



PAT Applied in Biopharmaceutical Process Development And Manufacturing: An Enabling Tool for Quality-by-Design (Biotechnology and Bioprocessing)

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As with all of pharmaceutical production, the regulatory environment for the production of therapeutics has been changing as a direct result of the US FDA-initiated Quality by Design (QbD) guidelines and corresponding activities of the International Committee for Harmonization (ICH). Given the rapid growth in the biopharmaceutical area and the complexity of the molecules, the optimum use of which are still being developed, there is a great need for flexible and proactive teams in order to satisfy the regulatory requirements during process development.

Process Analytical Technologies (PAT) applied in biopharmaceutical process development and manufacturing have received significant attention in recent years as an enabler to the QbD paradigm. **PAT Applied in Biopharmaceutical Process Development and Manufacturing** covers technological advances in measurement sciences, data acquisition, monitoring, and control. Technical leaders present real-life case studies in areas including measuring and monitoring raw materials, cell culture, purification, and cleaning and lyophilization processes via advanced PAT. They also explore how data are collected and analyzed using advanced analytical techniques such as multivariate data analysis, monitoring, and control in real-time.

Invaluable for experienced practitioners in PAT in biopharmaceuticals, this book is an excellent reference guide for regulatory officials and a vital training aid for students who need to learn the state of the art in this interdisciplinary and exciting area.

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