



Biotechnology Operations: Principles and Practices

Michael J. Roy

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Because of rapid developments in the biotechnology industry—and the wide range of disciplines that contribute to its collective growth—there is a heightened need to more carefully plan and fully integrate biotech development projects. Despite the wealth of operations experience and associated literature available, no single book has yet offered a comprehensive, practical guide to fundamentals.

Filling the void, **Biotechnology Operations: Principles and Practices** reflects this integrative philosophy, serving as a practical guide for students, professionals, or anyone else with interests in the biotech industry. Although many books emphasize specific technical aspects of biotech, this is perhaps the first to integrate essential concepts of product development and scientific and management skills with the seven functional areas of biotechnology:

- Biomanufacturing
- Clinical trials
- Nonclinical studies
- Project management
- Quality assurance
- Quality control
- Regulatory affairs

A practical roadmap to optimizing biotechnology operations, this reference illustrates how to use specific product planning, design, and project management processes to seamlessly merge plans and efforts in the key functional areas. Applying lessons learned throughout the nascent history of biotech, author Michael Roy highlights developmental principles that could bring future products to market more safely and efficiently. Drawing from his experiences working in industry and teaching a graduate course at the University of Wisconsin, this hotly anticipated book clarifies basic methodologies and practices to help reduce risks and resolve problems as future technological discoveries are developed into tangible products.



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