

# Controlled-Release Delivery Systems for Proteins & Peptides: A Third Generation Recombinant Vaccine-Delivery System for Single-dose Subcutaneous Administration

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## Abstract

The objective was to develop Microsphere-based Delivery Systems (MDS) for controlled-release delivery of recombinant anthrax vaccine via single-dose subcutaneous administration. Microsphere-based Recombinant Protective Antigen (RPA) delivery systems for subcutaneous immunization were successfully developed at PolyMicrospheres, wherein the MDS formulations, on a single-subcutaneous dose, produced extremely high antibody titers (over 150000 in mice after 84 days and over 85000 in mice after 106 days of immunization) compared to the aqueous RPA vaccine system (at 8100).

Mice immunized with selected MDS systems were challenged with anthrax-toxin. The MDS systems, on a single-subcutaneous dose, showed 100% protection against anthrax-toxin challenge in mice, compared to <13% protected by the aqueous RPA vaccine system and 0% in the non-immunized control group. Also, rabbits immunized with selected MDS systems were challenged with live anthrax-spores. The MDS systems, on a single-subcutaneous dose, showed 100% protection against anthrax-spore challenge in rabbits, compared to <17% protected by the aqueous RPA vaccine system and 0% in the non-immunized control group.

Figure 2. Immune Response to selected MDS systems in Mice via single-dose Subcutaneous Immunization: Antibody (IgG) Titers

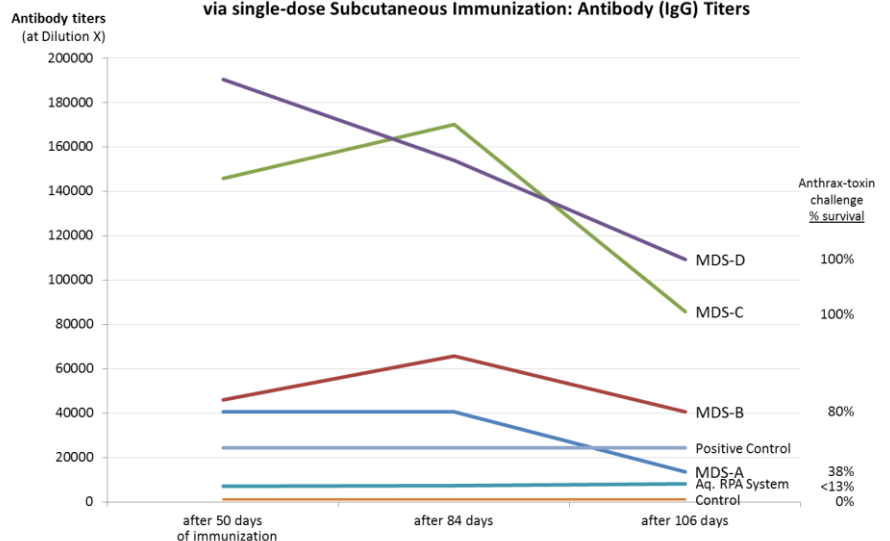


Figure 3. Efficacy of MDS formulations by a single-dose administration to rabbits followed by live anthrax-spore challenge

