

*International Conference on***PHARMACEUTICAL AND BIOMEDICAL ENGINEERING***October 16-17, 2017 Osaka, Japan***Statistics in action: A case study for a pharmaceutical active ingredient (API) manufacturing process in the USA****Dan Liu**
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Novel statistical tools have been applied to the manufacturing industry, process design/engineering and other industries for more than two decades. These tools are frequently used in process optimizations as well as the diagnosis of various process failures. The goal of using statistical techniques in a manufacturing environment is to improve the process efficiency and ultimately increase the batch consistency and/or reduce the overall project cost. This paper is to use a case study in a cGMP (current Good Manufacture Practice) pharmaceutical manufacturing environment to demonstrate how statistic techniques could be deployed to diagnose the bottleneck of a continuous manufacturing process. Multivariate analysis was used as a novel statistical tool to illustrate how variables to a process could affect the yield of an Active Pharmaceutical Ingredient (API) manufacturing process. Our results suggested that Human Factor (HF) variable such as lead operator involvement, positive-emotion operator participation will have a positive influence on the final API yield, while operator mentality variable such as knowing holiday approaching and numbers of operators in a production shift will have a negative impact on the API Yield (AY). We also examined Technical Factor (TF) variables specifically related to the chemical process in this case such as temperature, holding time, pH, etc., we discovered that only certain yield critical variables will have the influence on the final API yield, where explanations were given using reaction mechanism. Finally, we investigated cGMP Factors (GF) variables such as the number of deviations issued, the number of supplements issued, the number of Corrective Actions and Preventative Actions (CAPA) issued and the number of cGMP documentation corrections, the results suggested only certain GF variable will bear statistical significance against the API yield. We also documented the various level of statistical influence on independent variable such Machine Time (MT) using the same HF, TF and GF factors variables and we also proposed statistical relationship of those dependent variables against MT. We then proposed my recommendations as to how to increase the process yield and reduce the machine time strategically.

Biography

Dan Liu has obtained his Master's degree in Chemical Engineering from Temple University in Philadelphia, USA and his MBA degree from University of Iowa. He is currently the Process Engineer at Patheon Inc., a leading Contract Manufacturing Organization (CMO) in the USA specializing in Active Pharmaceutical Ingredient Manufacturing. He has significant knowledge in API manufacturing in a controlled cGMP environment.

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