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The significance of VBNC in the biopharmaceutical industry: A new challenge for small local producers

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Viable but non-culturable cells (VBNC) are defined as live bacteria, but which do not either grow or divide. Such bacteria lose the ability to be grown on media. This presents a problem to microbiologists because many current microbiological methods in the pharmaceutical sector include growth-based techniques, such as agar plating, membrane filtration and broth enrichments. The microbiological controls in the Institute Torlak Quality Control Department include testing of raw materials, water for injection, purified and highly purified water, in process bioburden testing, monitoring of environmental conditions (air, surface and personnel), testing intermediate and final products. In order to avert the risk and ensure quality at all stages of production, the QC Department collects thousands of samples for bioburden and sterility testing a year. The conventional cultivation methods require hard work, large media consumption and long incubation period. It is believed that the actual risk to patients regarding the VBNC microorganisms in pharmaceutical products is limited due to a number of antimicrobial processes involved in the production. However, many studies have shown that processes intended to achieve bactericidal effects can favour bacterial switch to VBNC. Rapid microbiological methods (RMM) provide an opportunity to improve the quality of microbiological control, especially in assessing the significance of VBNC or stressed microorganisms, reducing the duration of sterility test and delivering real time results. There are many barriers to applying this new concept, especially in the developing countries: Substantial time and money for development and implementation, long time to attain the objective and benefits, unclear regulatory requirements, etc. The international regulatory authorities assist the implementation of RMMs, e.g. with the revision of the related guidelines or pharmacopoeias. An effective dialogue between the national regulatory authorities and local manufacturers is essential for success.

Biography

Vesna Kovacevic-Jovanovic, MD, Microbiologist, is a Research Associate in Institute of Virology, Vaccines and Sera "Torlak", Belgrade, Serbia. Following completion of her internship at Clinical centre, University of Belgrade, she joined the Immunology Research Center "Branislav Jankovic" in Belgrade (1994). In the 1998, she joined the Department of Quality Control-Institut Torlak. Over the next 12 years, she specialized and improved control of vaccines in all aspects. She was deputy Director of Quality Control (2005-2010). In 2010, she moved to position Executive Director in Institute Torlak (2010-2013). Her academic qualifications include MSc and PhD in Immunology and Microbiology. Since 1994 she has engaged in projects funded by the Ministry of Science and Technological Development, Belgrade, Serbia. He has 20 years of experience in biotechnology in research, quality control, industrial and technology development.

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