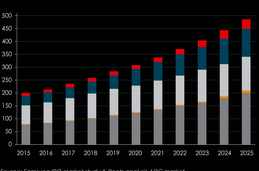
Vironova

STOP MEASURING THINGS IN THE DARK!

01.

Regenerative medicines (cell and gene therapy) **is a young but growing market**

Global biologics market, by product category (US $ billions)



Source: Samsung IPO market study & Roots analysis ADC market

02.

#1060 Number of Clinical Trials underway worldwide by end of Q1 2019

PHASE I: 349 **PHASE II: 618** **PHASE III: 93**

Most companies are just at the beginning of their journey (in phase I or II, very few have come to III) or about to enter when scale up for a commercialized manufacturing process is initiated.

This is when the costs increase sharply and one suddenly discovers problems that did not exist while working in lab scale.

03.

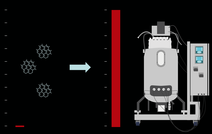
NO CLEAR FDA GUIDELINES
for cell and gene therapy yet

Because of its constant evolution and development the FDA and other regulatory authorities have yet to formulate clear guidelines to prove that:

- is safe and effective
- the manufacturing process is robust

04.

WHY IS SCALE UP SUCH AN ISSUE?



10ml cell culture

1000L cell culture

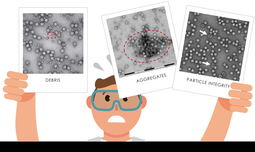
Moving from lab scale to production scale With biological material is not trivial. Process conditions that worked well in small scale can give you unwanted surprises when scaling up. There can be shear forces and stress for cells and viruses that make them break, clutter etc.

Critical quality attributes can be lost and safety of the patient can be at risk

05.

Problems can arise at many steps during the production process

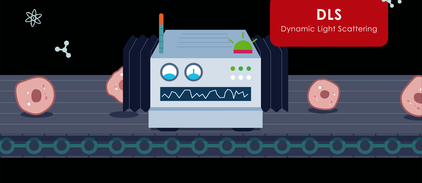
Unoptimized process conditions may affect the morphology of the virus.



06.

Drawback of indirect methods

When developing a manufacturing process for gene therapies you need to monitor critical quality aspects, but often the analytical methods used do not provide a full picture of what is going on in your viral vector sample.



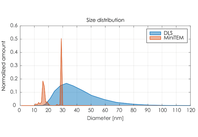
DLS for particle size distribution

For example DLS is standard equipment in most labs and first choice for particle size distribution, studies of particles and to detect aggregates.

However this method does only give limited information when returning a number and a graph that can be difficult to interpret.

07.

A COMPARATIVE STUDY OF MINITEM™ vs DLS ANALYSIS



Comparison of the size distribution data obtained with MiniTEM vs DLS analysis

IT CAN OFTEN FEEL LIKE WE ARE MEASURING THINGS IN THE DARK.

08.

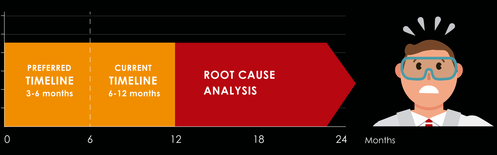
Analytical methods based on indirect measurements, may not give you the entire picture of the purity or integrity of your viral vector.

09.

A lenghty manufacturing process

... not to be delayed

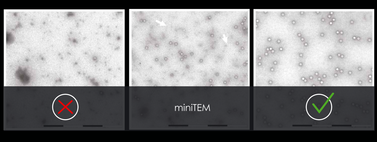
Because process developers are under pressure to shrink time to 3-6 months late surprises are unwelcomed as finding the root cause of the problem can delay the project up to a year.



10.

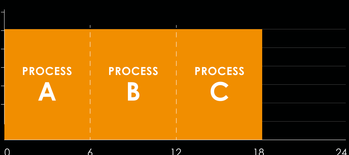
REDUCE YOUR DEVELOPMENT TIME WITH MiniTEM

MiniTEM can help you
speed up the decisions at the production line



11.

With meaningful analytics data you
can make better development decisions early



Reduce your process development time and triple the number of projects that can be run within the same timeframe

MiniTEM

REDUCE YOUR DEVELOPMENT TIME + TRIPLE THE NUMBER OF PROJECTS

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