MULTI-TIERED SIMULATION METHOD FOR EVALUATION, DESIGN AND SCALE-UP OFPROCESSES AND PROCESS EQUIPMENT IN THE PHARMACEUTICAL INDUSTRY

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ABSTRACT

The pharmaceutical industry faces new challenges as it enters the 21st century. These challenges can be met by integrating key technologies in the design and development process. Simulation methods of varying levels of rigor have been identified as one such technology. This article provides an overview of a multi-tiered simulation strategy for analysis, design and scale-up of processes in the pharmaceutical industry. This solution strategy is based on using a combination of analysis tools such as simple rules-of-thumb, empirical methods and detailed analysis based on computational methods.

The pharmaceutical industry involves a wide variety of process equipment and each process unit may be required to perform a wide variety of duties over its service life. Hence, it becomes essential to predict performance under a wide variety of operating conditions. The flow and thermal behavior in a process unit is quite complex and detailed measurement is not always possible. Simulation based methods provide a viable tool for examining and troubleshooting of such equipment. A typical unit operation processes a large amount of fluid. Given the economics of most unit operations, even small improvements in efficiency and performance can result in a significant increase in revenue and savings in costs. Predictive tools can be used to analyze existing equipment and scale process from lab to pilot and ultimately to production. Computer based simulation methods provide detailed flow and thermal information related to process equipment. Information that is not readily extractable using measurements can be obtained using simulation methods.

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