Wacker Biotech has an outstanding track record and more than 20 years of experience as a contract development and manufacturing organization (CDMO) producing biologics, live microbial products and vaccines using microbial hosts. Our experience, capabilities and capacities allow us to provide full service from process transfer and/or development to (pre)clinical and commercial manufacturing. Wacker Biotech has profound expertise in the process development and manufacturing of a variety of vaccine products, including live attenuated, inactivated, (conjugated) polysaccharide and protein-based vaccines.

During the 1990s, the use of protein-based and conjugate vaccines started to rise, with the aim of reducing adverse reactions to whole pathogen antigens and to induce stronger and longer-lasting immunity than could be achieved through unconjugated polysaccharides.6

Today, most approved bacterial vaccine products are conjugated (polysaccharides) and protein/toxoid antigens, which have gradually replaced traditional whole pathogen and polysaccharide products. This reflects a paradigm shift in vaccine production towards well-defined antigens, which in fact make up a large portion of the vaccine candidates currently evaluated in clinical trials.5

More Than 20 Years of Vaccine Manufacturing Experience
Wacker Biotech has an outstanding CDMO track record and uses a variety of microbial hosts to produce all types of established and future vaccine products. Our work rests on a foundation of more than 20 years of experience as a CDMO for vaccines, with deep expertise in manufacturing live attenuated, inactivated, (conjugated) polysaccharide and protein-based vaccine products.

Our production sites are home to state-of-the-art biosafety level 1 (Halle, Jena) and level 2 (Amsterdam) facilities, as well as explosion-proof room (Amsterdam) for manufacturing vaccine products under ICH and GMP quality guidelines. Our stainless steel fermenters range in capacity from 270 L to 1,500 L, and our single-use reactors can accommodate volumes up to 250 L.

### Vaccine Capabilities and Capacities
- >20 years of vaccine manufacturing experience
- From bench to commercialization (preclinical, phase I to III, commercial product)
- Process and analytical transfer, development and validation
- >650 GMP batches manufactured and released
- Inactivated, live attenuated, (conjugated) polysaccharide and protein-based vaccines
- Cutting-edge capacities
  - 270 L, 350 L, 2 x 1,500 L stainless steel bioreactors
  - Single-use bioreactors for volumes of up to 250 L
  - Biosafety level 1 (Halle, Jena, Amsterdam) and level 2 (Amsterdam) facilities
  - Explosion-proof room (Amsterdam)
  - Bulk lyophilization of up to 65 L
  - Fill-and-finish facility (DIN 2R to 20R vials) for up to 20,000 vials per batch

### Selection of Vaccine Strain Experience
- *Escherichia coli*
- *Corynebacterium diphtheriae*
- *Haemophilus influenza B*
- *Klebsiella oxytoca*
- *Neisseria meningitidis A, C*
- *Pseudomonas aeruginosa*
- *Salmonella typhi*
- *Saccharomyces cerevisiae*
- *Vibrio cholerae*
of up to 250 L. Furthermore, at our site in Amsterdam, we operate a modern GMP fill-and-finish facility for aseptic filling operations of DIN 2R to 20R up to 20,000 vials per batch as well as bulk lyophi-
zation up to 65 L. Wacker Biotech has pro-
duced and released more than 650 GMP vaccine batches for clinical (phase I to III) and commercial applications. We can provide quick, flexible and efficient solutions for customer-specific process development and process transfer, complemented by tailored analytics for quality control. Our expertise and capabilities make us a highly reliable partner for manufacturing classic vaccines as well as frontline and emerging future vaccine products. In addition to manufacturing a variety of live attenuated, inactivated and protein-based vaccines, Wacker Biotech also has a great deal of experience in manufacturing (conjugated) polysaccha-
ride vaccines for clinical and commercial applications. A schematic overview of how such conjugated polysaccharides are typically produced at Wacker Biotech is provided in the figure above.

References

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