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Accelerating Scientific Discovery

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What you can't see just might hurt (or maybe help) you and maybe someone else

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Biotherapeutic proteins have established a solid presence in the treatment of a wide spectrum of diseases. Yet biological drug therapy can lead to paradoxical effects such as an actual worsening of the disease or unexpected pharmacokinetic (PK) outcomes, which can range from benign to life threatening. The European Medicines Agency (EMA) and the US Food and Drug Administration (FDA) have recently published new guidelines calling for enhanced scrutiny-particularly with regard to analytical data, which could affect product PK and immunogenicity. This guidance has become most relevant in the realm of biosimilars or "biobetters" and is intended to assist companies in demonstrating that a proposed therapeutic protein product is fundamentally equivalent or superior to a reference product. The importance of extensive analytical characterization is critical to demonstrating that the proposed biosimilar product is highly similar to the reference product. To distinguish a candidate from a reference compound, variants can be efficiently identified and isolated by an approach known as displacement chromatography (DC). As manufacturing guidelines become increasingly more rigorous with a focus on detailed analytical parameters, this technology offers a new and insightful methodology for evaluation of factors contributing to the safety and efficacy of biotherapeutics. DC represents a novel approach for analysis and production of biological therapeutics as it offers the ability to enhance purity to levels ly unattainable, which can affect PK profile and performance. A biosimilar so purified becomes a "biobetter".

Biography

C. Patrick McAtee is the global manager for the biotechnology portfolio of SACHEM, Inc. in Austin, Texas. Dr. McAtee is the author of numerous publications and patents in biological drug discovery and translational medicine. He is the co-inventor of the Hepatitis E vaccine, an efficacious vaccine for non-A enteric Hepatitis (GSK) and was one of the early pioneers in the field of infectious disease proteomics. Dr. McAtee received his PhD in Biochemistry from The University of Chicago Pritzker School of Medicine and completed post graduate programs at Massachusetts Institute of Technology and The Harvard School of Public Health.

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