

Meeting the Challenges Raised by FDA's PAT Initiative at fermentation processes for recombinant therapeutic protein production processes

Kuprijanov, A.¹, Schaepe, S.¹, Sieblist, C.¹, Gnoth, S.¹, Simutis, R.², Lübbert, A.¹
¹Center for Bioprocess Engineering, Martin-Luther-University Halle-Wittenberg
²Institute of Automation and Control Systems, Kaunas University of Technology

Quality-by-design and feedback control are central issues of the PAT initiative of the FDA/EMA. The first aims in designing robust processes, the second in removing the remaining disturbances. At the example of microbial cultivation processes for recombinant therapeutic protein production, a straightforward solution is presented. It is a knowledge-based procedure focusing on process optimization, as well as on monitoring and feedback control. In order to show its immediate transferability from [Science to Market](#), its implementation into the commercial process automation system Siemens SIMATIC PCS 7 will be presented.