

# Introduction

## Prologue to a Postpandemic Future

Cheryl Scott

The COVID-19 pandemic energized the biopharmaceutical industry, invigorating the vaccines segment in particular. A number of technologies were poised for advancement and made ready (in record time) for implementation as part of the worldwide effort to combat the SARS-CoV-2 virus and its subvariants. Now, as the coronavirus fades into endemic rather than pandemic status — taking its place alongside seasonal influenza and many other viruses that people can get inoculated against — the industry is taking stock of its lasting technological effects.

Not so long ago, many people considered vaccine development to be a somewhat stagnant backwater of the pharmaceutical industry. With low profit margins, long development timelines, and uncertainties related to pathogen evolution, vaccines remained for decades a business arena with few players and slow innovation. But thanks to recombinant technology and related life-science advancements, the segment was already stirring when SARS-CoV-2 came around. Previous outbreaks such as swine and bird flus, Ebola, and human immunodeficiency virus (HIV) had propelled innovations such as protein-subunit vaccines, viral vectors, and new adjuvants and delivery methods. The COVID-19 pandemic served as a proof-of-concept for a number of biopharmaceutical approaches, including of course the much-celebrated mRNA technology.

In many ways, however, this recent past could be but prologue to an explosion of possibilities for enlisting immune-system help in fighting against the many infectious diseases (and other conditions) that threaten human and animal life around the world. This insert touches on just a few of those innovations in progress. Lessons learned from recent experience — if they are heeded and applied by product developers, policy-makers, healthcare providers, and patients alike — should improve all of our chances in the next pandemic as well as against cancer and other diseases. Advances in artificial intelligence and biotechnology provide the means if both industry and society have the will to apply them prudently and intelligently going forward.

FEATURED REPORT



Technological innovation is energizing and revolutionizing a once-stagnant industry segment.

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### IN THIS INSERT

**Pandemic Lessons Learned:** First, I asked frequent freelance contributor Gareth Macdonald to seek out answers to a number of questions: What shortcomings did COVID-19 expose in the vaccine sector? What technologies emerged that could be applied widely in the future? Which companies have invested in vaccine production capacity? How prepared are we for the next pandemic? How will technologies and development strategies used during this one change things? Have vaccine developers adapted their research and development (R&D) foci? Macdonald speaks with representatives of Longhorn Vaccines & Diagnostics and the Coalition for Epidemic Preparedness Innovations (CEPI) to elucidate some lessons the industry has learned.

**Cancer Vaccination:** Metastatic breast cancer remains the second leading cause of cancer-related death in the United States. BPI's managing editor, Brian Gazaille, speaks with the president and CEO of immunotherapy developer BriaCell Therapeutics about the value of vaccination approaches to treating breast cancer and other intractable indications. The conversation features BriaCell's Bria-IMT therapy, a

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genetically engineered human breast-cancer cell line that is designed to present tumor antigens to patient immune cells, enhancing tumor destruction.

**Protein-Subunit Vaccines:** Because of their efficacy and rapid development timelines, vaccines based on messenger RNA (mRNA) played a significant role in abating COVID-19 public-health emergencies around the world. However, challenges remain for the modality. BPI editors speak with the head of SK bioscience's biological R&D headquarters to learn why established production platforms for protein-subunit vaccines will be key to mitigating future infectious-disease outbreaks.

#### **Multiserotype Glycoconjugate Vaccine**

**Processing:** Glycoconjugate vaccines comprise immunogenic carrier proteins linked chemically to specific polysaccharides, which can be isolated from a target pathogen or (increasingly) expressed recombinantly in microbial hosts. Although the complexity of chemical coupling historically has made such vaccines difficult to produce, researchers are leveraging bacterial technologies to couple glycans and carriers, helping to decrease costs. However, drug companies still need greater understanding of basic steps in glycoconjugate manufacturing. BPI associate editor Josh Abbott speaks with a Penn State researcher whose team has provided key insights into sterile filtration of multivalent glycoconjugate products based on studies of a Pfizer meningitis vaccine.

#### **INNOVATION IS KEY**

As both data and life sciences advance, innovative technologies are developed to address questions that arise with real-world applications. CEPI's Dimki Patel spoke at the January 2024 CASSS Well-Characterized Biotechnology Products (WCBP) symposium held in Washington, DC. She described an ambitious goal that the organization has set forth: "Vaccines should be ready for initial authorization and manufacturing at scale within 100 days of recognition of a pandemic pathogen, when appropriate." With an eye looking back at the difficulties associated with mRNA vaccines, CEPI focuses part of that mission on drug-delivery technologies, especially associated with thermostability and alternative presentations. Patel highlighted microarray patches in development at Vaxxas that could improve the stabilization and delivery of mRNA vaccines; aVaxziPen's thermally stable, needle-free method for delivering vaccines as a solid dose; and Jurata Thin Film's formulation of room-temperature-stable vaccines for sublingual application. And she described regulatory strategies such as templates and master files for platform technologies that could set innovative products up now for future success. The recent pandemic may have given many such developments a head start. 🌐

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