Advancing Biopharmaceutical
Manufacturing in Low- and Middle-Income Countries
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Post-Webinar Report EBPMN

February 24th, 2022

Webinar on Technology Transfer as a basis for access to LMICs in the production of biosimilar products

Speaker: Dr. Tamal Raha, Founder, IBPS

Ms. Mireille introduced the speaker to the participants.
Dr. Tamal offered his presentation and expertise from working in various places. He states that present worldwide access to biological therapy is limited due to poor awareness of the disease in underdeveloped nations, but also in the developed. **Physician availability per capita is limited in poor nations.**

Disease awareness, physician availability per capita, and basic treatment indicate a problem in developing and rich nations alike. **We can address this by making drugs inexpensive.**

We can now distribute drugs because we have more predictable technologies. Distributed production reduces supply chain expenses. Creating material in-house allows you to control the pricing. Localizing commodities, processes, and template facilities, streamlining manufacturing software and documentation, building factories with globally standardized design, equipment, and unit operations may significantly reduce costs.

He described the various steps required in the production procedure. Depending on the demand we can replicate the modular design. Certain advantages of replicating manufacturing: no replication of preclinical and clinical work, cost-saving, high predictability and consistent performance, single vendor better price contract, similar facility, design and operation, easy to train people. **The COGS analysis can be reduced up to $ 36.55/g possible.**

Dr. Tamal also took questions after the presentation. He explained SUT and its environmental implications. According to him, SUT utilities use less pipe, so the carbon impact is reduced.
Modern SUT materials are ecologically friendly, making them readily degradable, as well as the facility's carbon footprint is smaller than a traditional facility's yield. He also explained the cost impact of regulatory guidelines for different nations.

The rules are being simplified, only a few nations still need local patient studies, which may add to expenses. To avoid this, design your clinical trial as a global clinical trial. Also, for manufacturing facilities, the regulators and the Department of Health are highly supportive of local production.