

Creating Markets for technological Innovation

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Introduction about Hikma:

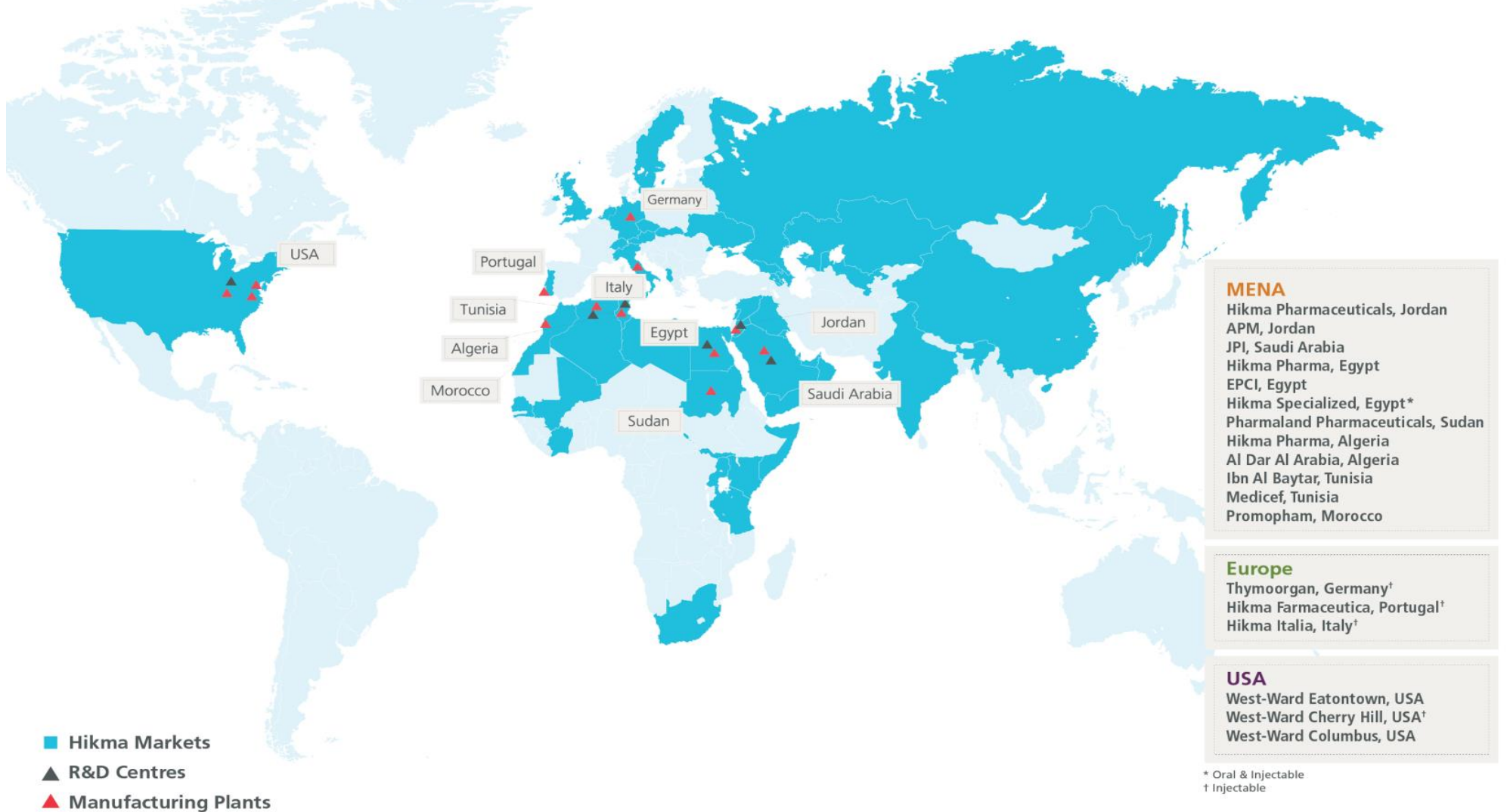


- Hikma Pharmaceuticals PLC (Hikma) is a fast growing multinational pharmaceutical group founded in 1978 in Jordan
- Hikma develops, manufactures and markets a broad range of branded, non-branded generic and in-licensed products
- Hikma operates in the US, Europe and across the MENA region
 - 6th largest generic company in the US by value
 - 3rd largest supplier of injectables in the US by volume
 - 5th largest pharmaceutical company in the MENA
- Hikma is committed to the highest quality manufacturing with multiple FDA approved facilities
- Hikma's global team is currently over 8,000 employees

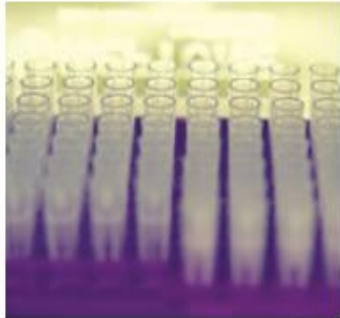
Hikma's Global Presence



29 manufacturing facilities in 11 countries – FDA approved facilities in 5 countries



Successful technology transfer elements:



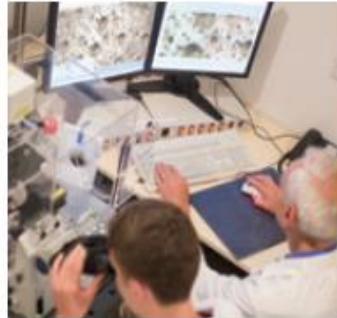
"Techno-ware":

for the pharmaceutical industry this would include the transfer of physical objects such as equipment for use in research laboratories or production equipment for the manufacture of pharmaceutical ingredients, or the formulation or packaging of final products.



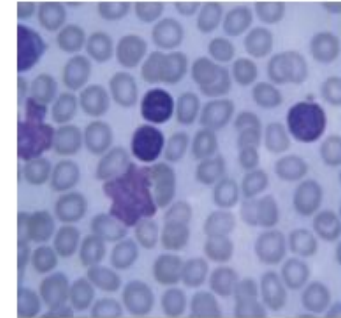
"Human-ware":

skills and human aspects of technology management and learning, such as training for researchers or general practitioners. Technology transfer can also create positive spillover effects into associated industries and into the supporting public sector research infrastructure.



"Info-ware":

all techniques related to knowledge, information, and technology, in the form of a technology license.⁴



"Orga-ware":

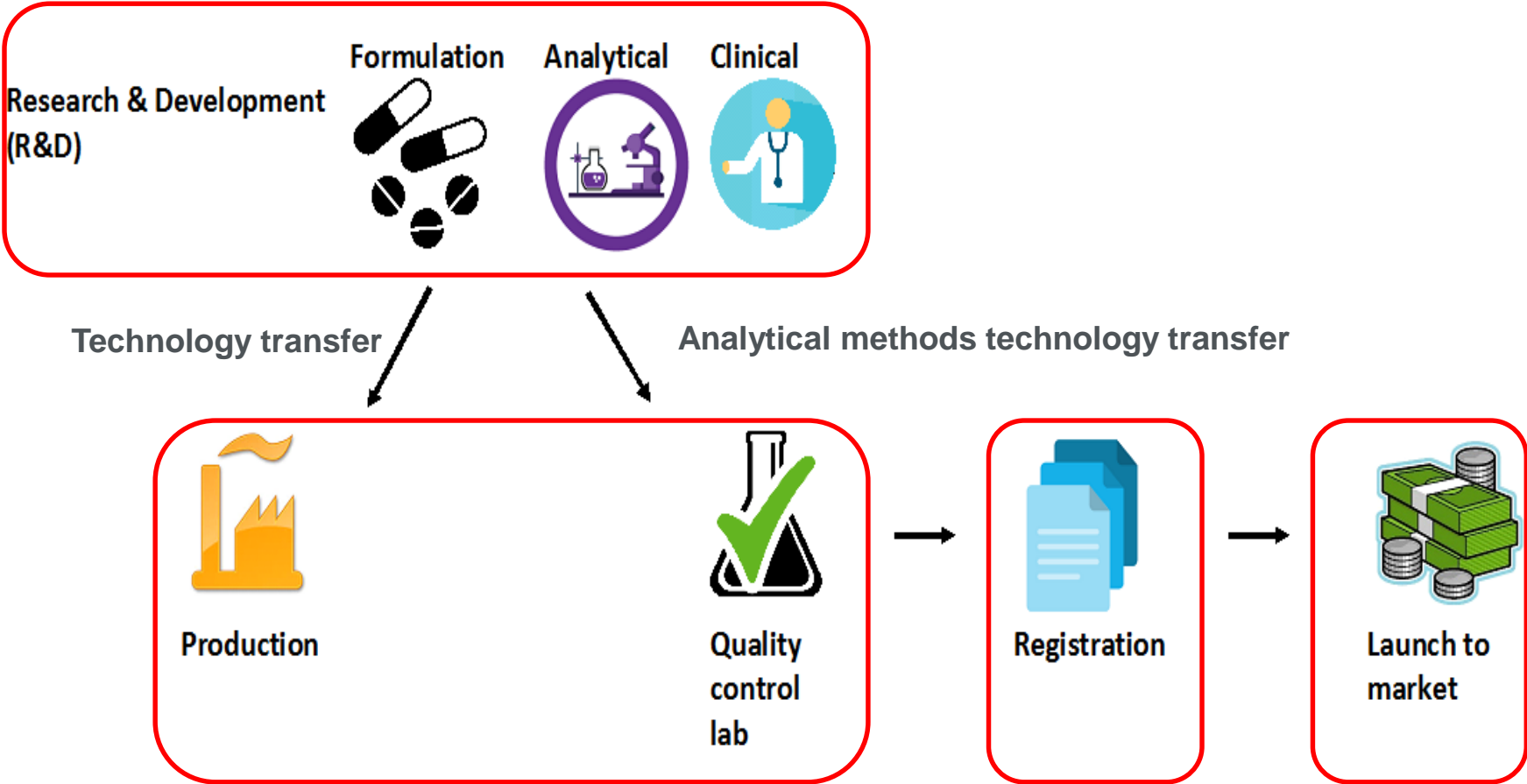
organizational and procedural knowledge needed to operate a given technology relating to a chemical or biological compound.



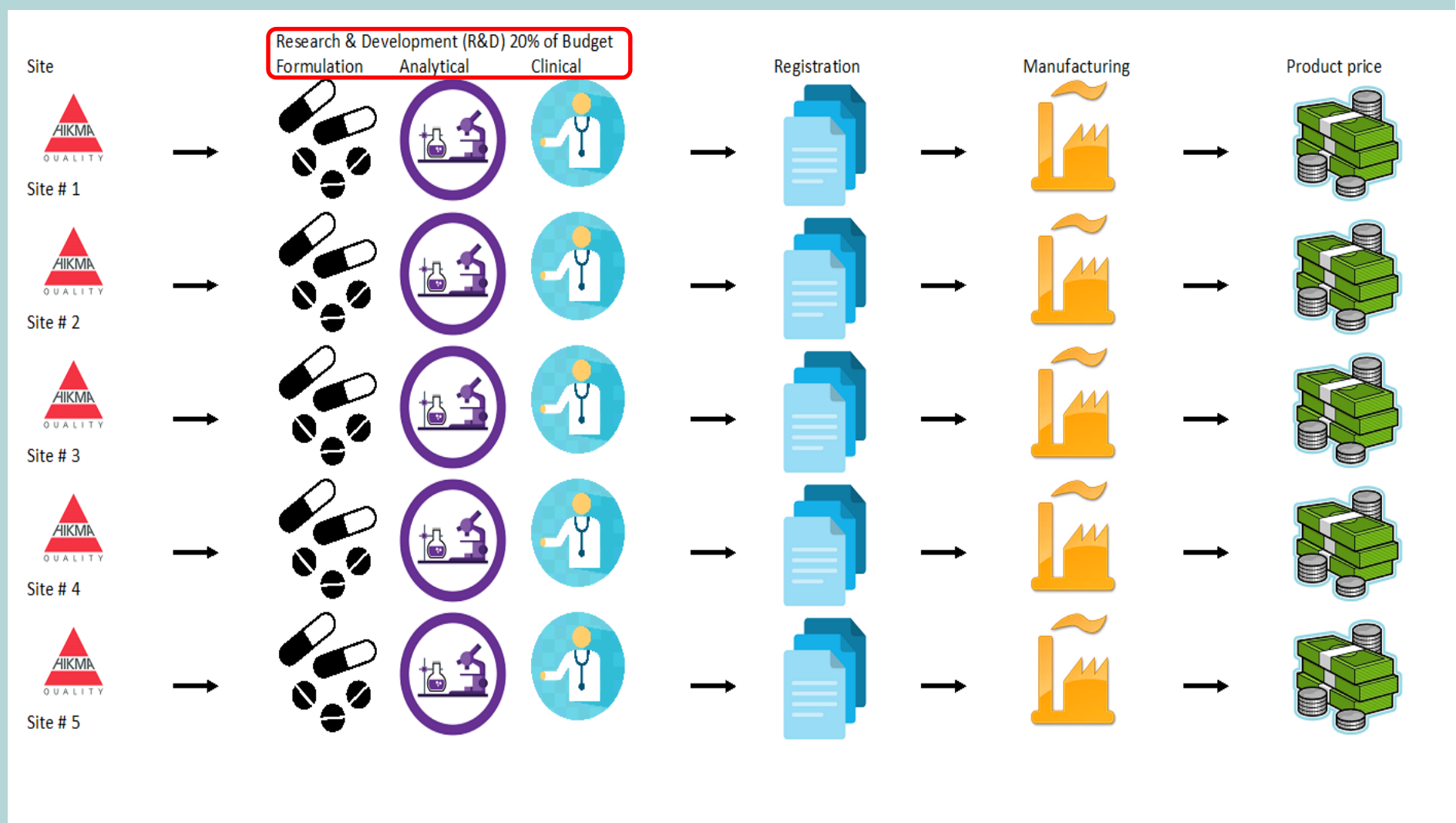
"Gov-ware":

Policies and procedures update to review and register high tech products

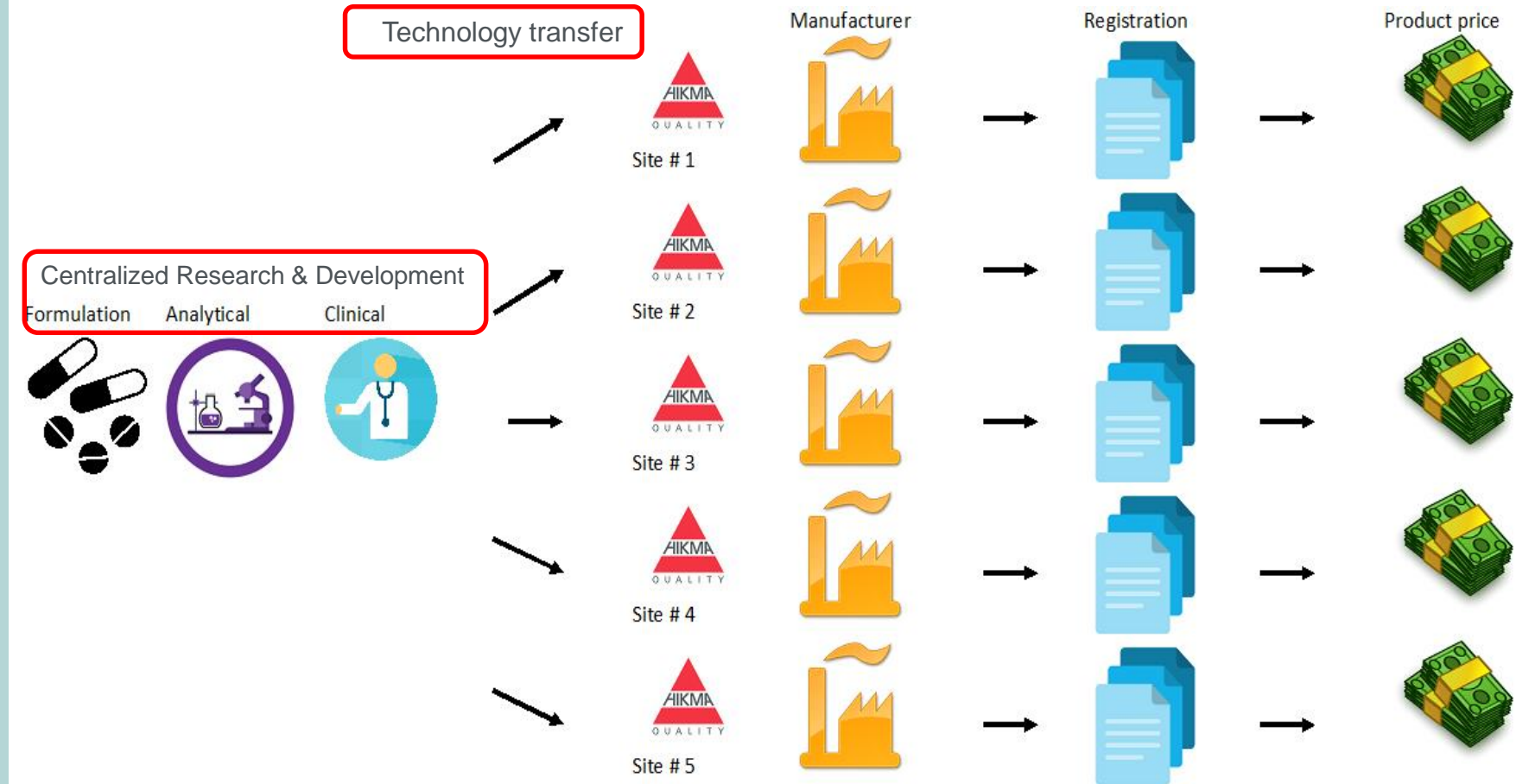
Internal TT:



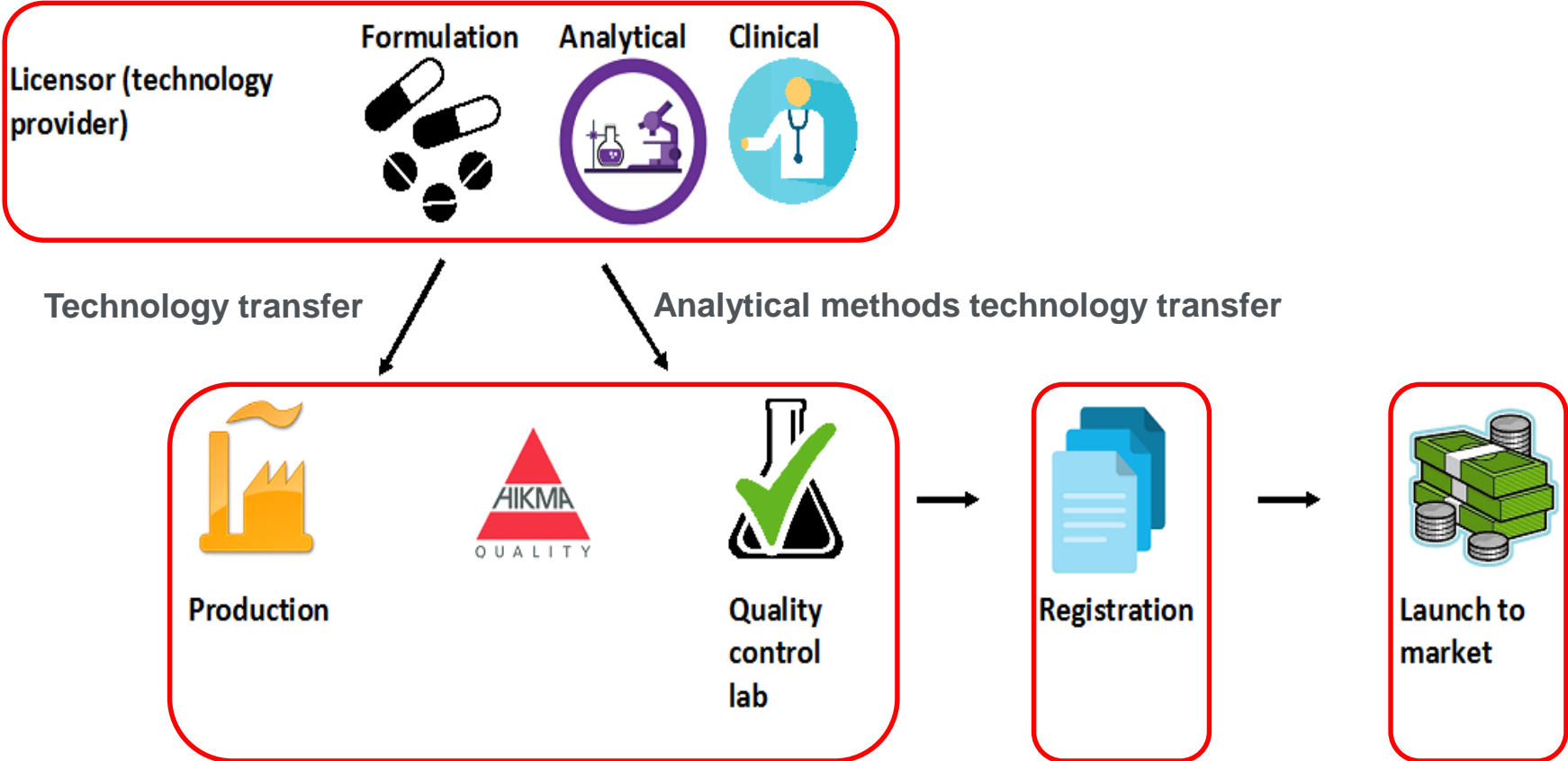
Multi- manufacturing site internal TT:



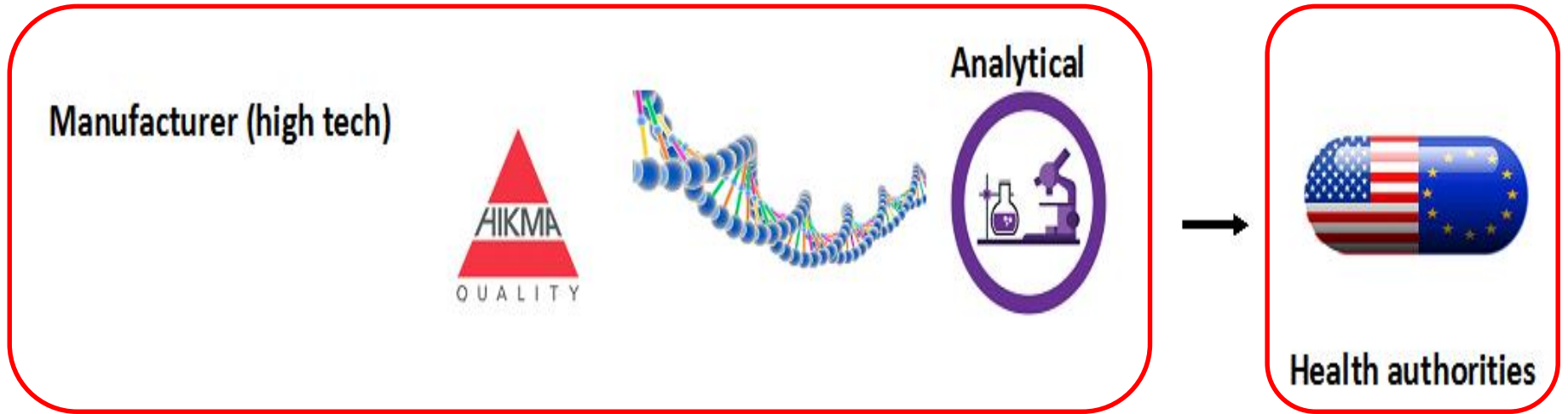
Multi- manufacturing site internal TT:



External TT:



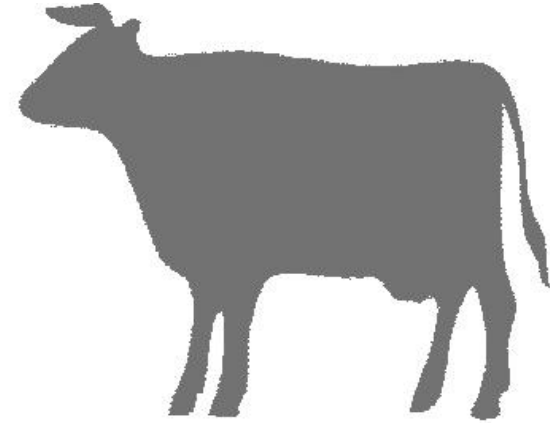
External TT:



Case study (high-tech pharmaceuticals products):

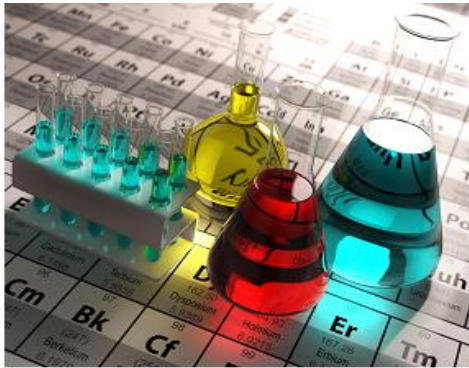


**Herbal products
Ancient world**



**Extraction from animal
Last century (19th Century)**





Chemical synthesis drugs
Modern drugs

(19th Century)



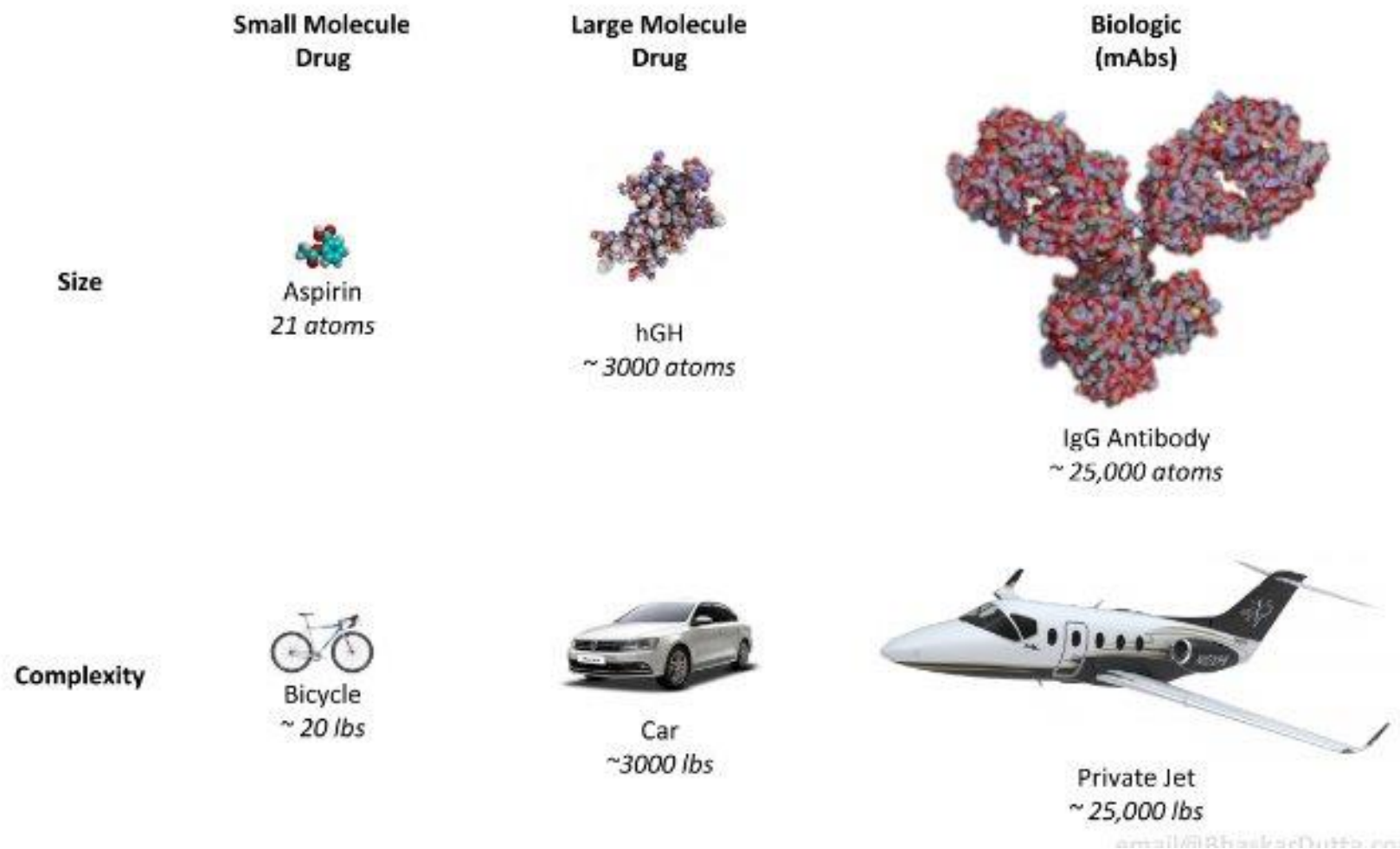
Recombinant DNA technology (mAbs)
High technology



Gene therapy
High technology

(20th Century)





- **Biotechnology** (sometimes shortened to "**biotech**") is the use of living systems and organisms to develop or make useful products.
- **Biosimilars** (Biologic generics) are term used to describe officially approved subsequent versions of innovator Biological products made by a different sponsor following patent and exclusivity expiry on the innovator product.
- To bring a new drug to market (from discovery through clinical trials) costs an estimated \$1 billion and can take 10 to 15 years or longer. Only one in 10 new drugs that makes it into human testing actually makes it to market.
- Development of Biosimilar product is about 100 M \$ while small molecules generics is about 1 M \$.
- Biosimilars reduce the cost by 20 – 40 % from the cost of the original innovator Biological product.
- In March, 2010 Obama signed policies that allow registration of affordable Biosimilars (ObamaCare)

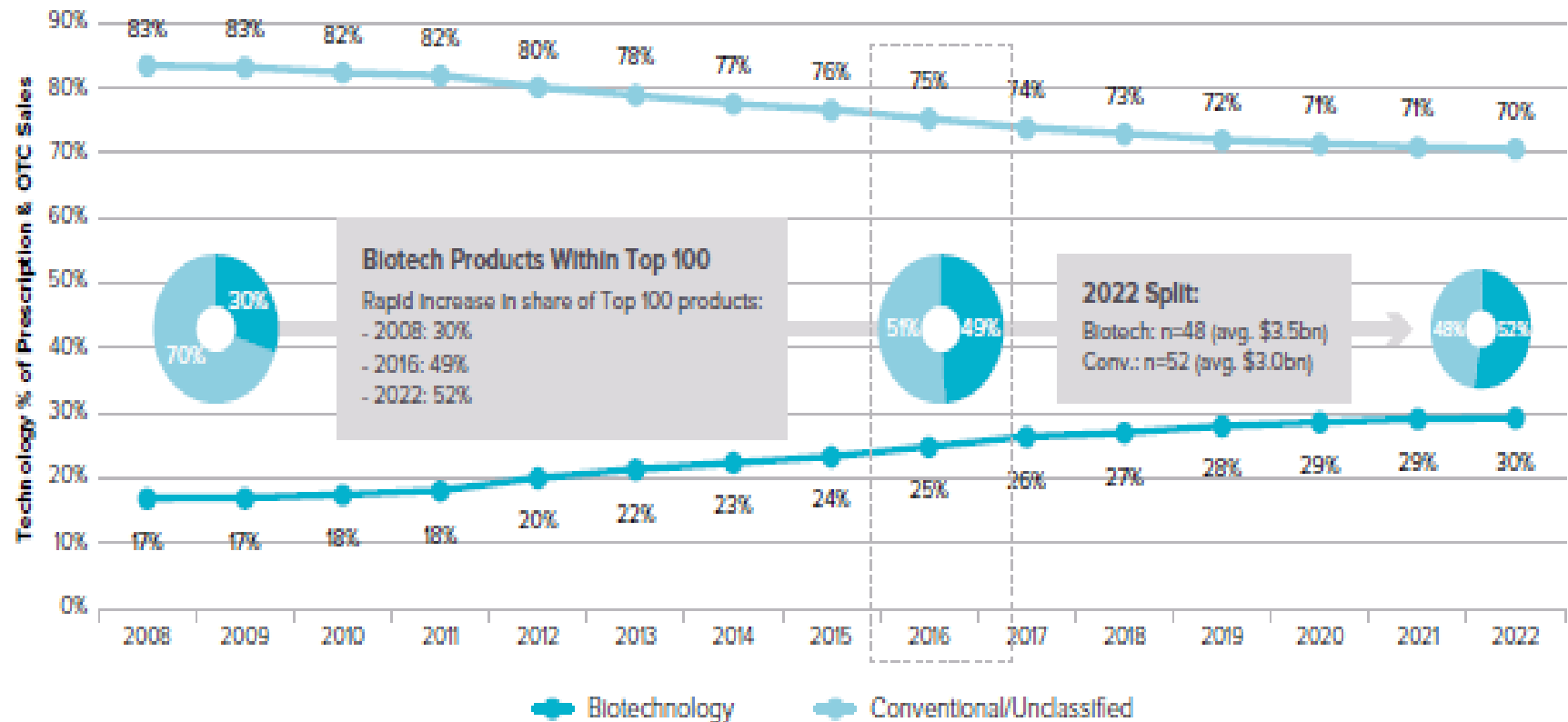
Top 10 selling products globally during 2016:

Rank	Product	Company	Technology	Sales (\$ billions)	Patent expiry (EU)
1	Humira	Abbott & Eisai	Monoclonal antibody	9.7	2016
2	Avastin	Roche	Monoclonal antibody	7.8	2022
3	Rituxan	Roche	Monoclonal antibody	7.7	2013
4	Crestor	AstraZeneca	Small molecule chemistry	7.5	
5	Enbrel	Wyeth, Amgen & Takeda	Recombinant product	7.2	2015
6	Advair	GlaxoSmithKline	Small molecule chemistry	7.0	
7	Januvia	Merck	Small molecule chemistry	6.8	
8	Herceptin	Roche	Monoclonal antibody	6.5	2014
9	Remicade	SGP, J&J & Mitsubishi Tanabe	Monoclonal antibody	6.1	2014
10	Pevnar	Wyeth, Pfizer	Vaccine	5.8	2012

- 4 Biotech product of the top 5 selling products
- 7 Biotech products of the top 10 selling
- Biotech products represents 50% of the 100 top selling products

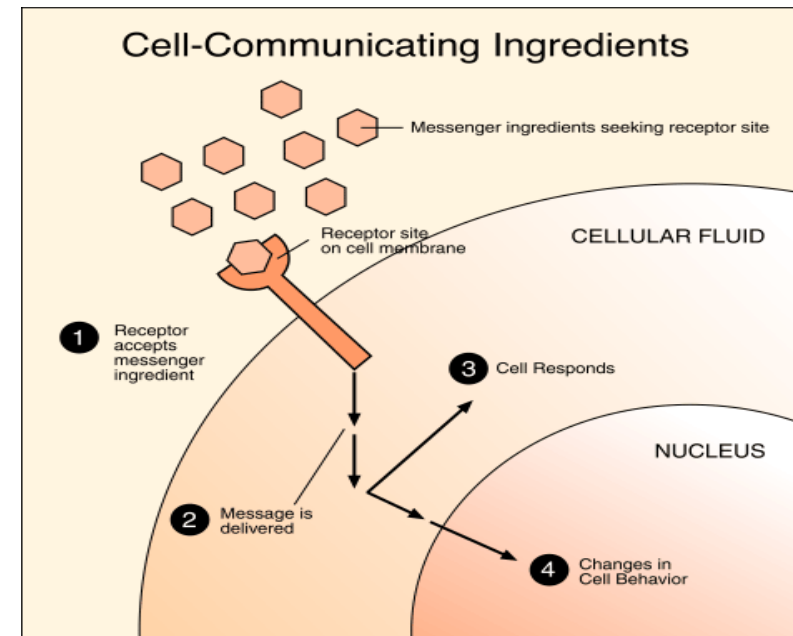
Worldwide Prescription Drug & OTC Pharmaceutical Sales: Biotech vs. Conventional Technology

Source: Evaluate, May 2017



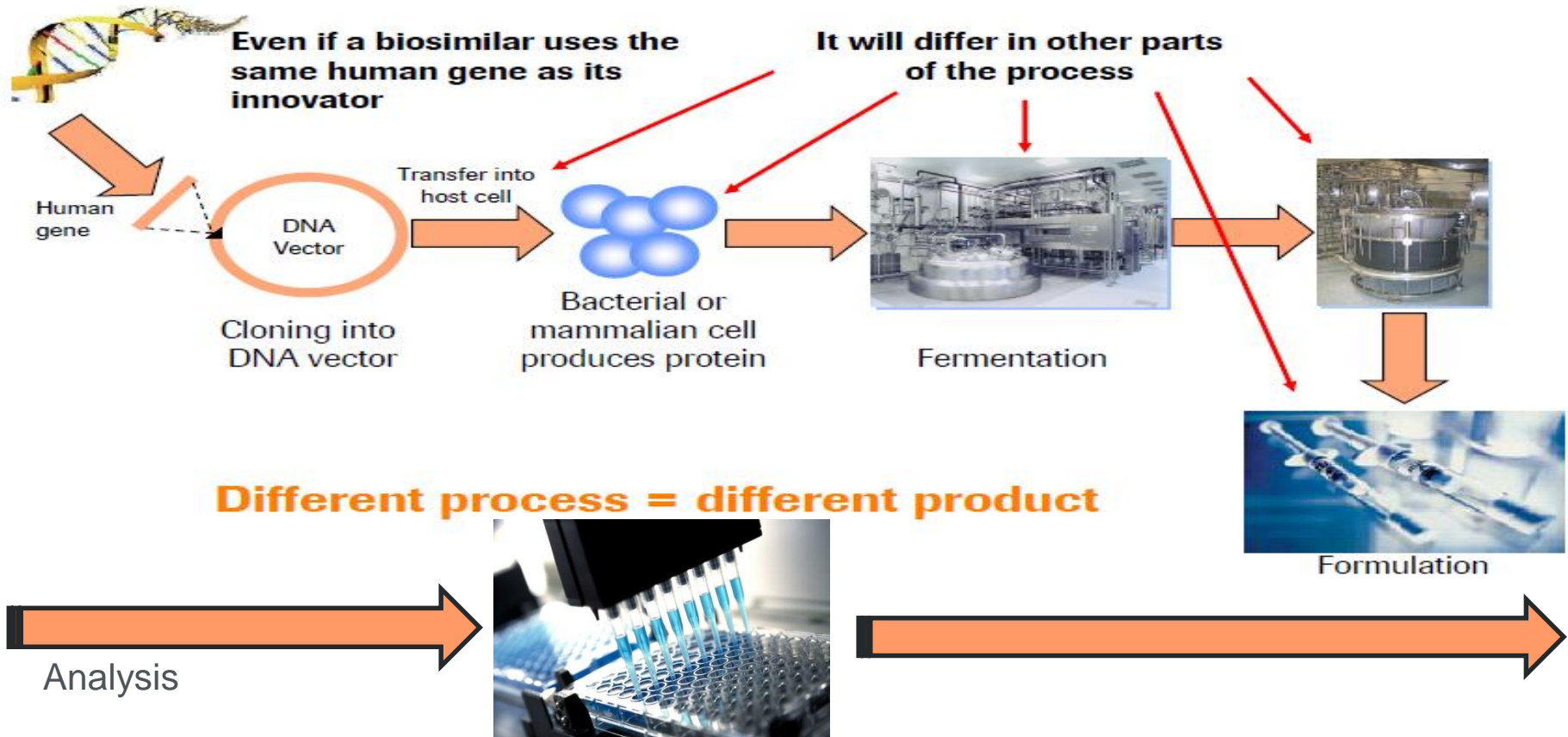
Advantage of using Biotechnology products:

- Highly effective and potent action
- Fewer side effects
- The potential to actually cure diseases rather than merely treat the symptoms

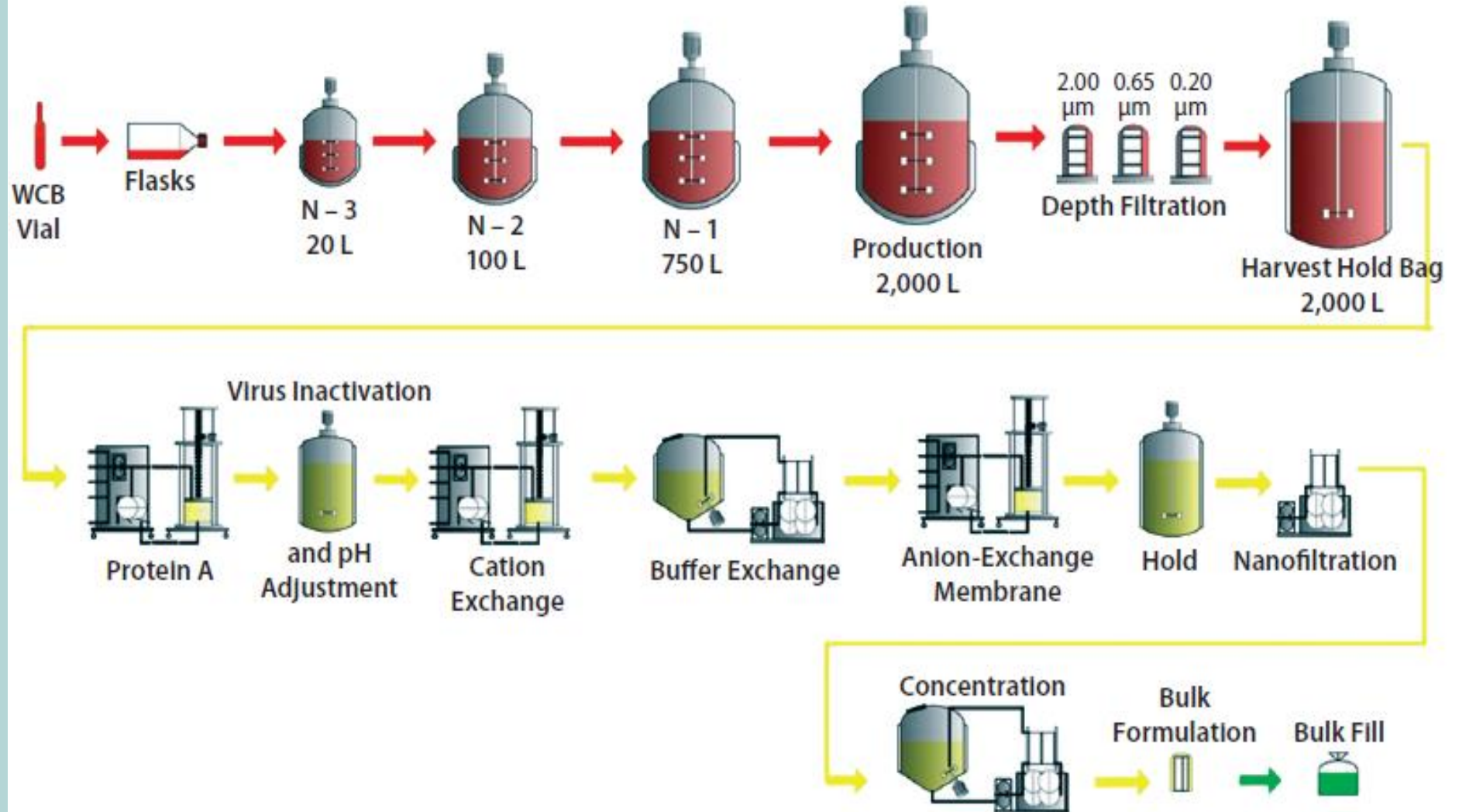


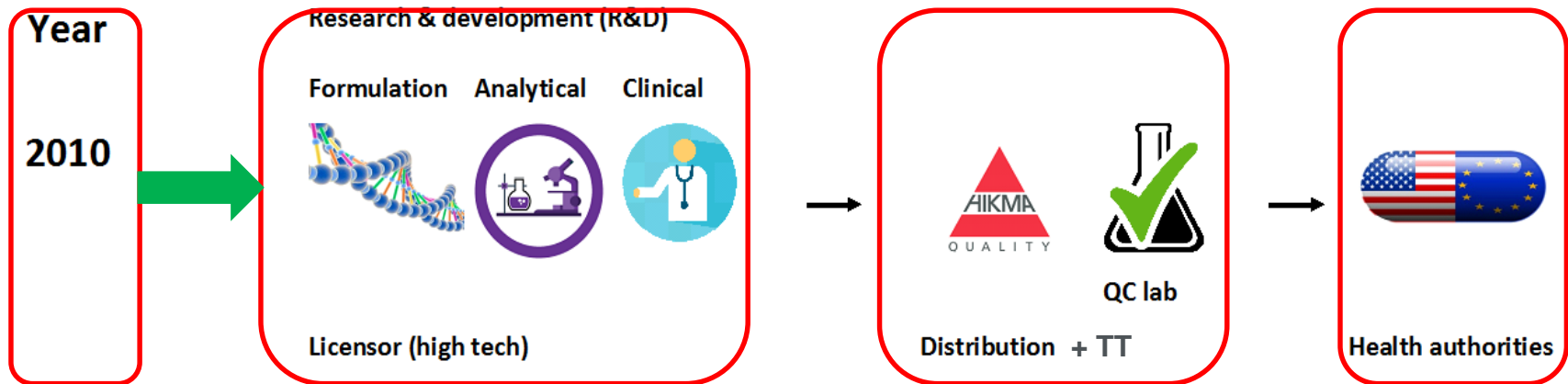
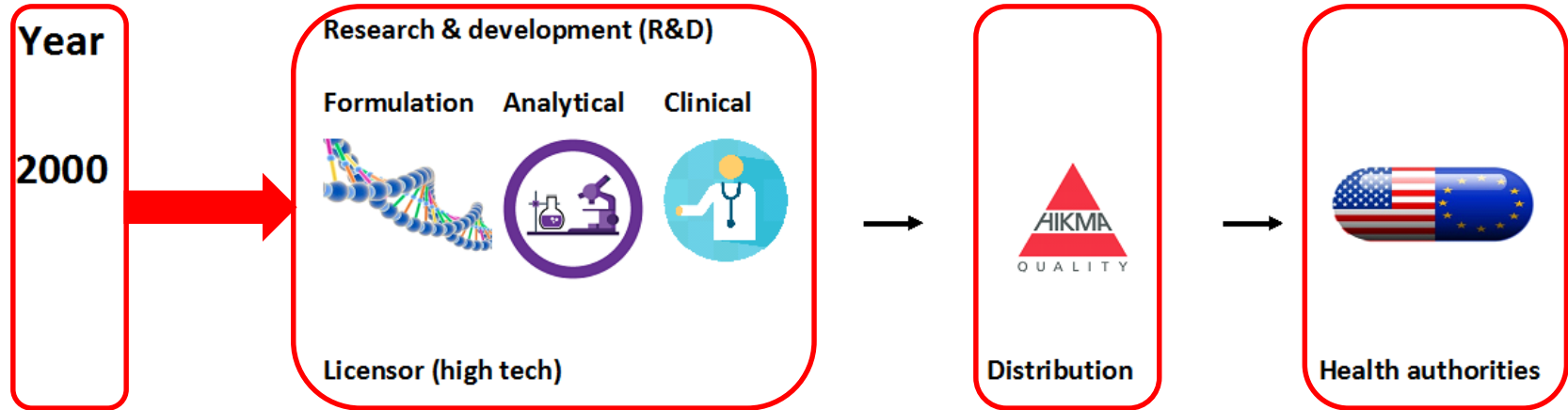
Manufacturing process:

Biologic manufacturing is complex *Biosimilars will always be different from the original*



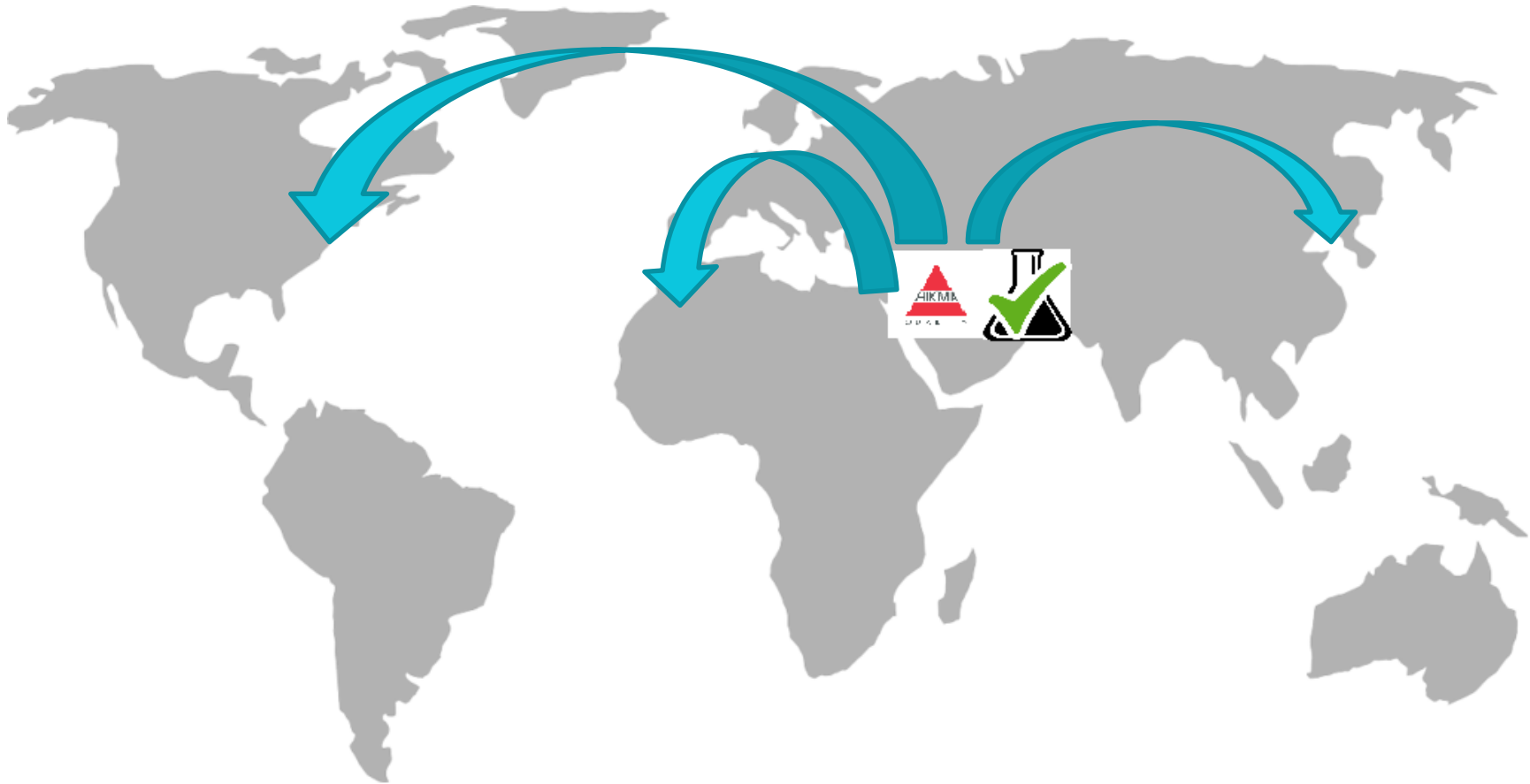
Manufacturing process (cont'd):

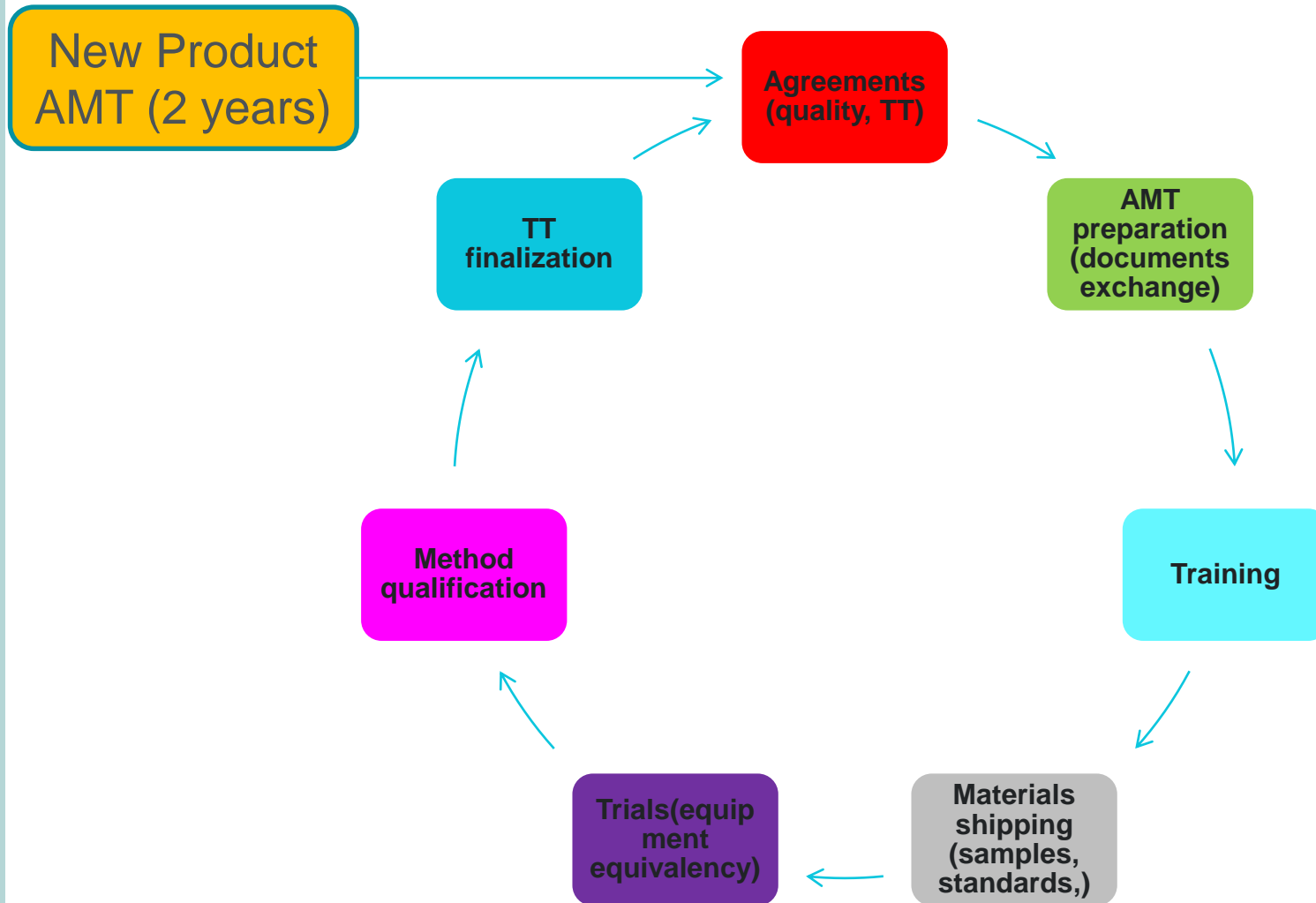




- Hikma's Biotechnology Initiative started in April / 2010 by signing agreement with a Korean company for marketing & distribution of high tech technology (Biosimilar products) in MENA region.
- State of the art Biotechnology QC laboratory was established in 2012 to:
 - Confirm quality of the product before distributing in the market
 - Some MENA countries require the MAH to do analysis
 - Reference lab: Facilitate registration & support authorities (TT with LNCPP, NORCB, Iraq, MOA with JFDA)
 - Knowhow for Hikma, analysis is the first & easiest way to start with

■ ISO 17025 lab accreditation





Thanks