Title: The Use of Surface Plasmon Resonance Spectroscopy from Development into Early Biomanufacturing

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Abstract:

Since quality attributes cannot be inspected or tested into a finished therapeutic protein product, biologics are characterized by the underlying process of making them. A wide panel of analytical methods is needed in order to describe the product as well as the process of making the product.
Automated sensor chip systems, such as the Biacore platform of instruments, provide an ideal platform for the characterization of antibody-based therapeutics as well as an outstanding tool for quality control.

Surface plasmon resonance can be used in a multitude of ways during product development:

- Detailed characterization of binding properties of lead candidates
- Use in the development of high producer cell lines
- Fermentation and downstream process development
- Formulation development
- Functional assays to assess product quality
- In-process controls
- Stability monitoring
- Assessing comparability upon process changes

Although alternative methods do exist, most of the approaches require more effort in maintaining systems, more hands-on labour, and longer development timelines. The automated surface plasmon resonance-based Biacore systems allow for very fast assay development and implementation into the development lab. Moreover, method transfer into the QC and production areas is facilitated due to the limited manual steps involved in performing the analysis.

The presentation covers applications of the Biacore system during product development as well as qualification and transfer to a CMO with special emphasis on method development and robustness testing. Validation of the Biacore system will be discussed with respect to current guidelines.