Sandra Saiz Balbastre et al., J Med Microb Diagn 2017, 6:2(Suppl)
DOI: 10.4172/2161-0703-C1-006

Development and application of rapid microbiology methods in manufacturing and control of pharmaceuticals

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Nowadays, microbiological control in the pharmaceutical industry is mainly based upon incubation of microorganisms to detect contamination. Analyses carried out are very time-consuming and results are poorly accurate due to low sensitivity of the equipment. The main goal of this project is to develop and apply rapid microbiology methods to the routine microbiological control of a pharmaceutical processing plant, under GMP conditions. For this, there are two different objectives to deal with: microbial detection and identification. Firstly, regarding rapid detection, a real-time air-borne microbial detection system has been validated to apply it to an aseptic production chain. This system is based on laser-induced fluorescence, which permits to distinguish between viable and non-viable particles present in the air, as the laser excites esterases in living microorganisms. The advantage of this system in front of the traditional air-sampler is that viable but non culturable microorganisms are also detected, in addition, it is real-time measuring, which makes problem-solving faster. Secondly, a rapid identification system based on MALDI-TOF has been validated, which permits to perform identifications from different contamination sources in less than 24 hours. In addition, a sequencing-based identification method has been developed for specific cases when molecular identification is required by authorities or MALDI-TOF can't provide an accurate identification. Also, a comparison between both methods has been performed regarding internally detected microorganisms. In conclusion, the setting up of these techniques will improve the sensitivity and quality of microbiological control and will also be time and cost saving for the company.

Biography

Sandra Saiz Balbastre has a degree in Biotechnology from Polytechnic University of Valencia and MSc in Pharmaceutical and Biotechnological Industry from Pompeu Fabra University in Barcelona. Currently, she is pursuing her PhD at a pharmaceutical company Reig Jofre Laboratories in Barcelona in collaboration with Autonomous University of Barcelona, Spain.

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