

# **SHELF LIFE ESTIMATION FOR SINGLE AND MULTIPLE STORAGE CONDITION**

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Experiments to evaluate shelf life are required in order to label product expiry date. In these experiments potency and degradation-products are followed until allowed limits are reached. Most shelf life experiments follow the ICH guideline “EVALUATION FOR STABILITY DATA” Q1E in the stability experiment planning (number of batches and time intervals for data collection and analysis).

This talk will explain the statistical methods indicated by the guideline to obtain product shelf life, and how this method can be extended in two special cases:

- a. When the company wishes to lower the released potency concentration
- b. When the product has 3 different storage conditions, freezing, 2-8C and room temperature.

Lastly, considerations for “good biostatistics consulting practices” will be discussed.

**Keywords: Shelf Life Estimation, multiple storage conditions, good consulting practices**