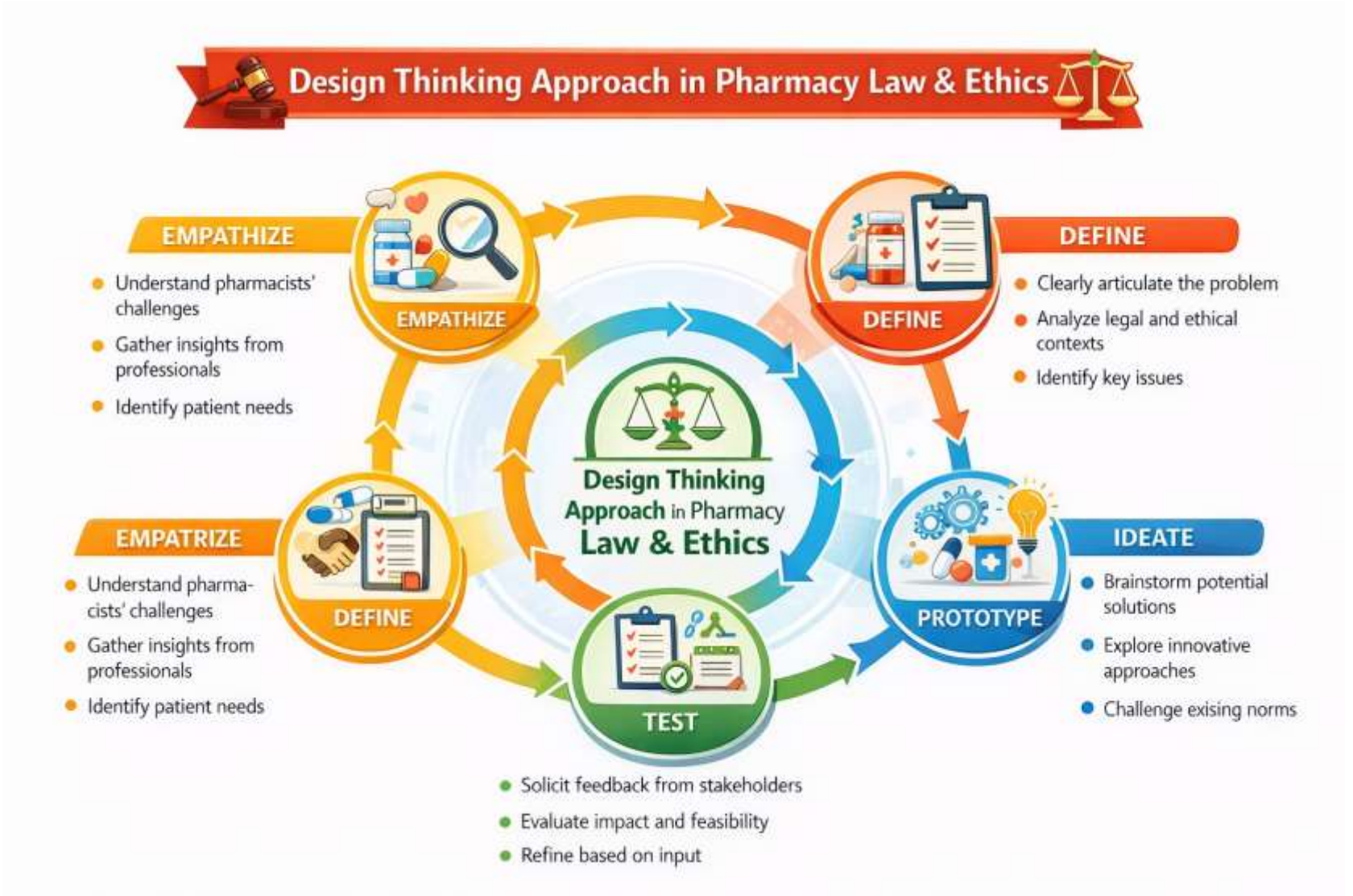
SNS COLLEGE OF PHARMACY AND HEALTH SCIENCES

Affiliated To The Tamil Nadu Dr. MGR Medical University, Chennai
Approved by Pharmacy Council of India, New Delhi.
Coimbatore -641035

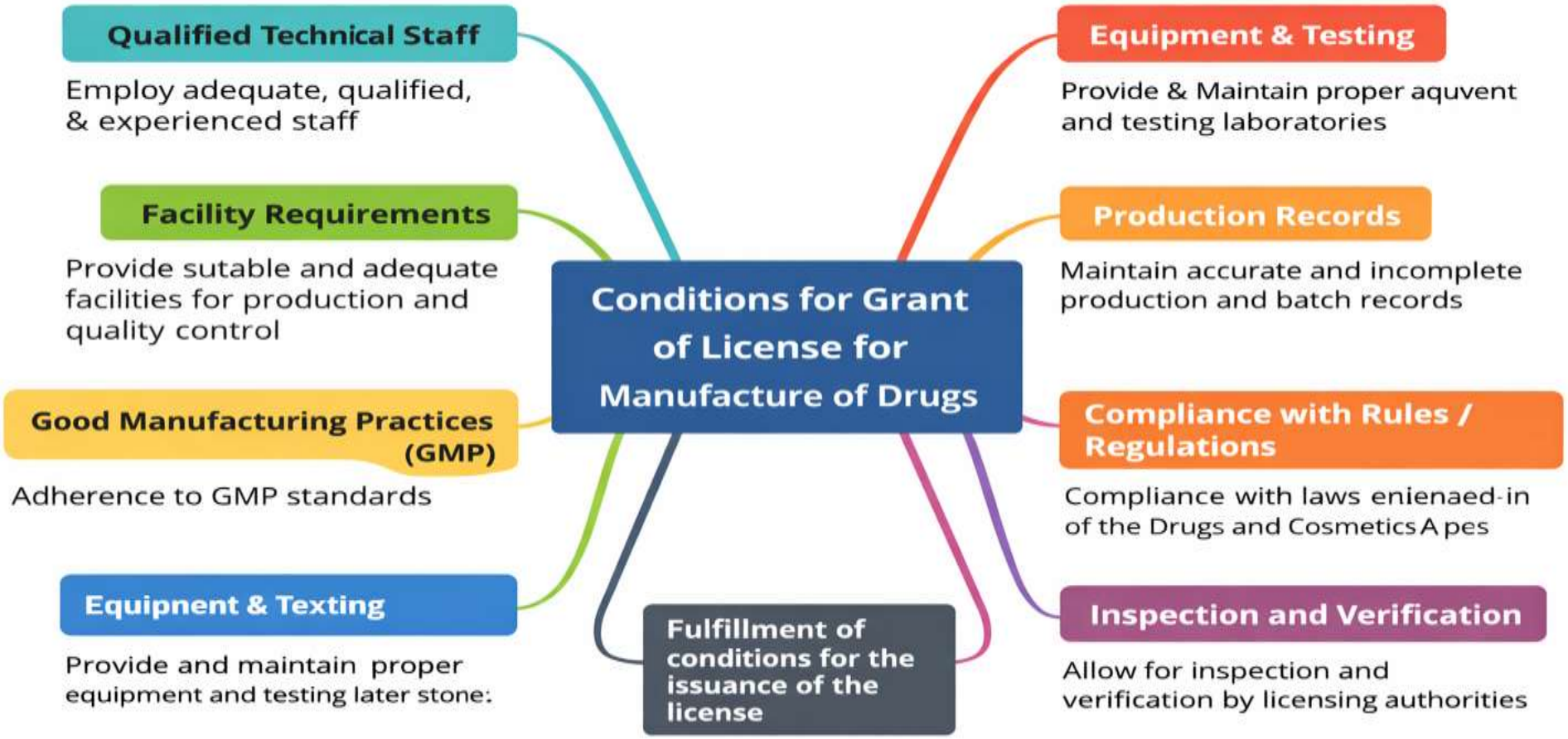
COURSE NAME: PHARMACY LAW AND ETHICS

D.PHARM/ II YEAR

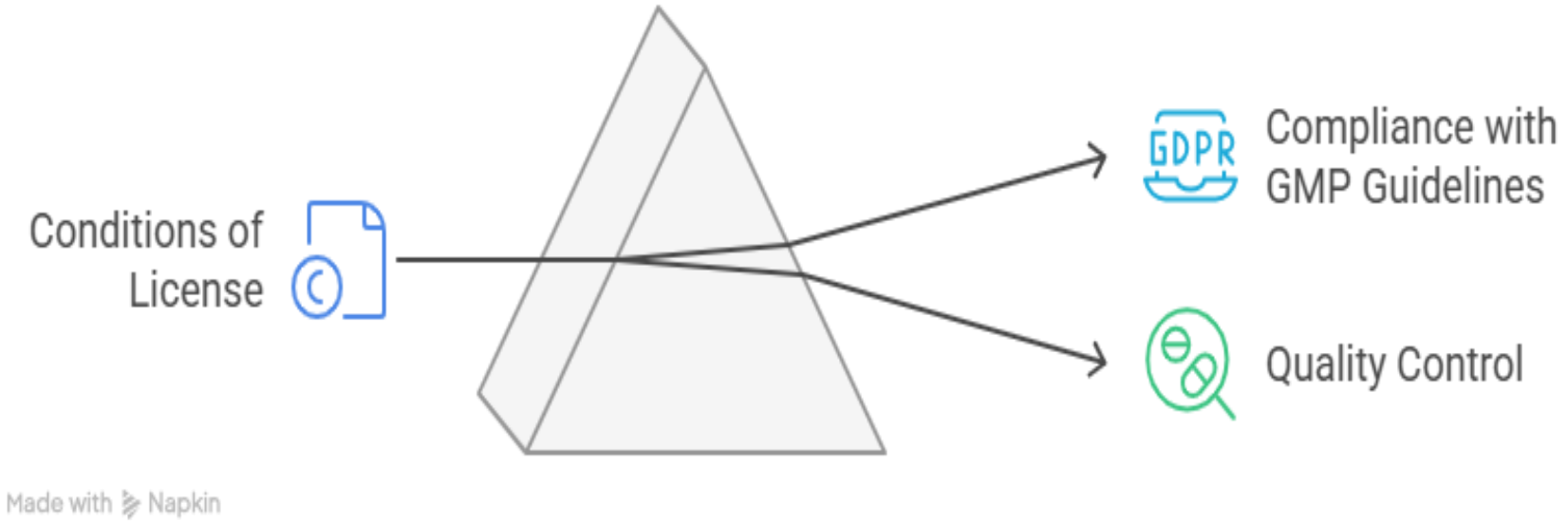
TOPIC:CONDITIONS FOR GRANT OF LICENSE FOR MANUFACTURE OF DRUGS


Design Thinking Approach in Pharmacy Law & Ethics
EMPATHIZE
Understand pharmacists' challenges
Gather insights from professionals
Identify patient needs
EMPATHIZE
DEFINE
Clearly articulate the problem
Analyze legal and ethical contexts
Identify key issues
DEFINE
Design Thinking Approach in Pharmacy Law & Ethics
EMPATRIZE
Understand pharma-cists' challenges
Gather insights from professionals
Identify patient needs
DEFINE
IDEATE
Brainstorm potential solutions
Explore innovative approaches
Challenge exising norms
PROTOTYPE
TEST
Solicit feedback from stakeholders
Evaluate impact and feasibility
Refine based on input

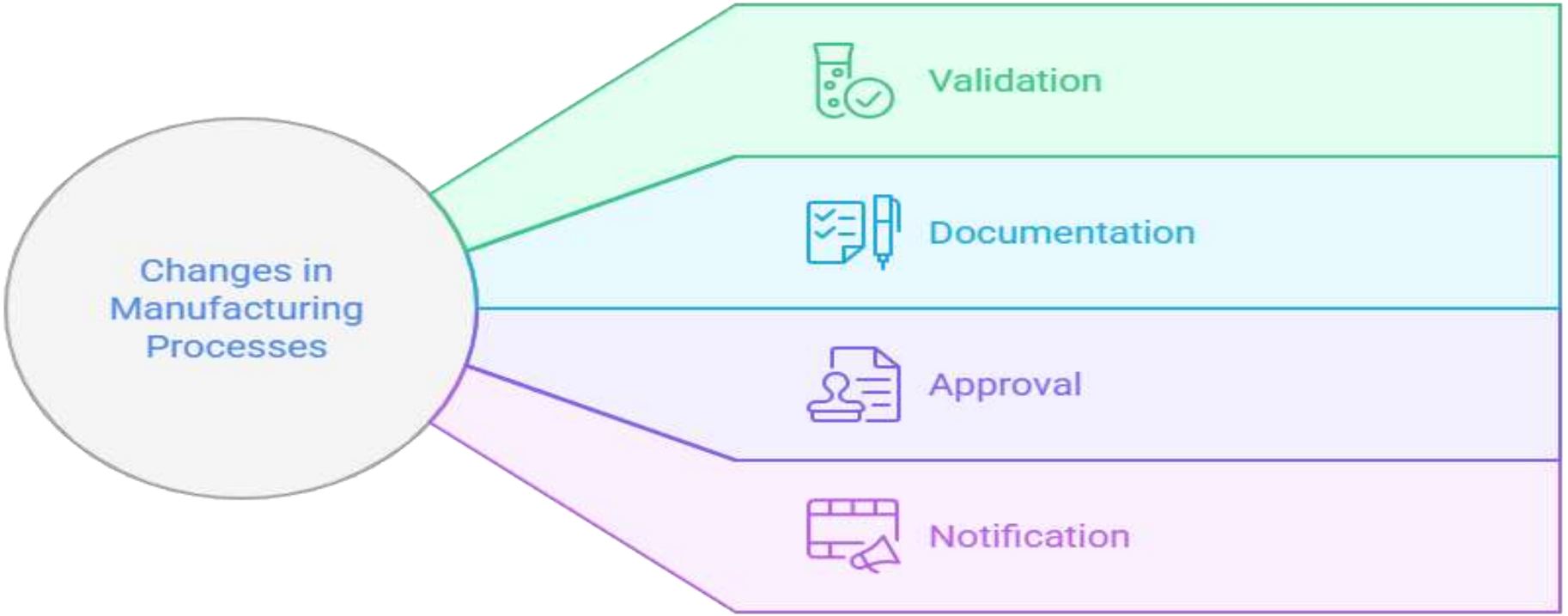
MINDMAP


Qualified Technical Staff
Employ adequate, qualified, & experienced staff
Facility Requirements
Provide sutable and adequate facilities for production and quality control
Good Manufacturing Practices (GMP)
Adherence to GMP standards
Equipnent & Texting
Provide and maintain proper equipment and testing later stone:
Conditions for Grant of License for Manufacture of Drugs
Fulfillment of conditions for the issuance of the license
Equipment & Testing
Provide & Maintain proper aquvent and testing laboratories
Production Records
Maintain accurate and incomplete production and batch records
Compliance with Rules / Regulations
Compliance with laws enienaed-in of the Drugs and Cosmetics A pes
Inspection and Verification
Allow for inspection and verification by licensing authorities

Unveiling the Conditions of Drug Manufacturing Licenses



Navigating Changes in Drug Manufacturing Processes



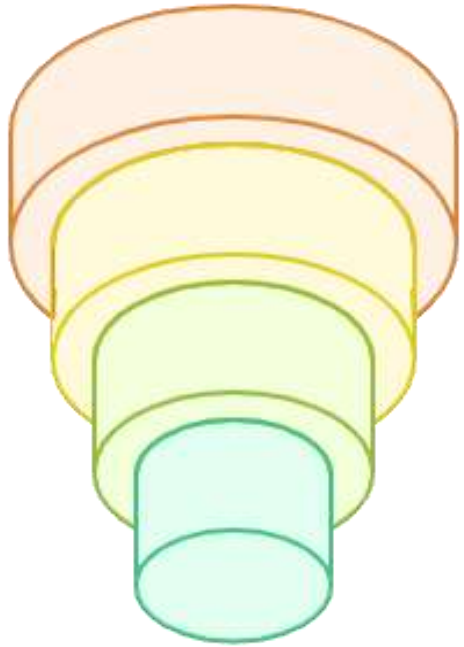
License Suspension and Cancellation Process

Deficiency Notification

Licensee is informed of deficiencies

Corrective Action Opportunity

Licensee is given a chance to fix issues



Suspension Decision

Authorities decide to suspend the license

Appeal Option

Licensee can appeal the suspension decision

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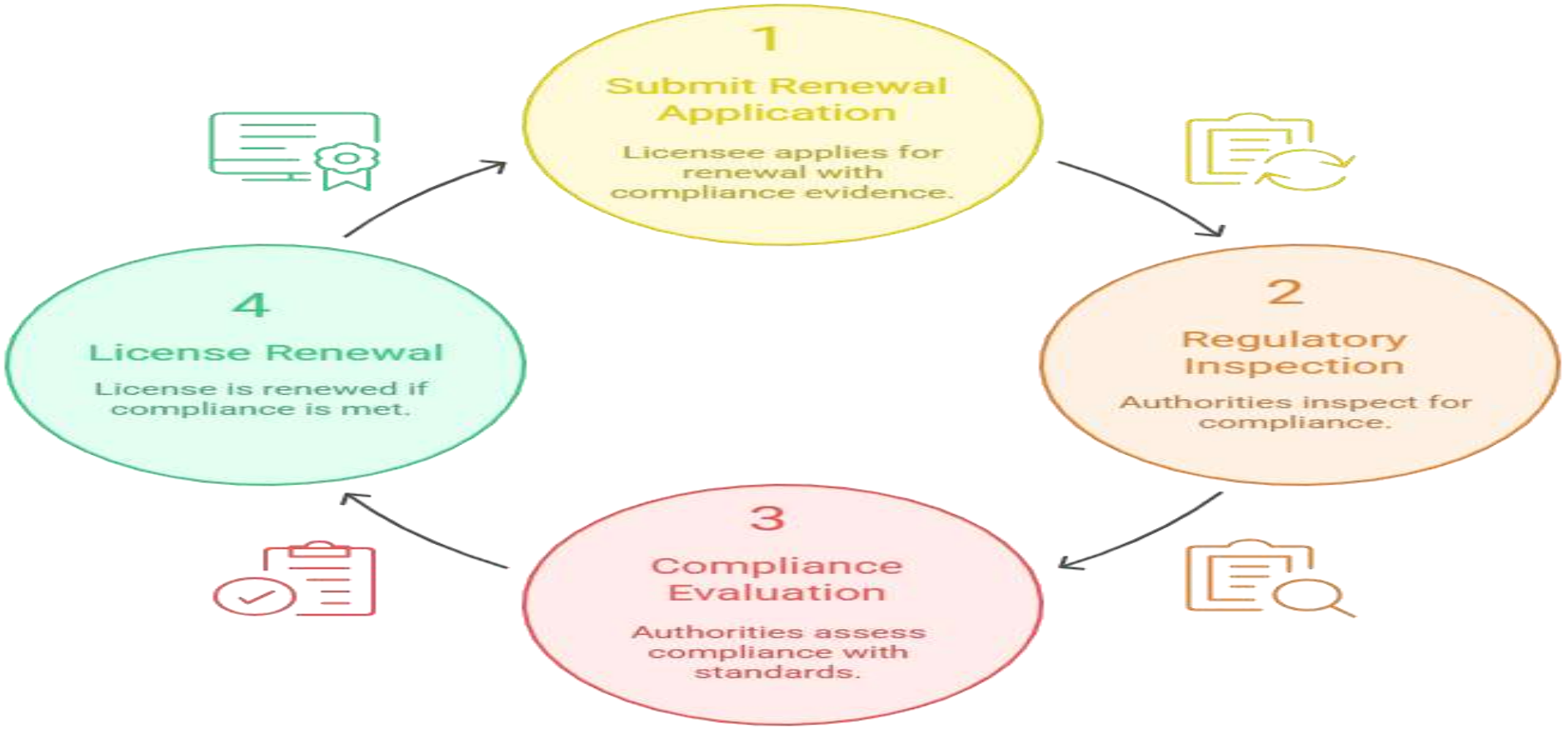
Manufacturing License Renewal Cycle



Regulatory Oversight of Drug Manufacturing

License Renewal
Ensuring continued compliance through periodic reviews.

GMP Compliance
Adherence to Good Manufacturing Practices in all aspects of production.

Process Changes
Validating and documenting any modifications to manufacturing.

Quality Control
Maintaining high standards to ensure drug quality and safety.

Inspections
Allowing regulatory authorities to verify compliance.

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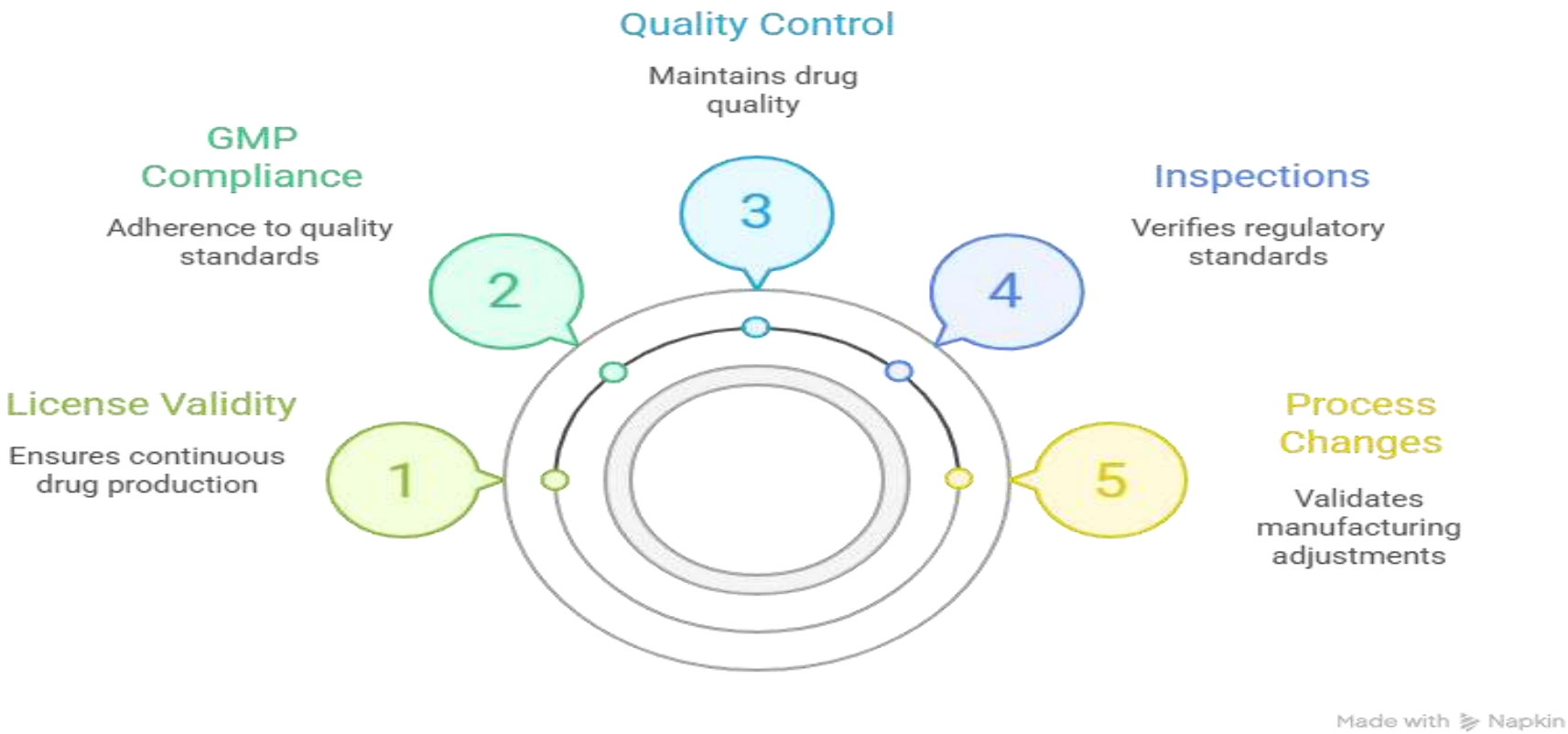
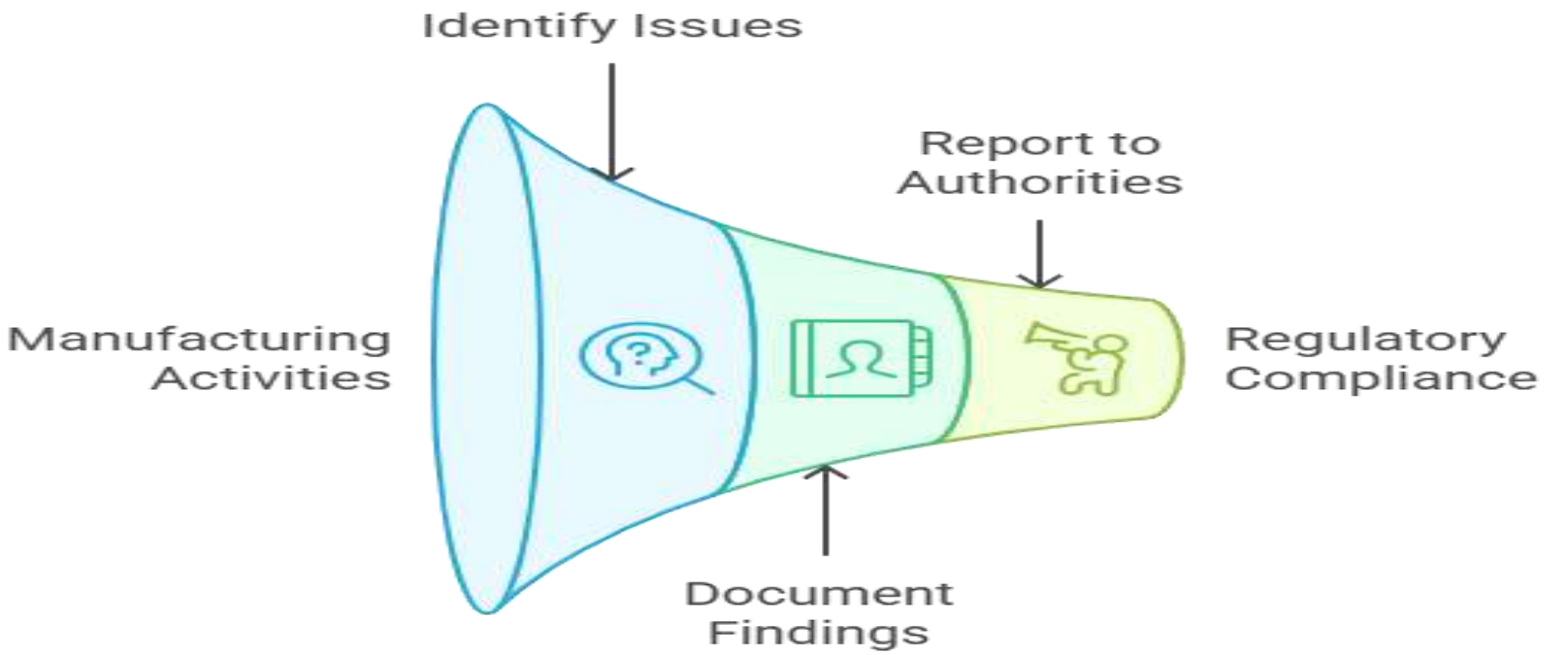
Drug Manufacturing License Compliance



Regulatory Reporting Process



Manufacturing records range from creation to secure storage.

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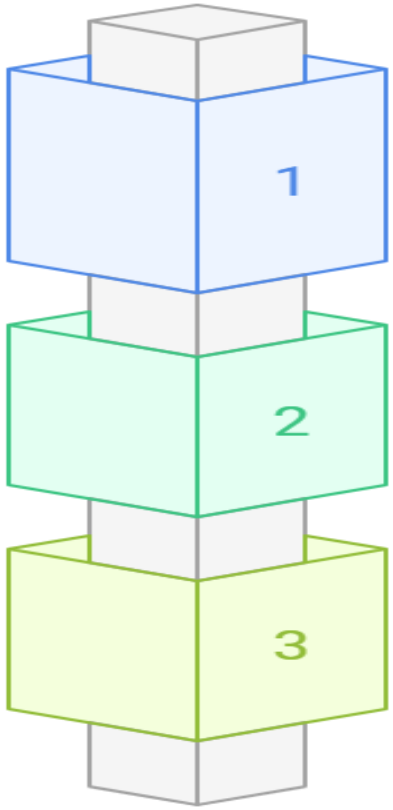
Ensuring Drug Quality



Testing and Release

Conducting thorough tests on materials and products before release.

Reference Standards

Utilizing appropriate standards for accurate testing.

Retain Samples

Storing samples for future testing and reference.

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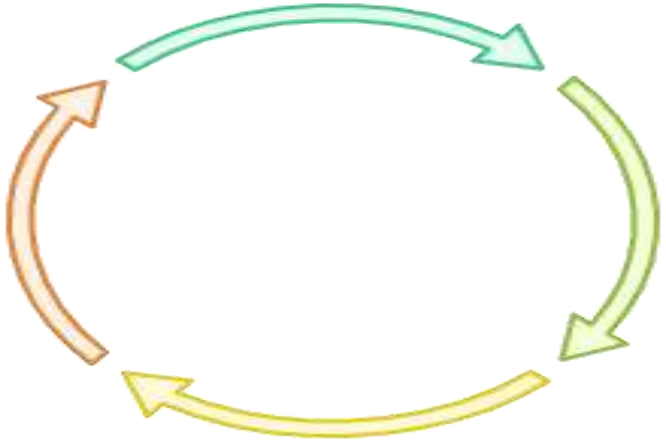
GMP Compliance Cycle



Maintain GMP Standards
Adhere to GMP regulations and guidelines.

Conduct Regular Audits
Assess compliance through regulatory audits.

Identify Deficiencies
Find areas needing improvement during audits.

Implement Corrective Actions
Address and document identified deficiencies.

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Foundations of Drug Manufacturing Quality

Documentation

Comprehensive and accurate records for traceability and compliance.

Quality Control

Rigorous testing and inspection to meet product specifications.

Validation

Ensuring consistent quality through process and equipment verification.

Stability Testing

Determining shelf life and maintaining product effectiveness.

Complaint Handling

Addressing and preventing recurrence of adverse events.

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Ensuring Equipment Quality in Drug Manufacturing

Calibration

Ensuring equipment accuracy through calibration

Maintenance

Keeping equipment in optimal condition through maintenance

Validation

Confirming equipment reliability through validation

Cleaning

Maintaining hygiene through effective cleaning procedures

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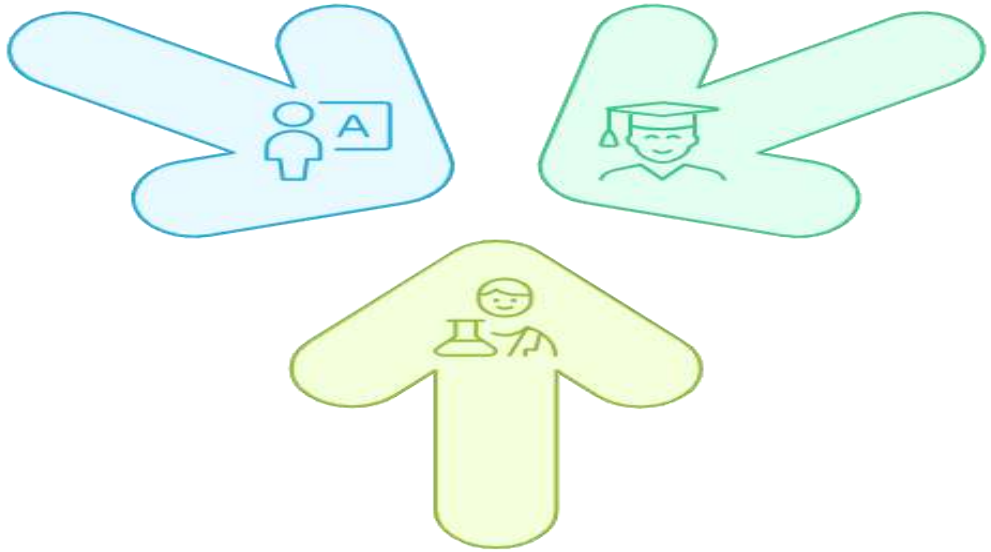
Personnel Requirements for Drug Manufacturing



Training

Regular sessions on GMP and safety

Qualified Staff

Experienced personnel in key roles

Technical Staff

Pharmacists, chemists, and microbiologists

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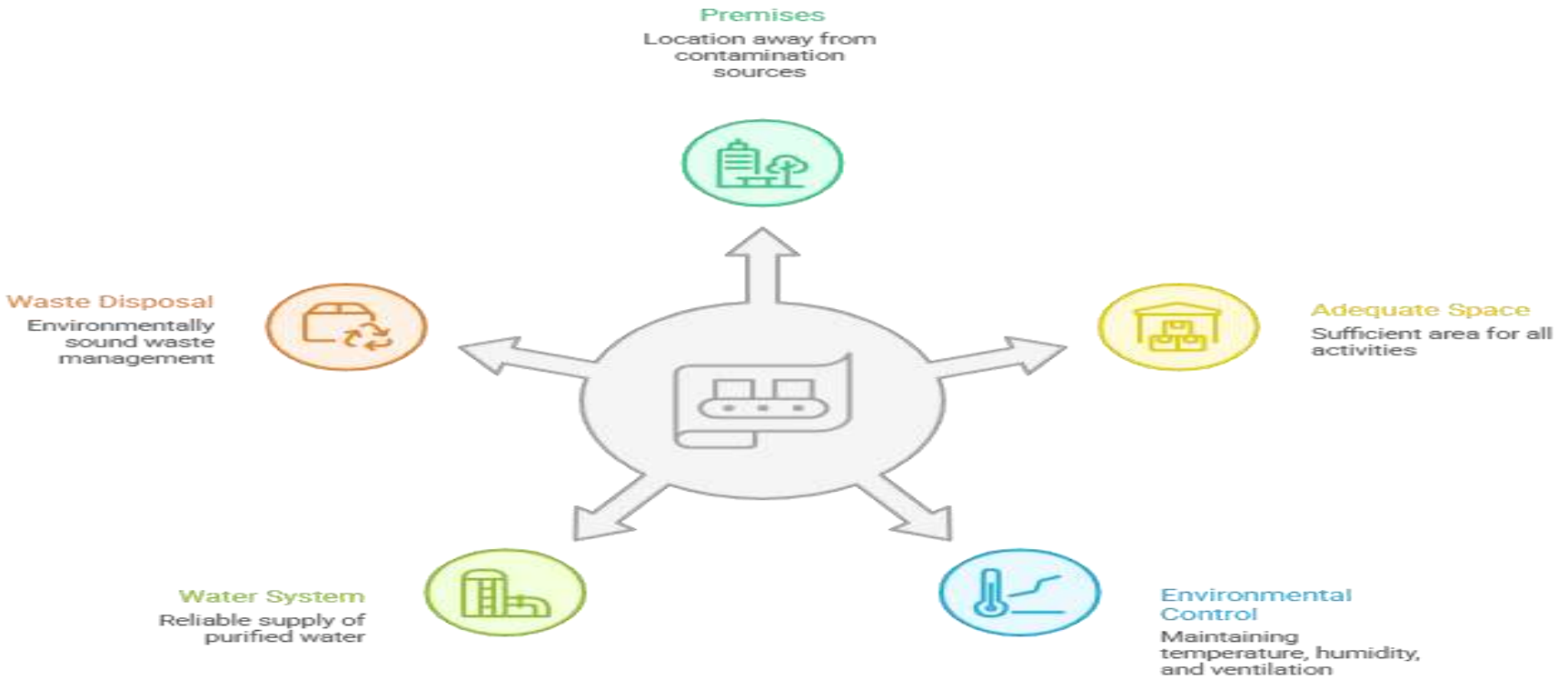
Manufacturing Facility Requirements



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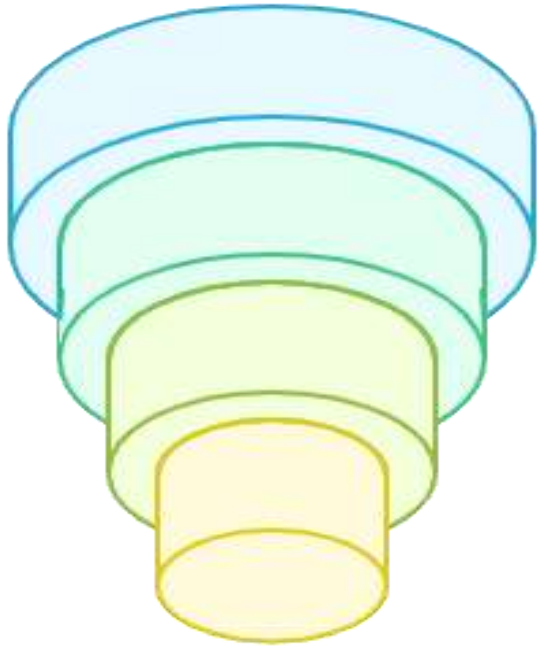
Drug Manufacturing License Approval Process

Infrastructure Assessment

Evaluating facilities and utilities

Equipment Inspection

Checking machinery and tools



Personnel Evaluation

Assessing staff qualifications and training

GMP Compliance

Ensuring adherence to manufacturing standards

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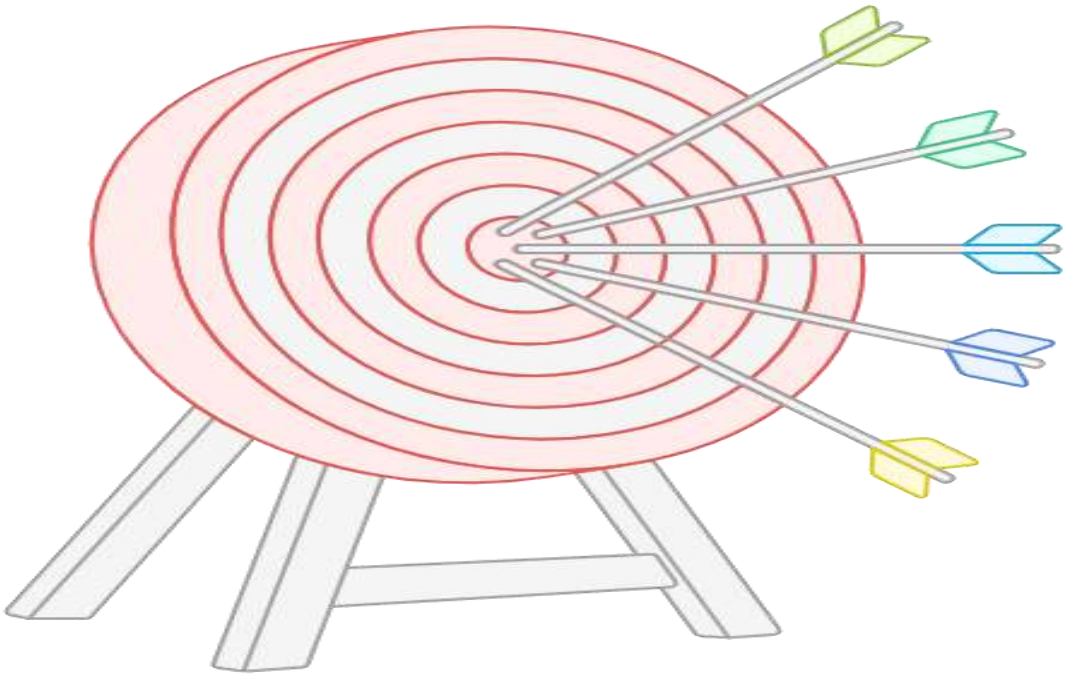
Drug Manufacturing License Conditions



Public Health

Ensures safety and quality of drugs

Regulatory Compliance

Adherence to standards and guidelines

Quality Control

Maintains drug quality and efficacy

Manufacturing Processes

Efficient and safe drug production

Infrastructure and Personnel

Necessary resources for manufacturing

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ASSESSMENT

How to ensure NewPharma meets the key conditions for obtaining a manufacturing license?

Infrastructure and Equipment

VS

Personnel

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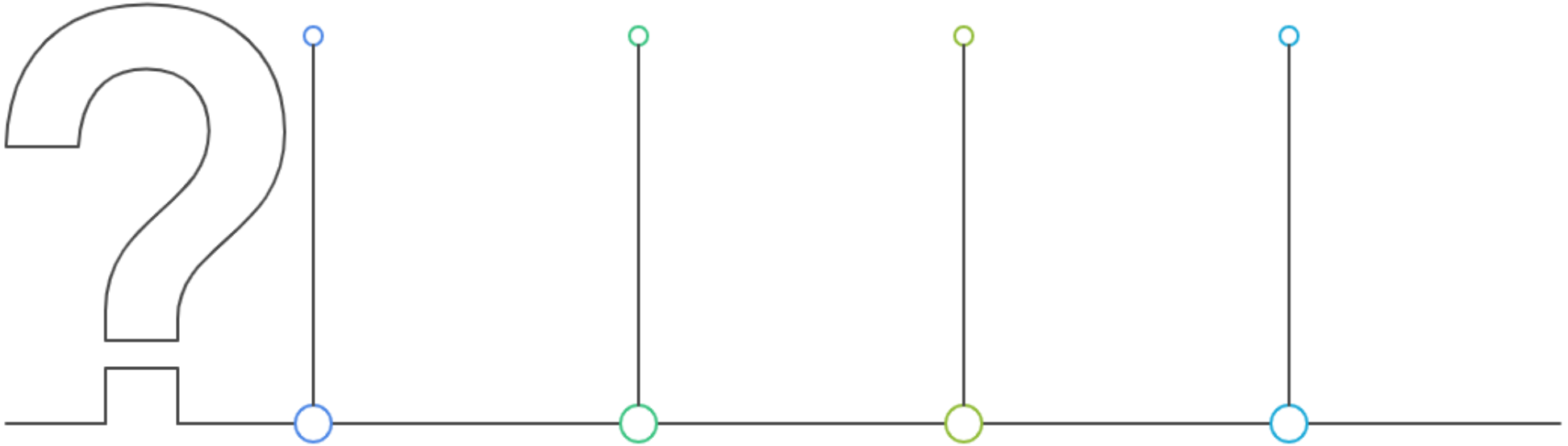
How to ensure GMP compliance for drug manufacturing license?



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How should PharmaTech address manufacturing deficiencies to maintain its license?

Inadequate Practices

VS

Corrective Actions

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REFERENCE

1.Law and Ethics – B. K. MathewEasy book for beginners on legal and ethical principles.
2.Ethics and Law – Dr. P. D. SharmaSimple explanation of ethics used in law and society.
3.Professional Ethics – K. C. JoshiExplains moral duties and professional conduct.
4.Legal Ethics – V. D. MahajanBasic book on ethics followed by legal professionals.
5.Legal Information Institute (LII) – www.law.cornell.edu
6.Britannica – Law and ethics – www.britannica.com


Thank You