### EDITORIAL CALENDAR

JANUARY	FEBRUARY	MARCH	APRIL	MAY	
	Respiratory diseases		Manufacturing: upstream & raw materials	RNA vaccines: research directions	
JUNE	JULY	AUGUST	SEPTEMBER	OCTOBER	
Understanding & enhancing immune responses	CMC & analytics		Preclinical & clinical research	RNA vaccines: formulation & production	
NOVEMBER	DECEMBER	@	Spotlights comprise:	Vaccine Insights provide you with fantastic opportunities to:	
Manufacturing: downstream, fill/finish, & delivery		Contact Nicola McCall +44 1732 463215 n.mccall@insights.bio to discuss thought leadership and lead generation opportunities	<ul> <li>Peer-reviewed Expert Insight articles written by leading experts in the field</li> <li>Webinars, featuring industry speakers and sponsors discussing key topics specific to the Spotlight</li> <li>Podcast, written and video interviews with key opinion leaders</li> <li>On demand roundtable discussions</li> </ul>	<ul> <li>Educate your target market about your company's expertise, capabilities, and experience</li> <li>Share your latest data with organizations looking for partners and service providers in your field</li> <li>Profile your executives and scientists as thought-leaders and KOLs</li> <li>Generate qualified leads from across the global sector</li> <li>Increase awareness of your company's role in vaccines R&amp;D</li> </ul>	



# EDITORIAL CALENDAR Spotlight details

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### FEBRUARY

### MARCH

#### **Respiratory diseases**

- What's next for COVID vaccines?
  - Prospects for developing next-gen vaccines capable of generating durable, broad-based antibody and T cell immunity
- Respiratory syncytial virus (RSV):
  - What will be the impact of newly approved RSV vaccines?
  - Determining the most appropriate schedule of RSV and other respiratory vaccines to maximize uptake and effectiveness
- Invasive pneumococcal disease:
  - the impact of new low-cost vaccines in a competitive market
  - the race for higher valency—where is the limit?
  - harmonizing pneumococcal vaccine schedules
- Quantifying the risk from avian influenza and developing vaccines

### **APRIL**

## RNA vaccines: research directions

### Manufacturing: upstream & raw materials

- ▶ How can manufacturers mitigate supply chain disruption?
- Localized vs centralized manufacturing
- Optimizing manufacturing footprint
  - In-house manufacturing vs CMO
- ▶ Could combined/flexible facilities improve efficiency?
- Scaling up vaccine manufacturing
- Novel expression systems for vaccine production
- Toward 100% chemically defined media, and easier generation of chemically defined media for individual processes
- ▶ Stainless steel vs single-use bioreactors for vaccine manufacture
- Maintaining "warm base" capacity for pandemic preparedness
- Challenges for training and tech transfer in vaccine manufacturing

#### What will be the next testing ground for RNA vaccines? Where, when, and how will it prove its capabilities, and how much optimization will be needed on a case-by-case basis?

- Will RNA be broadly applicable or only suited to narrow applications such as pandemic vaccines?
- Evolving knowledge on mechanisms of action—decreasing reactogenicity while retaining potency
- ▶ Modifying mRNA vaccines to induce mucosal immune responses
- ▶ Adapting mRNA for use in personalized cancer vaccines
- How will the drive towards cancer vaccines impact infectious disease applications?
- Latest on next-gen RNA vaccine platforms
- ▶ Regulatory expectations for RNA vaccines—a platform technology?

### Understanding & enhancing immune responses

 Addressing immune imprinting/original antigenic sin for COVID-19 and other circulating RNA viruses

JUNE

- Advances in immune profiling and understanding mechanisms of action
  - Profiling immune cells with single-cell analysis tools
- Applying tools such as NGS, flow cytometry, CyTOF
- Systems serology to decode vaccine-induced immune responses
- Understanding individual immune response to vaccination
- Standardizing data recording, storage, and sharing
- Embracing AI and machine learning for resolving immunological data and antigen design
- Understanding and targeting mucosal immunity
- ▶ Novel adjuvants, adjuvant platforms, and combinations





### EDITORIAL CALENDAR

JULY	AUGUST	SEPTEMBER
CMC & analytics		Preclinical & clinical research
<ul> <li>Greater connection of CMC with clinical design and understanding quality expectations to avoid bottlenecks</li> <li>How will control strategy evolve with digital twin and digitalization?</li> <li>Patient-centric specifications</li> <li>What is needed from a CMC perspective to achieve CEPI's 100 days goal for pandemic vaccines? Risk-based approaches and innovativations</li> <li>Advances in process analytical technology</li> <li>Monitoring online in real-time</li> <li>Overcoming limitations of current technology (e.g., sensitivity)</li> <li>Lowering barriers for implementation</li> <li>Increased automation</li> <li>High-throughput tools for process development and analytics—forward-looking methods while remaining QC-compliant</li> </ul>		<ul> <li>Closing the gap between preclinical and clinical results: better animal and in vitro models</li> <li>Measuring a wider range of immune markers</li> <li>Could evidence from human infection models support approvals?</li> <li>Clinical trials in populations with varied levels of immune competence</li> <li>Correlates of protection—regulators and licensure criteria</li> <li>Vaccine development for special populations</li> <li>Use of Al to clean up clinical data sets and reduce protocol deviations</li> <li>Making the most of real-world vaccine efficacy data</li> <li>Safety—understanding adverse events after vaccination</li> <li>What is a platform technology and how will they be regulated?</li> <li>Regulatory harmonization between regions</li> </ul>
OCTOBER	NOVEMBER	DECEMBER
RNA vaccines: formulation & production	Manufacturing: downstream, fill/finish, & delivery	

- Sourcing and supply of raw materials—addressing the cost of goods
- ▶ Addressing expense, manufacturing complexity, and IP hurdles of LNPs with next-gen delivery particles
- ▶ Toward temperature-stable formulations
- Overcoming hurdles in production
  - Traditional vs cell-free plasmid DNA production
  - Streamlining IVT and capping
  - Optimizing purification, especially of larger RNA constructs chromatography, TFF
- Analytical methods and control strategy for mRNA-LNPs
  - Evolving tools (e.g., NGS & mass spectrometry) for characterization
  - Moving to next-gen assay panels, specific to RNA products
  - Improved methods for detecting residual dsRNA (e.g., dPCR)

- Exploring the need for better purification solutions across platforms
- ▶ The environmental sustainability of vaccine manufacturing operations
- > Shared challenges and solutions for vaccines, biologics, and advanced therapy manufacturers
- Addressing extremes of volume
- Challenges of small-scale cancer vaccine production
- Efficient scale-up to meet pandemic preparedness needs
- ▶ Challenges and solutions in cold chain/controlled temperature chain:
  - Routine and corrective maintenance
- Sustainability
- Role of automation and Al

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- ▶ Increase awareness of your company's role in vaccines R&D

