BIOTECHNOLOGY and BIOPHARMACEUTICS

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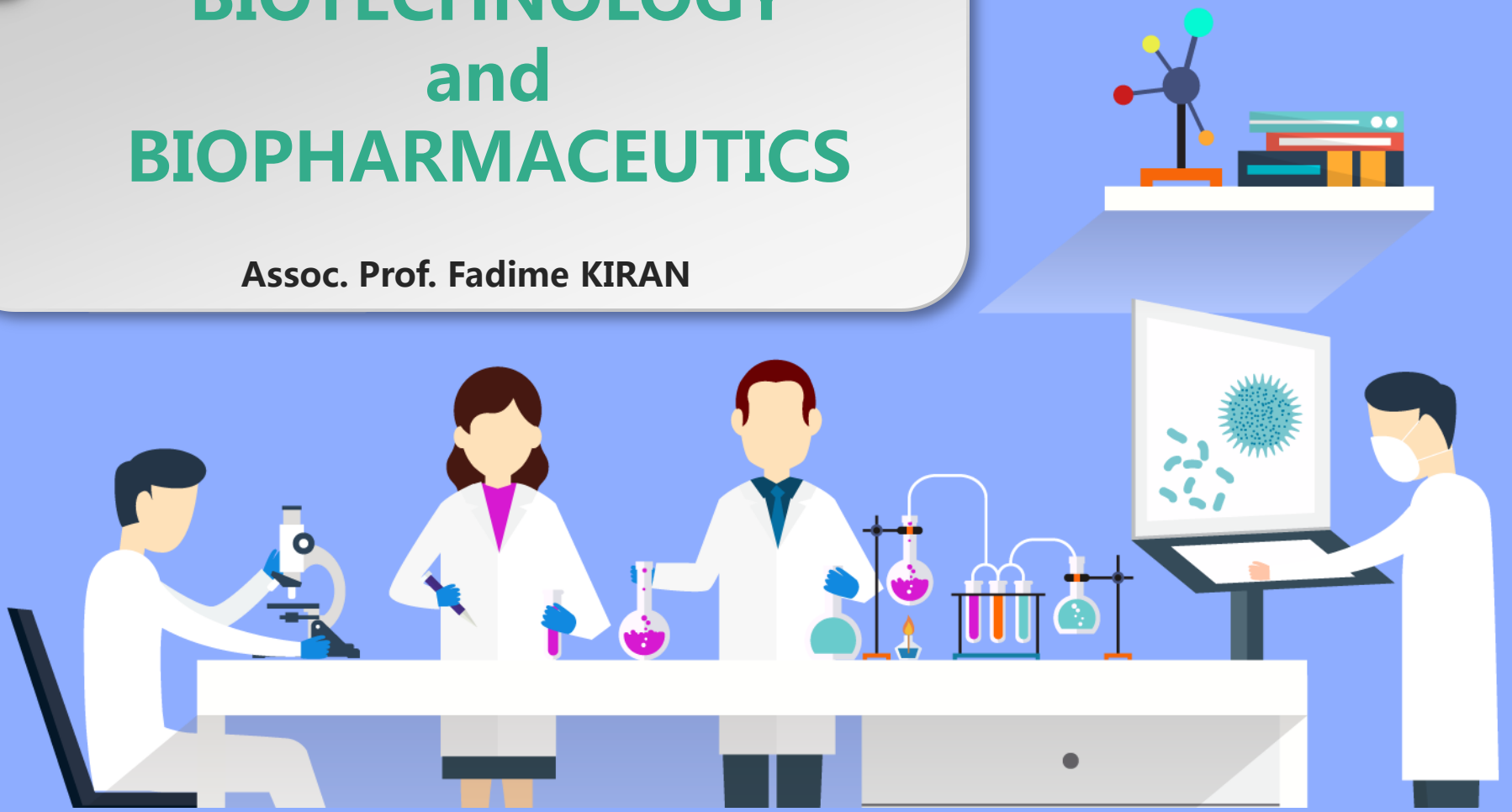

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-REGULATORY REQUIREMENTS of DRUGS/BIOPHARMACEUTICALS

How do drugs get from the point of discovery to the pharmacy shelf?

DRUG regulation incorporates several mutually reinforcing activities all aimed at promoting and protecting public health.

Its mission includes ensuring that new medical treatments reach the public as quickly as possible while simultaneously ensuring that new treatments are both safe and effective.

The Drug Development Process

1. Study Disease
2. Aspects of Disease
3. Consequences of the Disease
4. Genomics and Proteomics
5. Molecular Modeling
6. Combinatorial Chemistry
7. High Through-Put Screening
8. Screening In-Vivo -- In-Vitro
9. Pharmacology Profile
10. Toxicology Profile
11. IND Phase
12. Pre-IND Meeting
13. File IND
14. IND Effective
15. Clinical Trials
16. Phase 1
17. Phase 2
18. Phase 3
19. NDA Phase
20. Pre-NDA Meeting
21. File NDA
22. Approval
23. Post-Marketing Requirements

- What studies are regulated by the GLP Regulations?

- What are the requirements outlined by the regulations?


FDA
APPROVED

ANY QUESTION?


Thank you