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Analysis and Control of Variation—Over-Control

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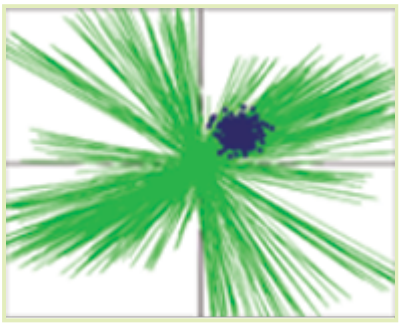

The result of the Nelson Funnel experiment for 500 drops where no adjustment is made (small dark dots) and where rule 3 (over-control) is employed (light lines).

INTRODUCTION Over-control is not a common term in the pharmaceutical industry, but it is a common problem. Many manufacturing and laboratory managers are unaware of both the definition and signs of over-control. Even fewer are aware of the devastating effects it can have on a process. The definition of over-control is reacting to (pure) random noise in data by making adjustments. It is contrasted with undercontrol, which is defined as treating a signal (e.g., special cause) in the data as random. Both over-control and undercontrol are serious issues and can have disastrous consequences to quality...