Emulsion-based Vaccine Adjuvants

The chapters in this volume provide a snapshot of emulsion adjuvant history, current human use and safety, and future development directions.

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The use of emulsion technology has evolved from the use of oil-rich Freund's adjuvant, used for decades in experimental immunology, cancer therapy, and briefly in an approved human vaccine to those incorporating minimal amounts of oil that have been mass produced and widely used by vaccine manufacturers. The stability as well as biological and immunological effects of emulsions are influenced by factors such as the amount of oil, type of oil, size of droplets and emulsifiers used. Because of the dramatic effects of emulsions as carriers of vaccine protein and of immune-stimulatory molecules, they have a wide and diverse potential in vaccine development. Emulsions are used to enhance the potency of antigens, enabling the use of pure, often weakly immunogenic proteins as vaccines. Similarly, emulsions can be used to lower the effective dose of antigen required or number of doses required to produce an effective immune response. Emulsions themselves are nonimmunogenic, enabling repeated administration without reduction in their effect. Despite controversy surrounding emulsions of squalene, there is an overwhelming body of data supporting their safety.

Aspects of emulsions discussed in this volume include the composition and mechanisms of action of the two leading emulsion adjuvants for human use: MF59® (Novartis, Basel, Switzerland) and AS03 (GlaxoSmithKline, London, UK). In Chapter 1, the preclinical development history of MF59 is summarized, followed by a comprehensive yet succinct review of the clinical efficacy and safety data, including postmarketing surveillance. Besides influenza vaccines, this chapter also mentions other MF59-containing vaccines under clinical evaluation, such as HIV and CMV. Chapter 2 presents the composition and biological mechanisms of AS03, and reviews the adjuvant effects on vaccine immunogenicity, efficacy and safety. In particular, the recent link to very rare cases of narcolepsy in young Scandinavian children receiving Pandemrix® (GlaxoSmithKline Biologicals, Rixensart, Belgium) is discussed. In Chapter 3, new directions in emulsion composition, manufacture, characterization and route of administration are addressed, highlighting important innovations for next-generation emulsion adjuvants.

Second only to alum-based formulations, emulsions are the most widely used adjuvants in human vaccines. Their importance in modern vaccines is underscored by their demonstrated record of stability, safety and enabling of antigen dose-sparing.
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