Manufacturing Medicinal Products in the Future

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The future of medicinal manufacturing has to enable the drivers facing the pharmaceutical industry – the need to decrease cost of goods, market globalization, allow for more rapid development of pipeline products, reduce risk to patient supply, increase product quality etc. The utilization of new technologies such as single use bioreactors, alternating tangential flow during fermentation, modular and closed process equipment, process analytical technology and Analytics of the Future will allow for a more robust process, reduced waste, increased titers, less non conformances, less staffing required and dramatically less risk to technology transfer to new sites. For example, single use bioreactors do not need the miles of piping and utilities that conventional stainless steel, hard piped bioreactors do. The ability to utilize single use, pre-sterilized bioreactors and raw materials in a closed process eliminates the need for cleaning and steaming in place and reduces the risk of contaminations. The ability to create a modular, essentially identical, manufacturing sites across the globe means that technology transfer will require much less effort and risk. PAT and analytics of the future should allow for much more real time control of the process and less reliance on lot release assays, as well as driving more testing onto the manufacturing floor and reducing the costly footprint of the Quality Control Laboratories. However, the use of these novel technologies and the design of future biotechnology manufacturing sites will challenge regulatory paradigms; hence the need to partner with regulatory authorities as the future becomes a reality.