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# Application of online CO<sub>2</sub> monitoring to enable a better understanding of cell culture performance variation between GMP-scale and scaled-down bioreactors

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**APPLICATION OF ONLINE CO<sub>2</sub> MONITORING TO ENABLE A BETTER UNDERSTANDING  
OF CELL CULTURE PERFORMANCE VARIATION BETWEEN  
GMP-SCALE AND SCALED-DOWN BIOREACTORS**

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Key Words: Cell culture manufacturing, Online pCO<sub>2</sub>, pH, Cell culture performance, Bioreactor

Dissolved carbon dioxide (dCO<sub>2</sub>) or partial pressure of carbon dioxide (pCO<sub>2</sub>) is an important process parameter that may impact process performance (product titer and viability) and product quality attributes (such as glycosylation) during mammalian cell culture process in a bioreactor. The impact of altered level of pCO<sub>2</sub> on the cell culture process may manifest itself upon process scale-up if the CO<sub>2</sub> removal rate is not consistent between the development scale and the manufacturing scale. The pCO<sub>2</sub> level during cell culture process is normally determined through offline measurement; however, the offset between online and offline pCO<sub>2</sub> may conceal the true effect of pCO<sub>2</sub> on the cell culture process. In this presentation, several studies using online pCO<sub>2</sub> monitoring will be summarized and discussed, including 1) implementation of online pCO<sub>2</sub> probe for measurement of actual pCO<sub>2</sub> levels in a large scale bioreactor, 2) comparison of online and offline pCO<sub>2</sub>, 3) correlation between pH and pCO<sub>2</sub>, 4) estimation of CO<sub>2</sub> stripping rate in large scale bioreactors, and 5) effect of sample handling on pCO<sub>2</sub> level measurement. The key findings in this presentation are intended to establish biopharmaceutical manufacturing process knowledge, which is valuable for all partners in the cell culture manufacturing network.