SDA BIO Adjuvant Systems – Technical Summary for USDA-Regulated Veterinary Vaccines

1. Product Overview

SDA BIO provides a portfolio of vaccine adjuvant and delivery systems for veterinary biologics, including:

- Nanoemulsion / Microemulsion systems (20–80 nm)
- Polymer-based gel adjuvants (Carbopol systems)
- Oil-in-water (O/W) emulsions
- Water-in-oil (W/O) emulsions
- Double emulsion systems (W/O/W)
- Saponin-based immunostimulants

Designed to support consistent immune response, scalable manufacturing, and regulatory compliance.

2. Formulation & Composition Control

Manufactured using defined and controlled raw materials:

- Pharmaceutical/industrial-grade oils (mineral oil, squalane)
- Non-ionic surfactants (sorbitan esters, polysorbates, PEG derivatives)
- Polymer excipients (Carbopol 971P / 974P)
- Purified saponin fractions

Key controls include raw material specifications, batch consistency, and controlled emulsification parameters.

3. Physical & Functional Characteristics

Typical measurable parameters include:

- Particle size distribution (DLS)
- Polydispersity index (PDI)
- Viscosity
- Emulsion type confirmation
- pH and conductivity

Functional attributes include high surface area, controlled antigen release, and adjustable immune profiles.

4. Manufacturing Compatibility

Compatible with standard vaccine production processes:

- Low to moderate shear mixing
- High-pressure homogenization (optional)
- Flexible dilution ratios (1:1 to 1:9)

Provides reproducible emulsification and scalable processing.

5. Stability Considerations

Evaluated under standard conditions:

- 2–8°C storage
- Accelerated conditions (25°C, 37°C)

- Freeze–thaw cycling

Monitored parameters include particle size, phase stability, and viscosity.

6. Regulatory Considerations (USDA Alignment)

Designed to meet expectations for veterinary biologics:

- Defined composition
- Batch reproducibility
- Safety compatibility
- Documentation readiness (CoA, specifications, stability data)

7. Application Scope

Suitable for:

- Viral vaccines
- Bacterial vaccines
- Subunit vaccines
- Emerging platforms (DNA/mRNA)

Compatible with IM, SC, and ID administration routes.

8. Risk Management Perspective

Designed to minimize risks such as formulation variability, scale-up failure, and regulatory uncertainty.

Focus on consistency, scalability, and compliance.

9. Technical Support

SDA BIO provides support for formulation development, emulsification optimization, scale-up, and stability evaluation.