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Editorial

Growing Importance of Bacterial Endotoxins Investigation in Latin America Biomedical Devices Industry

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Editorial

Bacterial Endotoxin Tests (BETs) are critical for the control and release of raw material in the biomedical devices industries, and for the quality assurance and release of finished products from the manufacturer to the distributor and finally to the consumer (in many cases, the patient). As one of the most interesting poles for the growing of the biomedical devices industries, Costa Rica has emerged as a leading global destination, outside Europe, for investment in Medical Technology, attracting 47 such projects in a period of 5 years, including 18 in 2012, and positioning itself as #7 at the level global in terms of the number of manufacturing projects, beating Holland, Brazil and Mexico, between 2008 and 2012 [1]. The country has evolved over the years, and has gone from producing Class I to Class III medical devices, including those in areas of medical-aesthetic, cardiovascular, endoscopy, cardiovascular, dental, drug delivery systems, neuro-endovascular, neuro-modulation, optical, orthopedic / sports medicine / ENT and surgical / diagnostic; which now serve markets in America, Europe, Asia and Oceania. Costa Rica is now the second largest exporter of Medical Devices in Latin America.

The cluster of medical devices producers are composed of 92 companies, representing 24,600 jobs (2018). The biomedical sector represents 1/3 of the value of the country's exports, with sales of $3,250 million in 2018 (>19% than in 2018). Some examples of the exponential grow rate of the biomedical devices industries are represented for top leading companies such as Medtronic (starts operations in 2015) has tripled its operations to reach 500 employees today; Boston Scientific expanded operations; Opening 600 new jobs in June 2019, being the largest local employer in the sector (approximately 5000 jobs). Thermo Fisher Scientific, opened in May 2019, a new distribution center of 1,400 square meters. Establishment Labs (national breast implant manufacturing company), reported an annual growth of 58.2% (Nasdaq), with revenues> $21.7million (second quarter 2019).

The need for an accurate system to ensure the microbiological quality of terminated products is critical, so, the need to face a changing landscape in the subject of the traditional methodologies used to determine the presence of bacterial endotoxins is a crucial point for all these companies that enhances its production without diminished quality. The conventional methods as the LAL-Clot gel assay (the most extended & used in the country) needs a trained & dedicated personnel to ensure its correct implementation and results, but, the complexity inherent to the test, the costs related to the need of re-test, and the limitations to a determined amount of products, let an open path to consider other strategies & methods to improve the ratio cost/benefit in the BETs determination. The use of semi or automatize methods, that enhances the capacity to test a more bigger amount of material, increasing the possibility to detect minimal endotoxins quantities, in a shorter time, with few re-test requirements, and reducing the possibility of human error (due to the use of semi-locked systems), and the ability to produce results with comparable variables and storage a huge amount of data (with the

chance for a respective cross-analysis), are priceless considerations to keep in mind at the time to evaluate (select) the BET technology.

The use of the cartridge technology, in which the LAL and the standard of endotoxins are held at the same time in a single in vitro test, allows the analysis process to be fast and the learning curve of the personnel in charge is shorter, significantly reducing errors in calculations of the Maximum Valid Dilution (MDV) and the preparation of the test controls. Cartridge technology has been approved by the FDA since 2006 and represents a saving of 95% on raw materials obtained from of horseshoe crab blood. The LAL is obtained from the crab's blood and although there are very robust protection regulations in the geographical sites where the animal is endemic, there has always been the possibility of looking for methods that do not include the use of these living beings. In this way, obtaining the LAL factor C by recombinant DNA techniques has emerged as an alternative that has already been included in an official chapter of the European Pharmacopoeia on 2020 [2].

With the arrival of this technology, possibilities are opened to carry out the test in an even more automated way and without using crab blood, however, to date there is no robust study of comparability between the LAL test with factor C recombinant that gives confidence to companies or contract laboratories to use such a solution. In terms of international harmonization among the most robust pharmacopoeias, makes trust in the LAL method still valid. The Parental Drug Association (PDA) has made some observations that would be appropriate to observe, especially in terms of harmonization and comparability of methods [3]. Patient safety will continue to be a pillar of biomedical device companies, health systems, regulatory systems and contract laboratories. The incorporation of faster, error-proof and increasingly robust, accurate and reliable methods, part of the commitment to health of the patients in such a growing fast market as biomedical devices.

References

1. (2015) MedTech report 2014 in review. EP Vantage, Boston, USA.
2. (2019) New general chapter on test for bacterial endotoxins using recombinant factor C. Give your feedback. European Pharmacopoeia Public Enquiry, Strasbourg, France.
3. (2019) Test for bacterial endotoxins using recombinant factor C. Proposed European Pharmacopeia Chapter 2.6.32.