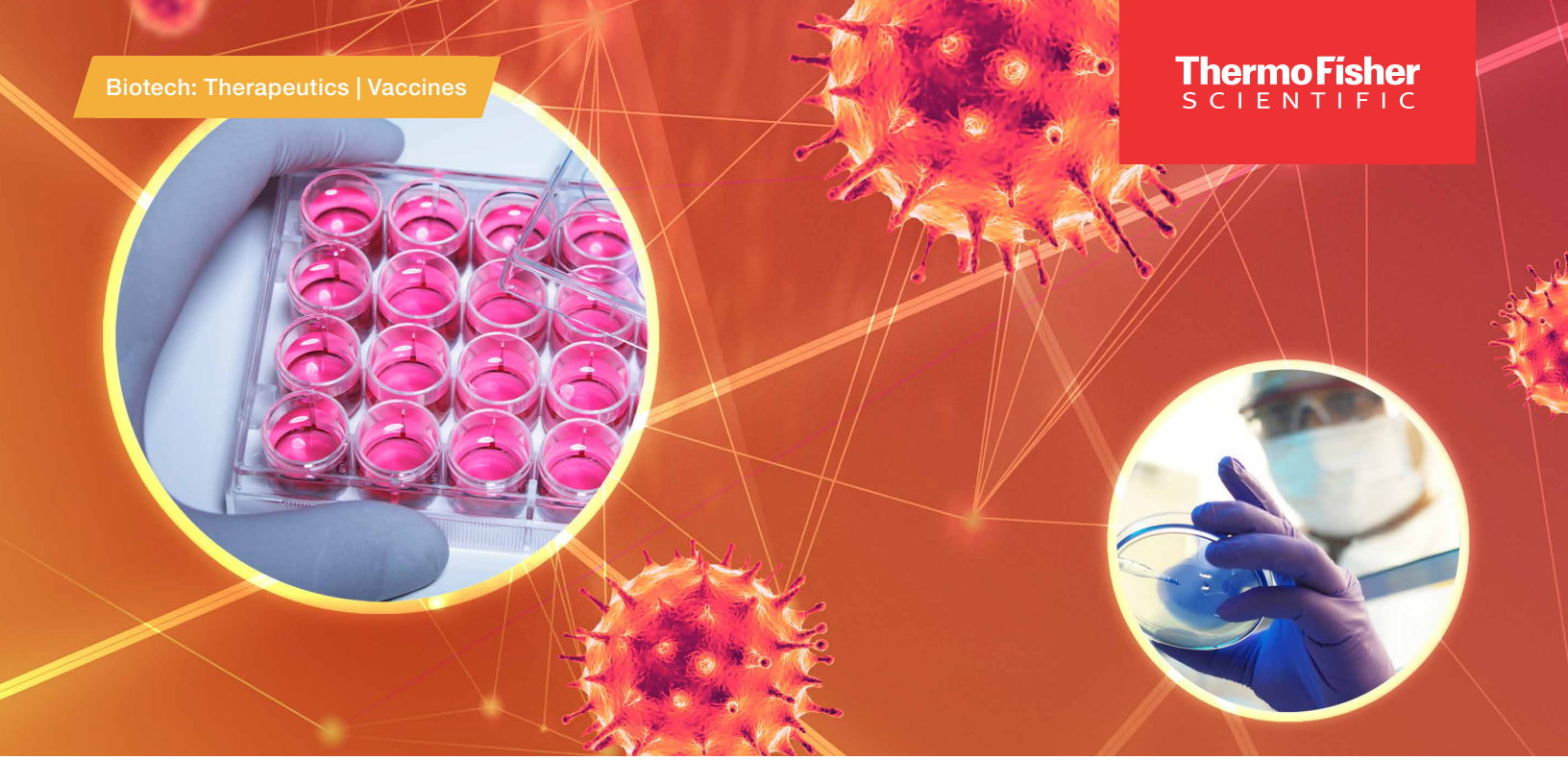

Navigating research challenges in vaccine development

Vaccines are often hailed as the ultimate weapon in the fight against infectious diseases, and for good reason—only clean water is more effective when it comes to reducing the global infectious disease burden [1]. It's no wonder biotech companies are investing time and resources in research and development in order to get these life-saving therapeutics into the clinic as fast as possible.

While they are often an effective way to induce immunity, developing a safe and effective vaccine is an uphill battle. For one thing, pathogens are constantly evolving. Even if an effective vaccine exists for a particular pathogen, this "evasion mechanism" can reduce its efficacy or render it completely ineffective, sending vaccine development researchers back to the drawing board (as in the case of the flu vaccine each year).

Navigating this and other challenges in vaccine development research can be a daunting task for biotechs fervently working to save lives today and eventually eradicate global infectious diseases. The list of hurdles is seemingly endless: shortening the timelines for discovery of vaccine candidates, production, and clinical development; ensuring high yield and quality—that vaccines are reproducible and that the immune response induced is strong enough to provide protection; predicting at early stages the safety and efficacy of vaccine candidates; and the list goes on [2].

There are also potential roadblocks associated with cost. In order to be prepared to take on regulatory challenges during the rapid scale-up to production and clinical trials, biotechs in the research and development phase of vaccine development must consider using cGMP raw materials. This high-cost, high-risk initial investment can exceed $1 billion over 12 years, but early-phase success rates are typically <10%.

Novel technologies developed in recent years can help alleviate some of the challenges in the research and development stages:

Target discovery

- Leveraging high-throughput, automated extraction technologies can enable researchers to consistently purify DNA, RNA, proteins, or cells from pathogens in a variety of sample types, thus reducing both hands-on and turnaround time as well as human error.
- Gene synthesis provides a reliable and cost-effective method for obtaining customized DNA constructs with 100% sequence accuracy, without the need to obtain template material.
- Real-time PCR systems and assays and sequencing solutions enable functional analysis.

Antigen identification and selection

- By using optimized, regulatory-compliant (i.e., animal origin–free) transient protein expression systems, vaccine development researchers can get the high protein yields they need, fast, and shorten the timeline to market. For example, the **Gibco™ Expi293™ Expression System** allows access to recombinant 293-derived proteins in just 5 to 7 days, with a 2- to 10-fold increase in protein yields compared to previous generations of transient expression systems.
- *In vitro* RNA synthesis solutions enable a streamlined workflow, which in turn shortens the timeline to market.
- Off-the-shelf or custom validated immunoassays enable detection of key proteins for proof of mechanism and concept, and response prediction. Multiplexing up to 65 targets per sample enables faster time-to-data with lower sample consumption.
- Innovative technologies in flow cytometry such as the **Invitrogen™ Attune™ NxT Flow Cytometer** enable characterization of cell populations 10x faster than traditional flow cytometers. The Attune NxT instrument allows up to 14 colors, so researchers can get more information about their cells with fewer runs.
- Fast, easy, and high-throughput solutions for gene expression quantitation allow the measurement of a gene of interest in a single well of a 96- or 384-well plate with no RNA purification, streamlining your workflow and shortening the time it takes to characterize the immune response generated by your vaccine candidate.

Count on connections

With both the pathogens and the competitive landscape rapidly and constantly evolving, biotechs have a need for speed. They also need to maintain tight control of processes. Selecting a partner with the right expertise and solutions can help vaccine development researchers quickly address challenges across the entire process—from identification, synthesis, and optimization of targets to vaccine production, delivery, and testing.

With extensive experience helping biotechs accelerate productivity and innovation, we understand your needs and offer a superior array of reliable and scalable tools, services, and support to help reach any vaccine development goals. As your ideal strategic partner, we can help you eliminate nonviable candidates quickly, and our target discovery solutions enable speed, accuracy, and the support you need to maximize screening throughput of vaccine targets.

Case Study: Cell Line Development Services for Vaccine Development

Situation

A large biotech was exploring cell line development services as part of their research to develop vaccines against SARS-CoV-2 and HIV. They wanted to screen plasma/serum samples of treated targets with the potential vaccine for antibody levels. They wanted to use inducible cell lines expressing the viral proteins on the membrane for screening purposes.

Outcome

Within two weeks, Thermo Fisher Scientific had provided access to innovative technologies, a direct connection with a team of experienced professionals, and breadth of support in both downstream and upstream vaccine development processes (including the ability to perform cell-based assays, plasma and serum sample screening for antibody levels, epitope mapping, protein–antibody binding assays, and more).

References

1. Plotkin SL, Plotkin SA. A short history of vaccination. In: Plotkin SA, Orenstein WA, eds. *Vaccines*, 4th edn. Philadelphia: WB Saunders; 2004:1-15.
2. Kaufmann SH, McElrath MJ, Lewis DJ et al. (2014) Challenges and responses in human vaccine development *Curr Opin Immunol* 28:18-26.

Our cost-effective and scalable antigen identification and selection solutions help you speedily transition from research to the clinic.

Find out more about our end-to-end solutions at **thermofisher.com/biotechvaccines**