

**References**  
**for**  
**Docket # 2005D-0047**  
**Guidance for Industry**  
**Considerations**  
**for**  
**Plasmid DNA Vaccines**  
**for**  
**Infectious Disease Indications**

2005D.0047

REF 1

**Reference List for Docket# 2005-0047, Guidance for Industry: Considerations for Plasmid DNA Vaccines for Infectious Disease Indications**

• **POINTS TO CONSIDER DOCUMENTS**

- 1.) Points to Consider in the Production and Testing of New Drugs and Biologicals Produced by Recombinant DNA Technology (4/85).
- 2.) Supplement to the Points to Consider in the Production and Testing of New Drugs and Biologicals Produced by Recombinant DNA Technology: Nucleic Acid Characterization and Genetic Stability (4/92).
- 3.) Points to Consider in the Characterization of Cell Lines Used to Produce Biologicals (7/93).
- 4.) Points to Consider in the Manufacture and Testing of Monoclonal Antibody Products for Human Use (2/97).

• **INTERNATIONAL CONFERENCE ON HARMONIZATION OF TECHNICAL REQUIREMENTS FOR REGISTRATION OF PHARMACEUTICALS FOR HUMAN USE (ICH) DOCUMENTS**

- 5.) ICH; Guideline for Industry: Detection of Toxicity to Reproduction for Medicinal Products (9/94).
- 6.) ICH; Guideline for Industry: Detection of Toxicity to Reproduction for Medicinal Products: Addendum on Toxicity to Male Fertility (4/96).
- 7.) ICH; Quality of Biotechnological Products: Stability Testing of Biotechnological/Biological Products (2/04).

• **FDA GUIDANCE DOCUMENTS**

- 8.) Guideline on Validation of the Limulus Amebocyte Lysate Test As An End Product Endotoxin Test for Human and Animal Parenteral Drugs, Biological Products and Medical Devices (12/87).
- 9.) Guideline for the Determination of Test Residual Moisture in Dried Biological Products (1/90).
- 10.) FDA Guidance Concerning Demonstration of Comparability of Human Biological Products, Including Therapeutic Biotechnology-Derived Products (4/96).

- 11.) Guidance for Industry: Guidance for Human Somatic Cell Therapy and Gene Therapy (3/98).
- 12.) Guidance for Industry: Content and Format of Chemistry, Manufacturing and Controls Information and Establishment Description Information for a Vaccine or Related Product (1/99).
- 13.) Guidance for Industry: Sterile Drug Products Produced by Aseptic Processing - Current Good Manufacturing Practice (9/04).
- 14.) Guidance for industry: Considerations for Developmental Toxicity Studies for Preventive and Therapeutic Vaccines for Infectious Disease Indications (2/06).
- 15.) Draft Guidance for Industry: INDs – Approaches to Complying with CGMP During Phase 1 (1/06) (This draft guidance when finalized will represent FDA's current thinking on this topic).

• **PUBLICATIONS RELEVANT TO THE ISSUE OF PLASMID DNA BIODISTRIBUTION, PERSISTENCE, AND INTEGRATION ANALYSIS:**

- 16.) Martin T, Parker SE, Hedstrom R, Le T, Hoffman SL, Norman J, Hobart P, Lew D. Plasmid DNA malaria vaccine: the potential for genomic integration after intramuscular injection. *Hum Gene Ther.* 1999; 10(5):759-68.
- 17.) Ledwith BJ, Manam S, Troilo PJ, Barnum AB, Pauley CJ, Griffiths TG 2nd, Harper LB, Schock HB, Zhang H, Faris JE, Way PA, Beare CM, Bagdon WJ, Nichols WW. Plasmid DNA vaccines: assay for integration into host genomic DNA. *Dev Biol (Basel).* 2000; 104: 33-43.
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- 19.) Parker SE, Monteith D, Horton H, Hof R, Hernandez P, Vilalta A, Hartikka J, Hobart P, Bentley CE, Chang A, Hedstrom R, Rogers WO, Kumar S, Hoffman SL, Norman JA. Safety of a GM-CSF adjuvant-plasmid DNA malaria vaccine. *Gene Ther* 2001; 8:1011-1023.
- 20.) Pilling AM, Harman RM, Jones SA, McCormack NA, Lavender D, Haworth R. The assessment of local tolerance, acute toxicity, and DNA biodistribution following particle-mediated delivery of a DNA vaccine to minipigs. *Toxicol Pathol.* 2002 May-Jun; 30(3): 298-305.

- 21.) Kim BM, Lee DS, Choi JH, Kim CY, Son M, Suh YS, Baek KH, Park KS, Sung YC, Kim WB. In vivo kinetics and biodistribution of a HIV-1 DNA vaccine after administration in mice. *Arch Pharm Res.* 2003 Jun; 26(6): 493-8.
- 22.) Bureau MF, Naimi S, Torero Ibad R, Seguin J, Georger C, Arnould E, Maton L, Blanche F, Delaere P, Scherman D. Intramuscular plasmid DNA electrotransfer: biodistribution and degradation. *Biochim Biophys Acta.* 2004 Jan 20; 1676(2): 138-48.
- 23.) Wang Z, Troilo PJ, Wang X, Griffiths TG II, Pacchione SJ, Barnum AB, Harper LB, Pauley CJ, Niu Z, Denisova L, Follmer TT, Rizzuto G, Ciliberto G, Fattori E, Monica NL, Manam S, Ledwith BJ. Detection of integration of plasmid DNA into host genomic DNA following intramuscular injection and electroporation. *Gene Ther.* 2004 Apr; 11(8): 711-21.
- 24.) Sheets RL, Stein J, Manetz TS, Duffy C, Nason M, Andrews C, Kong WP, Nabel GJ, Gomez PL. Biodistribution of DNA plasmid vaccines against HIV-1, Ebola, Severe Acute Respiratory Syndrome, or West Nile Virus is similar, without integration, despite differing plasmid backbones or gene inserts. *Toxicol. Sci.* 2006; 91(2):610-19.
- 25.) Sheets RL, Stein J., Manetz TS, Andrews C, Bailer R, Rathmann J, Gomez PL. Toxicological safety evaluation of DNA plasmid vaccines against HIV-1, Ebola, Severe Acute Respiratory Syndrome, or West Nile Virus is similar despite differing plasmid backbones or gene-inserts. *Toxicol. Sci.* 2006; 91(2):620-30.

• **PUBLICATIONS RELEVANT TO THE ISSUE OF PLASMID DNA MODIFICATIONS:**

- 26.) Krieg AM, Wu T, Weeratna R, Efler SM, Love-Homan L, Yan L, Yi AK, Short D, Davis HL. Sequence motifs in adenoviral DNA block immune activation by stimulatory CpG motifs. *Proc Natl Acad Sci USA.* 1998; 95(21): 12631-6.
- 27.) Krieg AM, Davis HL. Enhancing vaccines with immune stimulatory CpG DNA. *Curr Opin Mol Ther.* 2001; 3(1):15-24.