**Manufacturing challenges**

- **Viral vector manufacturing capacity** is a barrier that is limiting the development of therapies and places the industry at risk.
- We’ve seen an improvement in capacity but demand has increased.

**Cell line and media selection**

Two cell lines were cultivated in three media using historical culture parameters, on the Ambr® 15 system, transfection in triplicate.

**USP Optimisation**

Statistical design of experiments (DoE) was applied to determine the relationship between factors affecting the process and the output of that process. Transfection efficiency and AAV titre were selected as outputs of the process.

**USP Scale-up**

Scale-up from Ambr® 15 to Ambr® 250:
- Maintenance of geometric similarity
- Equal specific energy destruction rates (volumetric power input E/MV)

DSP optimisation

Multi-angle dynamic light scattering (MADLS®) from Zenises®. X-axis represents cycle (days) and Y-axis represents intensity of the signal.

**Conclusion**:

Here is presented a scalable AAV manufacturing platform using STRs bioreactor for production. Production process was defined and optimised at small scale and is now being scaled up to production scale. Purification and analytics are already enabling efficient end to end process but will be further optimised.