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## **SCALE DOWN MODEL IN INDUSTRIAL CELL CULTURE PROCESSES – A POWERFUL TOOL TO ENSURE RELIABLE PRODUCTION**

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Key Words: Scale-Down Model, raw material testing, lot-to-lot variations, product quality impact

Reliability and reproducibility of therapeutic protein production is one of the key objectives of GMP manufacturing with respect to product quality and supply to patients.

But even in the age of chemical defined media, QbD and well characterized cell culture processes during manufacturing deviations can occur. While those deviations caused by human errors, equipment failures or process control (e.g. pH) can be assessed in a straightforward manner coming to satisfying results in an appropriate period of time, deviation caused by raw material lot variations are usually hard to detect. Development of risk mitigation strategies is complex since sophisticated analytical methods need to be applied and most often, additionally, vendors have to be involved in the root cause analysis.

For risk mitigation change control assessments and QC testing covering a broad spectrum of parameters and quality attributes are applied before those materials are released for use in manufacturing. Even with this tight mesh of control quite a number of incidences can be reported, demonstrating that deviations based on raw material issues have a huge impact on our business.

Here we present several case studies, where neither QC testing nor vendor and customer change control could predict the deviating process behavior observed when these materials had been used in the cell culture process at production scale. As a consequence cell culture use tests by validated scale down models have been introduced for several raw materials in the meantime. These test procedures will be presented.