STIKES NOTOKUSUMO
YOGYAKARTA

KONTRAK PERKULIAHAN

PENGEMBANGAN PRODUK

TAHUN AJARAN 2025/2026

SISTEM PERKULIAHAN

1

TIM PENGAMPU

apt. Trifonia Rosa Kurniasih, M.Biotech (KOORDINATOR)
apt. Catharina Apriyani W.H., M.Farm

2

JUMLAH PERTEMUAN

14 PERTEMUAN TEORI
UJIAN TENGAH SEMESTER
UJIAN AKHIR SEMESTER

3

JADWAL PERTEMUAN

Jumat, 10.00 – 11.40 WIB

KONTRAK PERKULIAHAN

Kehadiran

- HADIR TEPAT WAKTU, SESUAI JADWAL
- TOLERANSI KETERLAMBATAN 15 MENIT

Jumlah pertemuan

- JUMLAH KEHADIRAN MINIMAL **75%** dalam 16x pertemuan, termasuk UTS dan UAS.
  - maksimal 4x absen, 2x sebelum UTS dan 2x setelah UTS
  - Melanggar = NILAI DEFAULT E (TIDAK LULUS)

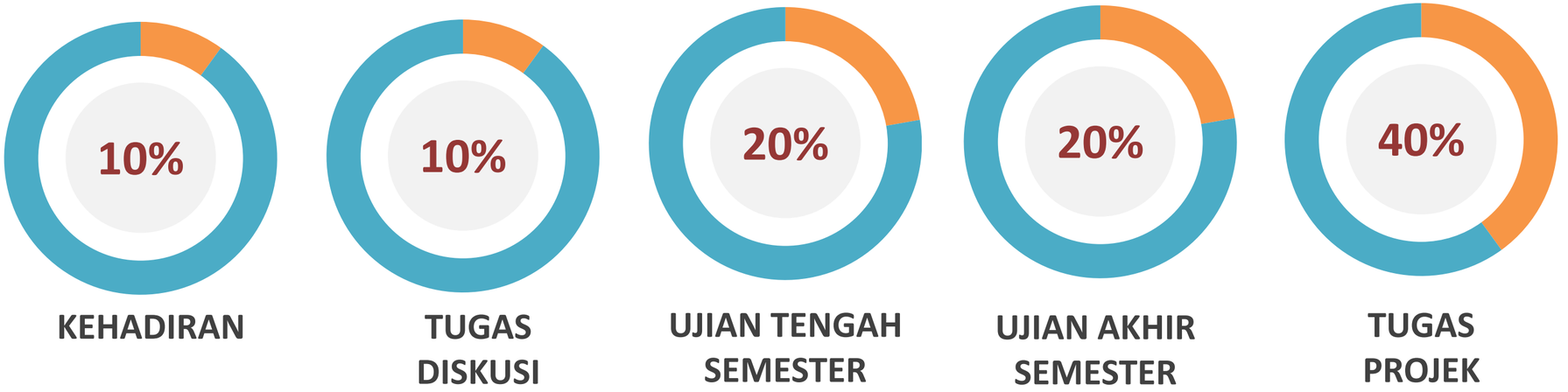
Sistem pembelajaran

- SELAMA KULIAH, MEDIA PEMBELAJARAN YANG DIGUNAKAN AKAN MENYESUAIKAN

Pembagian materi

- 7 TOPIK KULIAH : IBU ROSA
- 7 TOPIK KULIAH : IBU CATHARINA

BOBOT NILAI



RENCANA EVALUASI			
BASIS EVALUASI	KOMPONEN EVALUASI	BOBOT (%)	DESKRIPSI
Aktivitas Partisipatif	Kehadiran	10	Kehadiran mahasiswa selama mengikuti perkuliahan (16 pertemuan) melalui SIAKAD
Hasil Proyek	PROYEK (Tahap I dan Tahap II)	40	a.LAPORAN b.PRESENTASI
Kognitif / Pengetahuan	Tugas diskusi	10	Tugas analisis
	UTS	20	Ujian tengah semester dilaksanakan secara bersama sesuai jadwal
	UAS	20	Ujian akhir semester dilaksanakan secara bersama sesuai jadwal
Jumlah Nilai		100	

MATERI KULIAH

MATERI UTS
1.Overview pengembangan produk 2.Pengembangan struktur & Sistem Penghantaran 3.Strategi pengembangan obat 4.Uji praklinis 5.Stabilitas, market, konsep produk 6.Tugas projek 7.Tugas projek

MATERI UAS
1.CPOB 2.Optimasi formulasi 3.Validasi metode 4.Uji klinis 5.Integrasi kemasan, biaya, registrasi 6.Tugas projek 7.Tugas projek

REFERENSI

A. Referensi Utama (Wajib)

1. Bachhav, Y. (2019). Innovative dosage forms: Design and development at early stage. Wiley.
2. Gibson, M. (2018). Pharmaceutical preformulation and formulation: A practical guide from candidate drug selection to commercial dosage form (2nd ed.). CRC Press.
3. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). (2009). Q8(R2): Pharmaceutical development.
4. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). (2005). Q9: Quality risk management.
5. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). (2008). Q10: Pharmaceutical quality system.
6. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). (2019). Q12: Technical and regulatory considerations for pharmaceutical product lifecycle management.
7. Yu, L. X. (2020). Pharmaceutical quality by design: Product and process development, understanding, and control. Pharmaceutical Research, 37(1).

REFERENSI

B. Referensi Pendukung (Anjuran)

1. Meinert, C. L. (2013). Clinical trials handbook: Design and conduct. Wiley.
2. Mittal, B. (2017). How to develop robust solid oral dosage forms: From conception to post-approval. Academic Press.
3. Qiu, Y., Chen, Y., Zhang, G. G. Z., Liu, L., & Porter, W. (2009). Developing solid oral dosage forms: Pharmaceutical theory and practice. Elsevier.
4. Manurung, J. (2005). Pemastian mutu obat. EGC.
5. U.S. Food and Drug Administration (FDA). (2023). Guidance for industry: Pharmaceutical development and lifecycle management.

STIKES NOTOKUSUMO YOGYAKARTA

PENGEMBANGAN PRODUK

Pertemuan 1

apt. Trifonia Rosa K., M.Biotech

Topik Bahasan

Definisi pengembangan produk

Penemuan vs pengembangan

Perkembangan sediaan Farmasi di indonesia

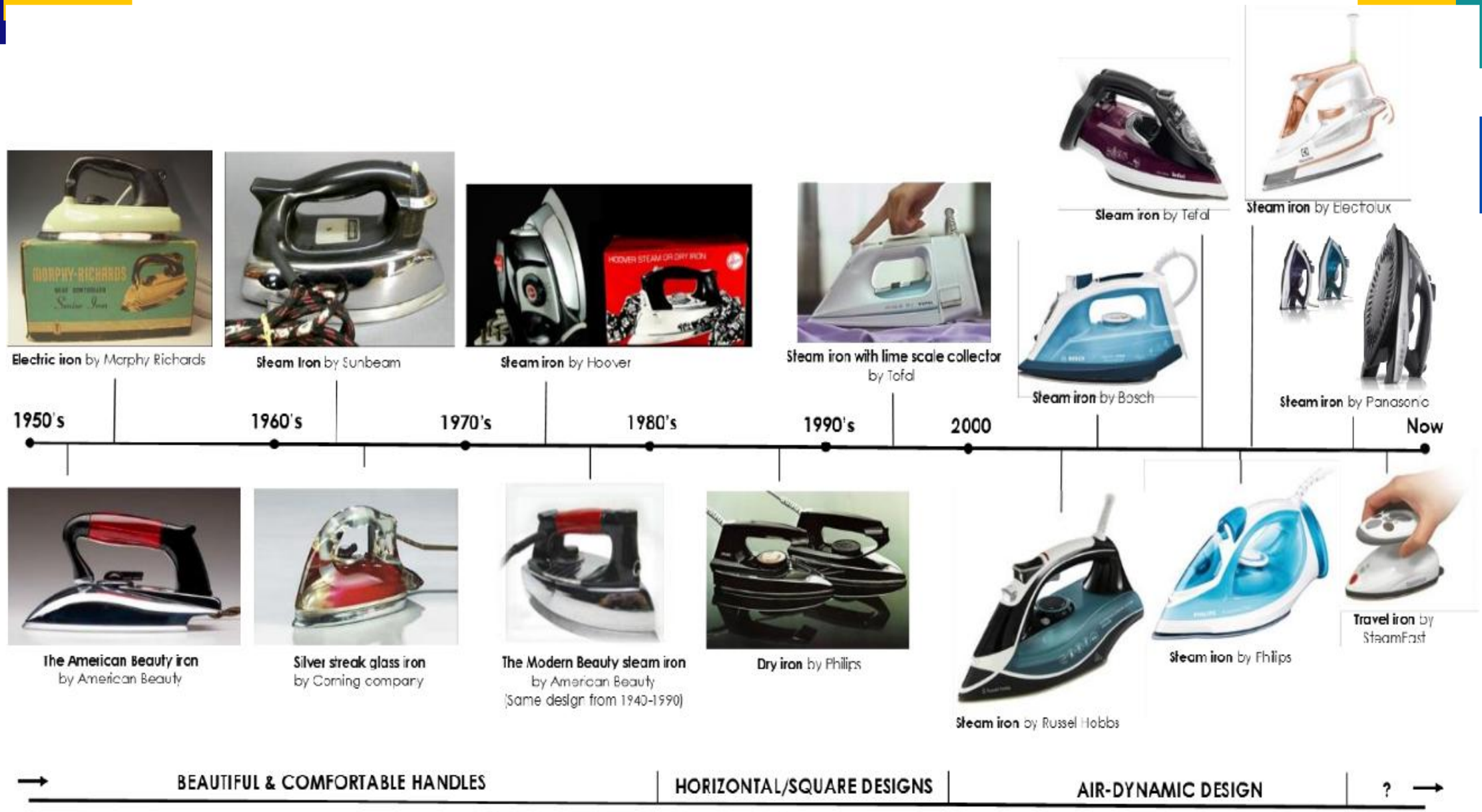
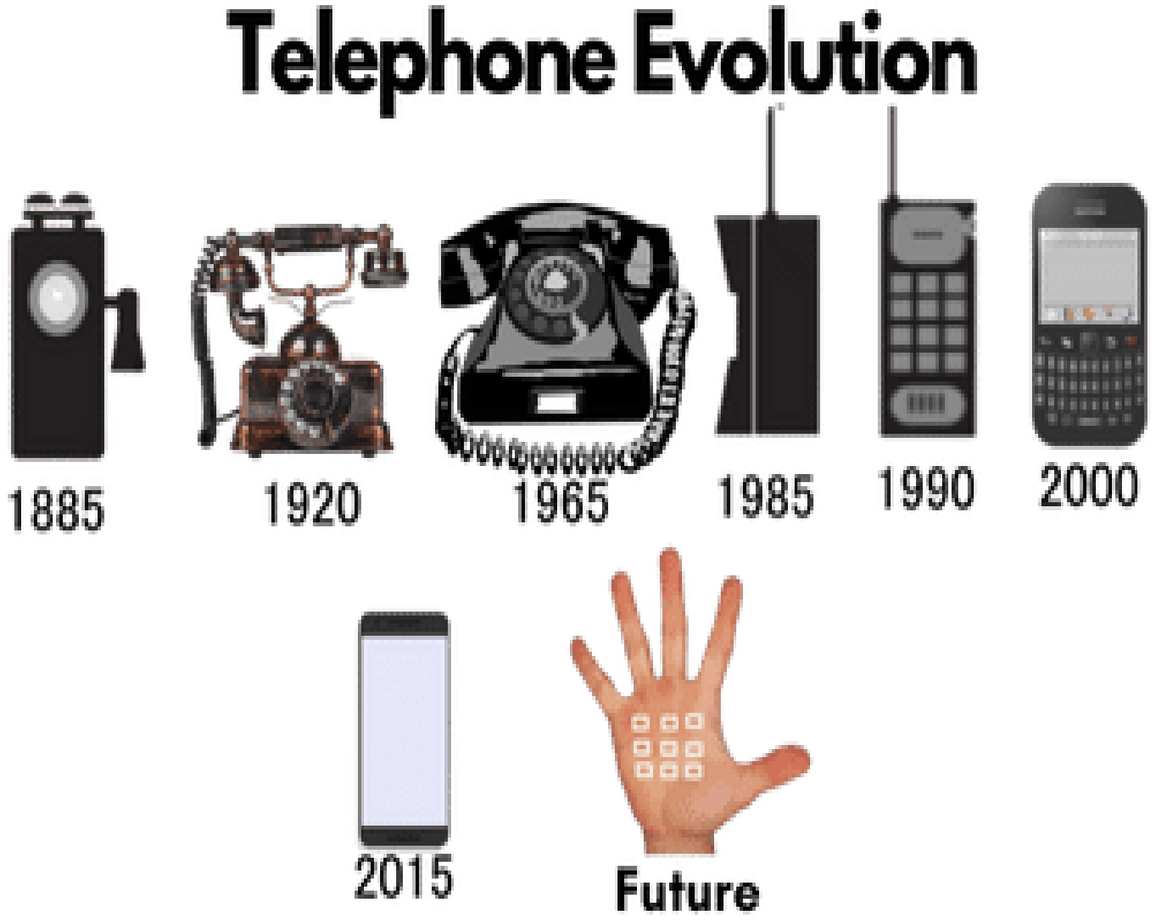
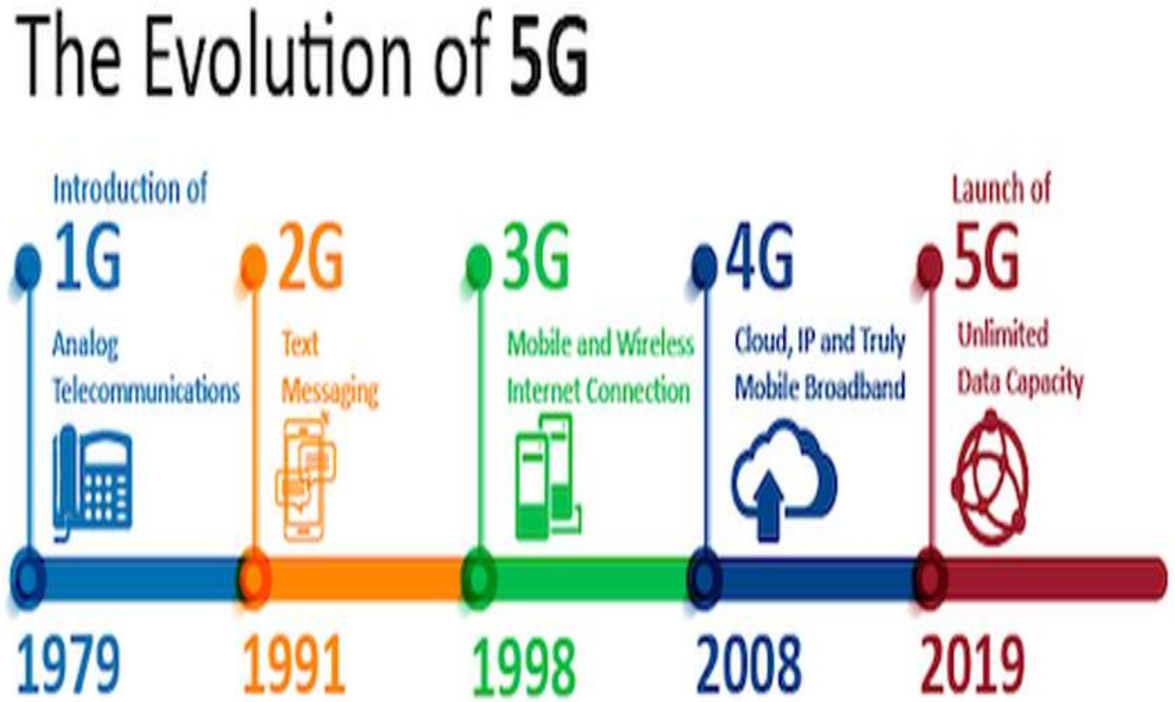


Figure 6. Design development of irons from 1950's to present time.


Telephone Evolution
1885
1920
1965
1985
1990
2000
2015
Future


The Evolution of 5G
Introduction of
1G
Analog
Telecommunications
2G
Text
Messaging
3G
Mobile and Wireless
Internet Connection
4G
Cloud, IP and Truly
Mobile Broadband
Launch of
5G
Unlimited
Data Capacity
1979
1991
1998
2008
2019

1984
Macintosh

1986
Macintosh Plus

1987
Macintosh II

1987
Macintosh SE

1989
Macintosh IIci

1989
Macintosh IIfx

1990
Macintosh Classic

1990
Macintosh IIsi

1990
Macintosh LC

1993
Macintosh Centris

1993
Macintosh TV

1995
Macintosh LC

1998
iMac

1999
iMac DV

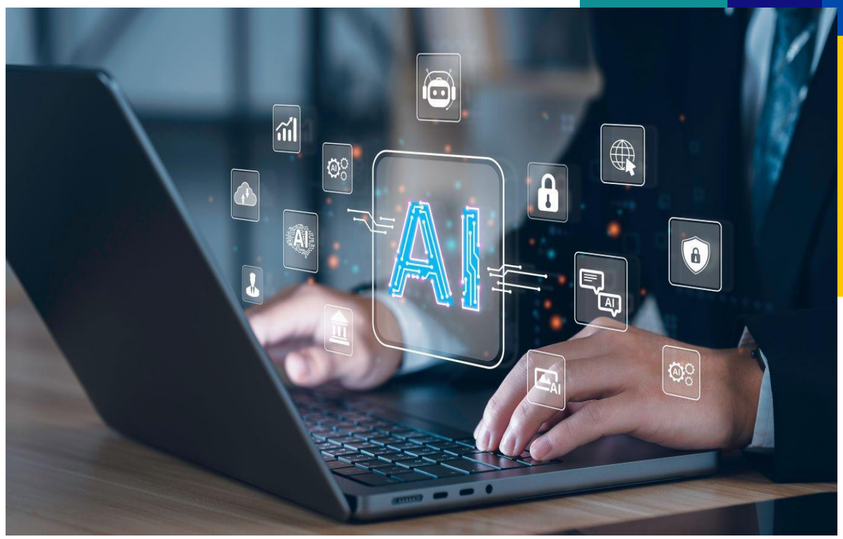
2001
iMac Patterns

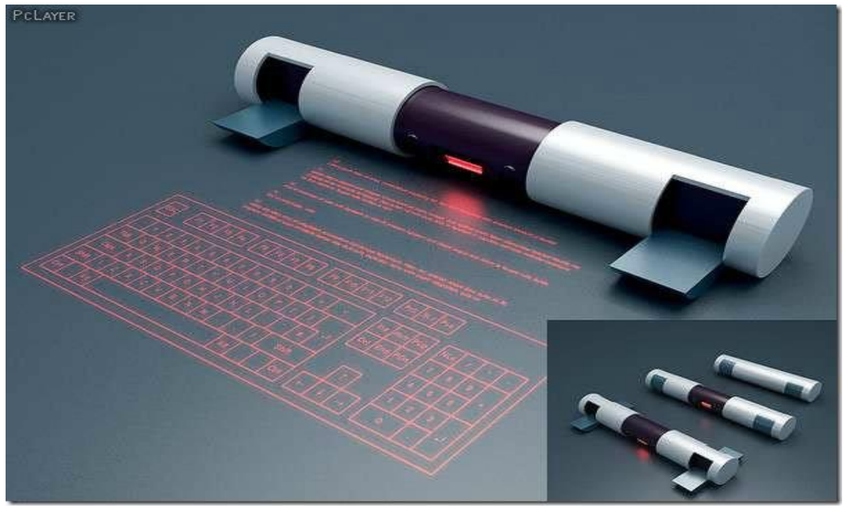
2002
iMac

2004
iMac G5

2006
iMac Slimmer Intel

2007
Novo iMac





1500 BCE

The first pill was developed by the ancient Egyptians.

100-200 AD

The Romans developed a form of tar pill.

1776

America starts contributing to medical advances as nation grows.

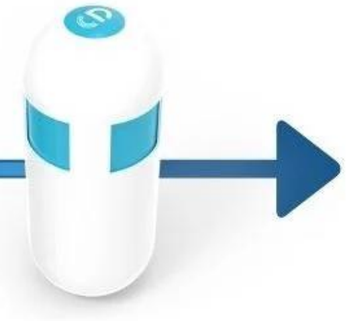
1853

The first needle was used to deliver medication.

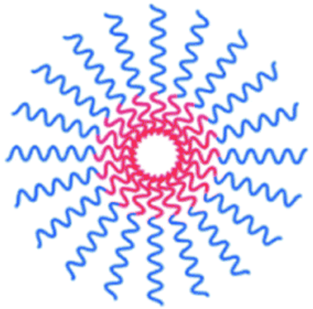
1940'S

Delayed release pills were developed, optimizing delivery.

2020'S

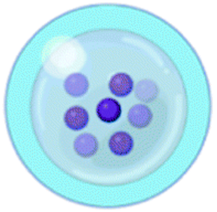


SmartTab is pioneering wireless drug delivery technology.



Indomethacin (IND) loaded polymeric micelles based on Amphiphilic Polyphosphazenes

2007

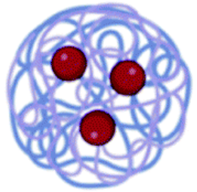


Indomethacin loaded Polymeric nanocapsules

2009

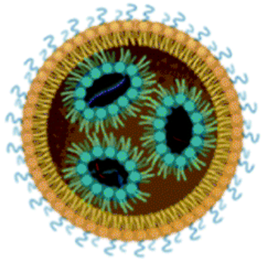
MTX loaded Gold half shell nanoparticle

2012



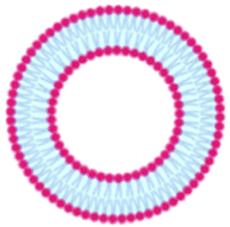
siRNA/thiolated glycol chitosan nanoparticles

2014



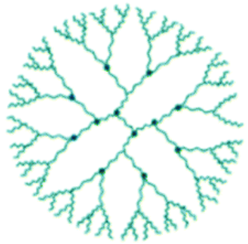
Lipid nanoparticles with TNF-α siRNA

2018



ROS-mediated liposomal dexamethasone

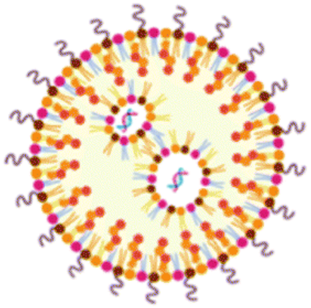
2021



PAMAM dendrimers functionalised with an anti-TNF α antibody and chondroitin sulphate

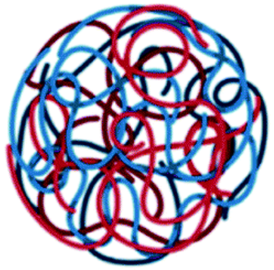
2021

2008



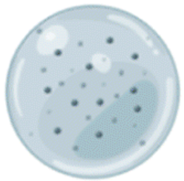
Solid lipid nanoparticles (SLNs) loaded with actarit

2011



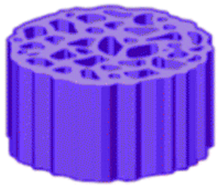
RGD peptide functionalized PLGA to deliver a STAT1 siRNA

2013



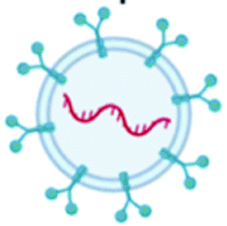
MTX associated to lipid nanoemulsions

2015



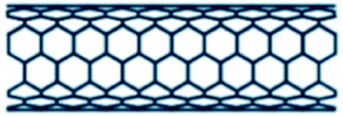
Carboxy methyl cellulose acetate butyrate (CMCAB)

2020



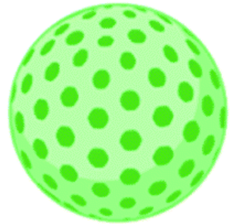
Exosome-based biomimetic nanoparticles

2021

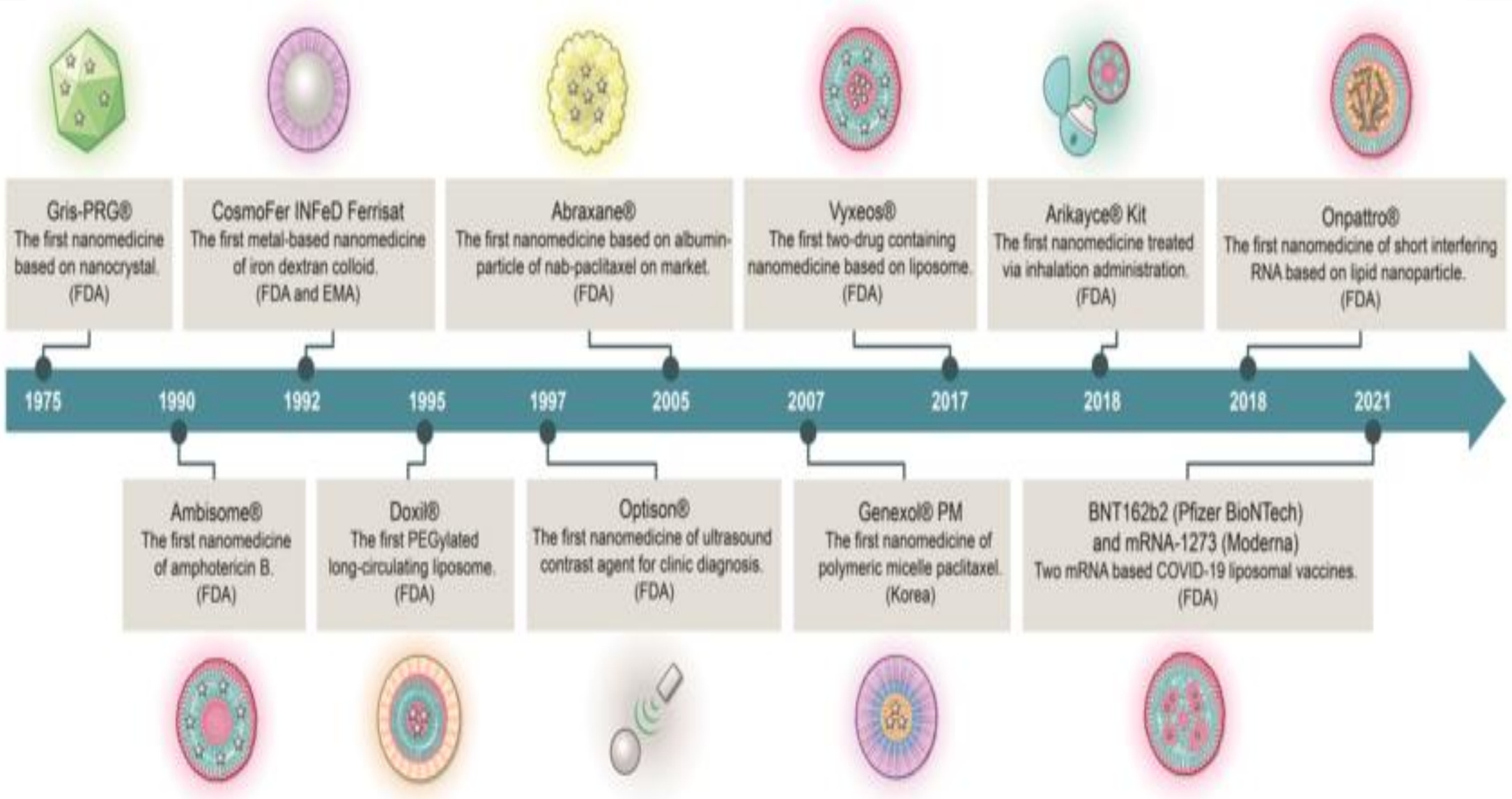


MTX and siRNA cojugated carbon nanotubes

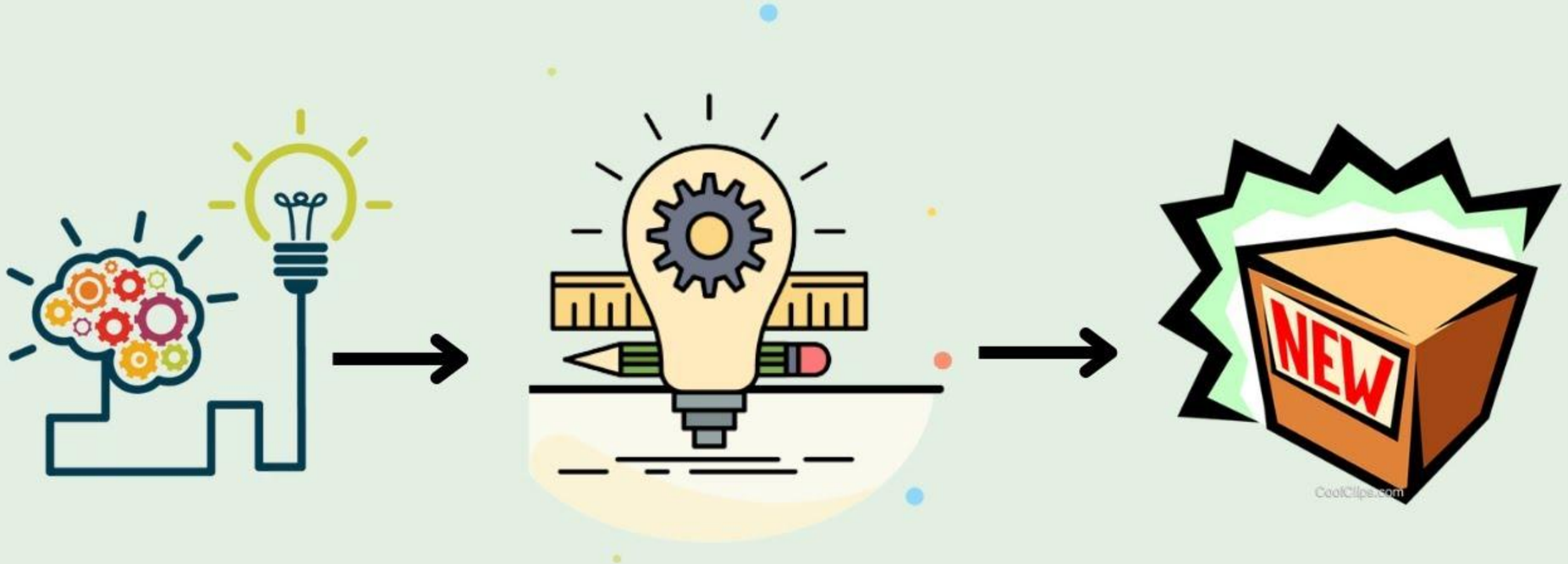
2022



Dexamethasone-Loaded Radially Mesoporous Silica


Gris-PRG®
The first nanomedicine based on nanocrystal.
(FDA)
CosmoFer INFeD Ferrisat
The first metal-based nanomedicine of iron dextran colloid.
(FDA and EMA)
Abraxane®
The first nanomedicine based on albumin-particle of nab-paclitaxel on market.
(FDA)
Vyxeos®
The first two-drug containing nanomedicine based on liposome.
(FDA)
Arikayce® Kit
The first nanomedicine treated via inhalation administration.
(FDA)
Onpattro®
The first nanomedicine of short interfering RNA based on lipid nanoparticle.
(FDA)
1975
1990
1992
1995
1997
2005
2007
2017
2018
2018
2021
Ambisome®
The first nanomedicine of amphotericin B.
(FDA)
Doxil®
The first PEGylated long-circulating liposome.
(FDA)
Optison®
The first nanomedicine of ultrasound contrast agent for clinic diagnosis.
(FDA)
Genexol® PM
The first nanomedicine of polymeric micelle paclitaxel.
(Korea)
BNT162b2 (Pfizer BioNTech) and mRNA-1273 (Moderna)
Two mRNA based COVID-19 liposomal vaccines.
(FDA)

Product Development



educationleaves.com

Pengertian

Menurut Tjiptono (2008)

Pengembangan produk adalah **strategi untuk produk baru** meliputi produk orisinil, produk yang **disempurnakan,** produk yang **dimodifikasi,** dan merek baru yang **dikembangkan** melalui usaha **riset dan pengembangan**.

Menurut Kotler dan Amstrong (2008)

Pengembangan produk adalah **strategi untuk pertumbuhan perusahaan** dengan menawarkan produk **memodifikasi** atau produk baru ke segmen pasar yang ada sekarang pengembangan konsep produk menjadi produk fisik dalam upaya memastikan bahwa ide produk bisa diubah menjadi produk yang bisa diwujudkan secara efektif.

Menurut Alma (2002)

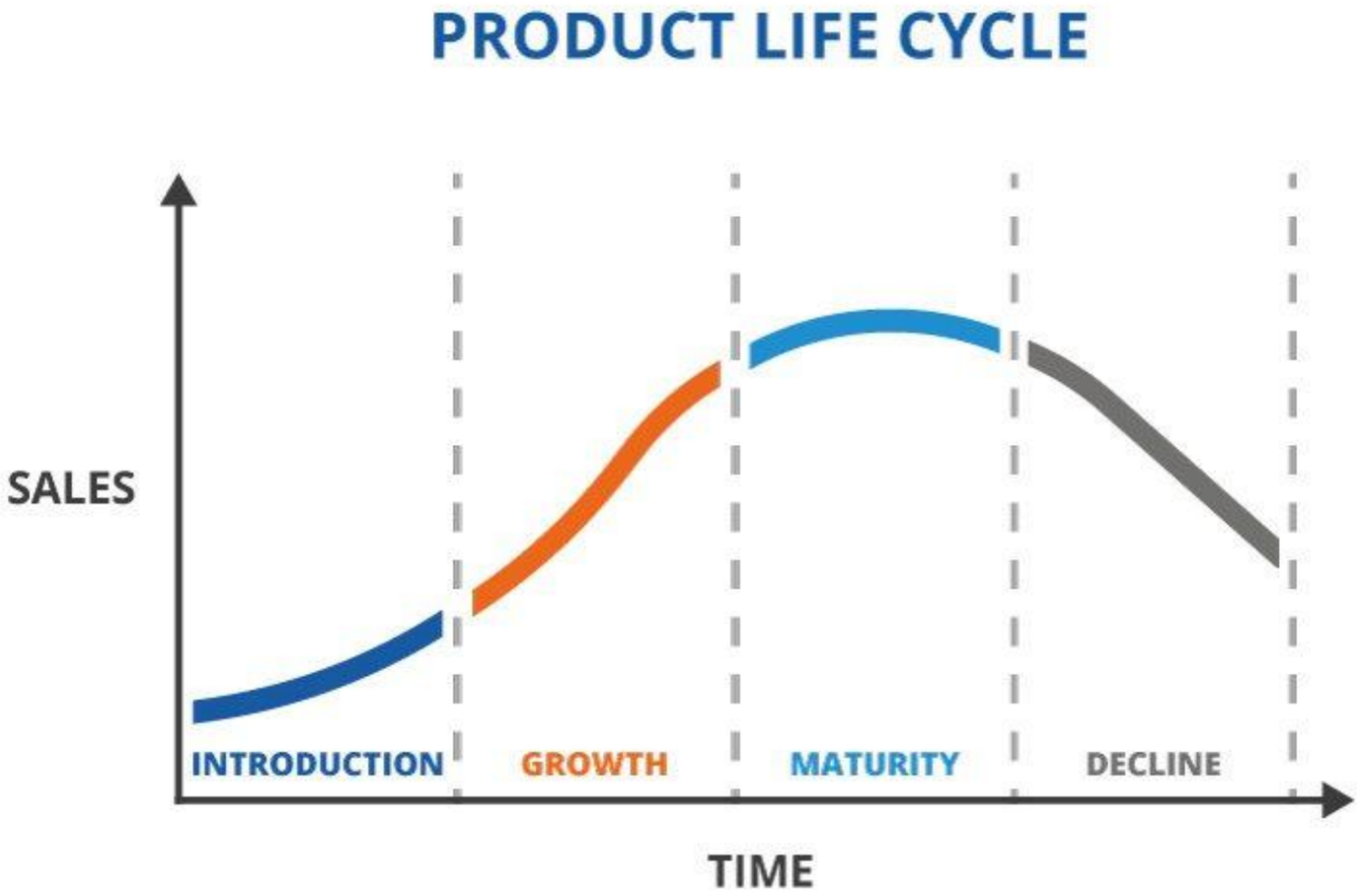
Pengembangan produk adalah semua kegiatan yang dilakukan oleh pabrikan atau produsen dalam **menentukan dan mengembangkan produknya**, **memperbaiki produk lama**, **memperbanyak kegunaan** dari produk yang sudah ada dan mengurangi biaya produksi dan biaya pengemas.

Menurut Simamora (2000)

Pengembangan produk adalah **proses pencarian gagasan untuk barang dan jasa baru** dan mengkonversikannya ke dalam tambahan lini produk yang berhasil secara komersial. Pencarian produk baru didasarkan pada asumsi bahwa para pelanggan menginginkan unsur-unsur baru dan pengenaan produk baru akan membantu mencapai tujuan perusahaan.

Menurut Ullman, 2009; Ulrich &Eppinger, 2004

Pengembangan produk adalah **penciptaan produk dengan karakteristik baru atau berbeda** yang menawarkan manfaat baru atau tambahan bagi pelanggan. Pengembangan produk mungkin **melibatkan modifikasi** produk yang sudah ada atau presentasi atau formulasi produk yang sama sekali baru yang memenuhi keinginan pelanggan atau kekosongan pasar yang baru ditentukan.



Introduction stage: maintenance cost is high at this stage, and profit is limited. Product needs to be sold immediately to earn profit

Growth: maintenance cost is lower than the introduction stage, and sales are increased. Competitors are appearing in the market, too.

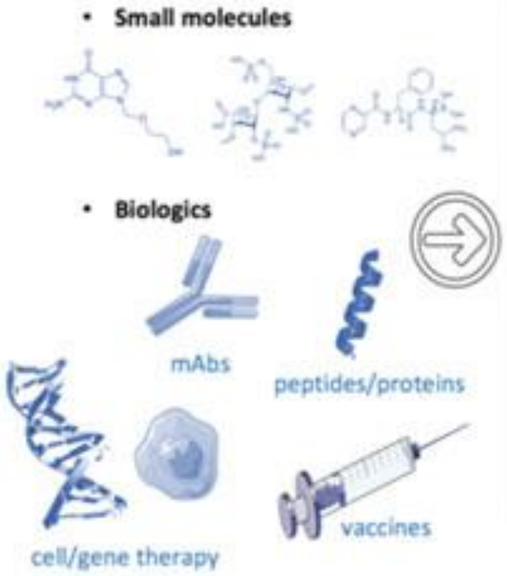
Maturity: this stage brings the most profit to the business, sales increase and maintenance cost gets much lower

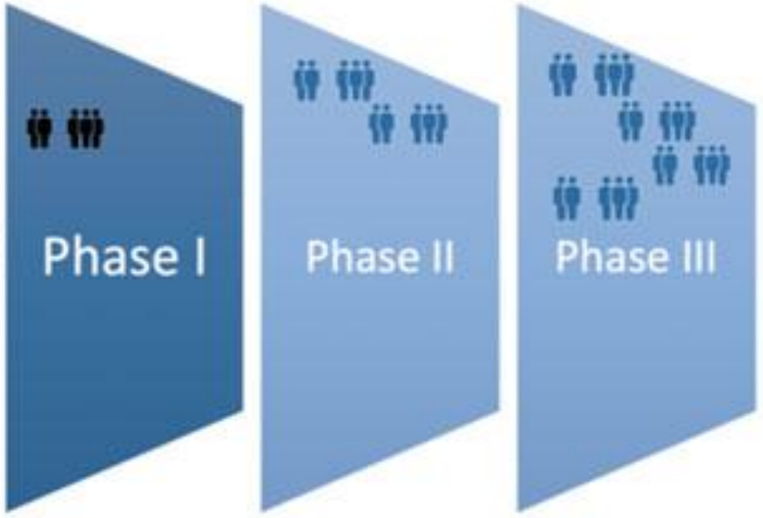
Decline and withdrawal: at this stage, products of competitors are preferred; therefore, profit decreases significantly

Stage 1	Stages 2 and 3	Stage 4	Stage 5	
"Pre-discovery"	Drug discovery & Preclinical studies	Clinical trials	Review & Approval	Phase IV

~12-15 years

Basic research
Clinical observations





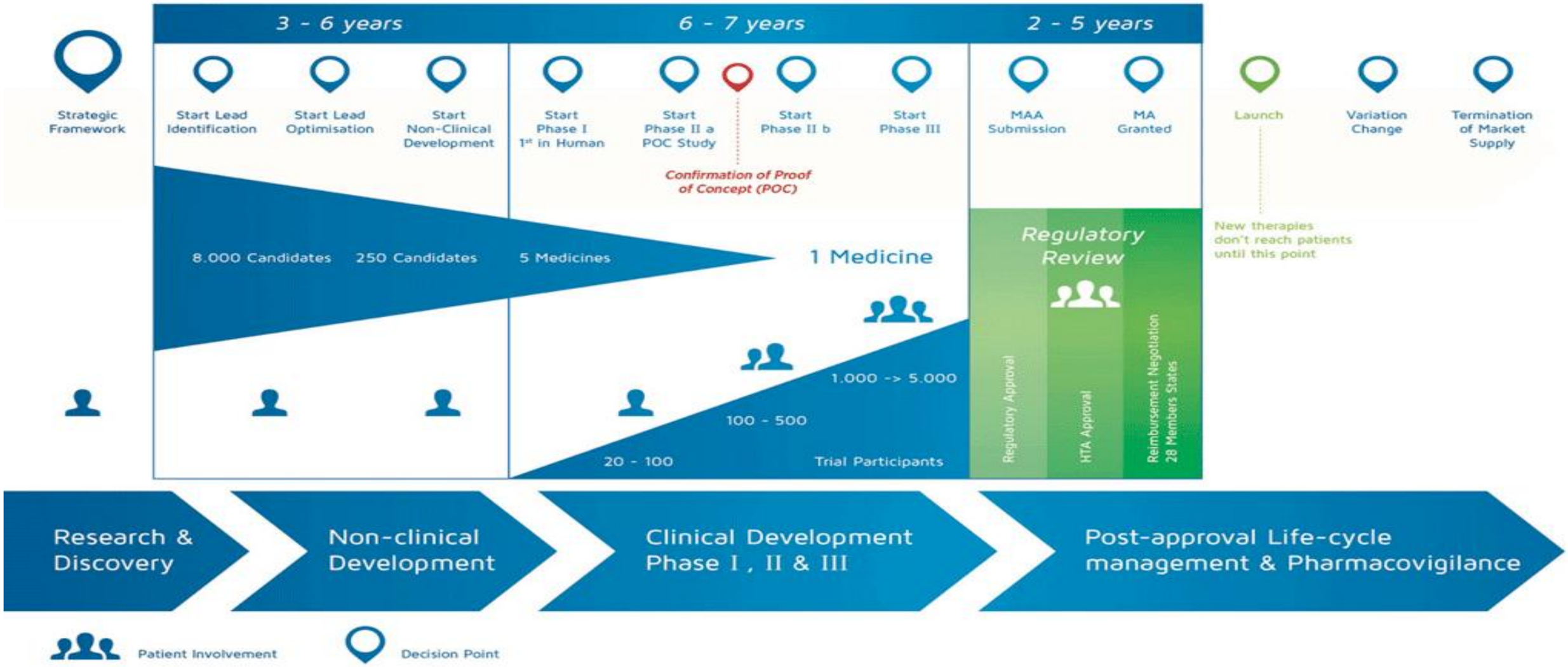
Molecular mechanisms involved in the disease state, identification of putative targets...

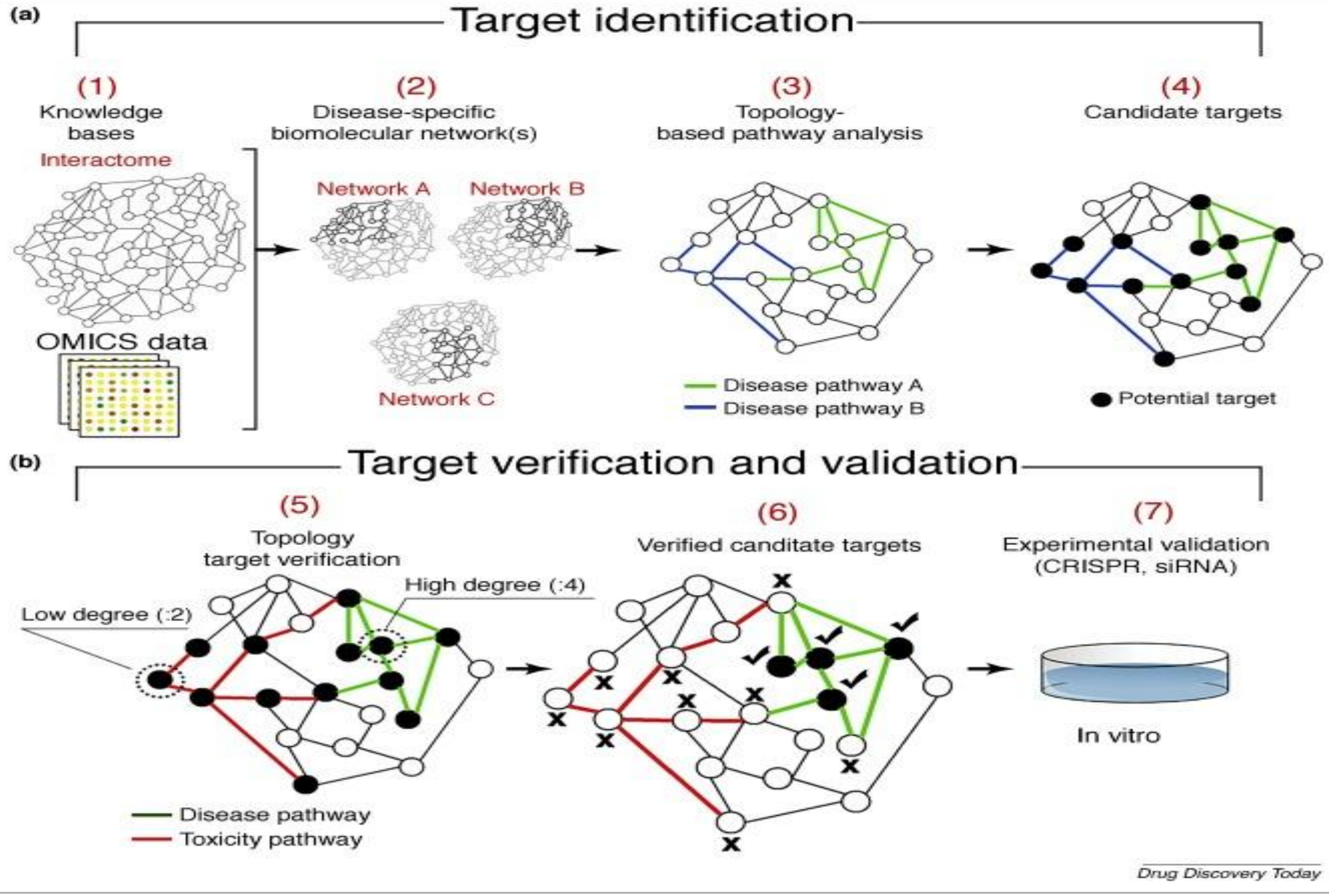
Identification of the therapeutic agents modulating the selected target(s), ADMET, efficacy,... first evaluations silico-vitro-vivo

Evaluations in humans
PK, dose, efficacy, toxicity...

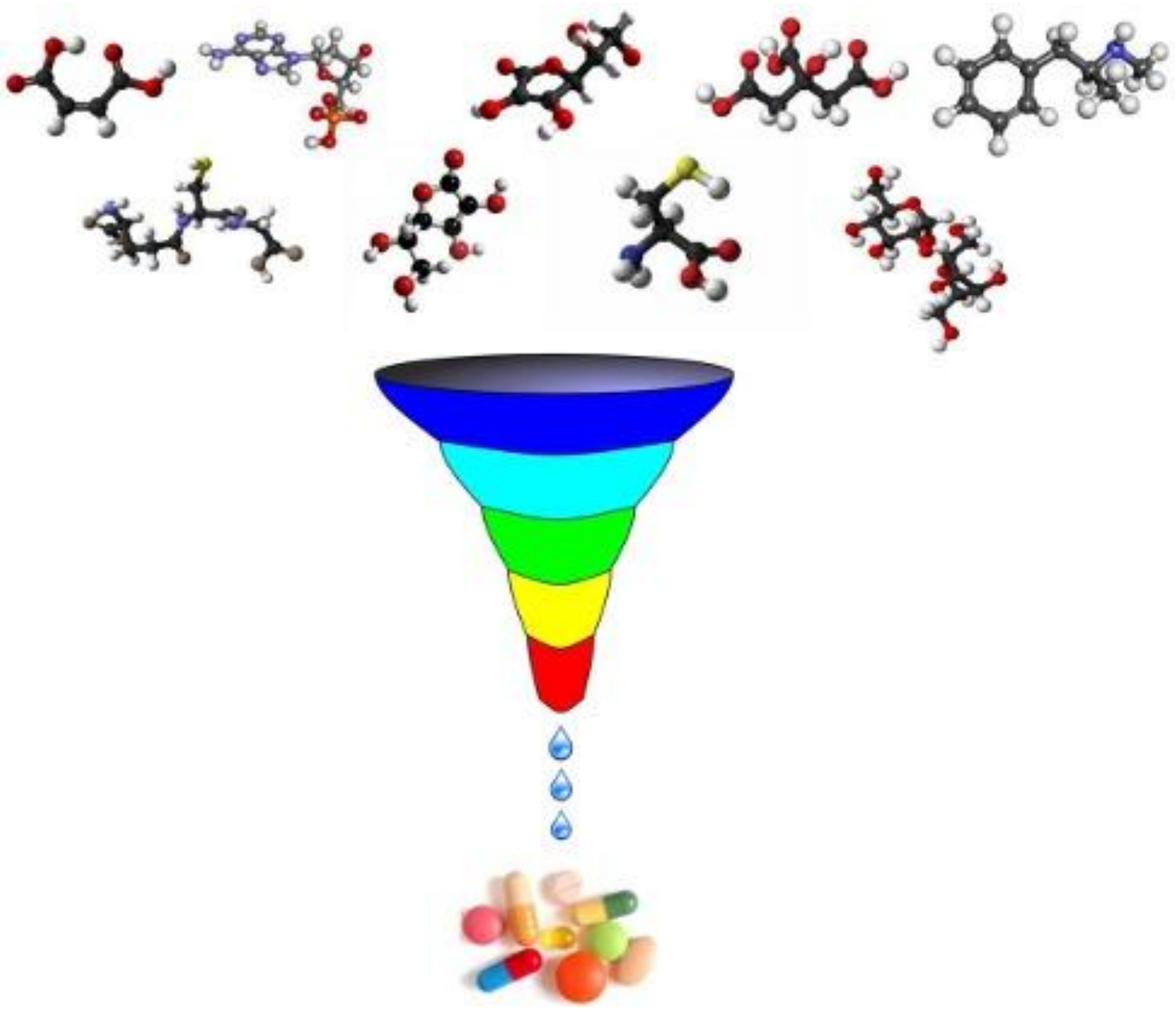
Reviewing, approval & post-market monitoring

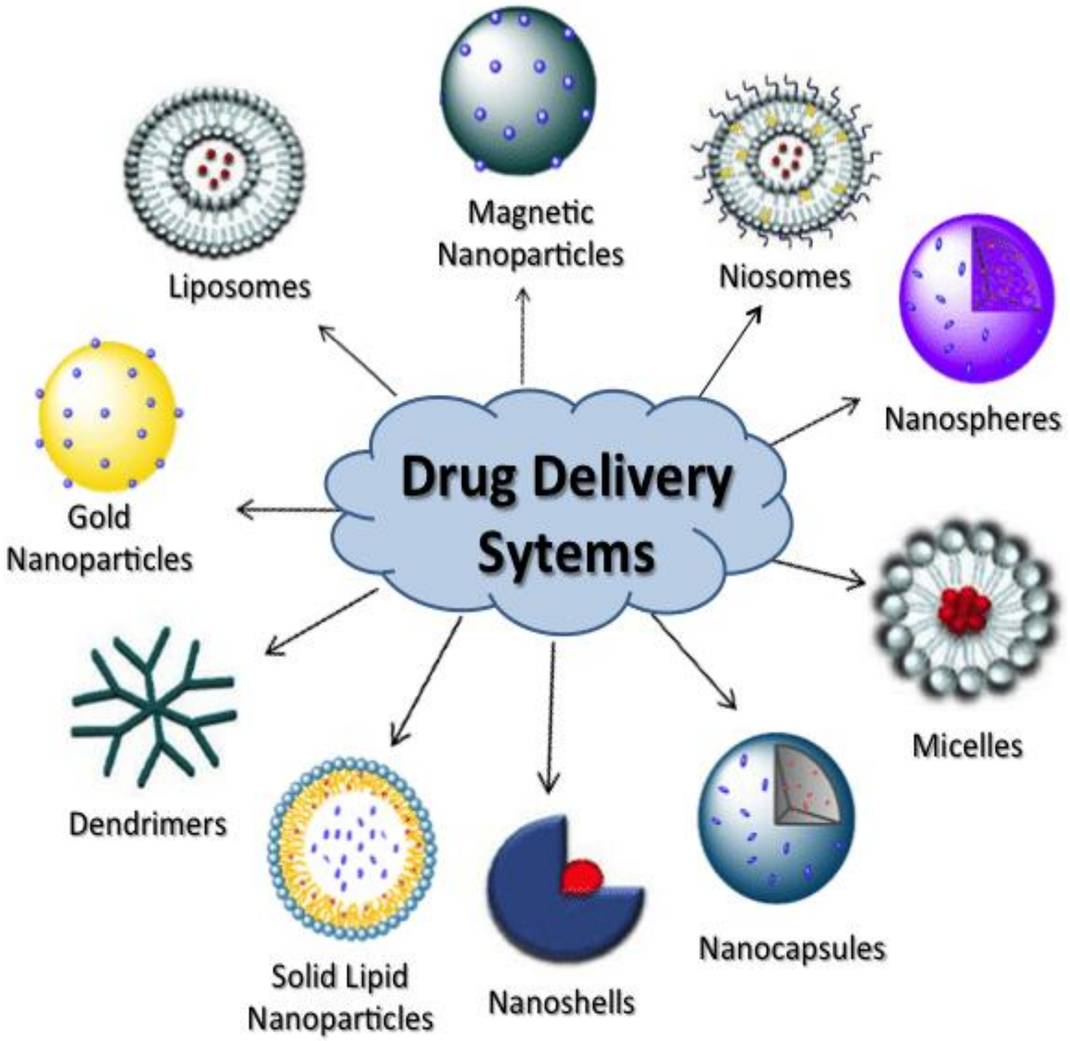
Overview of Decision Points and Development Steps in Medicines R&D





Network-based technologies for early drug discovery

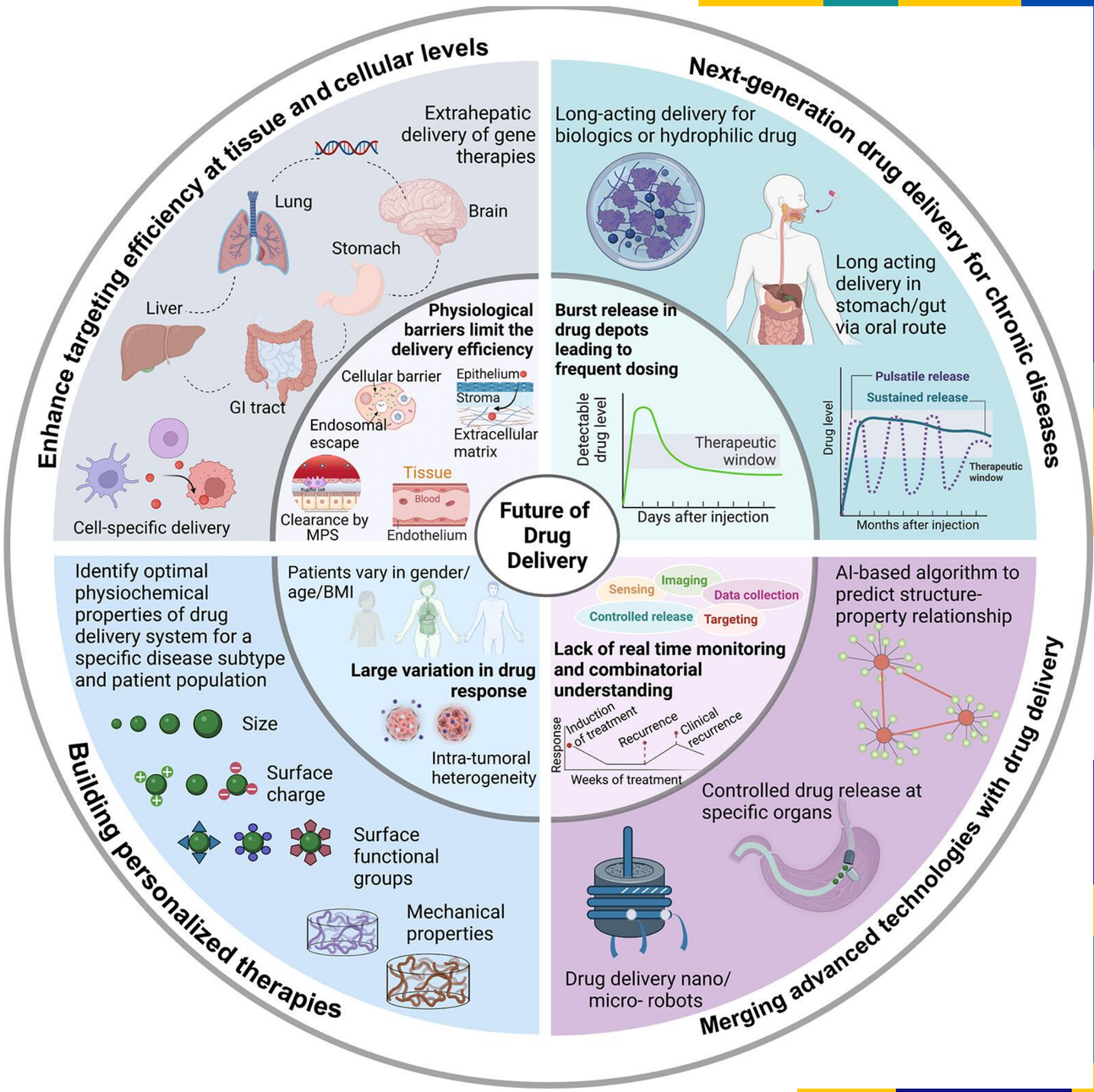


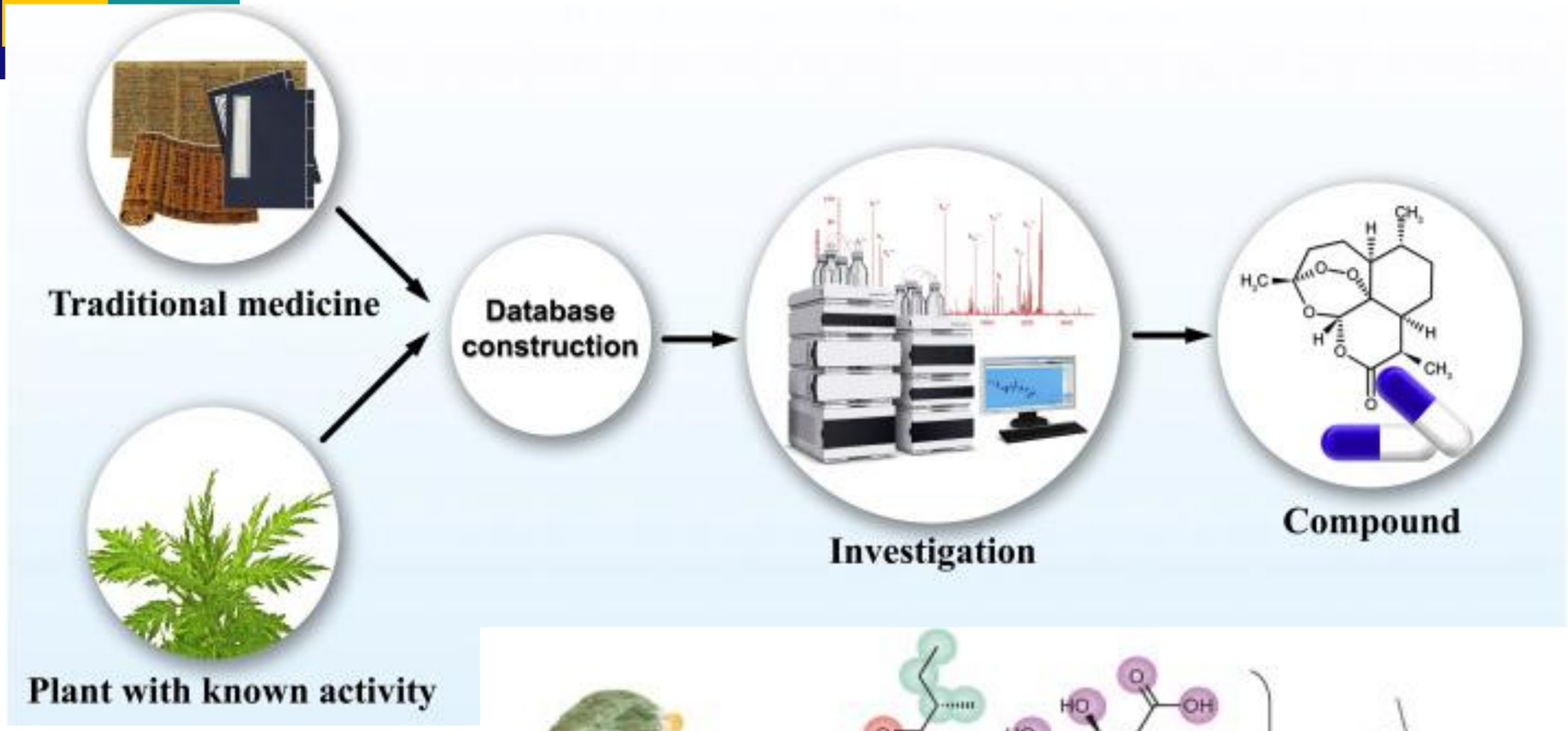


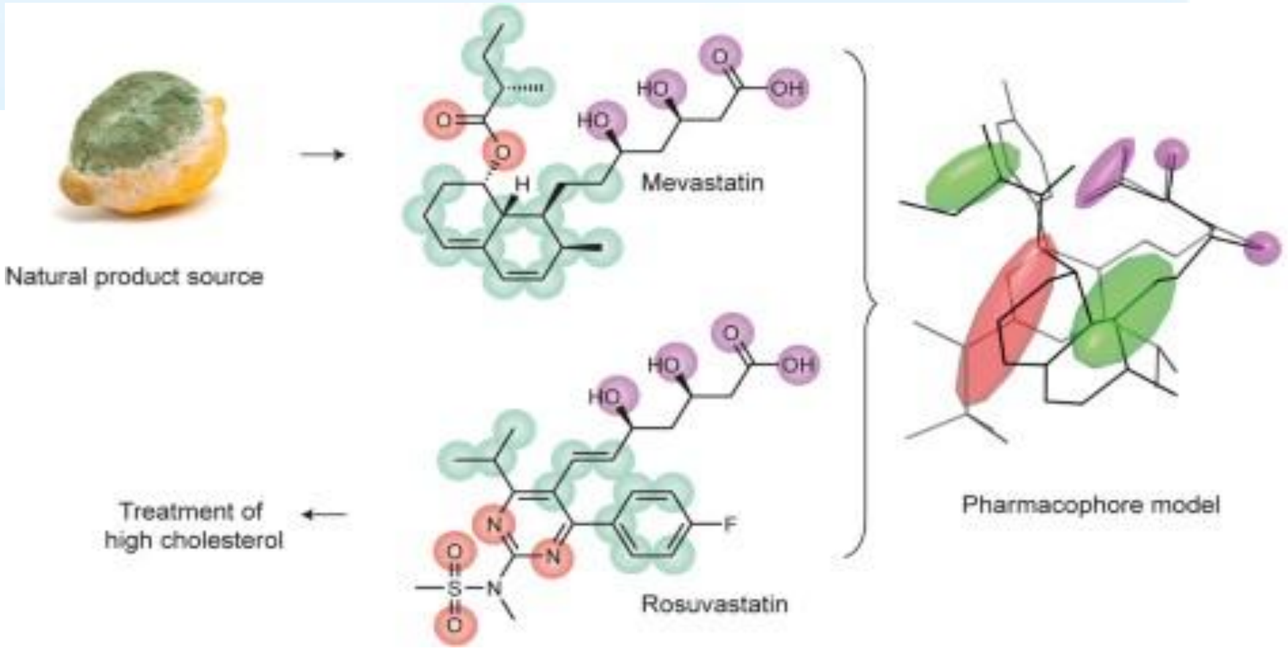
Drug discovery

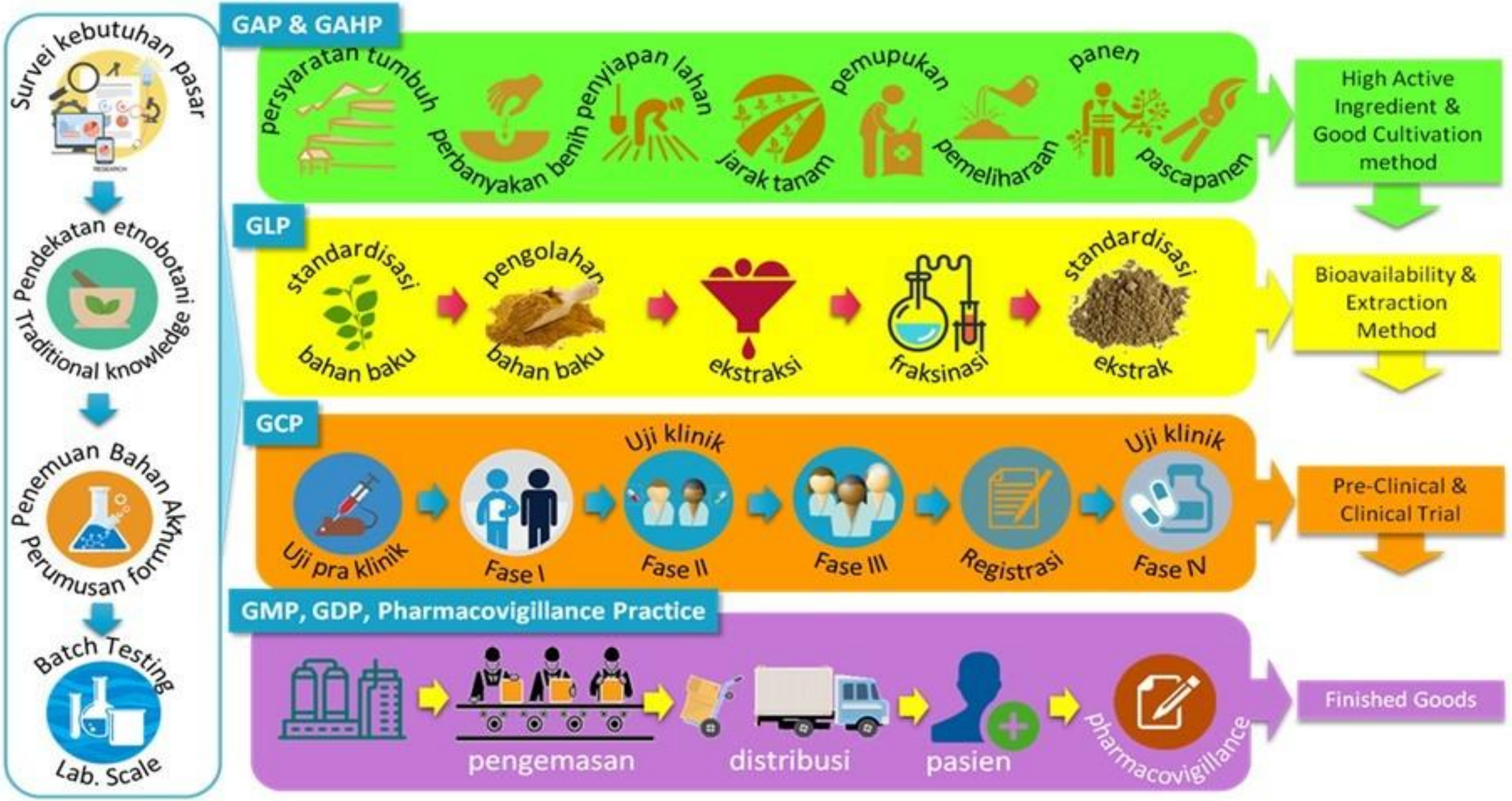
Limitations

- Poor absorption from target site
- Poor Bioavailability
- High First-pass Metabolism
- Fluctuations in Plasma drug level
- Premature excretion from the body
- Repeated dosing
- High dose dumping




Traditional medicine
Plant with known activity
Database construction
Investigation
Compound


Natural product source
Mevastatin
Treatment of high cholesterol
Rosuvastatin
Pharmacophore model
Superimposed crystal structures


Survei kebutuhan pasar
Pendekatan etnobotani
Traditional knowledge
Penemuan Bahan Aktif
Perumusan formulasi
Batch Testing
Lab. Scale
GAP & GAHP
persyaratan tumbuh
perbanyakan benih
penyiapan lahan
jarak tanam
pemupukan
pemeliharaan
panen
pascapanen
High Active Ingredient & Good Cultivation method
GLP
standardisasi
bahan baku
pengolahan
bahan baku
ekstraksi
fraksinasi
standardisasi
ekstrak
Bioavailability & Extraction Method
GCP
Uji pra klinik
Fase I
Uji klinik
Fase II
Fase III
Registrasi
Uji klinik
Fase IV
Pre-Clinical & Clinical Trial
GMP, GDP, Pharmacovigillance Practice
pengemasan
distribusi
pasien
pharmacovigillance
Finished Goods

OMAI

Jamu

> 8000

Kriteria :

- Aman
- Memenuhi persyaratan mutu
- Khasiat dibuktikan secara empiris

Obat Herbal Terstandar (45)

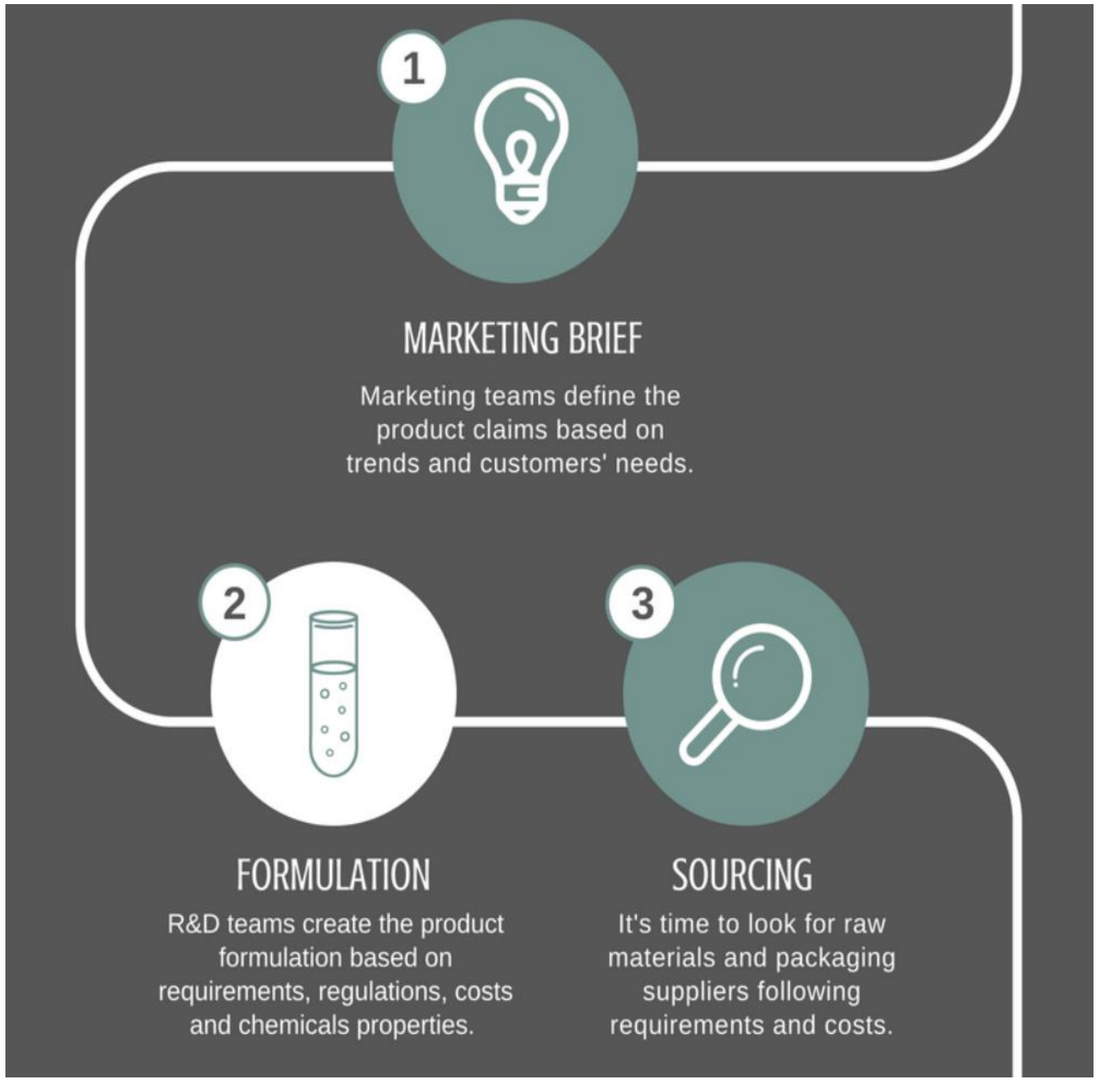
Kriteria :

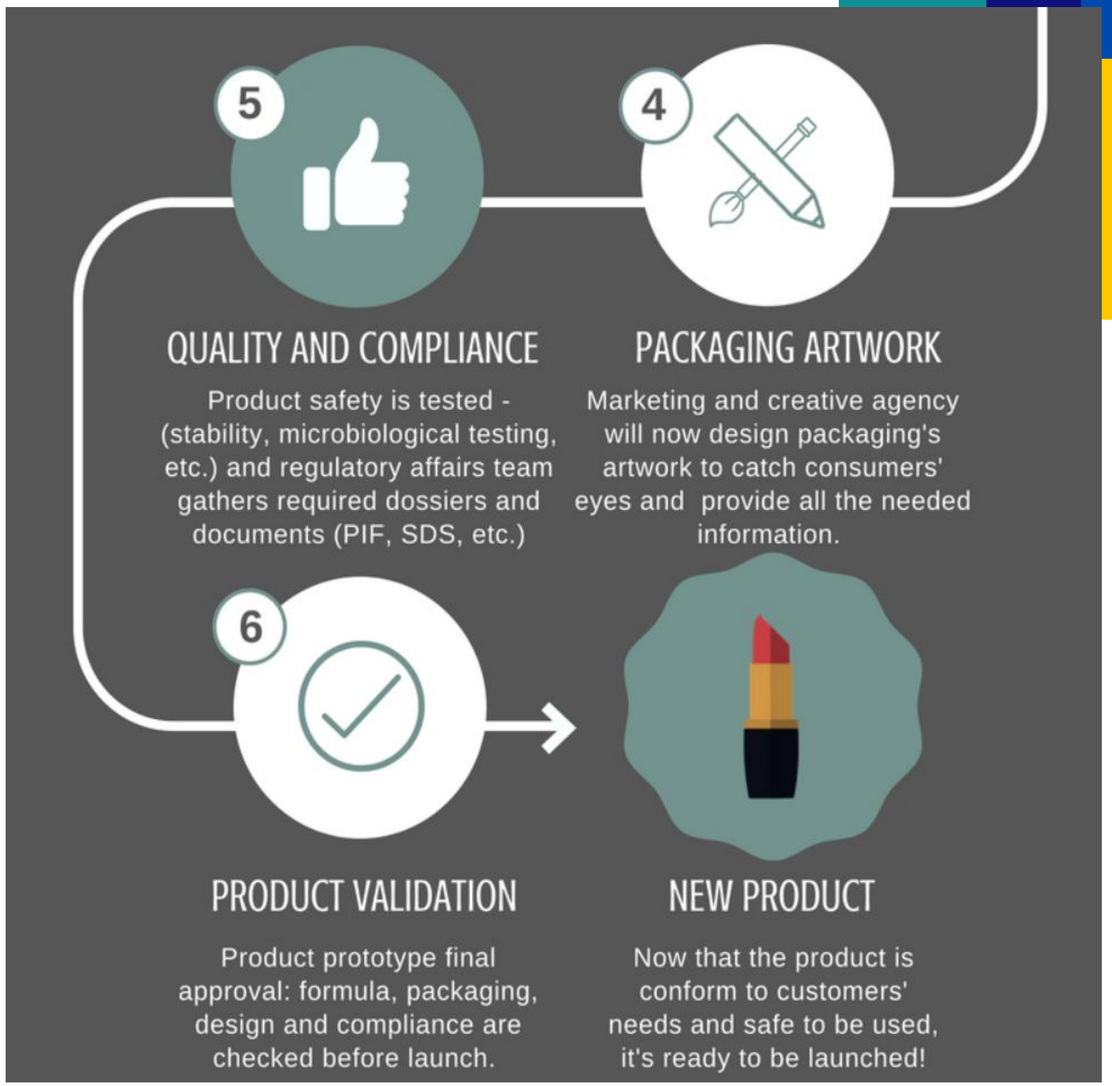
- Aman
- Memenuhi persyaratan mutu
- Khasiat dibuktikan secara ilmiah atau praklinik
- Bahan baku yang digunakan terstandar

Fitofarmaka (21)

Kriteria :

- Aman
- Memenuhi persyaratan mutu
- Khasiat dibuktikan secara klinis
- Bahan baku yang digunakan terstandar





PENGEMBANGAN KOSMETIK

Table 1. Main effects of cosmetic vehicles on the skin.

Effect	Definition
Protective	Protects the skin from external harmful factors (dry air, pollution, UV light)
Cleansing	Eliminates dirt and microorganisms from the skin
Hydrating	Provides water in order to restore or maintain fluid balance
Moisturizing	Establishes an effective barrier that prevents water loss through the epidermis
Soothing	Provides a gently calming effect
Firming	Makes the skin more toned and smoother

PENGEMBANGAN KOSMETIK

Produk Anti Jerawat

Shampo Anti Ketombe

Antiperspirant / Deodoran Medicated

Obat Quasi (Quasi Drug)

Obat quasi adalah istilah regulatori untuk produk yang berada di antara **kosmetik dan obat**. Artinya, produk ini tidak sekuat obat keras, tetapi memiliki klaim dan fungsi lebih spesifik dibanding kosmetik biasa karena mengandung bahan aktif dengan efek fisiologis ringan–sedang.

Masuk dalam kelompok **OTSK** (Obat Tradisional, Suplemen Kesehatan, dan Kuasi)

Aspek	Obat	Obat Quasi	Kosmetik
Tujuan	Mengobati/ menyembuhkan	Mengatasi keluhan ringan	Membersihkan/ merawat
Klaim	Terapi penyakit	Pencegahan ringan/ fungsi khusus	Estetika/ perawatan
Registrasi	Ketat (uji klinis)	Menengah	Lebih sederhana
Contoh	Antibiotik	Krim anti jerawat	Pelembab wajah

Obat Quasi (Quasi Drug)

Examples of different categorizations of products are illustrated:

Function/ Claim	Europe	Japan	Korea
Hair Dye	Cosmetics	Quasi-drug	General/ functional cosmetics
Skin Whitener	Cosmetics/ drug	Quasi-drug	General cosmetics
Sunscreen	Cosmetics	Cosmetics/ quasi-drug	Functional cosmetics
Hair Growth	Cosmetics/ drug	Quasi-drug	Functional cosmetics
Depilatory	Cosmetics	Quasi-drug	Functional cosmetics
Body Beauty	Cosmetics/ drug	Depending on a specific case	Drug
Deodorant	Cosmetics	Quasi-drug	Quasi-drug

https://signicent.com/quasi-drugs-cosmeceuticals/

Perkembangan di Indonesia

1.2020–2022 → Penguatan sistem OSS & registrasi online
2.2023 → Regulasi spesifik kriteria & evaluasi klaim
3.2024 → Pengetatan aturan labeling dan klaim

Tantangan

- Overclaim di marketplace
- Tumpang tindih persepsi dengan kosmetik
- Literasi masyarakat

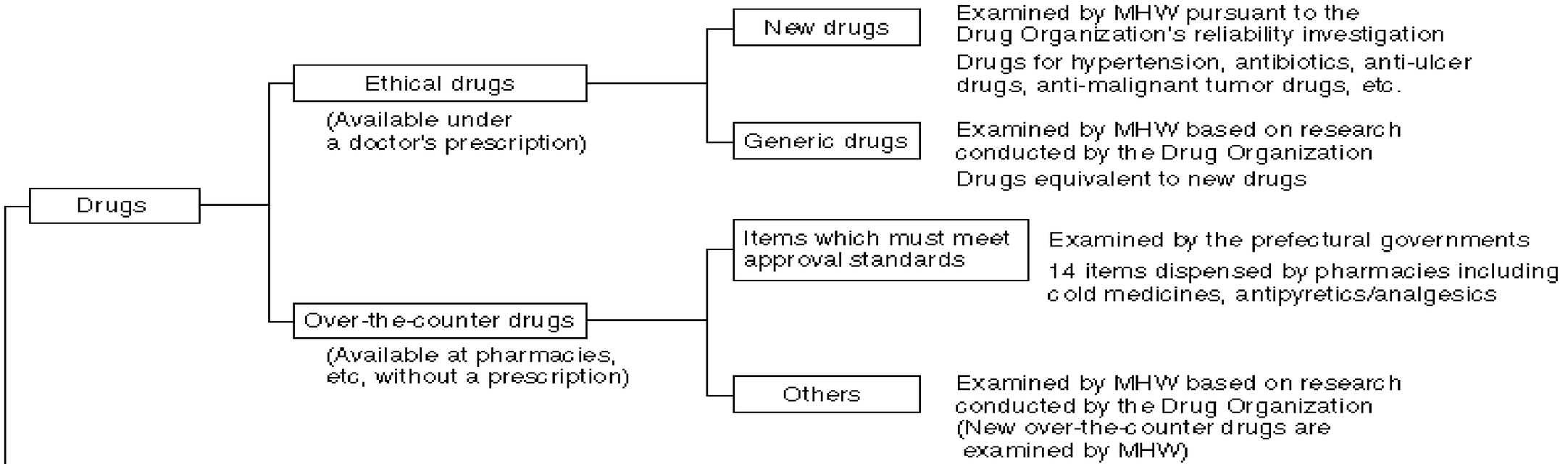
Obat Quasi (Quasi Drug)

Criteria for pharmaceuticals, quasi-pharmaceutical products or cosmetics	Criteria for license
Pharmaceuticals designated by the Minister of Health, Labour and Welfare provided in Article 49, paragraph (1)	First-class marketing license for pharmaceuticals
Pharmaceuticals other than pharmaceuticals falling under the preceding paragraph	Second-class marketing license for pharmaceuticals
Quasi-pharmaceutical products	Marketing license for quasi-pharmaceutical products
Cosmetics	Marketing license for cosmetics

NOTE: This is just one of the article under Chapter IV. Similarly, there are many other articles under different chapters for the approvals of Quasi-drugs.

https://signicent.com/quasi-drugs-cosmeceuticals/

Obat Quasi (Quasi Drug)



Quasi-drugs

New quasi-drugs: Examined by MHW
Items which meet approval standards: Examined by the prefectural governments
Other items: Examined by MHW based on equivalency research conducted by the Drug Organization

(Medicated toothpastes, hair dyes, bath products, mouth washes, etc.)

Cosmetics

Items that do not contain ingredients designated by the Minister: Application for approval exempted.
Notification to MHW must be submitted for each individual product after the category license has been issued.
Items that contain an ingredient designated by the Minister: Examined by MHW based on research conducted by the Drug Organization.
New cosmetics: Examined by MHW

(Perfumes, lipsticks, shampoos, conditioners, etc.)

Note: The Drug Organization stands for the Organization for Drug ADR Relief, R&D Promotion and Product Review.
It started its research on equivalency in April 1994, and on reliability in April 1997.

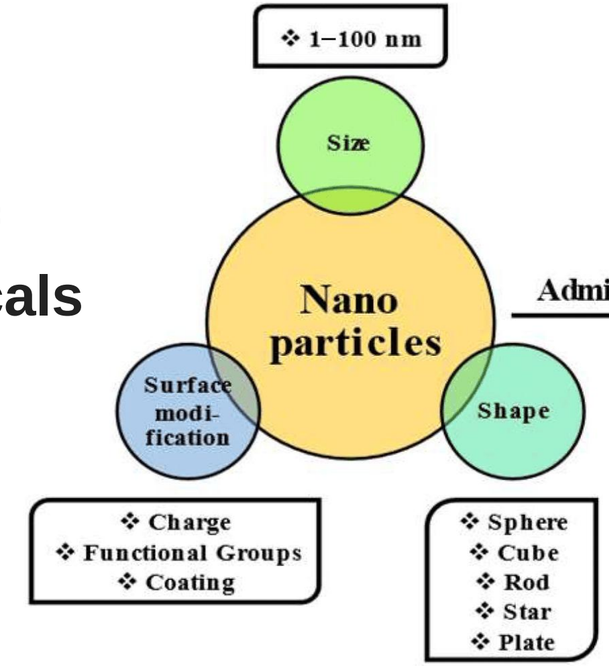
Obat Quasi (Quasi Drug)

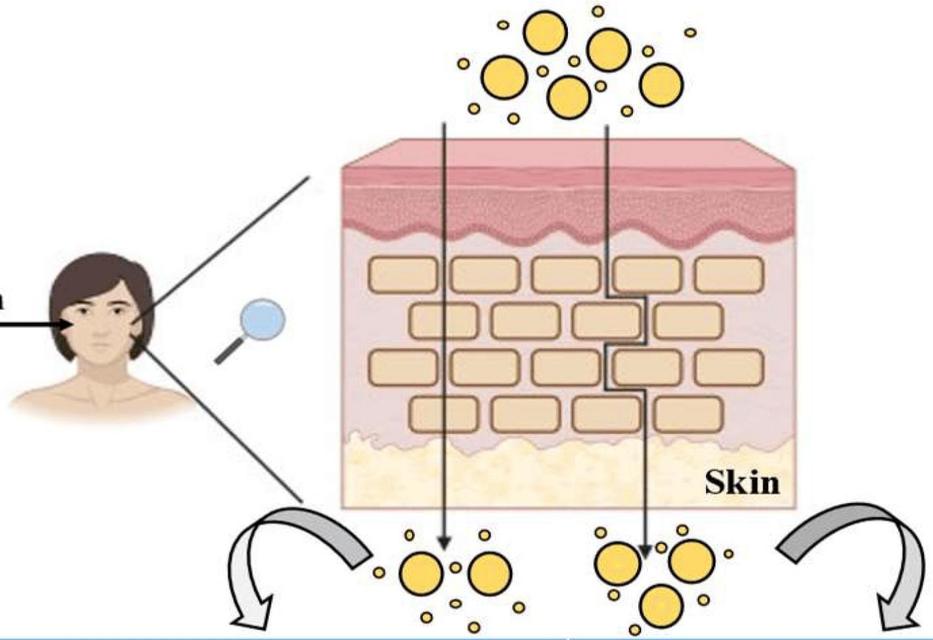
Arctigenin-Enriched Burdock Seed Oil (ABSO): A New Skin Brightening Botanical Extract

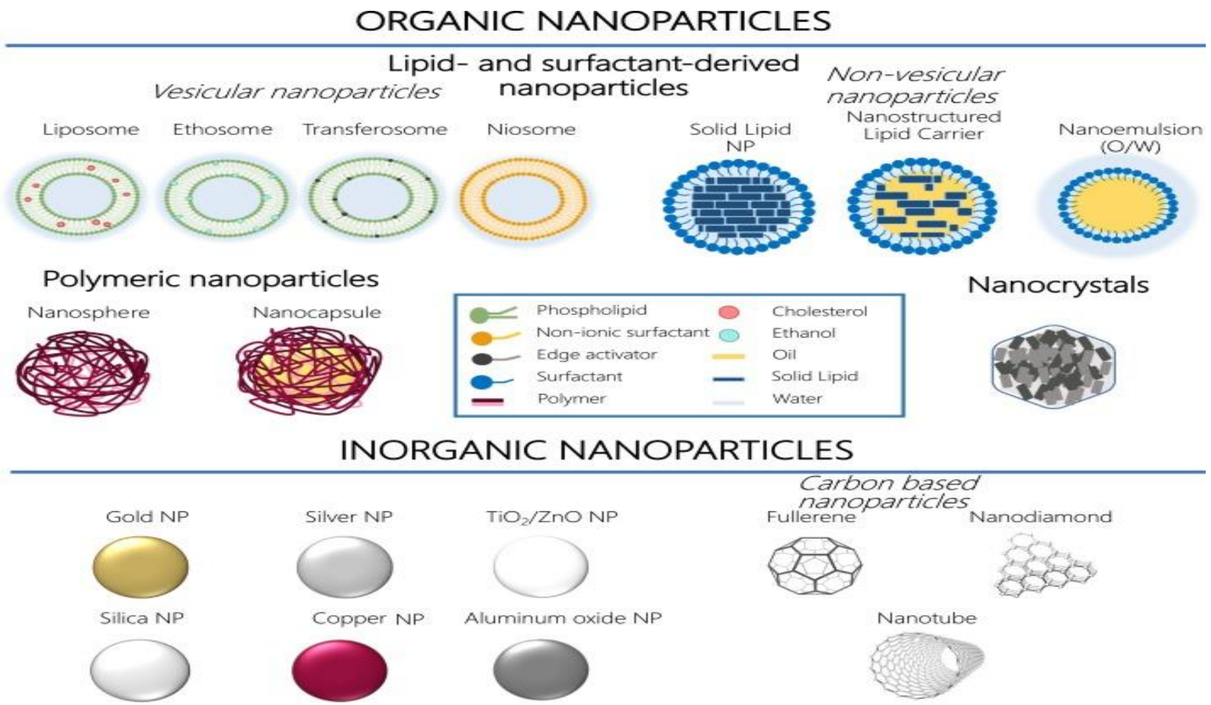
Test Item	Specification	Result
Description	A light yellow to yellow liquid. A slightly characteristic odor	Meets Requirements
Identification	FTIR absorbance at 2950 cm^{-1}, 2850 cm^{-1}, 1750 cm^{-1}, 1460 cm^{-1}, and 1160 cm^{-1}	Meets Requirements
Acid Value	<5	3
Saponification Value	150–250	182
Iodine Value	120–220	129
Unsaponifiable Matter	<5%	1%
Purity	-	-
Heavy Metals	<20 ppm	Meets Requirements
Arsenic	<2 ppm	Meets Requirements

* Conformity according to The Japanese Standards of Quasi-Drug Ingredients [15] as specified by the Pharmaceuticals and Medical Devices Agency of Japan.

Advantages of nanocosmeceuticals







Advantages	Disadvantages
Control & targeted delivery	Nanoparticle toxicity may lead to inflammation, oxidative stress, & consequent damage to membranes & proteins
↑ Texture & transparency of the cosmetic formulation	Require sophisticated equipment for manufacturing
↑ Dermal penetration & bioavailability	↑ Cost of production
↑ Appearance, covering power, aesthetic appeal & adherence over the skin	↑ Environmental concern
↑ Stability & efficacy to the cosmetic formulation	Teratogenic in nature, due to easy placenta penetration
Better drug holding capacity	May damage DNA & lead to malignancy

Nanoparticles

Polymer micelle
Dendrimer
Nanosphere

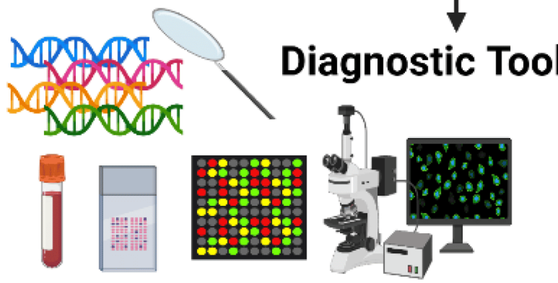
Polymeric

Gold nanoparticle
Silver nanoparticle
Iron oxide nanoparticle
Quantum dot

Inorganic

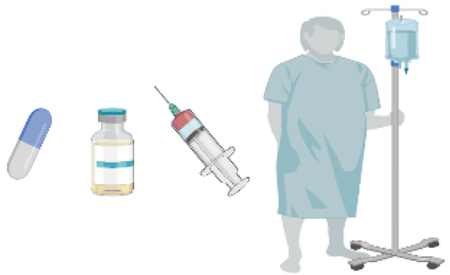
Liposome
Lipid nanoparticle

Lipid-based

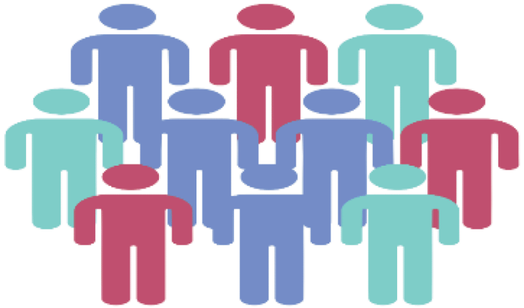


Diagnostic Tool

Therapeutic Approach



Personalized Medicine



Patient response

Good response

No response

Toxic effect

Tujuan Pengembangan Produk Baru

1. Untuk memberikan nilai maksimal bagi konsumen
2. Memenangkan persaingan perusahaan dengan memilih produk yang inovatif, produk yang dimodifikasi serta mempunyai nilai yang tinggi baik dalam desain warna, ukuran, kemasan, merek, dan ciri-ciri lain.

REFERENSI

1. Liu, Q., Zou, J., Chen, Z., He, W., & Wu, W. (2023). Current research trends of nanomedicines. Acta Pharmaceutica Sinica B, 13(11), 4391–4416. https://doi.org/10.1016/J.APSB.2023.05.018
2. Fotis, C., Antoranz, A., Hatziavramidis, D., Sakellaropoulos, T., & Alexopoulos, L. G. (2018). Network-based technologies for early drug discovery. Drug Discovery Today, 23(3), 626–635. https://doi.org/10.1016/J.DRUDIS.2017.12.001
3. Vargason, A. M., Anselmo, A. C., & Mitragotri, S. (2021). The evolution of commercial drug delivery technologies. Nature Biomedical Engineering 2021 5:9, 5(9), 951–967. https://doi.org/10.1038/s41551-021-00698-w
4. Gupta, V., Mohapatra, S., Mishra, H., Farooq, U., Kumar, K., Ansari, M. J., Aldawsari, M. F., Alalaiwe, A. S., Mirza, M. A., & Iqbal, Z. (2022). Nanotechnology in Cosmetics and Cosmeceuticals—A Review of Latest Advancements. Gels 2022, Vol. 8, Page 173, 8(3), 173. https://doi.org/10.3390/GELS8030173
5. Salvioni, L., Morelli, L., Ochoa, E., Labra, M., Fiandra, L., Palugan, L., Prosperi, D., & Colombo, M. (2021). The emerging role of nanotechnology in skincare. Advances in Colloid and Interface Science, 293, 102437. https://doi.org/10.1016/J.CIS.2021.102437
6. Ferreira, M., Matos, A., Couras, A., Marto, J., & Ribeiro, H. (2022). Overview of Cosmetic Regulatory Frameworks around the World. *Cosmetics*, *9*(4), 72. https://doi.org/10.3390/cosmetics9040072
7. Ishii, T., Shimizu, T., Imai, M., Healy, J., Rouzard, K., Tamura, M., & Fitzgerald, C. (2023). Arctigenin-Enriched Burdock Seed Oil (ABSO): A New Skin Brightening Botanical Extract. *Cosmetics*, *10*(1), 10. https://doi.org/10.3390/cosmetics10010010

THANK YOU