Critical Material Attributes in the Antibody Drug Conjugates Production Processes

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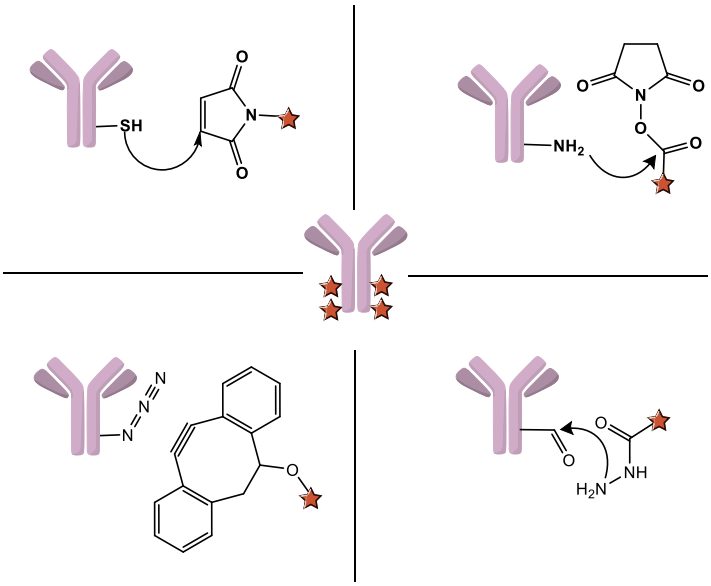
Antibody Drug Conjugates (ADCs) are a transformative class of cancer therapeutics, combining monoclonal antibodies with potent cytotoxic drugs[1]. However, ADCs present unique production challenges compared to small molecules. This presentation explores the critical chemistry and production processes of ADCs, with a focus on conjugation technologies and within the Quality by Design (QbD) framework[2], emphasizing the importance of Critical Process Parameters (CPPs) and Critical Material Attributes (CMAs).



The high molecular weight of monoclonal antibodies, compared to linker-payloads, poses unique challenges in conjugation reactions. Low concentration contaminants in solvents and buffers can significantly impact ADC quality. We will present use cases demonstrating the successful management of CMAs in ADC production, illustrating how rigorous control over material attributes and robust analytical methods lead to effective ADCs.

Understanding the impact of impurities in starting materials and reagents, along with robust analytics and a secure supply chain, is crucial for producing safe and effective ADCs.

[1] Udofa E, Sankholkar D, Mitragotri S, Zhao Z. *Bioeng Transl Med.* 2024; e10677.
[2] Li, M., Zhao, X., Yu, C. *et al. Pharm Res* **41**, 419–440 (2024).