This presentation will summarize recent advances in immunology and vaccinology which have provided new insights into the type of effective immune responses that are required to treat or prevent different diseases and the design of adjuvants to aid in developing the desired immune response. There is a need to maintain a delicate balance between vaccine immunogenicity and reactogenicity. Evaluation of vaccine immunopharmacology (the desired immune response) and vaccine immunotoxicology (unwanted/unexpected effects on the immune system) are critical components in the development of new vaccines. In addition to pharmacology and toxicology studies in animals, new tools and technologies are being developed to distinguish between the desired immunogenic response, which will result in long-lasting immune protection and the unwanted proinflammatory response, which might result in severe injection site impact and a fever or pyrogenic response. This presentation will review the current approach for vaccine immunopharmacology and immunotoxicology assessments, including a description of the studies and assays used for these assessments.