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Keynote Presentation

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Demonstrating method suitability for a rapid microbial detection method applicable to biologic products

Methods: New and emerging cell therapies medicinal products present new challenges in the assurance of quality and safety in terms of end-product testing. While traditional pharmaceutical drug products have long established standards for sterility assurance, these established processes are not optimized for cell therapies. For example, the Compendial sterility test requires not less than fourteen days of incubation for a reliable result, making it a rate limiter in the distribution of therapies to patients. Rapid Microbial Methods (RMM's) offer reliable alternatives to aging microbiological methods to solve the problem of reducing cycle time in cell therapy manufacture. ATP Bioluminescence is a matured technology that is used in the quality testing of various product samples in different industries. Detection of microbial ATP using the luciferin-luciferase reaction allows for detection of microbes before they can be cultured to visual detection levels on microbial media. Until recently, ATP bioluminescence was not a viable contamination detection option for cell-based products, because these samples also contain cellular ATP. The established ATP Bioluminescence platform, Celsis was further developed to address this limitation. A sample cell lysing procedure allows for the extraction and, more important, the depletion of "non-microbial-ATP", while leaving microbial ATP intact. A case study on tests performed on different cell-lines demonstrates the detection of a wide panel of typical and critical microbial species including spore former, yeast, moulds and "slow grower" as C. acnes.

Conclusion: Studies performed using Celsis platform, and Celsis Adapt complimentary technology, demonstrated the successful depletion of cellular ATP from various type of samples, while also allowing a fast detection of microbial presence contamination for a superior microbiological contamination control

Biography: Lucia Ceresa has Extensive international professional experience, demonstrated capabilities, a proven track record, and expertise in promoting sales strategy and marketing programs. & Manages quality, regulatory, and compliance projects with multiple competing priorities having a direct impact on commercial opportunity. She Develops strategies for governmental approval to introduce new products to market, Broad capabilities and experience in all aspects of validation, quality control, and addressing the challenges of the pharmaceutical manufacturing process. She has Extensive industry experience with regulatory bodies and agencies regarding documentation for the submission and approval process. Lucia's Expertise from the initial R&D project phase through the final product release for commercialization.

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