**Key Analytical Challenges**

**Covance Solutions**

**Regulatory compliant analytical strategies for cell banks, virus seeds, adjuvants, intermediates, drug substance and drug product**

Vaccine subject matter expertise and regulatory consultation to align your Analytical Control Strategy and Plan with product CQAs

**Analytical and stability assay development for testing of the broad range of vaccine types to ICH, WHO guidance and regulatory standards**

Broad range of fit-for-purpose analytical capabilities for most vaccine types

**Assay progression to global GMP expectations**

Qualification and testing to global cGMP quality standards including ICH specified stability chambers

**Subunit, toxoid and conjugate vaccine structural characterization, including characterization of process and analytical anomalies**

Expertise, experience and equipment to understand peptide, protein, polysaccharide, and conjugate structure and structural anomalies

**Management of reference standards and antibody reagents supply and qualification**

Robust characterization and control of reference standards and antibodies

**Specialty Expertise**

- Biopharmaceutical development
- Platform and custom assays, most biochem and cell-based assay platforms (physicochemical, in vivo and in vitro potency)
- Biosafety testing, including Next Generation Sequencing for adventitious virus detection
- High-resolution MS, Edman sequence analysis, AAA, CD
- Polyclonal and monoclonal antibody reagent manufacturing

**Preclinical**

**Clinical Development**

**Commercialization**

**Specialty Expertise**

- Global project management
- Global GMP quality systems
- Control charting and review of all analytical data

**Vaccines have many CMC analytical challenges throughout the product lifecycle. Covance has the solutions.**
VACCINES
CMC ANALYTICAL SOLUTIONS

PRODUCT LIFECYCLE
Increasingly, regulatory agencies encourage management of the product lifecycle as an element of the new Quality Paradigm outlined in the ICH Q8/Q9/Q10/Q11 Harmonized Guidelines. Whether you employ the minimalist approach or an enhanced Quality by Design (QBD) approach, Covance can help you make better choices of how you manage and what you spend to support the product lifecycle. Your path to achieving this is the Covance Central CMC Analytical Solution.

CENTRAL CMC ANALYTICAL SOLUTION
By choosing Covance as a single, centralized CMC analytical laboratory, you can obtain higher quality analytical data more efficiently and at lower cost/fewer resources than by working with multiple providers/CMOs. This analytical data is the key to knowledge and quality risk management throughout the product lifecycle.

Avoid the inherent assay variability and analytical bias created when multiple testing laboratories/CMOs test process, drug substance and drug product

Reduce the number of analytical quality agreements that you manage

Eliminate the need for increased resources required to manage technical transfer involving multiple CMOs and filling providers

Avoid the cost of staffing and maintaining internal capabilities to support development, GMP testing, validation, in-process testing and structural characterization

VACCINES CMC ANALYTICAL SOLUTIONS FACTS AND FIGURES
• Vaccines CMC analytical experience: More than 12 supported in the last three years
• BSL-2 and BSL-3 containment
• Audited by FDA, EMA and other Boards of Health
• More than six subject matter experts in biopharmaceutical product development and regulatory CMC
• Structural characterization using OrbiTrap® and QToF MS, c-IEF, UHPLC and many other techniques
• cGMP stability chambers in accordance with ICH conditions
• Dedicated global project management
• Global GMP quality systems