Report
Webinar November 17th, 2020

Biopharmaceuticals in Brazil

This webinar presented two inspiring cases of successful introduction of locally made biotherapeutics in Brazil, by ***Debora Schoenfeld Prusch (Cristália Ltd)*** and ***Marcia Martini*** **(Libbs Ltd.)**. Both Brazilian companies are privately held. Cristália Ltd was established in 1972, has around 6000 employees, 6 facilities, and has about 350 products on the market. Libbs Ltd started in 1958, has about 2900 employees, 2 facilities, and about 90 products on the market. Both companies have invested significantly over the last twenty years in biotechnology and biopharmaceutical R&D as well as in modern GMP production facilities.

Libbs Ltd invests about 10% of its annual revenue in R&D, has currently two biosimilars on the Brazilian market (for rituximab and trastuzumab) and uses primarily single use technology. Various partnerships have been concluded Libbs' rituximab biosimilar was the first Brazilian biosimilar to obtain market authorization in 2018 from Brazil's national authority (ANVISA). The introduction was successful and Libbs now has captured around 14% of the national private market. Marcia covered various aspects and challenges encountered during the product development pathway, including the need to close development partnership, the conduct of clinical trials, the regulatory strategy followed and technology transfer experiences. A new GMP facility was completed within 18 months. Partners provided training to staff on how to work in GMP facilities; comparability studies had to be subcontracted abroad which took time and was costly. Health experts from US and Europe were invited to provide advice also to governmental bodies in Brazil. Currently a nation-wide "real world evidence-survey" has started to evaluate the efficacy and safety of Libbs second biosimilar for adjuvant trastuzumab for the treatment of HER2-positive cancer in 22 centres working together all over Brazil.

The ***Cristália Ltd*** case was about the local development of collagenase for the enzymatic treatments of wounds. The company currently has a modern biopharmaceuticals facility that opened in 2013 with two (ANVISA) certified technology platforms for manufacturing (microorganisms and animal cells). It also contains a GMP anaerobic bacteria manufacturing facility. It is now in use to manufacture collagenase under BSL3 conditions. Debora presented the successful product development (12 years) using a Brazilian (local) strain of Clostridium (T248) which now yields around 40% more collagenase than the strain originally obtained from ATCC. Along the development an animal component free culture medium was developed, and the entire process is now exclusive, and patent protected.

Q&A session: unfortunately, the audio-connection with *Débora Schoenfeld Prusch* got lost halfway in her presentation and consequently she was not available for the Q&A session. Questions posed to *Marcia Martini* centered around some practical challenges of setting up biosimilar production, such as required land space and the major cost drivers in the process development. She replied that in Libbs experience the most expensive stage of the process development was the clinical trial phase and the comparability studies. Libbs currently has an annual production capacity of 400 kg of monocloal antibodies which is not all utilized yet. They are therefore actively looking for partnerships to increase the number of locally made monoclonals for the Brazilian market. A challenge is the choice for single use technologies: till date everything has to be imported, despite some supply agreements with partners it would be much better if these products were made locally in Brazil. Another challenge is that samples for comparability studies still need to be send abroad for analysis; this is also very expensive, and an environment should be created that local laboratories can run these assays.

The webinar was moderated by Maureen Dennehy and attended by about 40 participants. EBPMN will strive to present the ***Cristália*** case again in another webinar event in 2021.