Subunit Vaccines - Inactivated Vaccines

Subunit Vaccines - Adjuvants

- Adjuvant/antigen formulations (not adjuvants alone) will be licensed
- Augmentation of immune responses should be demonstrated in pre-clinical studies
- Potential toxicity concerns from adjuvant use
- Clinical formulations should be tested in toxicity studies
- If novel, adjuvant should be tested alone in toxicity studies

Subunit Vaccines – Potential Contaminants

- Endotoxin
- Residual antibiotic
- For his-tagged proteins, residual Ni
- Often difficult to differentiate protein break-down products from contaminants

Subunit Vaccines – Important Product Assays

- Potency
- Purity
- Stability

Subunit vaccines – Other Concerns

- Consistent Manufacturing
- Immune cross-reactivity to self-antigens
- Consistent secondary and tertiary protein structure
- Liquid vs. lyophilized formulations

Inactivated Vaccines - Concerns

- Validated method of inactivation
- Consistent manufacturing
- Standardized potency assay