

Case Study: Evolution of Drug Development

Background:

The pharmaceutical industry has witnessed a remarkable evolution, transitioning from herbal remedies to sophisticated recombinant drugs. This journey demonstrates the interplay of traditional knowledge, scientific discovery, and technological innovation in addressing human health needs.

Task:

You are a team of biotechnology entrepreneurs planning to start a pharmaceutical company. Your goal is to understand the evolution of drug development to make informed decisions about the type of drugs you want to develop. Examine the progression from herbal medicine to recombinant drugs and analyze the implications, opportunities, and challenges at each stage.

1. Herbal Medicine:

- **Task**: Research and identify three examples of plant-based remedies used in traditional medicine and their therapeutic effects. Analyze the benefits and limitations of herbal medicine.
- **Question**: How can the principles of herbal medicine inform modern drug development in identifying potential new drugs?

2. Synthetic Small Molecule Drugs:

- **Task**: Investigate the synthesis and mechanism of action of Aspirin, a notable synthetic small molecule drug. Evaluate the impact of synthetic drugs on medicine.
- **Question**: How does the development and production of synthetic small molecule drugs compare to herbal medicine in terms of scalability, specificity, and safety?

3. Biological Drugs and Early Biotechnology:

- **Task**: Study the development of insulin from extraction from animal pancreases to recombinant human insulin. Assess the challenges and breakthroughs in developing biological drugs.
- **Question**: How have biological drugs addressed the limitations of synthetic small molecule drugs, and what challenges are unique to biological drugs?

4. Recombinant DNA Technology:

- **Task**: Explore the principles and applications of recombinant DNA technology in drug development, focusing on the production of a specific protein in bacterial and mammalian cells.
- **Question**: How has recombinant DNA technology revolutionized drug development, and what are the considerations in choosing bacterial or mammalian cell lines for production?

1. **Herbal Medicine:**

- **Historical Background:**

- The use of plants for healing purposes predates recorded history and forms the origin of much of modern medicine. Ancient cultures in China, India, and Egypt have documented extensive pharmacopeias of herbal remedies.

- **Key Achievements:**

- The documentation of herbal remedies in texts like the Ebers Papyrus (circa 1550 BC) in ancient Egypt and the compilation of extensive lists of medicinal plants in ancient China and India, such as in the texts of Ayurveda.

- The development of the field of botany and the classification of plants enabled more systematic study and use of herbal remedies in the Middle Ages and Renaissance periods.

2. **Synthetic Small Molecule Drugs:**

- **Historical Background:**

- The 19th century saw rapid advancements in organic chemistry, allowing for the isolation of pure compounds and synthesis of chemical drugs, marking the beginning of the modern pharmaceutical industry.

- **Key Achievements:**

- The synthesis of salicylic acid, the precursor to Aspirin, by Italian chemist Raffaele Piria in 1838, and the subsequent development of Aspirin by Felix Hoffmann at Bayer in 1897.

- The discovery of the first antibiotic, penicillin, by Alexander Fleming in 1928, followed by its development as a drug by Howard Florey and Ernst Boris Chain in the 1940s.

3. **Biological Drugs and Early Biotechnology:**

- **Historical Background:**

- The 20th century brought the development of biological drugs, with proteins like insulin being extracted from animal sources to treat human diseases.

- **Key Achievements:**

- The isolation of insulin from the pancreases of dogs by Frederick Banting and Charles Best in 1921, leading to the development of insulin therapy for diabetes.

- The development of hybridoma technology by Georges Köhler and César Milstein in 1975, allowing the production of monoclonal antibodies, and spurring the development of numerous antibody-based drugs.

4. **Recombinant DNA Technology:**

- **Historical Background:**

- The 1970s and 1980s saw the advent of recombinant DNA technology, enabling the production of human proteins in bacterial or mammalian cells, revolutionizing the biotechnology and pharmaceutical industries.

- **Key Achievements:**

- The development of the first recombinant DNA molecules by Paul Berg in 1972.

- The production of the first recombinant human insulin, Humulin, by Genentech in 1978, using E. coli bacteria. The founding of biotechnology companies like Genentech (1976), Amgen (1980), and Biogen (1978), pioneering the development of recombinant protein therapeutics.