

Hitchhikers Guide to the Galaxy of Prior Knowledge – What Makes Sense for the More Efficient Development of Biologics

WCBP Workshop

Prior Knowledge: Molecules, Methods and Process

Prior Knowledge Definition and Abstract

Definition:

Knowledge of established and accepted scientific principles that can be used as a guidance to derisk and/or expedite development

Abstract:

The speed and efficiency of development are critical success factors for the next generation of biological therapeutics. While there is an abundance of prior knowledge that can facilitate accelerated development, it is essential to understand how best to apply this knowledge. This workshop will concentrate on prior knowledge related to the established and accepted scientific principles that can serve as guidance to mitigate risks and/or expedite development. The emphasis will be on protein-based modalities, including monoclonal antibodies (MAbs), multi-specifics, and conjugates; however, many aspects of this discussion are anticipated to be universally applicable to other biologics.

Questions for Discussion

"Exactly!" said Deep Thought. "So once you do what the question actually is, you'll know what answer means."

1. Where do you use prior knowledge?
2. How can prior knowledge derisk development work or facilitate selection of most optimal process designs?
 - What are the best practices / success examples of using prior knowledge?
3. To what extent articulation of established scientific principals is helping empirical studies and expedite reviews?
 - How do you make it work to reduce development work and communicate effectively with reg authorities?
4. What are the universal aspects of prior knowledge? What is the “legitimate” prior knowledge?
5. Can proprietary prior knowledge be used effectively to facilitate review process?
6. What are the down sides of using prior knowledge? Can it be overused?
7. What are the roadblocks to use of prior knowledge?