Viral Vector Manufacturing

Viral vectors are highly valued to transfer genetic material into target cells and therefore are explored as vehicles in diverse therapeutic areas. Part of the enthusiasm of the scientific community for vectors is their promise of low cost and safe manufacturing coupled to high product efficacy and excellent safety. Engineered via molecular biology, viral vectors from well-studied natural viruses have been engineered including adeno-associated virus (AAV), lentivirus, adenovirus, or Modified Vaccinia Ankara (MVA) and have been explored for several decades now. Vectors are predominantly used to carry desired genetic material into cells or tissues with the purpose to correct genetic deficiencies or elicit host immune responses against either self-antigens (cancer) or foreign antigens (microbial, parasitic or viral pathogens).

Therapeutic use of viral vectors

In the field of vaccines, several viral vectors have shown high promise in combatting human or veterinary pathogens that demand a broad spectrum immune response from the host to gain control. Here, the ability to induce potent T-cell reactivity is unique for viral vectors as compared to, for example, protein-based, whole killed, split-, or subunit vaccines. Therefore, viral vectors are very promising as vaccines against complex pathogens such as HIV (AIDS), *Plasmodium falciparum* (malaria), *Mycobacterium tuberculosis* (TB), and diverse bio-threat targets like filoviruses (Marburg, Lassa, Ebola) to name but a few.

Sidus®

Viral vector-based products are new molecular entities and therefore the development of platform technologies, i.e. vector design, packaging systems, production procedures, purification methods, and release testing requirements are under development while already assessing efficacy and safety aspects of viral vectors in clinical trials. It is therefore that often companies developing viral vector products seek support from external expert organizations to help develop a robust process and deliver clinical grade product while focusing internal resources on platform improvement technologies thereby delivering next generation, improved vectors (safer, more immunogenic, less pre-existing immunity, higher yield, cell targeted etc.).

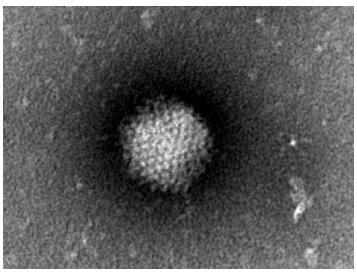
While most companies have researched, and developed a vector best suited for their therapeutic application, many don't have the experience, facilities or internal resources for process development and GMP manufacturing. In these cases, outsourcing such activities to an experienced partner is a valid option. At Batavia Biosciences, production of diverse viral vectors is deeply imbedded under our SIDUS® technology brand.

Advances of outsourcing clinical manufacturing

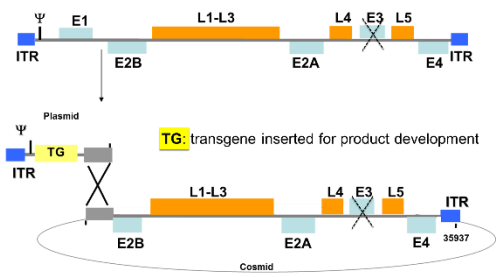
Under the SIDUS® brand name, Batavia Biosciences markets in-depth knowhow on research, development and clinical manufacturing, thereby offering a platform to accelerate the journey from bench to clinic for novel and existing vector systems. SIDUS® technology offers an end-to-end solution, i.e., optimized process development (production & purification), production and release of Phase I/II clinical batches, and provide a scalable process and support to ensure a smooth transfer for Phase III testing and to a commercial manufacturer.

The SIDUS® technology platform

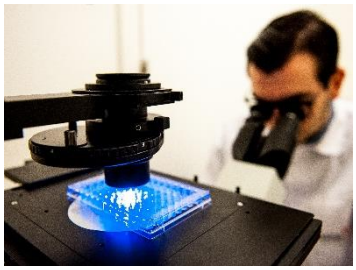
The SIDUS® platform covers the entire range of activities from bench to clinic, i.e., (I) manipulation of vector back genome, (II) insertion of desired genetic material in vector genome, (III) generation of recombinant virus from DNA or RNA, (IV) generation of pre-master virus seeds and master virus seeds, (V) process development up to 100 L scale (production & purification), (VI) development of assays for in process control and release of research and clinical material, (VII) drug substance and drug product manufacturing, (VIII) tech transfer to a late stage/ commercial manufacturer. The SIDUS® technology, anchored in protocols, work instructions, pharmaceutical grade raw materials and selected equipment, allows to perform the viral vector manufacturing process from miniature scale to rapidly lock in the process to direct scale-up to 200 L scale for a Phase I product. This linear scalability of production allows cost effective delivery of drug product in record time. Batavia Biosciences experienced in house QP, QA system and QC department facilitates the release of clinical product.



Electron Microscopy: Adenovirus



Adenoviral vector



Full analysis capabilities

SIDUS® offers

- Full-fledged viral vector capabilities and in-depth knowhow
- Delivers cost and time effective viral vector development
- 100% successful track record in delivering Phase I and II viral vector products
- Support in IND as well as IMPD filing of viral vector products

for more information: **www.bataviabiosciences.com**