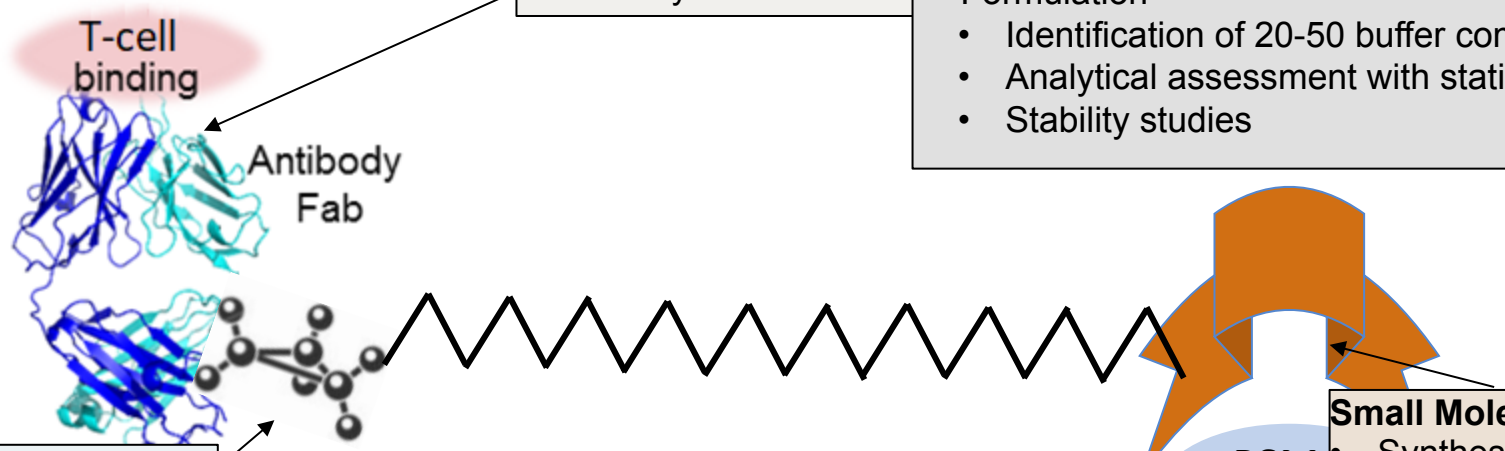
PROCESS DEVELOPMENT & GMP MANUFACTURING AT 5 CMOS

Fab with incorporated UAA – US & EU
- Extensive fermentation development due to low titer
- Analytical and bioanalytical development and qualification
- Purification development
- Conjugation development
- Formulation of DS
- Several proving and d
- GMP campaign: 6X fe
- Specification developr
- Release, labeling & sh
- Stability studies & stor

Formulation of DP - US

Pre-formulation
- Forced degradation studies
- Initial screen of buffers & excipients
- Analysis of aggregation & degradation

Formulation
- Identification of 20-50 buffer combinations and DoE
- Analytical assessment with statistical methods
- Stability studies



UAA – unnatural amino acid - US
- Analytical development and qualification
- non-GMP & GMP lots
- Specification development
- Release, labeling & shipment
- Stability studies & storage

Fill/Finish – US
- Tech transfer of analytical methods
- Process engineering
- non-GMP & GMP MFG runs
- Specifications for DP
- GMP Stability

Small Molecule Ligand & Linker – China
- Synthesis development
- Analytical development and qualification
- non-GMP & GMP MFG lots
- Specification development
- Release, labeling & shipment
- Redevelopment of final MFG step
- Stability studies & storage