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Improving the Development of the I-Chart For Use in Biopharmaceutical Manufacturing Operation

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Improving the Development of the I-Chart For Use in Biopharmaceutical Manufacturing Operation

College of Sciences and Health Professions

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Abstract

The Shewhart control chart is a statistical tool used by pharmaceutical companies, as well as chemical and other batch manufacturers, to help detect errors in the manufacturing process and ensure control of product quality. One particular type of control chart is the I-chart. The average run length (ARL) statistic of the I-chart can easily be determined when output from the manufacturing process is normally distributed with known population parameters. This paper investigates the impact on the ARL statistic when the I-chart is based on mean and standard deviation estimates obtained from small sample sizes of less than 50 batches. The methodology of Quesenberry (1993) is employed to ascertain the impact of small sample estimation on I-chart performance and provide recommendations for how I-charts should be constructed to account for the uncertainty of using a small number of batches to construct them.

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