



Trend and Out-of-Trend Analysis for Pharmaceutical Quality and Manufacturing Using Minitab®

By Lynn D. Torbeck

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A trend is a series of events or data collected, generally over time, that has an established and expected pattern. The trend can be observed or it can be based on theoretical models. Any departure from the trend is then an unexpected out-of-trend event. It is atypical and begs for investigation. Trend analysis is good business and good science. The need for a trend analysis book is justified by the continued interest in presentations and discussions, both public and private, and the lack of a widely accepted, clearly defined approach by the industry that lends itself to consistent interpretation and uniform application. Trend and Out-of-Trend Analysis for Pharmaceutical Quality and Manufacturing Using Minitab®, a new publication by Lynn Torbeck, answers this call, contributing to an industry/regulatory dialogue and consensus that will serve and benefit all stakeholders, and patients in particular. This book is for pharmaceutical professionals working in product discovery, development, manufacturing, quality assurance and quality control. It presents a basic introduction to data and Trend and Out-of-Trend definitions, and proposes terminology to clarify the use of the word "control"• in several contexts. Outtakes from FDA warning letters, plant audits and investigations for trend and out of trend are presented to highlight the agency's viewpoint. Helpful graphs, charts and tables are also included throughout the book and in the appendices.

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