

## **REPLACING ANIMAL-BASED HYDROLYSATES IN BIOPHARMACEUTICAL PROCESSES WITH ANIMALFREE AND CHEMICALLY DEFINED ALTERNATIVES TO REDUCE REGULATORY CONCERNS**

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Many biopharmaceutical products are routinely manufactured with biological systems (i.e. mammalian and/or microbial cell lines) and consequently, concerns regarding the product's quality, efficacy and safety are raised. Due to the complexity of these "biological systems," many regulatory agencies intensely scrutinize these products prior to approving them for human usage. When working with biological systems, it is presumed that the cultivating medium plays a significant role in product manufacturing; specifically, in terms of product efficacy, quality and titer. To achieve cost efficiency and titer requirements in commercial scale processes, protein hydrolysates are classically used complex sources of nitrogen to support cellular growth and productivity. Over the past century, the main types of protein hydrolysates are typically made from animal-based materials such as milk (e.g. casein), muscle tissue, and organ meats (i.e. heart, brain, spleen). These animal-based hydrolysates have been shown to play a crucial role in vaccine production and food fermentations where high-density, productive cultures are required to achieve the final output. However, with incidences of bovine spongiform encephalopathy occurring over the past decade, regulatory bodies have become more concerned with the use of animal-based materials in fear of transmitting animal diseases to humans. To address these concerns, many hydrolysate suppliers are starting to produce vegetable-based hydrolysates (i.e. soy, wheat, corn, pea, etc.) and yeast extracts. In addition to these vegetable sourced hydrolysates, a handful of companies are developing chemically-defined media and/or supplements to completely remove hydrolysates from media formulations. As a leading, global manufacturer of complex nitrogen sources, Kerry offers a multitude of various protein hydrolysates, yeast extracts and chemically defined media to meet the needs and desires of numerous markets.