

Cell-based assays with Bob White

Interviewer: Hi, we're here with Dr. Bob White, a group leader with our labs, who specializes in biologics analysis focusing on cell-based assays. To start our discussion on cell-based assays, could you please tell us why cell-based assays are important to protein drug discovery, development and characterization?

Bob: Cell-based assays provide a valuable research tool for drug discovery and development. Whether used in high-throughput screens of small molecule libraries or during refinement of a protein sequence, these assays illustrate the utility and flexibility offered by *in vitro* approaches that retain biological relevance. Increasingly, cell-based assays are included during protein drug product release and stability as a measure of potency.

Interviewer: What are the reasons for inclusion of cell-based assay in biopharmaceutical product characterization and testing?

Bob: Subtle changes in protein structure can occur as a result of manufacturing process alterations or product degradation -- for example, misfolding and other high-order changes -- and may not be detectable by other complex characterization methods. Conversely, subtle changes in the structure of a large molecule may be detected by an analytical method without affecting drug potency. With this juxtaposition of capabilities, PPD can maintain a cell-based assay for drug potency, giving the product manufacturer or sponsor rapid means of identifying meaningful product changes.

Interviewer: How do cell-based assays support the goals of product safety and efficacy?

Bob: Our first charge in the pharmaceutical industry is to deliver a safe and efficacious product to the consumer. Cell-based assays can provide the most direct measure of a product's efficacy. Unlike small molecule drugs, biopharmaceutical potency does not always correlate with concentration. A properly developed cell-based potency assay will assist a manufacturer in process development by offering a rapid assessment of potency.

Interviewer: And finally, what are the regulatory requirements regarding cell-based assays?

Bob: Regulatory agencies expect potency assays, such as cell-based assays, for new generations of biopharmaceutical drug products. The United States Pharmacopeia has made a significant investment in normalizing expectations of cell-based potency assays with recent revisions to Chapter <111>, *Design and Analysis of Biological Assays*. This new guidance takes the focus away from directives and requirements and discusses biological assays in terms of concepts and expectations. While important to the goals of a cell-based assay, this paradigm shift creates many uncertainties. With our expertise in quality and regulatory issues, PPD is prepared to guide cell-based potency assay development and validation for new generations of biologics.

Interviewer: Thanks, Bob, for taking the time to provide this introduction to cell-based assays, and their unique applications and requirements for biomolecule analysis.

Bob: My pleasure.

Interviewer: For further information about this topic, please visit our cGMP Web pages or fill out the [contact form](#).