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# Process scale-up issues: Relics of the past or continues to cause major headaches

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## **Process Scale-up Issues: Relics of the Past or Continues to Cause Major Headaches**

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Since the inception of biopharmaceutical industry, scale up issues hampered the success of process transfers and product commercialization. In the last 30 years, the field evolved significantly, we have gained significance experience, broadened our understanding of cell culture, and resolved issues such as shear, mixing, and aeration. Requirement of maintaining geometric similarity and scale-up parameters (power per volume or tip speed) was proven not to impact the performance of the bioreactors significantly. Today's processes could be scaled up from micro-bioreactors to full-scale production bioreactors rather easily. This talk will discuss the factors that played a significant role for this accomplishment. While we can claim we solved most of the scale-up issues, new areas of concern, mostly peripheral issues, prevent us from claiming victory. These points will be discussed with examples.