

# Lyophilization of Therapeutic Proteins in Vials: Process Scale-Up and Advances in Quality by Design

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## Introduction

Recent advances in biotechnology have resulted in various modalities of therapeutic proteins, which cover diverse forms of antibodies (e.g., monoclonal, domain, fused), small proteins (e.g., cytokines, hormones, enzymes), and complex biologics (e.g., antibody drug conjugate, pegylated proteins). Each modality of the protein pose unique challenges in stabilization due to differences in the biophysical and chemi-

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