2 days at Rome, Italy.



#### **Christopher J Leintz, Pfizer, USA**

"Generic Biosimilars 2017 was attended by many professional speakers from all over the world. We would like Generic Biosimilars to continue and support this conference as this is beneficial to all of us. We also appreciate the organizers for this wonderful event."

# **Testimonials**



Christoph Volpers, Michalski Hüttermann & Partner, Germany "Distinguished Guest Speakers, well presented important biosimilars topics."



Fabienne Danhier, Louvain Drug research Institute, Belgium
"Interesting 2 days at Generic Biosimilars 2017. Very good speakers and lot of good presentations on various topics of biosimilars and clinical research. Good job".



**Greg Koski, Alliance for Clinical Research Excellence and Safety, USA**"Generic Biosimilars 2017 interesting 2 day conference, lot of presenters, interesting topics and discussions. Rome is gorgeous and the organization is great."



Julia Lain-Abril, CEO San Pablo University, Spain "Generic Biosimilars 2017 conference is very good and very informative. I have learned a lot. Great experience so far. Thanks to the organizers for this wonderful conference".



**Ulrike Konrad, Protagen Protein Services, Germany**"I learned a lot from Generic Biosimilars 2017 and love to chair or co- chair a session. I will help recruit speakers to the next meeting as an organizer member of the conference committee."

# **Testimonials**



**Tom Carver, Wragge Lawrence Graham & Co, UK** 

"Generic Biosimilars 2017 was one of the best and even brilliant I have ever attended. There was very nice to have a mix between theory, basic science, sharing best practices and practical recommendations. The quality of the panels was outstanding, and I think you arranged a great cross-section of topics!".



**Tim Demuth, Sandoz Pharmaceuticals GmbH, Germany** 

"There are a lot information we can get during the Generic Biosimilars 2017 conference including building a network with other researches. Everything went very well. Thanks for everything".



Ruideger Janwosky, Cinfa Biotech GmbH, Germany

"I had a lovely time at Generic Biosimilars 2017, thank you so much for inviting me to your esteemed event."



Magd Zakaria, Ain Shams University, Egypt

"Very interesting Generic Biosimilars 2017 conference which contain several scientific topics and new research and I had a good time in Rome very much.I hope I'll join the next conference also, thank you."



**Laszlo Endrenyi**, University of Toronto, Canada

"I enjoyed the conference and the many nice participants that I met at the meeting that were in attendance. I hope to meet again in the next conference in 2018".

# Market Analysis

Biosimilars industry is sharing upper hand over the develop advertise with lower work costs, financial crude materials and prepared access to the extensive household and local market. In the greater part of the cases, the administration experts are likewise advancing the commercialization of biosimilars, Generic Drugs, Generic Pills and Generic Medication in their household showcase Emerging economies are seeing sound development in biosimilars industry from requesting clinical necessities of blockbuster therapeutics, ascend in GDP and in Pharmaceutical Industry medicinal services uses, expanding in desire of the patients from the pharmaceutical suppliers for practical therapeutics, Pharmacology, Clinical Trials & Drug Development arrangements. The organizations working in creating economies have some future getting ready for the biosimilar advancement are embracing coordinated effort and partnership with the do minating players from the rising economies, for example, United States and Europe. This may also include GMP, GCP and Quality Control techniques to improve the quality of Biosimilars these players are giving subsidizing, worldwide exchange and administrative learning and mechanical help to the creating Pharmaceutical Industry.

This includes the recent studies in Patent Access, Intellectual property, FDA Regulations, Quality Control, R & D, Pharma Pricing, Market Access, Global Pharma Market, Pharmacovigilance & Safety of Biosimilars, Novel Drug Delivery Technologies, Protein Bio therapeutics and all the fields of Pharmaceutical Industry and Growth of the economic growth in Pharma Industry.

Attracting industry, regulatory & academic experts working in all areas of protein, antibody & biosimilar research this two-day interactive meeting will explore a variety of topics across three streams. The first stream focuses on the latest innovations in antibody based therapeutics; leaders from the industry will be presenting updates on their strategy, pipeline and exciting candidates. The second stream includes presentations on expression, purification and characterisation, discussing issues around stability and half-life, as well as presenting novel cancer therapy approaches. The Biosimilars stream explores themes of similarity, regulation and public perception, alongside presentations on candidate generics in various stages of development. Executive panels and roundtables will foster discussion on the direction of the field, and the approaches required to ensure that the industry continues to flourish and Created with a top panel of industry thought leaders, this year's event will capture expert insight by honing in on the biosimilar product life-cycle from early stage developments, protein characterisation, and pricing & reimbursement; through to emerging markets and global developments.

# Market Analysis

Market Growth Biosimilars & Generics The biosimilars market was estimated at USD 3.1 billion in 2017. Since the guidelines on the similar biological medicinal products came into effect in Europe, in 2016, there has been a significant development in the field of biosimilars. These drugs are highly similar copies of a previously approved biologic (reference product) and may differ from the reference drug in terms of clinically inactive components without consequential clinical implications. The global biosimilars market is expected to reach USD 10.90 Billion by 2021 from USD 3.39 Billion in 2016, at a CAGR of 26.3%. The market is broadly classified into product, manufacturing type, application, and region and most of the pharmaceutical developing companies in Birmingham & Studies after research predict the world market for biosimilars and related follow-on biologics will reach \$9.2bn in 2018, and multiply in size to 2024. By 2020, some \$55 Billion worth of biologic patents are due to expire. Key factors driving market growth include patent expiries of key biological drugs, cost containment measures from governments, aging population, and supporting legislations. The recent establishment of regulatory guidelines for biosimilars in the US is expected to add further momentum to the growth of the global biosimilars market. Increasing pressure from governments and insurers for greater biologic competition, there exists an incredible opportunity for biosimilar producers to capitalise on what is set to become the fastest growing sector of the pharmaceutical industry.

#### **2018 KEY THEMES:**

- Adopting and rolling-out a multi-stakeholder approach in Europe
- Reducing the information gap on biosimilar medicines
- Supporting international regulatory convergence
- Additional Panel discussions
- Legal Hurdles & Intellectual Property Protection
- Biosimilars vs. Biobetters
- Advances in Biosimilar Production & Technologies
- Biosimilar Comparability & Interchangeability
- Biosimilars Opportunities in Europe USA & Asia

#### **Major Generic Pharmaceutical Industry are:**

- Teva
- Novartis Sandoz
- Allergan
- Mylan
- Sun Pharmaceutical
- Aspen
- Hospira
- Sanofi

- Fresenius Kabi
- Lupin
- Dr. Reddy's Laboratories
- Apotex
- Stada Arzneimittel
- Aurobindo

# About Us

#### **Our International Open Access Journals**

- 700+ Leading-edge Peer Reviewed Open Access Journals
- 21 Day Rapid Review Process
- 50000+ Editorial Board Team, 35000+ Reviewers team
- 30 Million Readers and High Visibility
- 1000+ Scientific Associations Collaborations
- 100000+ facebook Likes
- **Publication** immediately after acceptance
- Quality and Quick editorial, review processing

#### **Salient Features**

- Easy to Submit and Review Systems
- High Quality and Fast Publishing Guaranteed
- Unbiased, quality-oriented, and transparent reviews
- Truly impartial recognition of the best papers
- Feedback on the impact of every article
- Enhanced feature: Audio version of published paper
- Digital articles to share and explore
- Sharing option: Social networking enabled
- Authors, reviewers and editors are provided with scientific credits
- User friendly/feasible website articles translations across more than 50 world languages

#### **Our International Scientific Conferences**

- More than **3000 Conferences** happening across the globe
- Conferences organized in Medical, Pharma, Engineering,
   Science, Technology and Business.
- CME/CPD Accredited Conferences fostering professional and Personal development
- Continuum of education through organized scientific program
- Renowned speakers and scientists representing from 40 countries
- **Highly Interactive sessions** and Panel Discussions
- B2B Meetings offers perfect platform for Global Networking

#### **Salient Features**

- Robust on-line publicity for all the speakers and organizing committee members
- Career Guidance Workshops for students and early career researchers
- Accepted Abstracts will be published in various indexed journals
- Accepted abstracts will be labeled with a Digital Object Identification Number (DOI) provided by Cross Ref
- Creation of speakers and abstracts pages in Google
- Opportunity to publish full Manu Scripts in our Open Access Journals

Special Issues : All accepted abstracts will be published inrespective Conference Series LLC Journals

• **Generic-Biosimilars 2018** Conference website is attracting **25000+** Pharma Industry will be an arena for researchers, Biosimilars, Bio scientists, Policy makers, young individuals and industry experts to come together, share experiences, discuss research findings and acquire the desired knowledge for practical exercise. This unique opportunity that we extend to our speakers and attendees is not being offered by any other conference organizers. Through this the abstracts and research profiles of our speakers and organizing committee members getting global visibility which is an additional feature that you would be receiving in addition to networking opportunities before, during and after the conference

#### **How Conference Series Conferences differs from others?**

- 3000+ Conferences across the globe in 30+ countries all through the year
- Over 25 Million+ Visitors and 20000+ Unique Visitors per conference
- Participation by Stalwarts from various international societies
- Internationally renowned speakers and scientists representation
- Career guidance for early career researchers and students
- Interesting scientific deliberations and discussions
- Perfect platform for Global Networking

#### **Generic Biosimilars 2018 salient features**

- Meet Academia and Industry visionaries to get inspired
- Expand your knowledge and find solutions to problems
- Knowledge, Benchmarking and Networking offered at one place
- Forge connections and for global networking
- Highly Organized and Structured Scientific programs
- Poster presentations and world class exhibitions
- Meet with new vendors and suppliers



#### **Purpose**

• 14<sup>th</sup> International Conference on Generic Drugs and Biosimilars is an global event of pharmaceutical Industry This conference is an International collaborations between companies have become a strategic priority, and we remind you that Generic Biosimilars 2018 is the forum that brings together both mid-sized and small companies from different countries to meet and forge new contacts and business deals and hope the Private b2b meetings will be benefit to you and increase your company profits.

#### Goals

- The conference program emphasizes evidence-based practice, educational innovation, practical application, and peer to peer networking and collaboration. The goals of the conference is to provide a transformative professional development experience through
- Bringing together the world's scientific experts to catalyze and advance scientific knowledge about Social Sciences
  and Medicine present the most recent research findings, and promote and enhance scientific collaborations around the
  world
- Bringing together community leaders, scientists, and policy leaders to promote and enhance programmatic collaborations to more effectively address regional, national and local responses to Elderly Population around the world and overcome barriers that limit access to care and services.

#### **Objectives**

After participating in this meeting, attendees should be able to

- Discuss emerging issues in Social Sciences and Medicine.
- Discuss and apply recent research findings related to Social Sciences and Medicine.
- Reflect on the place of critical distance in Generic Drugs and Biosimilars

#### Who should attend

**14**<sup>th</sup> **International Conference on Generic Drugs and Biosimilars** is exclusively designed for Directors, CEO's of Organizations, Business Development Managers, Chief Scientific Officers, R&D Researchers from Biosimilar and Biologics Industries, Professors, Associate Professors, Assistant Professors, PhD Scholars, Patent Attorneys, Intellectual Property Attorneys, Business Entrepreneurs& Exhibitors.

#### **About hosting organization**

Conference Series is the world's leading specialist in organizing Academic, Scientific and Business conferences, meetings, symposiums and exhibitions in different verticals and horizontals like Medical, Pharma, Engineering, Science, Technology and Business to promote scientific research. Every year we host more than 3000+ global events inclusive of 1000+ Conferences 1000+ Symposiums 1000+ Workshops in USA, Europe, Middle East and Asia with the generous support and cooperation from our 30000+ Editorial Board Members, 1000+ Scientific Societies. All the conference proceedings are published in the special issues of our 700+ Open Access International Journals with the DOI provided by

#### **Major sessions**

- Generic Drugs, Generic Pills and Generic Medication
- Office of Generic Drugs (OGD)
- Biologics & Biosimilars
- Pharmacology and Drug Developement
- Array of Clinical Trials in Biosimilars
- GMP, GCP and Quality Control
- Patent Access& Intellectual property& FDA Regulations
- Quality Control/ R & D
- Pharma Pricing & Market Access
- Licensing, Manufacturing& Health Economics
- Generics Biosimilars Industry Strategy

- Global Generic Trends & Global Pharma Market
- Pharmacovigilance & Safety of Biosimilars
- Biosimilar development challenges
- Biosimilars Differentiated Through Novel Drug Delivery Technologies
- Protein Biotherapeutics & biosimilars
- Developing Biosimilars And Biobetters
- Biosimilars Uptake & Patient Safety
- Chronicles of a Biosimilar Production Facility
- Case Study Mitigating Risk in Biosimilar Development
- Innovation & Technology for Biosimilar Development

### Collaborators









### Media Partners





















































# **About Berlin**

Berlin is the capital and also the largest city in Germany as one of its 16 states, contains population around 3.7 million. Berlin, the German capital, renowned for its exceptional and numerous varieties of attractions, its flourishing cultural scene. Berlin is a city of museums, art, and artists. There are more than 170 museums, including those on the famous museum island, put the treasures of the world on public display. Visitors from all around the world visit Berlin to entertain and enhance their cultural interests in watching performances by leading orchestras, such as internationally celebrated Berlin Philharmonic, And to attend ballets and operas at the three major opera houses. A multitude of theaters specializing in plays, variety, revue and cabaret offer stage entertainment in all its forms.

- Reichstag building
- Brandenburg Gate
- Museum Island
- Berlin Wall
- Pergamum Museum
- Checkpoint Charlie
- Memorial to the Murdered Jews of Europe

- Fernsehturm
- Berlin Cathedral
- Spree
- Berlin Zoological Garden
- German Museum of Technology
- Aqua Dom and much more awaits for you to take a tour.

## Venue & Accommodation

#### **Venue & Accommodation**

**Best Western Premier Airporthotel** 

Fontane Berlin Jonas-Lie-Straße5-11 15831 Berlin (Mahlow) Germany



**Missy Christen** 

Program Director | Generic Biosimilars 2018
Conference Series Ilc LTD
47 Churchfield Road
London, W3 6AY, United Kingdom

E: genericpharma@pharmaceuticalconferences.org







### Formats to Excite



#### PARALLEL CONFERENCE TRACKS

One great interactive event with two complementary conference tracks. Generic Drug Market & Contract manufacturing brings together decision makers, influencers to provide a true insight on the best development, manufacturing, clinical and commercialisation strategies for biosimilars in the global market.



#### **ROUNDTABLE DISCUSSIONS**

Pick a roundtable that focuses on the industry challenge of highest priority to you. Each round table host will open a topic up for discussion and debate. This is your opportunity to contribute, discuss, engage, share ideas and learn directly from your peers. This informal setting may generate some different perspectives and innovative solutions you haven't considered before.



#### **NETWORKING LUNCHES**

Make the most of your time outside the conference room with our networking lunches. This is your opportunity to benefit from informal chat, explore the exhibition hall and meet some new business contacts.



#### **SOLUTION PROVIDER EXHIBITION**

Explore the exhibition hall during dedicated breaks and meet with solution providers that offer innovative services and technologies. You can be sure to meet those that can help fast-track your evidence generation strategy.



#### **SPEED NETWORKING**

Put some faces to names with this fast and fun networking session. Rotate around the room and meet, greet and exchange business cards as you go. Create the first links with potential business partners.

# Registrations

#### **ACADEMIC**

Only Registration USD 699

Package A (Registration + 2 night's accommodation) USD 899

Package B (Registration + 3 night's accommodation) USD 1049

#### **BUSINESS**

Only Registration USD 799

Package A (Registration + 2 night's accommodation) USD 999

Package B (Registration + 3 night's accommodation) USD 1149

#### **STUDENT**

Young Research Forum (YRF) USD399

Student Registration USD 349

Registration and 2 Nights Accommodation USD 599

### **Important Dates**

Abstract submission opens: March 01, 2018

Registration opens: March 01, 2018

Early bird Registration: July 31, 2018

On spot Registration: November 15, 2018