India's Association of Biotechnology Led Enterprises (ABLE) and the US-based Biotechnology Innovation Organization (BIO) have assembled a rigorous two-day open-enrollment "Boot Camp" to help accelerate the scientific, clinical, medico-legal and commercial knowledge base of industry and promote and facilitate the right policies that will assure broad participation in the production and global distribution of cutting-edge medicines that can transform human health care. This is an education and interaction session of regulators, SEC and industry along with global speakers.

Biosimilars Bootcamp –2016
"Development and Regulatory Workshop for Biologics & Biosimilars"

December 1 – 2, 2016- Thursday & Friday
India Habitat Center (Gate 3)
Venue Address: Lodhi Road,
Near Airforce Bal Bharati School,
New Delhi, Delhi 110003
Tel: 91-11-4366 3333
Fax: 91-11-2468 2052, 2468 2054
Click here to Register

DAY ONE PLENARY TRACK		
Session	**Topics**	**Speakers**
8:30 to9:30 AM	**Registration (Tea/Coffee)**	
9:30 to 9:45 AM	**Welcome and Program Structure** Stephen M. Sammut, Senior Fellow Health Care Management, Wharton School; Boot Camp Co-chair	
9:45 to 11:00 AM **Session 1**	**Keynote Addresses and Commentary** Keynote: Prof. K. VijayRaghavan (Secretary, DBT) Special addresses and commentary: **Shri. C.K. Mishra - Secretary Department of Health & Family Welfare** **Dr. G. N. Singh – Drug Controller General (India)**	

	Dr. SoumyaSwaminathan - Director General ICMR **Sh. K. L. Sharma – Joint Secretary, MOH**
11:00 to 11:15 AM	**BREAK**
11:15 AM to 12:15 **Session 2**	**An Overview of Biosimilars:** The challenges of a biosimilar vs. a new biologic Speakers: Kiran Mazumdar Shaw, Chairman & MD, Biocon
12:15 to 2:00 PM **Session 3**	**Developmental Considerations with Biosimilars** **Speakers:** Dr. SundarRamanan, Global Regulatory Affairs &Policy, Amgen. Dr. Dominik Heinzmann, Ph.D., Associate Director Biostatistics, F. Hoffmann-La Roche Ltd. on "Study design, statistical aspects & sample size while designing Clinical trials for Biosimilar development as per international guidelines vs current revised guidelines" Dr. Inger Mollerup, Corporate Vice President Regulatory Affairs Novo Nordisk A/S on "Key Aspects of Biologicals vs Biosimilars: Production, Quality & Comparability"
2:00 to 2:45 PM	**LUNCH**
2:45 to 3:45 PM **Session 4**	Regulatory Requirements for Market Authorization in India Guidelines on SimilarBiologics August 15' 2016 **Dr. S. R. Rao -Member Secretary RCGM and Adviser DBT** **Dr. V. G. Somani -Joint Drugs Controller (India)** **Dr.S. Eswara Reddy - Joint Drugs Controller (India)** **Dr. A. Ramkishan – Deputy Drugs Controller (India), Biologic Division.** **Dr. Jagdish Prasad - DGHS** Open Dialogue and Q&A with Regulators

3:45 to 4:00 PM	**BREAK**
4:00 to 5:30 PM **Session 5**	**Regulatory Pathway in EMA** 4:00 to 4:45 PM EMA: background; clinical data; product guidance; safety; approved products Dr. Inger Mollerup, Corporate Vice President Regulatory Affairs Novo Nordisk A/S **Regulatory Pathway in USA** 4:45 to 5:30 PM US: background; clinical data; product guidance; safety; approved products Dr. SundarRamanan, Global Regulatory Affairs & Policy, Amgen
5:30 to 6:50PM **Session 6**	**Regulatory Pathway in Asia, Latin America** **5:30 to 5:50 PM** **South Korea**: background; clinical data; product guidance; safety; approved products Dr. SundarRamanan Global Regulatory Affairs & Policy, Amgen **5:50 PM to 6:10 PM** **India:**background; clinical data; product guidance; safety; approved products Dr. Binay Swarup, AD Medical Affairs, Roche **6:10 PM to 6:30 PM** **Latin America :** background; clinical data; product guidance; safety; approved products Dr. Tamal Raha, VP Cipla **6:30 PM to 6:50 PM** **Japan :** background; clinical data; product guidance; safety; approved products Dr. Sriram Akundi, VP Biocon

7:30PM **Session 7**	**DINNER FOR ALL REGISTERED PARTICPANTS** **INNOVATE IN INDIA&MAKE IN INDIA** **Participants:** **Sh. Amitabh Kant – Chairman NitiAayog/ Secretary Pharmaceuticals** **Kiran Mazumdar Shaw** **Barkha Dutt**

FRIDAY, DECEMBER 2, 2016 **Education Track**		
Session	**Topics**	**Speakers**
8:00 – 9:00 AM	**Registration (Tea/Coffee)**	
9:00 to 11:00 AM **Session 8**	**Plenary Session for All Boot Camp Participants** Establishing goals/objectives of the Round-Table: Dr Y. K. Gupta (Chair) Lila Feisee, International Affairs, BIO (Co-Chair) Agenda Review Formation of 3working sub-groups Invited Panelists: Dr. V. G. Somani Dr. Sundar Ramanan Tamal Raha – Cipla Dr. Inger Mollerup, Corporate VP Novo Nordisk Dr. Dominik Heinzmann, AD Biostatistics, Roche Dr. Suresh Anekal – Biocon Dr. M.S. Ramakrishna - Biocon Dr. Guljit Chaudhri Dr. Sid Advanta – Kemwell Dr. Reddy's Glenmark Mylan Cadila Lupin Reliance Serum Institute of India INTAS *The goal of the Round-Table is to continue our dialogue with the Indian government about implementation of the biosimilars*	

	guidelines. We will present factual and practical examples of industry experiences with biosimilars regulations in India and other countries. The Round-Table will also present specific issues for which the Indian regulators should be alert.	
11 to 11:15AM	**BREAK &ROOM EXCHANGE FOR EDUCATION TRACK**	
11:15 AM to 1:30 PM **Sessions 9 and 10 (Parallel Tracks)**	**Session 9** **Marketing Considerations for Biosimilars** Stephen M. Sammut, Wharton School:"An overview of marketing issues and strategies for biosimilars" Anne Marie Polak, TITLE, Leavitt Partners: "Labeling Considerations" Eric Marshall, TITLE, Leavitt Partners, "Serialization" Case Study Phase IV / Pharmacovigilance	**Session 10** **Subject Expert Committee (SEC) "Mock" Project Review** Members of SECs are invited to a special mock review session of a product application Dr. Inger Mollerup Regulatory Affairs Novo Nordisk A/S Dr. Heinzmann or Dr. Swarup are available depending on cases *Case study (Glargin Approval In Japan by M S Ramkarishna)* *Case study* *key quality attributes (KQA) & critical quality attributes CQA* *Dr Sundar Ramanan/Case Study* *In a session designed primarily for members of CDSCO Subject Expert Committees, attendees will review 1-2 case studies (time permitting) relating to approval requests for two different biosimilars. As part of the technical discussion, the attendees will discuss the questions related to type and design of clinical trials, the results and whether they are sufficient to determine efficacy and safety, equivalence vs. non-inferiority to the reference biologic, and thoughts on whether the product is approvable. The attendees will also discuss differences in guidelines between the Europe and India and whether those differences might impact approvability.*

		Prior to the session, attendees will be provided technical documents assessing the biosimilar applications prepared by EMEA reviewers. Only documentation that is publicly-available will be made available; all information of a commercially-confidential nature has been deleted. In addition, the attendees will be provided short summaries introducing the cases and questions for discussion. To have a productive and informative session, it is important that attendees be familiar with the technical aspects of the biosimilar applications. Prior to discussion of the two case studies, the moderator will give a short overview presentation.
1:30to 2:30PM	**LUNCH**	
2:30 to 3:30 PM **Session 11**	**MAKE in India – CRAMs for Biologics & Biosimilars in India** **Moderator – Sh. Rajiv Aggarwal – Joint Secretary, Ministry of Commerce & Industry** Panelist Dr. Dinesh Dua, Vice Chairman, Pharmexcil Dr. Sid Advanta - Kemwell Reliance Syngene	
3:30 to 3:45 PM	**BREAK**	
3:45 to 5:15 PM **Session 12**	**The Convergence of Legal and Regulatory Issues** Discussion of legal issues affecting biosimilars with a focus on several existing approved biosimilar products and their legal hurdles as examples. *Moderator:* *Krishna Sharma, Esq. Partner Corporate Law Group*	
5:15 PM	**Adjournment & Summation** Stephen Sammut	

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