Quality by Design for the Pharmaceutical Industry

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1 INTRODUCTION: WHY DESIGN AND RUN EXPERIMENTS IN THE PHARMACEUTICAL INDUSTRY?

While some discoveries and revolutionary improvements have come about by ad hoc methods, tinkering, or even accidents, a disciplined approach to discovering new products, developing them into salable form, and improving the processes by which they are produced is more efficient and effective. With such a disciplined approach, the quality of products and processes are embedded in their designs. This "quality by design" may be achieved through effective use of experimental methods. In this brief overview, we discuss many different methods that may be used to explore how changes to inputs (factors, explanatory or independent variables) affect outputs (responses or dependent variables). As opposed to passively observing changes and reacting to them, we describe methods in which we purposively change the values of factors in order to study their impact on one or more responses.

When attempting to optimize a product, process, or system, researchers often vary one factor at a time (OFAT), holding others fixed, in order to assess the impact of the factor on the response or responses. Design of experiments (DoE) methods allow

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