Club Founder
Dr. Mahmoud Bahgat

International
Factories Club
Sharpen your skills

Co-Founder & Host:
Dr. Ahmed Rafat

International Factories Club

R&D Roles

R&D Role from Design to Registration

Online zoom

9 pm EGY-10 pm KSA-11 pm UAE

Dr. Mohamed Nouh
R&D General Manager EIPICO

SATURDAY 23RD NOV. 2024

Dr. Muhammad Nouh

Experience:

- EIPICO (General Manager R&D)
- Wadi EL-Neel Benta in alliance with Bioxell (R&D Director)
- Obour Modern Pharmaceutical Industries (Technical Manager)
- COPADPHARMA (Research and Development Manager)
- Grand Pharma (R&D Assistant Manager)
- WESTERN PHARMACEUTICAL INDUSTRIES (R&D Section Head)
- Delta Pharma (R&D supervisor).

Education:

- Arab Academy for Science, Technology and Maritime Transport

Master of Business Administration – MBA

- Suez Canal University

Master's degree Pharmaceutical Sciences

- Al-Azhar University

Bachelor of Pharmacy & Pharmaceutical science.

- Zagazig University

Doctor of Philosophy - PhD (In Progress) Pharmaceutics and Drug Design


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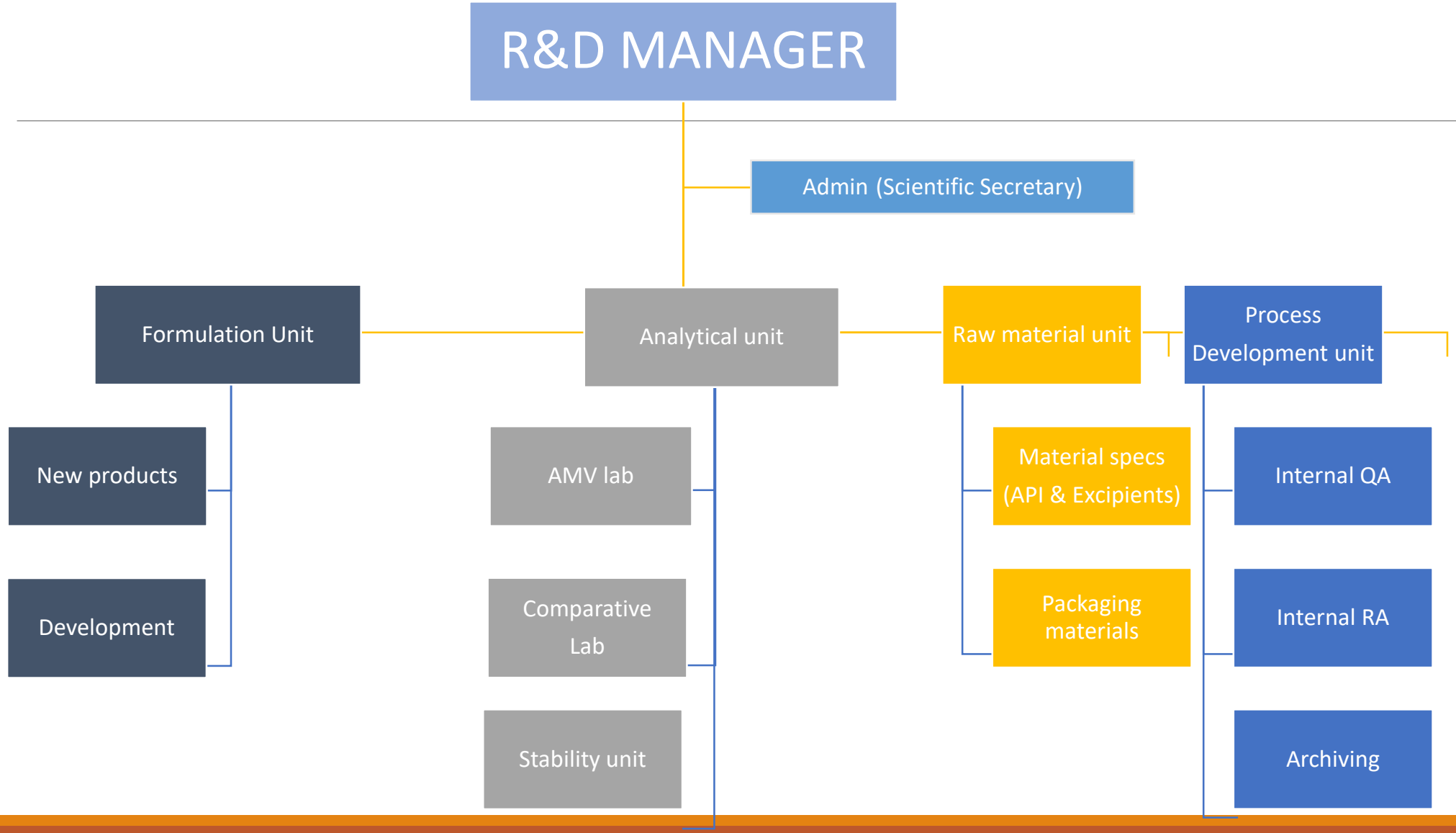
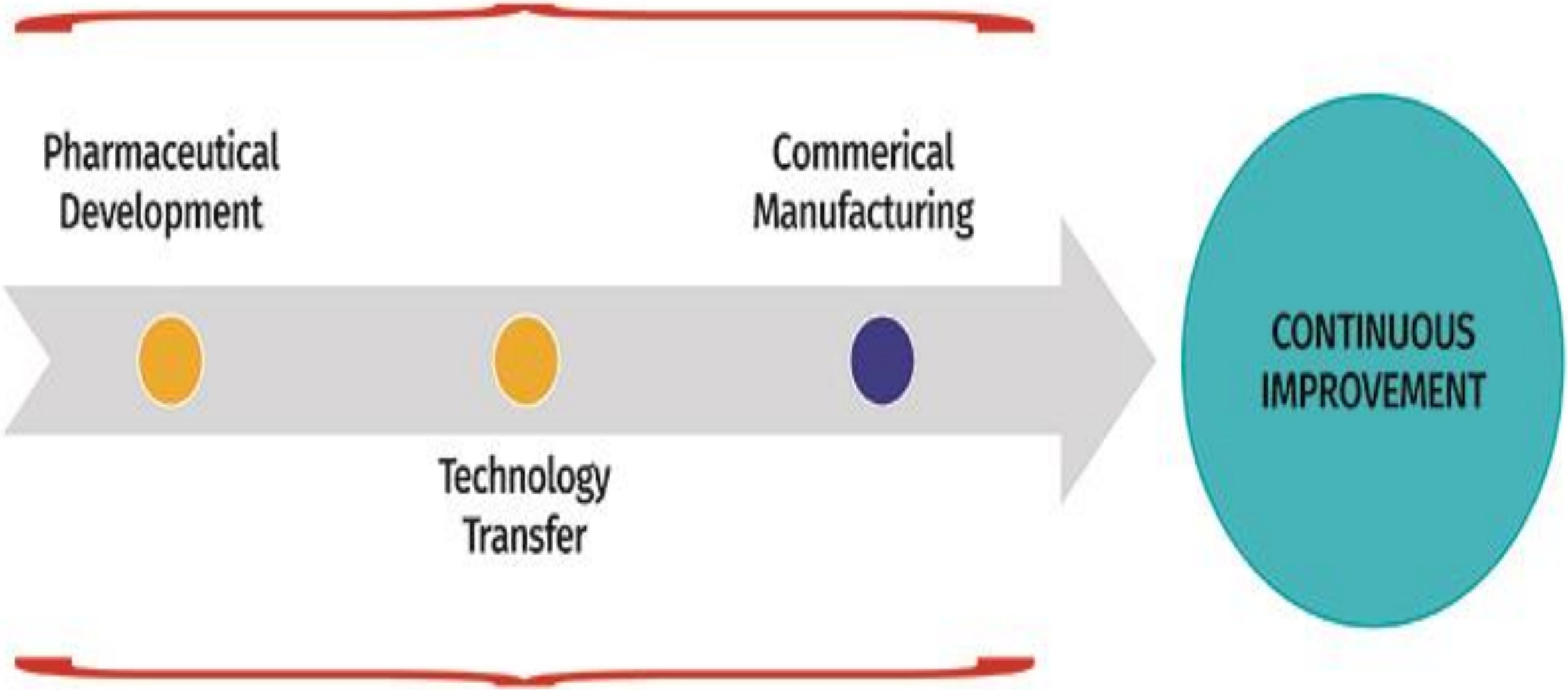
RESEARCH & DEVELOPMENT ROLES

R&D Role From Design To Registration

By Dr. Muhammad Nouh

R&D ORGANOGRAM





PRODUCT DEVELOPMENT LIFECYCLE

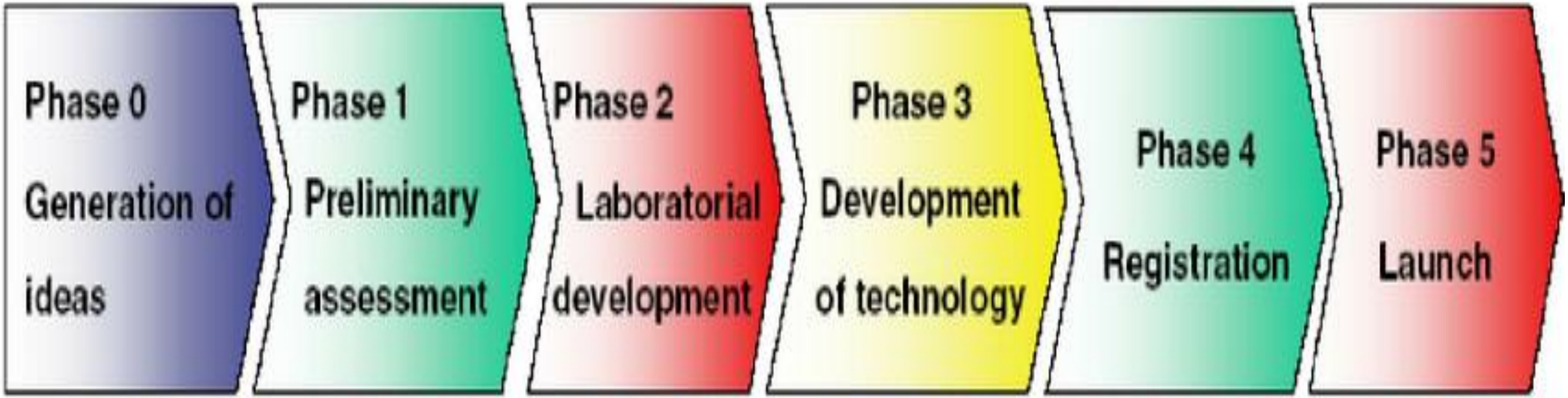
FORMULATION DEVELOPMENT

- Pharmaceutical formulation development is the process of designing, creating, and verifying that the selected drug product is safe, effective, and consistently delivers a desired therapeutic effect.
- It involves the selection of appropriate ingredients (excipients), dosage form, manufacturing process, and packaging to optimize the drug's properties and ensure its stability.
- The formulation development process involves several stages, which are crucial for the successful development of a drug product.

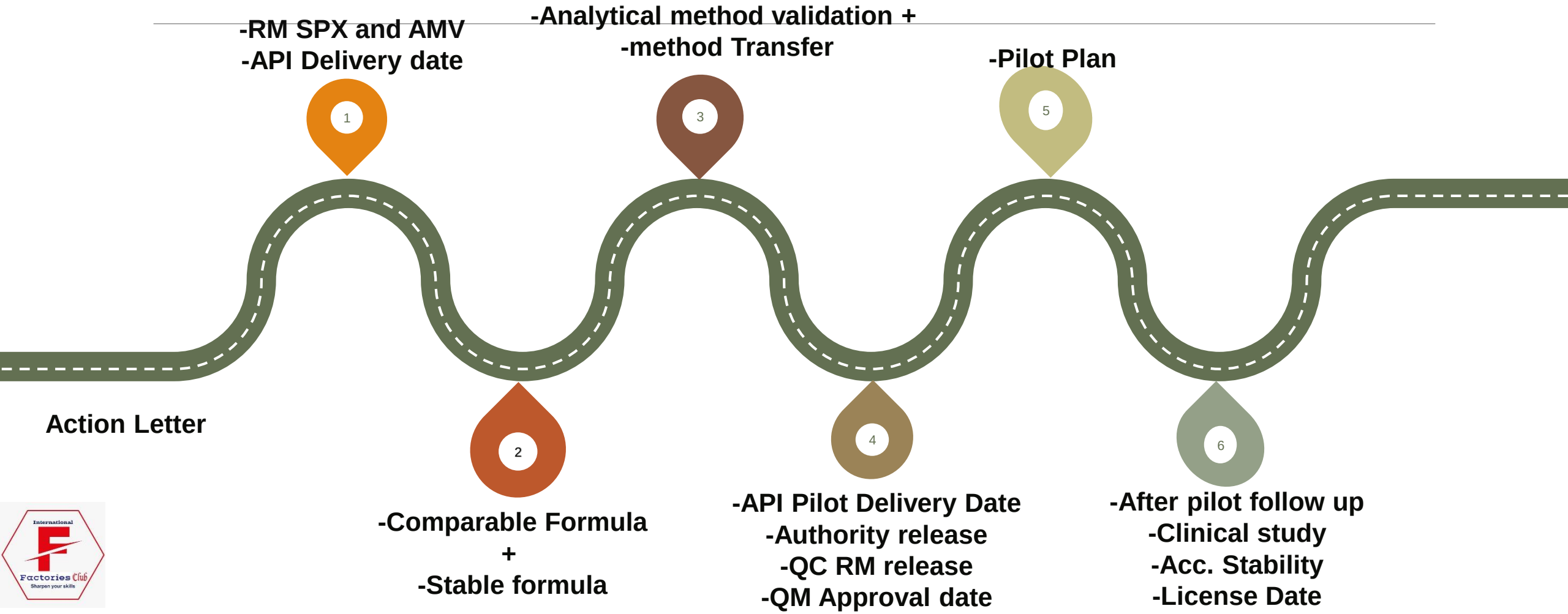
FORMULATION DEVELOPMENT

- Formulation Development includes:
  - Pre-formulation studies,
  - Formulation design & Evaluation,
  - Manufacturing scale-up
  - Process development,
  - Analytical development and characterization,
  - Stability and shelf-life determinations.

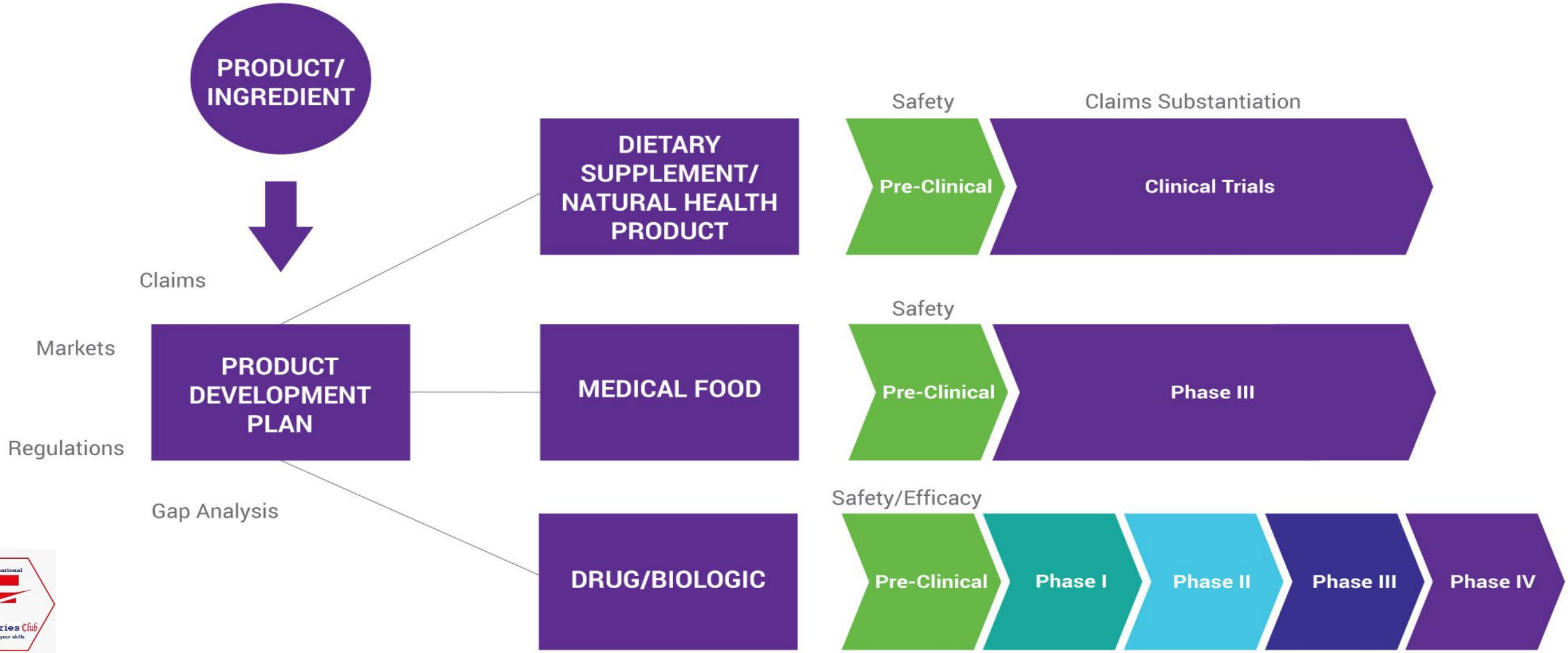
PHARMACEUTICAL PRODUCT LIFECYCLE



New Product Roadmap



Product Development Strategy



Pre-Formulation Studies

- Pre-formulation studies evaluate the chemical properties of the drug substance, such as solubility, stability, and compatibility with other excipients.
- The results of pre-formulation studies help in selecting the appropriate dosage form and excipients for the formulation

Formulation Design and Evaluation

Formulation design is the process of selecting excipients for the drug substance depending on the drug's physical and chemical properties and the target patient population. The excipients are selected based on their compatibility with the drug substance, their function in the formulation, and their safety profile.

Evaluation of the drug product with analytical, in vitro studies ensures that it meets the desired target product profile.

Manufacturing Scale-up and Process Development

- Process development is the optimization of the manufacturing process to ensure consistent quality, yield, and purity of the drug product.
- The manufacturing process is designed to ensure that the drug product meets the required specifications and is produced in compliance with regulatory requirements.
- The appropriate scale of the manufacturing process needs to be consistent with the needs of clinical and commercial requirements for the drug product.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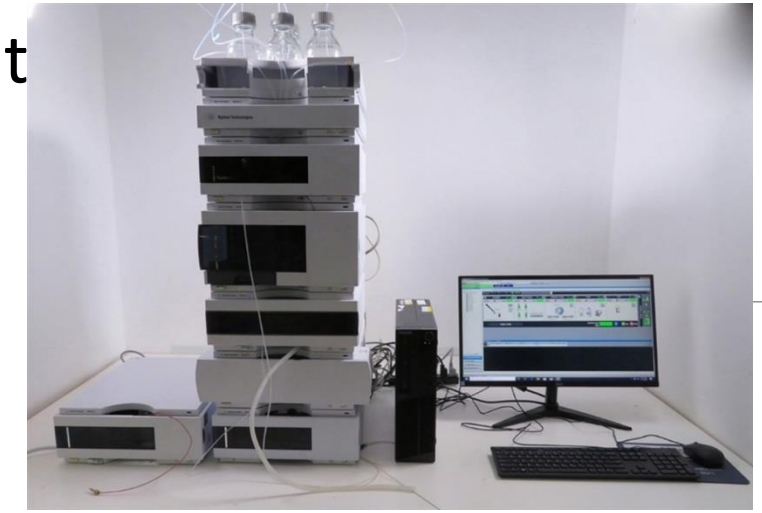
Analytical Development and Characterization

- Analytical methods must be developed to ensure that the drug product meets the identity, purity, and potency specifications and requirements.
- Analytical methods are also employed to quantify residual water, critical excipient levels and other impurities, drug dissolution or release, pH, appearance, particle size, and other critical quality attributes.

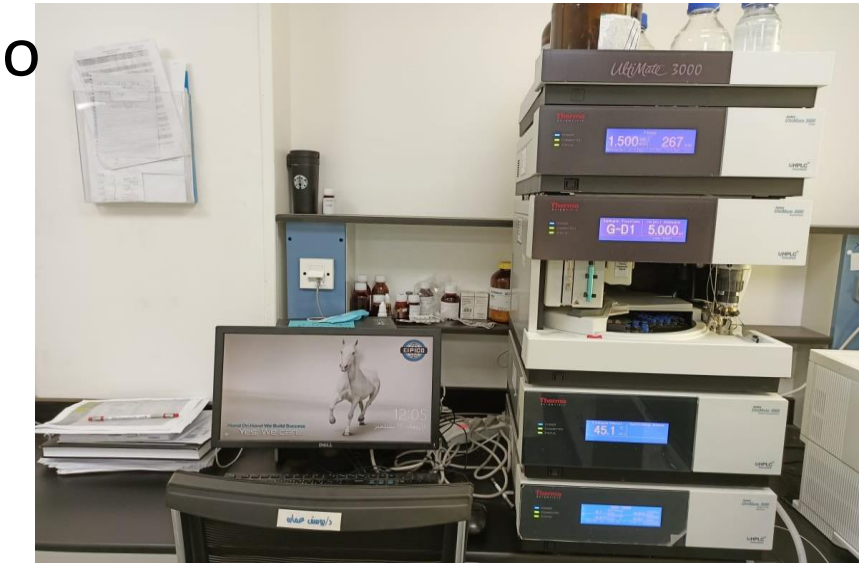
Agilent



Shimatzu

Waters

Thermo



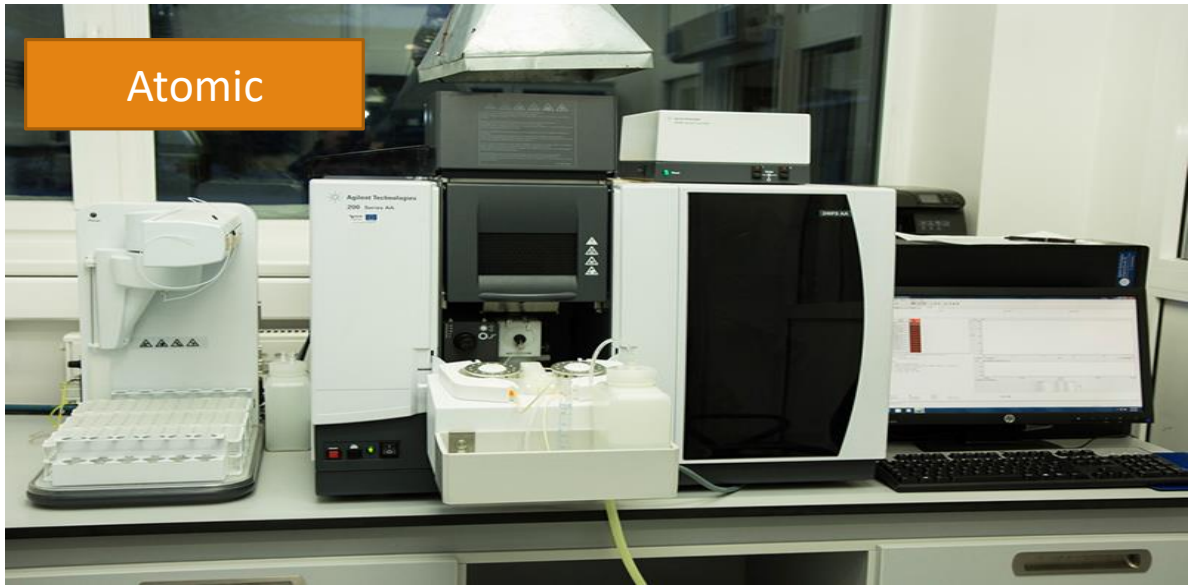
GC

UV

ICP

Dissolution

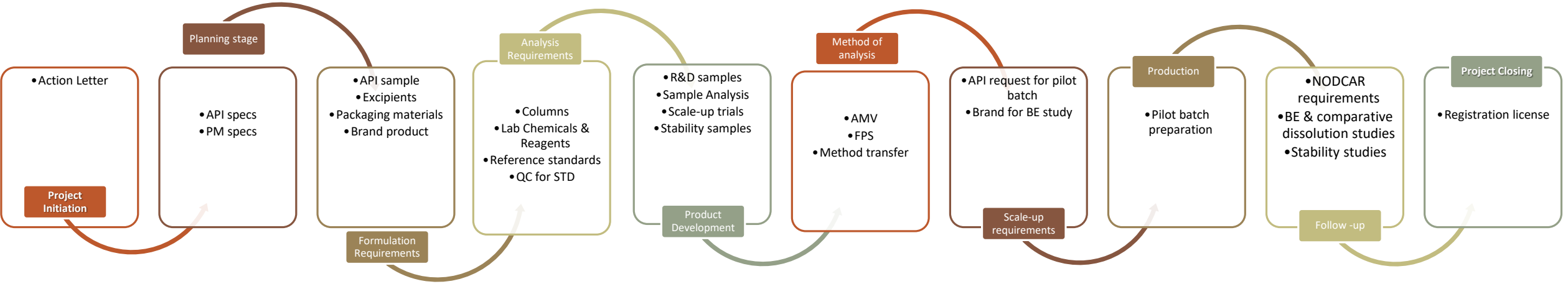
Atomic



Stability and Shelf-life Determination

- Stability testing is a critical aspect of the formulation development process. It ensures that the drug product maintains its quality and efficacy over time.
- Pharmaceutical stability testing involves storing the drug product to various environmental conditions, such as temperature, humidity, and light, and monitoring its physical and chemical properties over time.
- The stability data is then used to determine the appropriate storage condition and the shelf-life of the drug product.

New product Flowchart:
Integration between Supply chain , QC , production and R&D



Regulatory Requirements:

Pharmaceutical formulations must comply with regulatory requirements to ensure patient safety and efficacy. Regulatory authorities, require that drug products meet certain quality, safety, and efficacy standards before they can be approved for marketing.

In conclusion, pharmaceutical formulation development is a complex process that requires a multidisciplinary approach. Pre-formulation studies, formulation design, process development, pharmaceutical stability testing, and regulatory requirements are all essential in formulation development.


Thank you