

# Vaccines

- Preclinical Efficacy
- Preclinical Safety
- Clinical Bioanalysis



Vaccine development follows a strictly regulated pathway. At Intox, a subsidiary of Aragen, and an OECD GLP certified Test Facility with a legacy of 25+ years, we offer you a spectra of preclinical and clinical research services. Our high precision bioanalytical/ bioassay services support both non-clinical and clinical studies on vaccines and novel adjuvants.

## End-to-End Services Enabling Successful Development of Vaccines, Novel Adjuvants, Vectors

- Proof-of-concept studies
- IND supporting non-clinical efficacy/ immunogenicity (Non-GLP)
- Product characterization
- IND supporting GLP non-clinical safety assessment
- Clinical sample bioanalysis

## Proof-of-concept & Early Efficacy Studies

### *In Vitro* Assays

- Screening peptide antigens/live viruses
- In vitro immunogenicity assays

### *In vivo* potency assays

- Immunogenicity – Humoral & Cellular
- Cytokine cascade analysis
- Challenge studies
- Bio-distribution & persistence;
- PK-TK for novel adjuvants

## Product Characterization, Reagent Generation

- Purity; Impurity analysis
- Potency; Sterility
- Binding studies – affinity, avidity; ligands per particle
- Viral clearance/ inactivation
- Genomic and virus/vector DNA sequencing
- Biomarker discovery and development
- Antisera generation

### Pyrogen testing

- Endotoxin Testing (LAL)
- Monocyte activation testing (MAT)
- Rabbit pyrogen test

## IND Enabling GLP Compliant Non-Clinical Safety Assessment Services

### Test systems and routes of administration

#### Test Species

- Rats, mice, guinea pigs, rabbits, hamsters
- Dogs and Non-Human Primates, available through our collaborating test facilities

#### Routes of Administration

- Oral, dermal, parenteral (Subcutaneous, Intra-muscular, Intradermal)
- Other – Intranasal, inhalation
- Use of devices, such as needle-free injection devices

## *In vivo* Toxicity Studies Supported by

- Single dose toxicity studies
- Repeated dose toxicity studies
- Reproductive toxicity assessments
- Effects on fertility
- Prenatal developmental toxicity
- Post-natal developmental toxicity
- Pharmacokinetics / Toxicokinetics of adjuvants or vehicles
- Immunogenicity – Humoral and Cellular
- Immunotoxicology
- Biomarkers
- Acute Phase Response Assessments
- Biodistribution & Persistence

## Long Track-record of Vaccine Development

Studies performed at Intox have enabled clinical trials in India, Africa, Europe, Thailand, Australia, and several countries. Intox has been a preferred partner to world's leading vaccines manufacturer since 1996, and has supported several vaccine programs. For instance, we have partnered with

- European malaria vaccine initiative (EMVI): A collaborative project between Bharat Biotech and ICGEB
- Meningitis vaccine project (MVP) - A collaborative project between PATH, Intox and Serum institute of India
- Acellular pertussis (aP), DTaP & Tdap, and rDNA Covid-19 vaccines for a Thai-French Biotech
- The first Asian mRNA Covid-19 Vaccine
- Qualifications of novel adjuvants – for International/Inter-university/ Inter-Governmental vaccine projects

### Safety studies on vaccines - Pre COVID-19

#### Non-recombinant vaccines

- Influenza H1N1 inactivated vaccine
- Influenza H1N1 live attenuated vaccine
- Meningitis - a conjugate vaccine
- Meningococcal polysaccharide vaccine
- Rabies vaccine, inactivated

#### Recombinant vaccines

- Plasmodium falciparum vaccine.
- Malaria vaccine
- 10-valent pneumococcal polysaccharide conjugate vaccine
- Recombinant epsilon toxoid vaccine (veterinary product)
- Diphtheria, tetanus and acellular pertussis vaccines (aP, Tdap/DTaP)

### Safety studies on vaccines - Post COVID-19

- VLP (covid-19) vaccine
- mRNA (covid-19) vaccine
- DNA (covid-19) vaccine
- Novel malaria vaccine
- Novel leishmaniasis (live) vaccine
- Pneumococcal Conjugate Vaccine, 20-16 valent
- Immunogenicity booster studies / vaccine mixing studies
- Recombinant BCG vaccine

### The Intox- Aragen Advantage:

- 25 years of experience and a US board-certified team.
- Comprehensive safety testing services for regulatory driven industries.
- Comprehensive vaccine toxicology from acute and chronic to DART.
- Backed by Aragen's globally integrated team of over 3700 scientists.
- Access to Aragen's full discovery, development and manufacturing services

