Accelerate Analysis

**Only 1 out of each 50 biopharmaceutical new prod-
uct candidates makes it through the research phase
into clinical trial testing and subsequently to the
market. This high attrition rate is predominantly in
the early development phases. It is therefore imper-
ative that technologies become available that allow
significant de-risking of biopharmaceutical product
trajectories in the early research and development
phase.**

Why SCOUT® ?

With the introduction of the "Design of Experiments"
(DoE) approach, identifying critical quality attributes
and performance attributes like yield, glycosylation, po-
tency, a big step was made in de-risking. That said, it is
often found that due to the complexity of many novel
molecules, the number of parameters that need to be
tested still requires vast numbers of experiments which
are time consuming and costly. Therefore, Batavia Bio-
sciences has developed SCOUT®, a platform that inte-
grates scaled down, high throughput cell culture sys-
tems with high throughput purification and analytical ca-
pabilities. SCOUT® allows for the rapid and cost effec-
tive generation of vast data sets and has proven to help
you to de-risk your program in the early phases of de-
velopment and significantly improves the success rate.

How it works

The SCOUT® platform represents a qualified, scaled-
down high throughput system for optimizing upstream
and downstream processes for all major classes of bio-
pharmaceuticals be it proteins, antibodies, viral vac-
cines, or viral vectors for gene therapy protocols. In the
upstream development SCOUT® is frequently used for,
yield and growth optimization projects and has proven
its worth with documented increases in yield of at least
5-fold. The upstream process is typically performed at
5-20 mL scale and allows hundreds of cultures to be
tested in parallel. Results obtained with SCOUT® have
been successfully scaled up to 1000 L bioreactor vol-
ume hence demonstrating scalability of the obtained re-
sults. In downstream development SCOUT® is used to
process high numbers of samples using scaled-down
purification technology ranging from 50 μL (96 well
plates) to 2 mL tubes (customized spin filters and spin
traps).

Accelerate biotechnology

The influenza case study

The high throughput, SCOUT® technology is able to provide sufficient purified material to generate robust, representable analytical data, including glycan profiling, aggregation analysis, glycan analysis, and in vitro potency testing (figure 1). After demonstrating that the SCOUT® upstream and downstream technology mimicked data from a commercial influenza vaccine manufacturing process (1000 L; HA purification by centrifugation; three influenza virus strains), the technology was used to screen for >60 new production media with the aim to increase the HA production for each strain (figure 2). In total, the experiment was performed in one run with 66 different production media, 3 different influenza strains, 5 samples per medium, thus 2250 conditions were tested. The entire experiment was executed within three weeks' time and fully occupied only two skilled technicians.

The example with influenza virus described above was based on the MDCK platform where the cells were growing on micro-carriers. Batavia has mastered the growth of a wide range of mammalian cell lines (CHO, HEK293, Vero, and MDCK) as well as diverse microbial species for optimization of protein production for growth in its SCOUT® system. In conclusion, SCOUT® provides a powerful cost effective tool in biopharmaceutical product development and is employed by Batavia Biosciences hand-in-hand with the DoE approach and Quality by Design principles as outlined in the FDA guidance on Pharmaceutical Development (Q8).
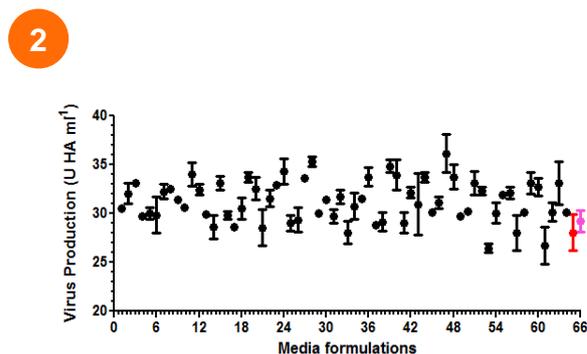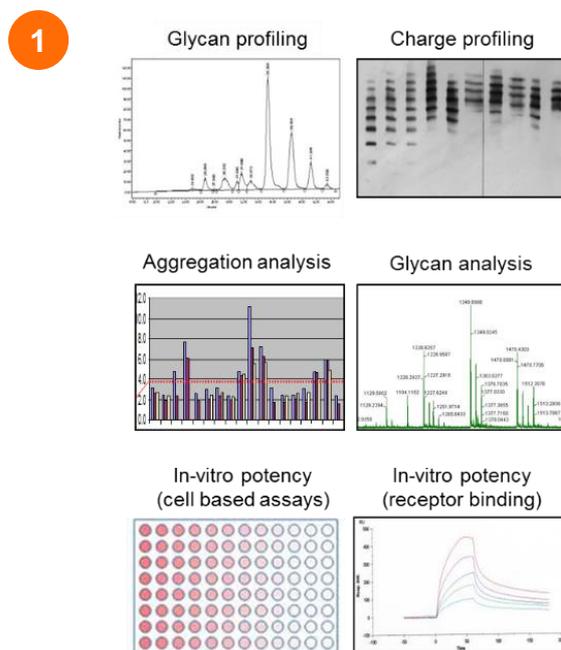
SCOUT® offers

- High throughput analysis platform
- Scaled-down testing, requires minimal amounts of material
- process hand in hand with DoE approach

- Downstream development can be initiated when upstream development is still in progress
- Powerful cost effective tool

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

BATAVIA biosciences