Statistical Tools

Antje Christensen and Sille Esbjerg
Novo Nordisk A/S, Bagsværd, Denmark

1 INTRODUCTION

1.1 Examples

Example 1-1: During a fermentation process, a sensor registers temperature measurements at regular time intervals, resulting in a large dataset for each fermentation batch. A process chemist who is new to the factory is given data from a couple of batches to familiarize himself with the way the process behaves with regard to temperature. Looking down the long list of data is not helpful, he needs some tools.

Example 1-2: A pharmaceutical company is considering two types of tanks for their fermentation process. It is believed that the yield from one tank is higher than from the other, but the company would like to investigate this before deciding which tank to use.

Example 1-3: Measurements of assay from two stability studies, each consisting of three batches, are analyzed together. The analysis is supposed to show how an assay develops over time, if the development is the same for batches in the same study or, if possible, the same in all batches.

Example 1-4: In a production process, one wants to raise the yield. There are a number of factors that may influence the yield, such as holding time, feeding speed, and various conditions of the raw materials. Which of these actually has an influence, and how large the influence is, has not been established. While a lot

Pharmaceutical Sciences Encyclopedia: Drug Discovery, Development, and Manufacturing,
Edited by Shayne C. Gad