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Significance of stability and temperature excursion studies for biologistics

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To ensure product safety and efficacy, protein therapeutics must meet defined quality characteristics after manufacture as well as at the end of their designated shelf lives. Many physical and chemical factors can affect the quality and stability of biopharmaceutical products, particularly during long-term storage in a container-closure system likely to be subject to variations in temperature, light and agitation with shipping and handling. Compared with traditional chemical pharmaceuticals, proteins are considerably larger molecular entities with inherent physiochemical complexities. Proteins are typically sensitive to slight changes in solution chemistry. They remain compositionally and conformationally stable only within a relatively narrow range of pH and osmolarity and many require additionally supportive formulation components to remain in solution, particularly over time. Even lyophilized protein products experience degradation. Advances in analytical chemistry have identified many degradation pathways that can occur in recombinant protein therapeutics over time. These pathways generate either chemical or physical instability. The presentation will cover significance of stability studies with reference to cold chain management, types of stability studies and there trend analysis with case studies and temperature excursion studies and its significance with case studies.

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