Industrial Expert Lecture on "Overview of Biopharmaceutical Product Development and Commercialization" in the Dept. of Biotechnology, NIT Raipur

by

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Mode of Lecture: Online (Date: 25.09.2024)

Key Points:

1. **Discovery and Preclinical Development**

Target Identification and Validation: Identify biological pathways and molecular targets associated with specific diseases; Lead Discovery: Develop and optimize biologic molecules (e.g., antibodies, proteins) with therapeutic potential; Preclinical Testing: Evaluate the safety, efficacy, and pharmacokinetics of the product in vitro (e.g., cell cultures) and in vivo (animal models).

2. Clinical Development

Clinical trials are conducted in phases to ensure safety and efficacy in humans:

Phase 1 (Safety and Dosage): Test the product in a small group of healthy volunteers or patients to assess safety, dosage range, and side effects; Phase 2 (Efficacy and Side Effects): Test the product in a larger group of patients to evaluate efficacy and further assess safety; Phase 3 (Confirmatory Trials): Conduct large-scale trials to confirm effectiveness, monitor side effects, and compare the product to standard treatments; Phase 4 (Post-Marketing Surveillance): Continue monitoring the product after approval to gather long-term safety and effectiveness data.

3. Regulatory Approval

Submission of a Biologics License Application (BLA): Companies submit comprehensive data to regulatory agencies (e.g., FDA, EMA) for review; Regulatory Review: Agencies assess the data to determine whether the product meets standards for safety, efficacy, and manufacturing quality; Approval: If approved, the product can be marketed for the intended indication.

4. Challenges and Considerations: Challenges and scope were also discussed along with the new era of future development.