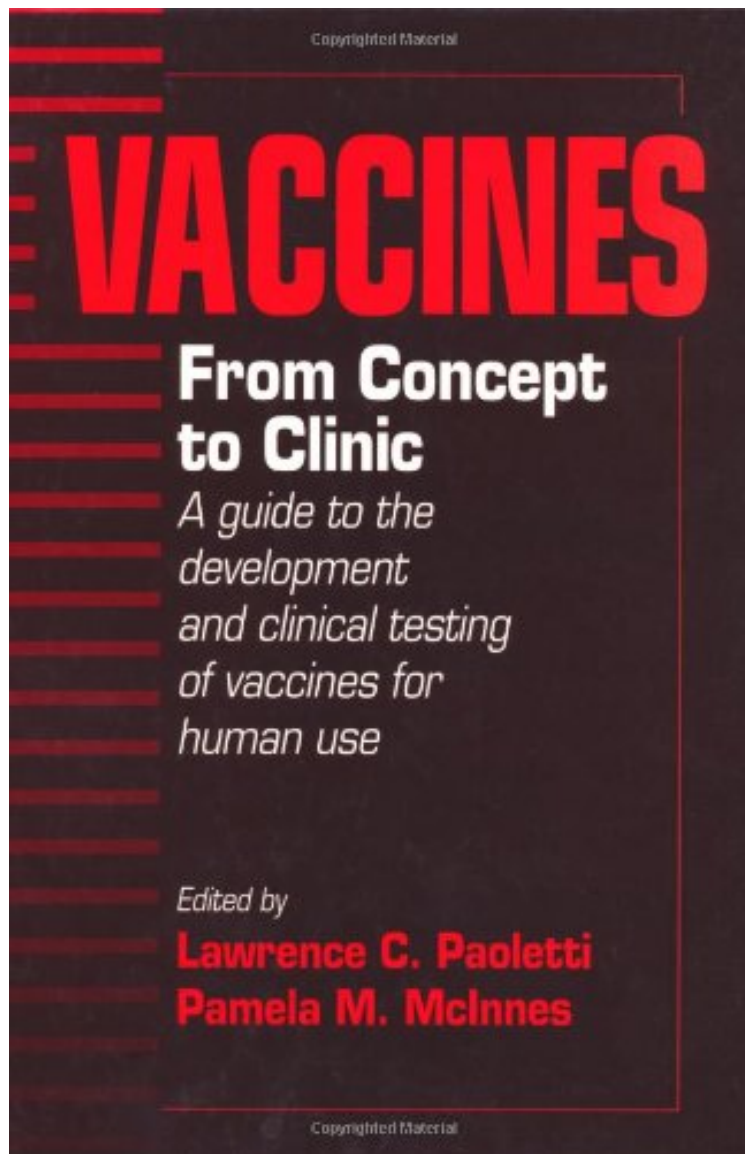


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Designed with academic vaccine researchers in mind, this book presents a road map of how a vaccine develops from an idea in a researcher's imagination, to the lab bench, through preclinical evaluation, and into the clinic for safety and immunogenicity. The result of the editors' own efforts to glean practical information on the steps necessary to manufacture, bottle, and test their vaccines for clinical trials, this book provides answers to researcher questions such as: How do I identify antigens that would produce effective vaccines? Can I produce a clinical lot of vaccine in my laboratory? How should a vaccine be bottled? Which FDA expectations must I meet? What is an IND application and how do I file it? Which CFRs apply to production of a vaccine?