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PROCESS ANALYTICAL TECHNOLOGY IMPLEMENTATION IN MICROBIAL PESTICIDE PRODUCTION

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Process Analytical Technology or PAT is a quality control system widely used in bioprocessing. Generally PAT focuses on pharmaceuticals production as the system that guaranty preparation quality from batch to batch on the basis of technological process control at different stages. However, current PAT applications are used for biological processes control in microbiological, food and chemical industry. It seems that some PAT approaches could be useful in microbial pesticide production for quality guarantying of the product – biopreparations.

The analysis of different scale microbial pesticide production was done for PAT tools implementation opportunities. System analysis methods such as SWOT analysis were used for this purpose.

Three logical elements were selected on the basis of system analysis general methodology for process quality evaluation of fermentation technology. They are an aim, an implementation strategy, and a result evaluation.

The aim of PAT using is microbial pesticides quality guaranty from batch to batch. Three main alternative implementation strategies can be distinguished:

– standard procedure compliance;

– certain number of process parameters maintaining within optimal, predetermined limits;

– adaptive regulation, based on direct or indirect measurements of parameters that characterize process variability caused by variations in microbial cultures, nutrient medium components, etc.

The results of each strategy as a rule are evaluated by separate methods. Sampling and further microbiological lab analysis (off-line methods) are used for standard procedure compliance quality evaluation. However, the results of such analyses are obtained after the finished product has been produced, which means it is

too late to respond operatively to any process changes. This method can be applied only for laboratory systems.

The second method is typical for small-scale production and pilot systems. A minimally sufficient level of automation for key technological operations ensures that they are carried out within predetermined optimal ranges of specific parameters (temperature, pH, dissolved oxygen, redox, conductivity, etc.). Quality control of the final product in such systems is carried out using express sample analysis made directly near the production line (at-line methods). However, rapid responding to specific deviations in culture growth also remains beyond the system's capabilities.

Adaptive real-time process parameter control is particularly useful in industrial systems where losses resulting from substandard products are greatest. Implementing this method requires a deep understanding of the interrelationships among parameters within the system.

As one can see three strategies combined with three quality evaluation methods described above predetermine microbial pesticide production at small (lab) scale, pilot-scale and industrial-scale. SWOT analysis of each production scale was made.

Lab-scale production strengths are implementation engineering simplicity, availability of technical specifications and requirements. The main weakness is absence of variability factors consideration. Processes investigation and production scaling are the main opportunities. The threats are touched with production losses and uncertain product quality until bioprocessing end.

Pilot-scale systems strengths are technical implementation relative simplicity, and main procedures control. The weakness of such production is limited parameters control does not guarantee the product quality from batch to batch. The main opportunity of such system is the certain production volumes achievement ability with moderate investment. Inability of products manufacturing of consistent quality is the main threat.

Finally industrial-scale production strength is connected with total process control. The weakness is uncertainty regarding the priority of the controlled parameters for product quality at different process stage. The opportunity of industrial-scale systems is results correction during the obtaining process of this result. A large amount of process data in the absence of a standard model for their organizing is the threat.

Thus, SWOT analysis showed that the greatest need of PAT tools implementation is in industrial-scale microbial pesticide production systems. However, this production scale is the most difficult for engineering and technological support of PAT. The lowest need of PAT tools is in lab-scale systems. Such systems as usual

equipped by different control devices as they generally used for researches but not for production. It seems that pilot-scale systems are the most suitable for PAT implementation into microbial pesticide production. They are widespread in this industry, and usually equipped by basical control systems. Thus, pilot-scale systems can be optimal for PAT principle adaptation for microbial pesticide production and models development for industrial-scale systems.

Keywords: PAT, microbial pesticides, production scale, SWOT analysis

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