cv and photograph form

2016 apec biotherapeutics coe pilot training
September 13-16 / Northeastern University, Boston / United States

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<td>Dr. Sreedhar</td>
<td>Sreedhar</td>
<td>Sagi</td>
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Department / Organization
Sandoz Biopharmaceuticals, Novartis Asia-Pacific Pharmaceuticals Pte Ltd

Job Title / Position
Head of Medical Affairs Asia-Pacific

*Please write your CV briefly (approximately 150 words)*

Dr. Sreedhar Sagi is Head of Medical Affairs Asia Pacific for Sandoz Biopharmaceuticals, a Novartis company. He oversees all Medical Affairs activities and is responsible for the Medical Affairs strategy and its implementation in the APAC region.

Prior to his current role, he was Head Safety Risk Management at Sandoz Global Headquarters in Germany, with responsibility for all Sandoz products worldwide, for Risk Management Plans and for Medical Risk Assessments for product quality issues.

In a previous role, he was managing the Safety of Biosimilars, where he was responsible for the set-up, optimization and implementation of Safety Risk Management processes for Biosimilars at a global and national level. He has been with Sandoz/Novartis since May 2007.

He holds Master’s Degrees in Pharmacy (Andhra University, India) and Master’s Degree in Biotechnology (Hochschule Mannheim, Germany), and a Ph.D in Medical Biotechnology (Heidelberg University, Germany).

section iii: abstract form
**ABSTRACT FORM**

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**Topic**

POST APPROVAL MONITORING

*Please write your abstract briefly (approximately 250 words)*

Biologics are generally more complex than small molecules. Variability is inherent in biologics. Consequently no batch of any biologic is “identical” to the other batch. However, Variability is natural even in the human body and usually not problematic. Further, manufacturing changes occur due to process improvements, scale up, etc. Differences in attributes sometimes are significantly larger than batch-to-batch variability, but generally known. Biosimilars are approved biologics with comparable safety, quality and efficacy to a reference product in head-to-head studies throughout development. Non-comparable or alternative biologics are NOT biosimilars and are not approved for use in highly regulated markets.

The Guideline on good pharmacovigilance practices (GVP) Product- or Population-Specific Considerations II: Biological medicinal products details the Pharmacovigilance aspects specific to biologicals:

- Immunogenicity
- Manufacturing variability
- Stability and cold chain
- Product traceability

These are applicable to all biological medicinal products, irrespective of the regulatory pathway of approval or market exclusivity status. All general ICH, EMA and FDA guidelines on the quality and safety (including immunogenicity) of biological medicinal products apply equally to all such products, including biosimilars.

EMA and FDA have various structures and processes which ensure the post approval monitoring of all biologicals.

Current reporting insufficiently ensures the traceability of individual batches of biopharmaceuticals,
although the identifiability of at the product level is reasonably well ensured. Traceability and pharmacovigilance of biological drugs’ at batch level is needed.

Continuous, life-cycle pharmacovigilance and risk management is needed to rapidly detect any important changes in product safety and efficacy over time. Life-cycle pharmacovigilance at the levels of products and batches is therefore an important issue for biologicals.