الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Biotechnology Applications in Medical Devices Industry and Regulatory Authority Role and Contribution (SFDA Perspective)

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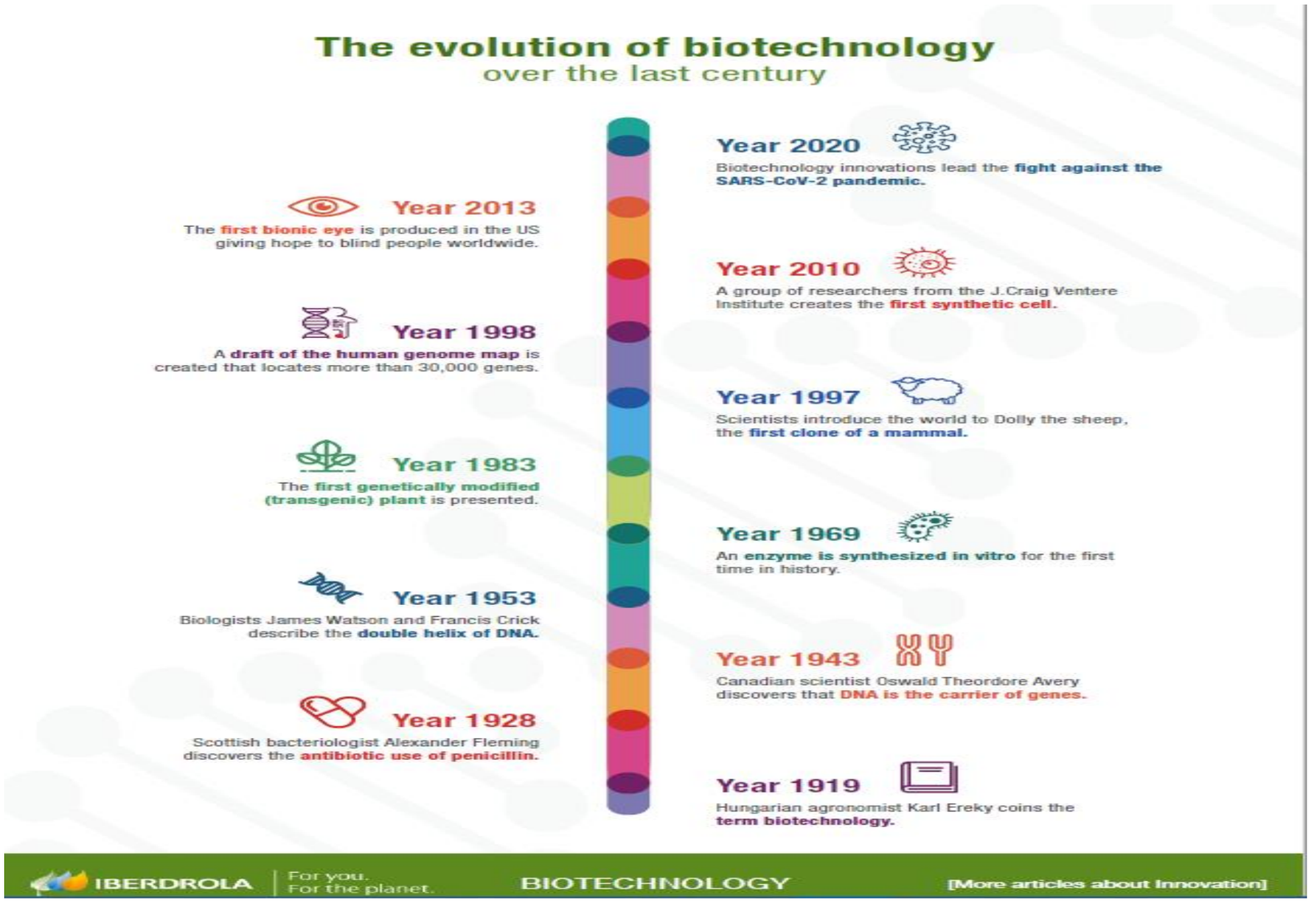
Outline

- Background information about biotechnology
    - Definition of biotechnology
    - Evolution of biotechnology
    - Categorization of biotechnology
- Current Active area of applications of biotechnology in medical devices
- Future area of applications of biotechnology in medical devices
- Regulatory authority role (SFDA perspective)
- Current progress and future plan

Definition of biotechnology

- Biotechnology is an industry that is focused on the manipulation of living organisms to create commercial products.
- Biotechnology is a science-driven industry sector that uses living organisms and molecular biology to produce healthcare-related products.
- At its simplest, biotechnology is technology based on biology - biotechnology harnesses cellular and biomolecular processes to develop technologies and products that help improve our lives and the health of our planet.
- Biotechnology is technology that utilizes biological systems, living organisms or parts of this to develop or create different products.

Evolution of biotechnology



https://www.iberdrola.com/documents/20125/40303/Infographic_Evolution_Biotechnology.pdf/1e1ec8d8-bc5b-ce87-2d71-633ec1f57f1d?t=1627276472096

Categorization of biotechnology

Biotechnology has been categorized and color coded to 10 main categories depending on the focused field of this technology (see table 1 below).

https://zymvol.com/2021/04/20/what-are-the-colors-of-biotech/

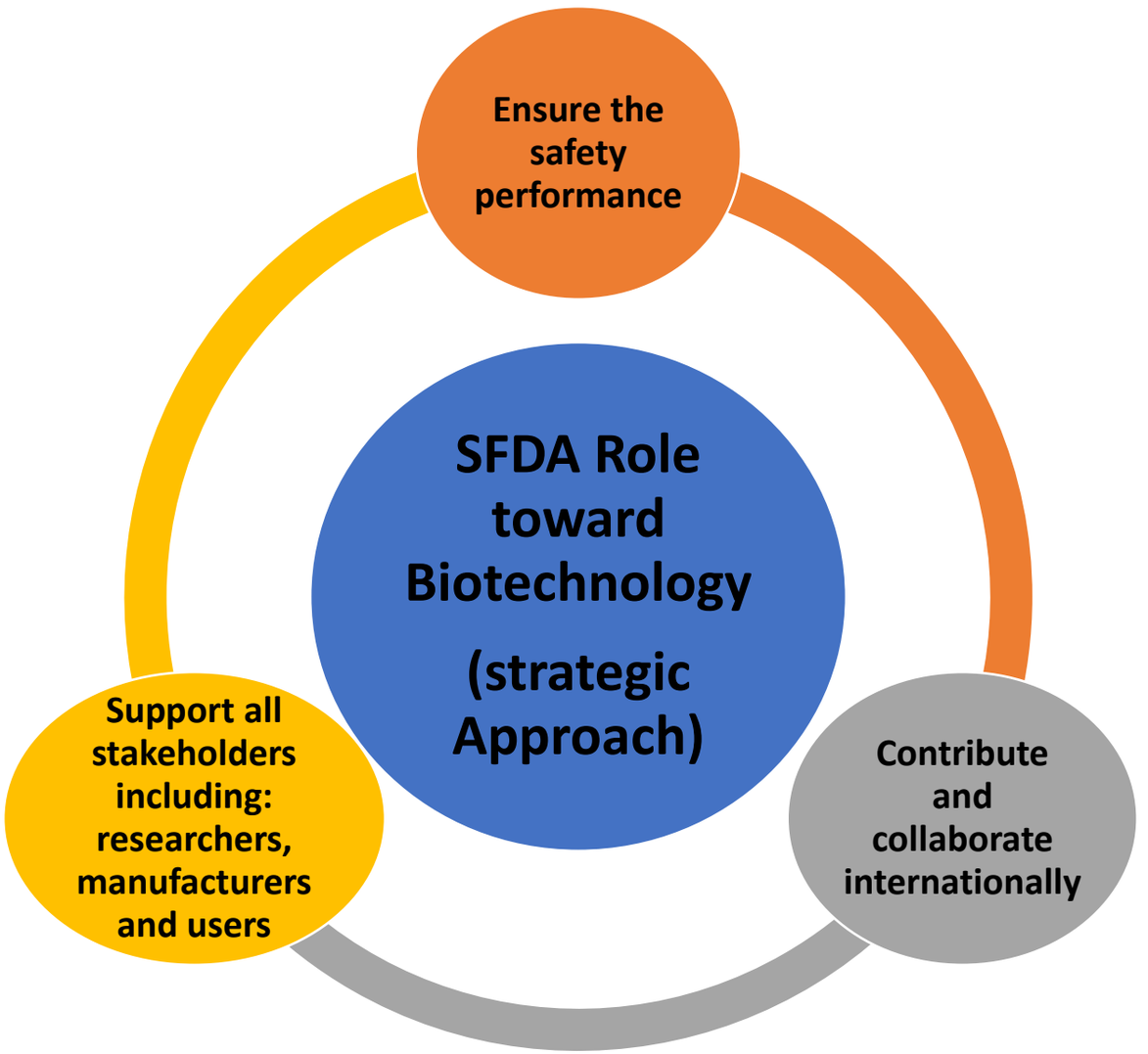
Current Active area of applications of biotechnology in medical devices for diagnosis, prevention, treatment …etc

- In-vitro Diagnostic (IVDs) including Companion Diagnostics
- Biological products which have physical mode of action such as:
  - skin grafts
  - Biological Implants (bones and Cornea).
- Biocompatible coatings
- Biological reagents for medical devices disinfection and cleaning
- Wetting solutions of contact lenses
- Biofunctional materials
- Bio-membranes and Bio-Gel
- Biosensors

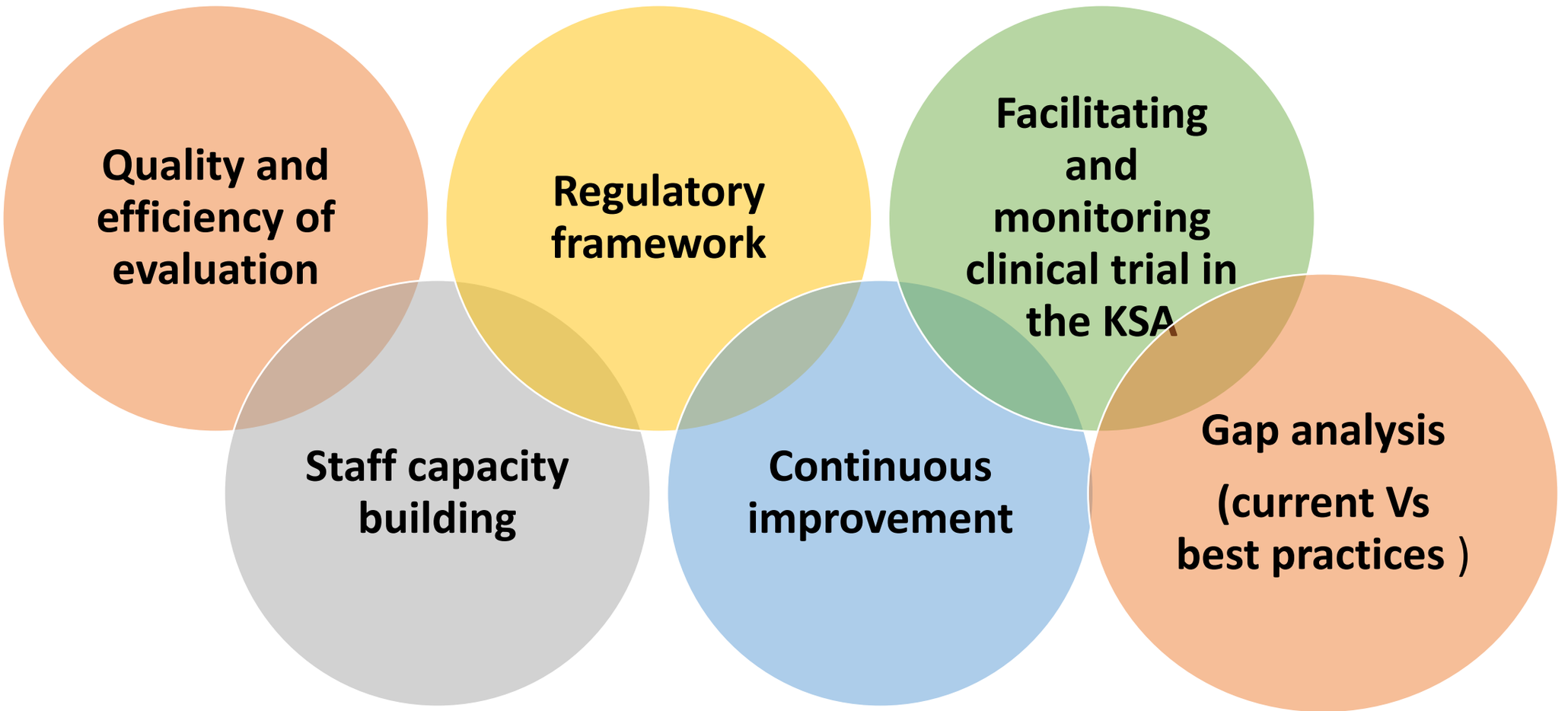
Future area of applications of biotechnology in medical devices for diagnosis, prevention, treatment …etc

- Software utilizing genomic databases for diagnostic outcomes
- Automated image analysis for diagnostic outcomes
  - Histology and radiology images
- Applications related to microbiome in medical devices and IVDs
- Acoustic bio-markers
- 3D printing applications (Stem cells)
- Biobots

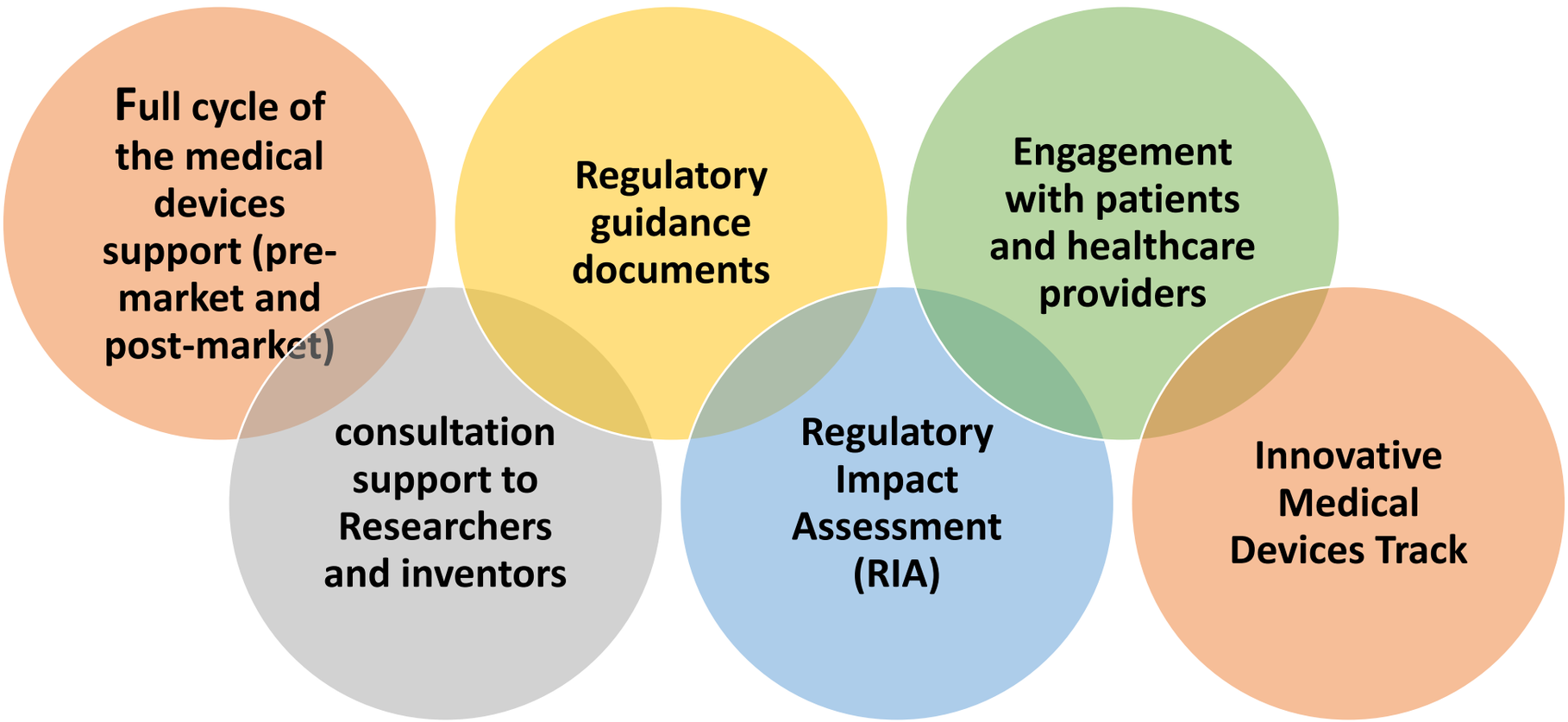
Regulatory authority role towards biotechnology (SFDA perspective)



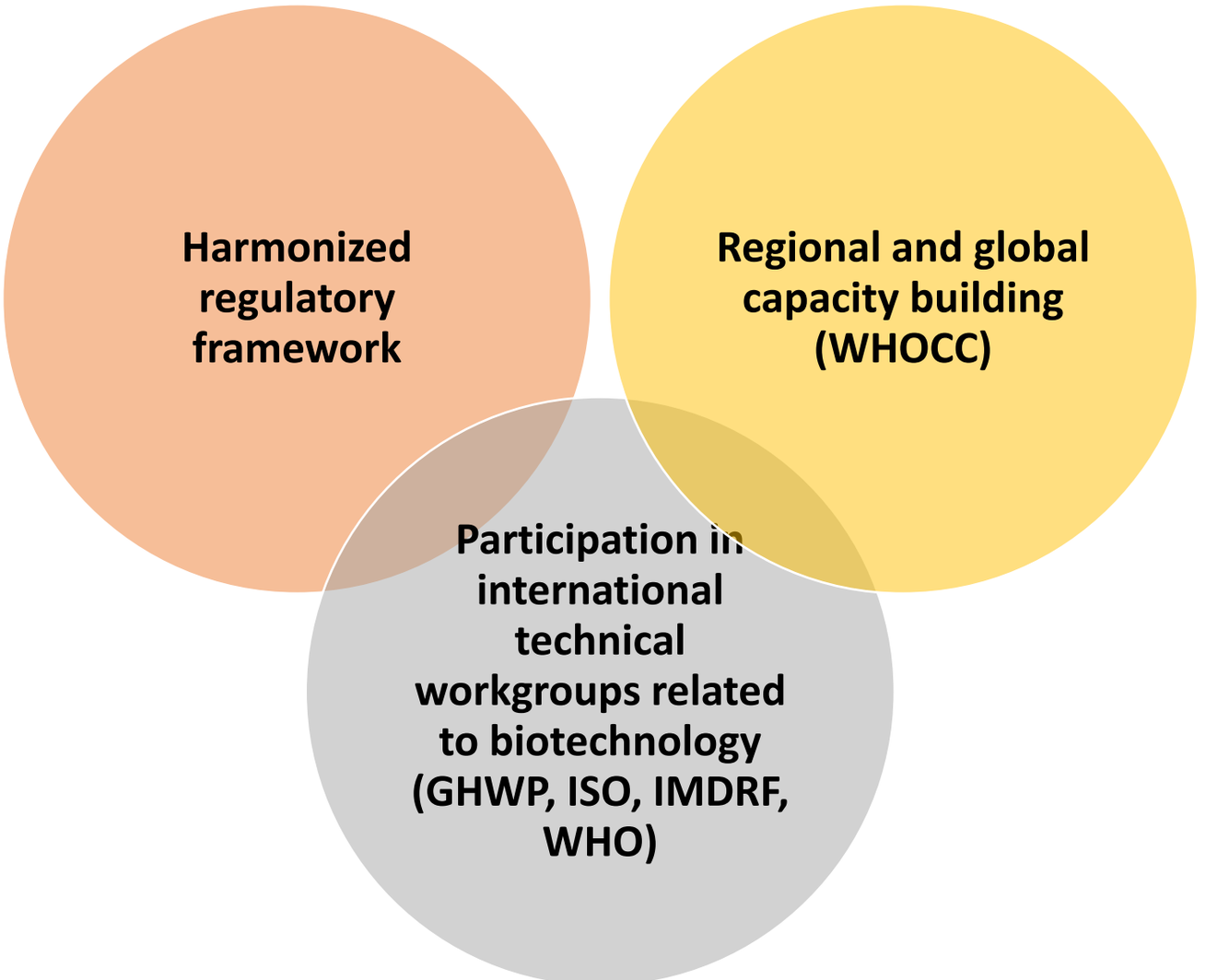
Ensure the safety performance of medical devices developed based biotechnology



Support all stakeholders



International contribution and collaboration



Current progress and future plan

Completed

- Benchmarking and Gap analysis in regulations related to biotechnology
- Innovative Medical Devices Track

Under process

- Plan placed based on the gap analysis which include:
  - Updating regulations
  - Creating specific and related guidance documents
  - Capacity building program
  - Regulatory Impact Assessment (RIA) (establishing tools and process)
  - Engagement with patients and healthcare providers (policies completed and starting pilot phase)
  - Continue to Participate in international technical workgroups related to biotechnology (GHWP, ISO, IMDRF, WHO)

Future plan

- Annual biotech conference for medical devices and regulatory affair related
- Continuous improvement

Thank You

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