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VIBRATIONAL SPECTROSCOPY TECHNOLOGIES IN BIOPHARMACEUTICALS PROCESSES MONITORING

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Biopharmaceuticals manufacturing presents critical constraints, mainly resulting from the structure complexity of these molecules, difficult to characterize, and since are produced by living cells presenting high sensitivity to small fluctuations of the culture environment. Aiming the bioprocess control, the global regulatory agencies have changing the stringent quality guidelines for a more flexible framework based on Quality-by-Design, build on the scientific understanding of the process. The present work, describes how vibrational spectroscopy can be applied in biopharmaceutical process monitoring according to process analytical technology, by in situ and in real-time based on near-infrared spectroscopy (NIRS) or by at-line and high-throughput based on mid-infrared spectroscopy (MIRS) [1]. NIRS enables in situ acquisition, with a steam-sterilized probe, of all the critical variables of the bioprocess towards a real-time control while minimizing the risk of the bioreactor contamination [1]. MIRS enables a large-data base acquisition concerning the metabolic fingerprint of the host cells in a highly sensitive mode, that can result in a better understand of the bioprocess, and specially of the complex interrelationship between cells metabolic status, biopharmaceutical yield and the bioreactor environment [2]. In resume, vibrational spectroscopy techniques, as NIRS and MIRS, presents advantageous characteristics for the biopharmaceutical process monitoring and analysis, that ultimately complement each other according to the quality framework of Quality-by-Design.

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