
Advancing Biomanufacturing and Regulatory Modernization:

Innovation · Implementation · Operationalization

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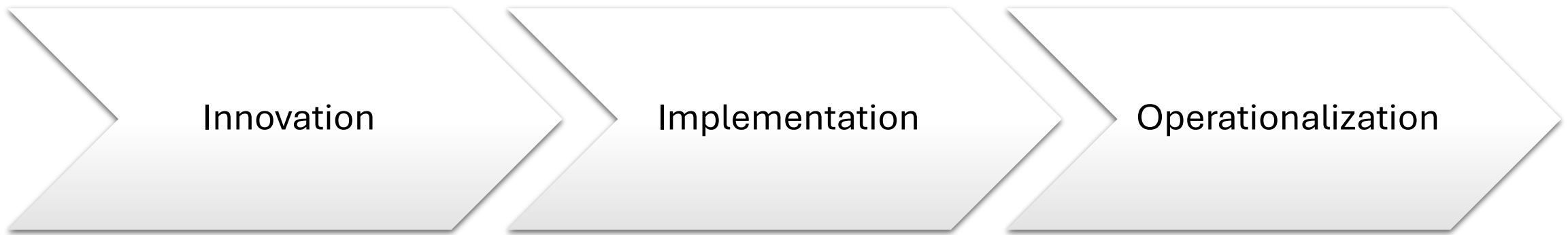
Vaccine Quality Divisions (VQD)

Biologics and Radiopharmaceutical Drugs Directorate (BRDD)

Disclaimer

The views and opinions expressed in this presentation are those of the presenter and do not necessarily reflect the official policy or position of Health Canada or the Government of Canada.

Stages of Progress



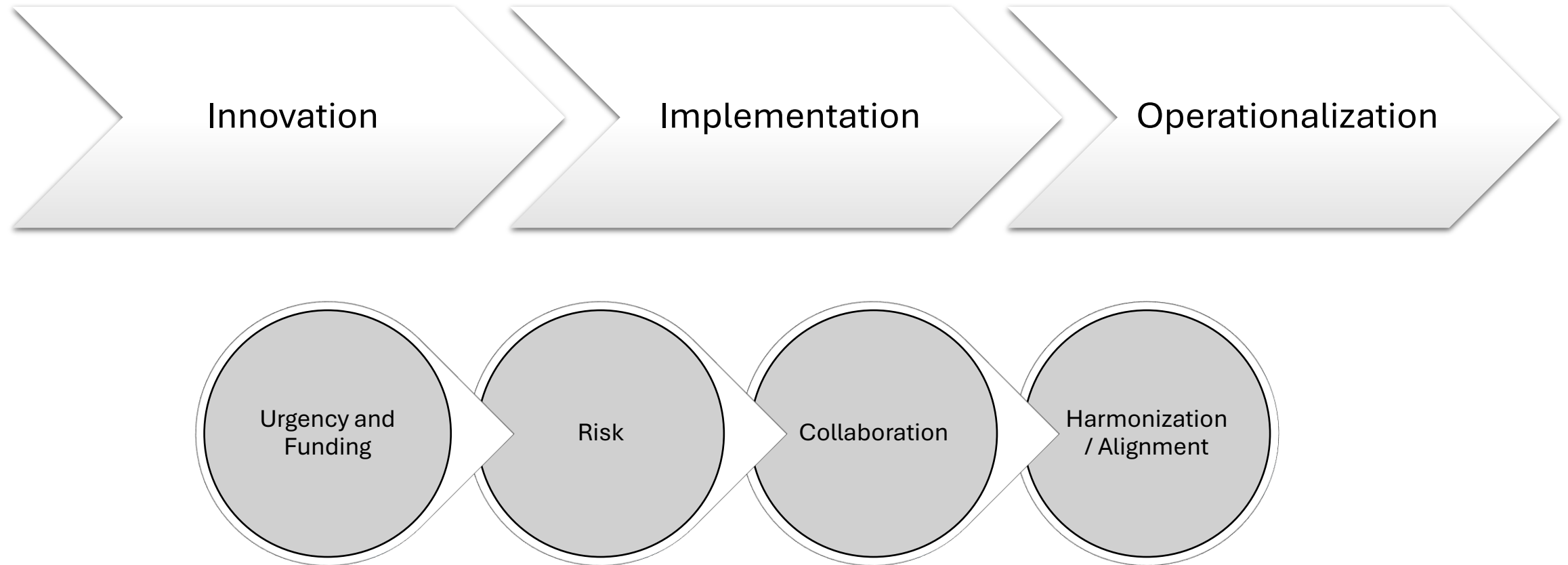
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graph LR; A[Innovation] --> B[Implementation]; B --> C[Operationalization]
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Innovation

Implementation

Operationalization

Accelerants of Progress



What changes is the tempo not the need for evidence.

Scope



INNOVATION:
SPONSORS VS REGULATORS



IMPLEMENTATION:
MODERN REGULATIONS

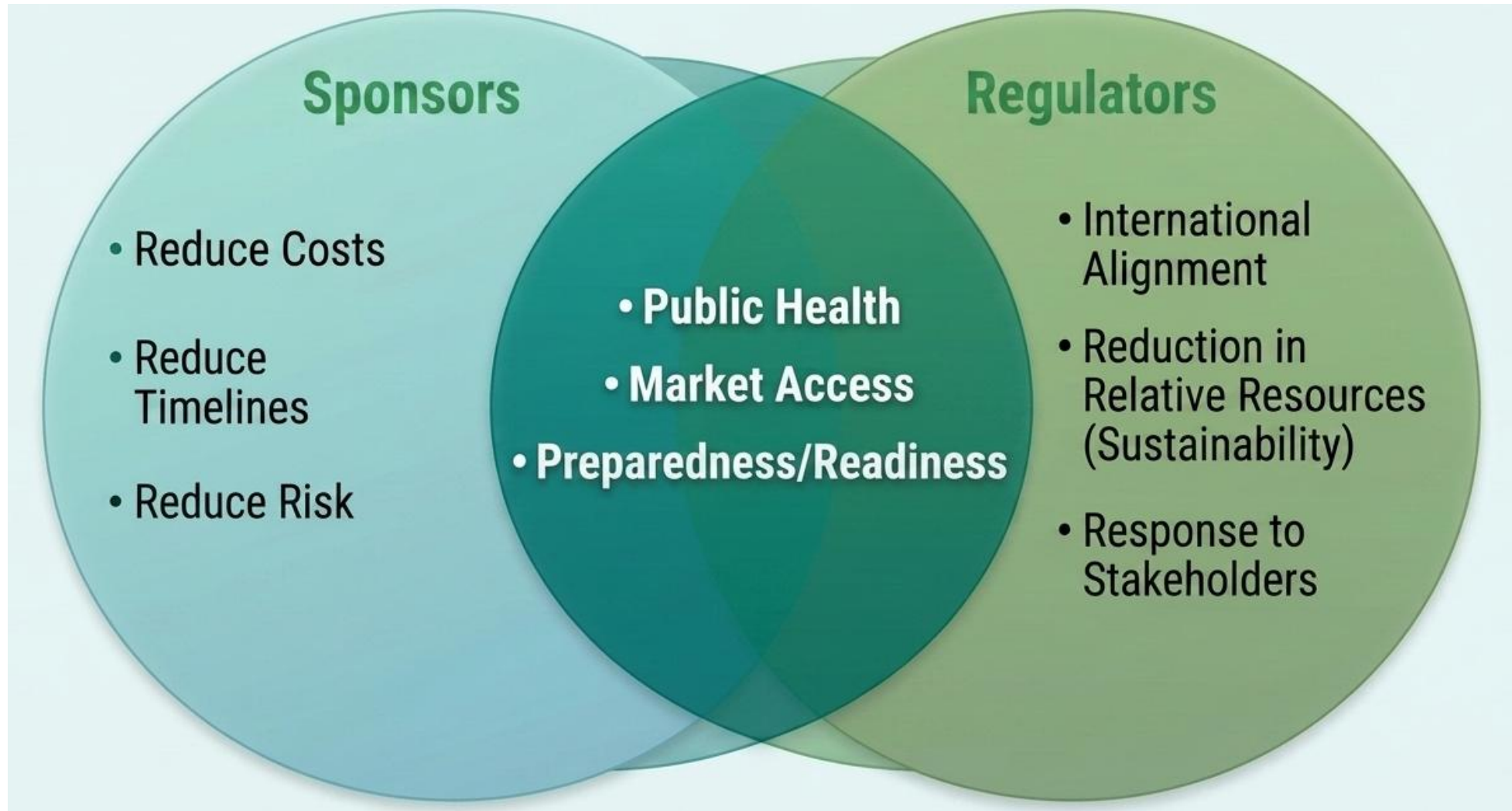


OPERATIONALIZATION:
GAP ANALYSIS

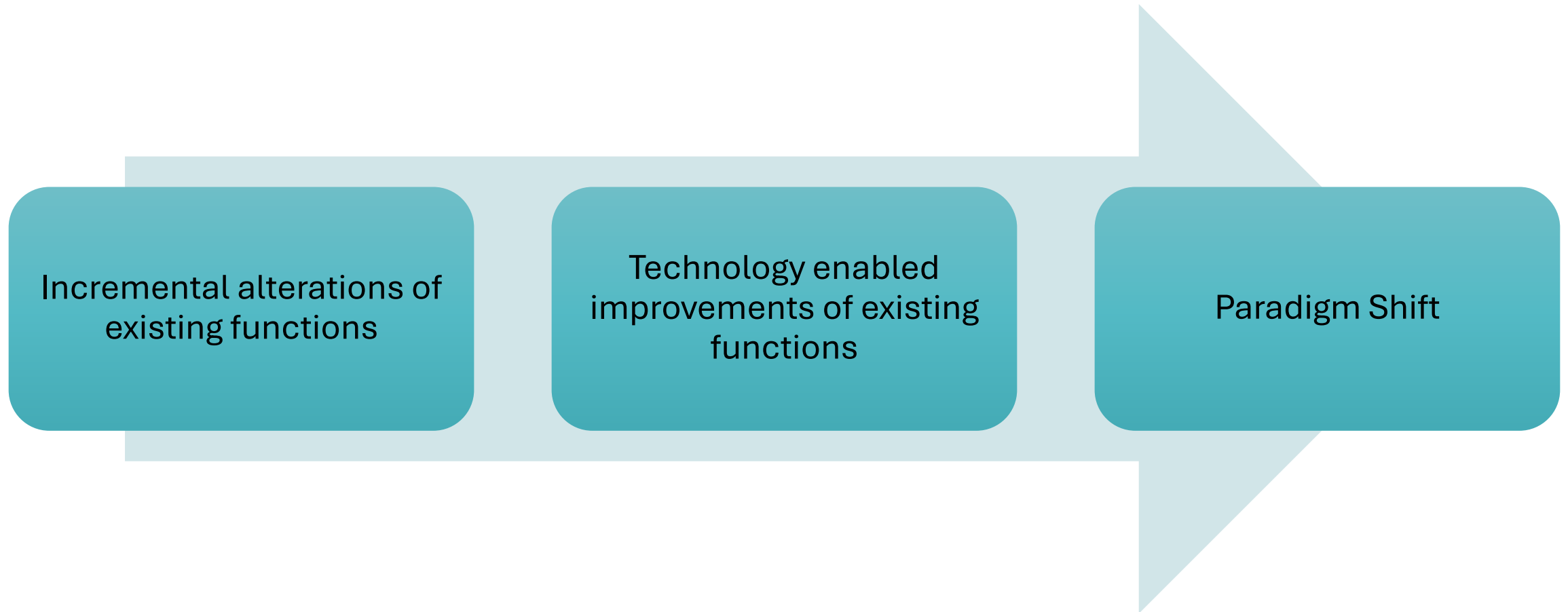
Innovation



Drivers of Innovation



Spectrum of Innovation



Key Outcomes of Innovation



Sponsors

Develop tools/processes which reduce risk and cost throughout product lifecycle



Regulators

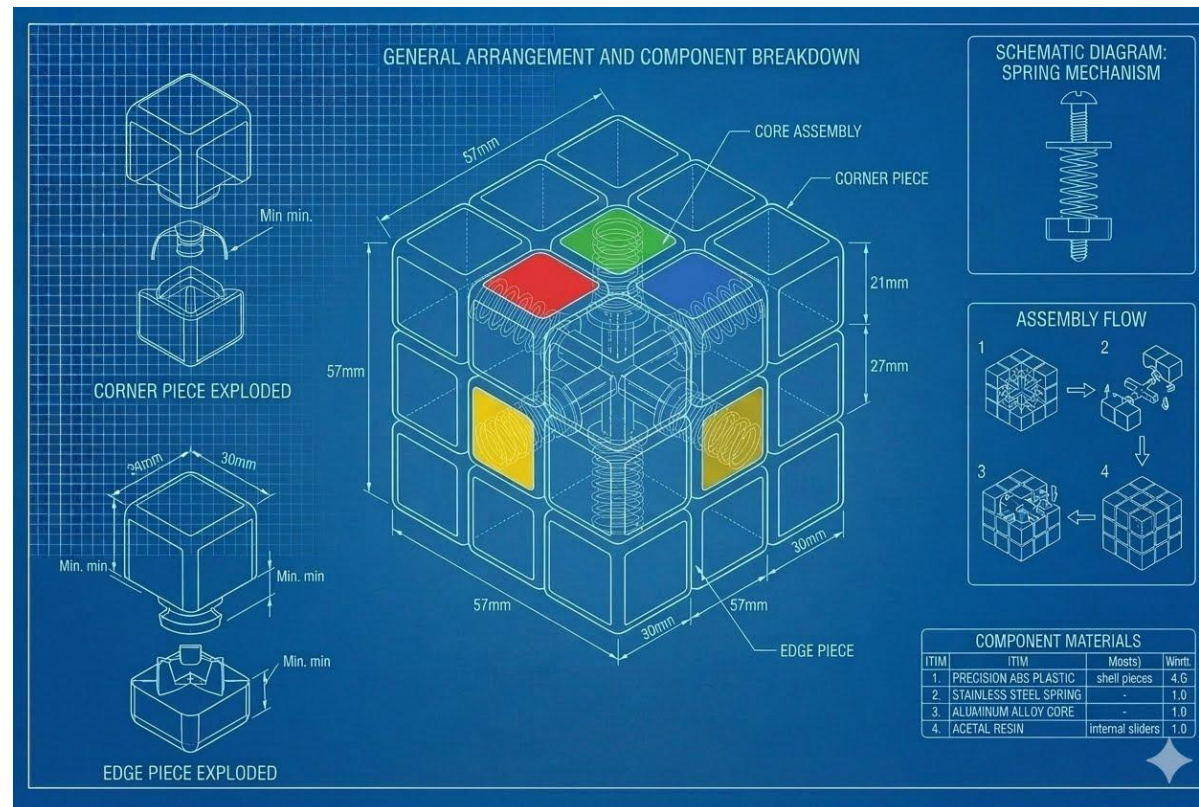
Develop pathways which improve the predictability and timeliness of decision making



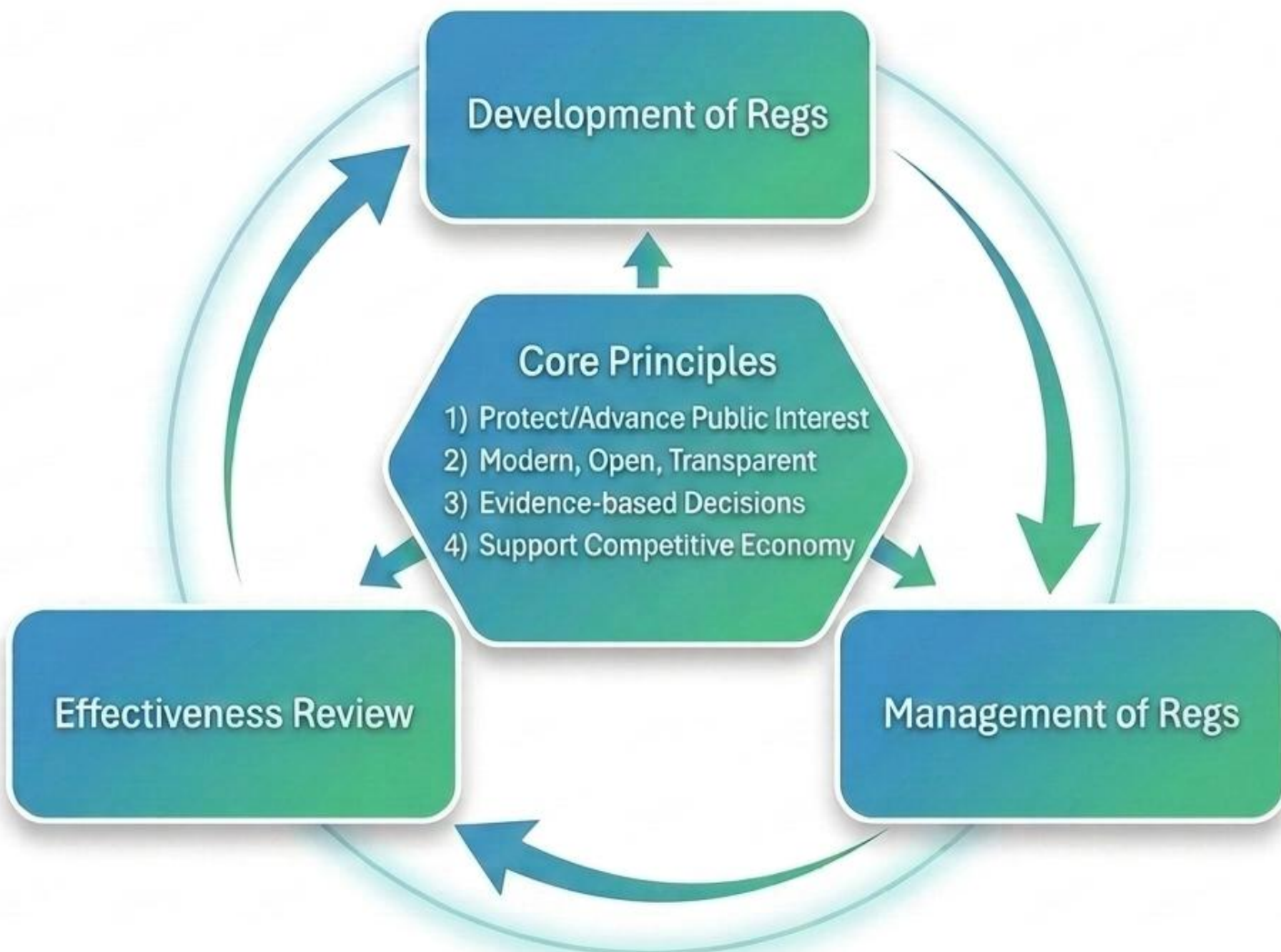
Evidence

Innovation does not come at a cost of evidentiary standards for quality, efficacy and safety of medicines.

Implementation

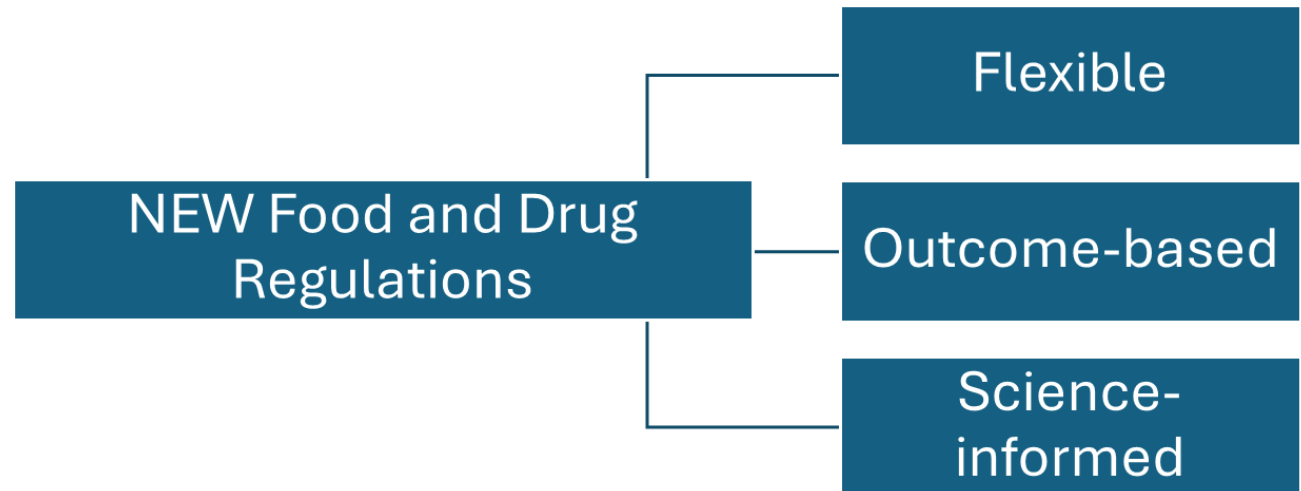


Health Canada Regulatory Lifecycle

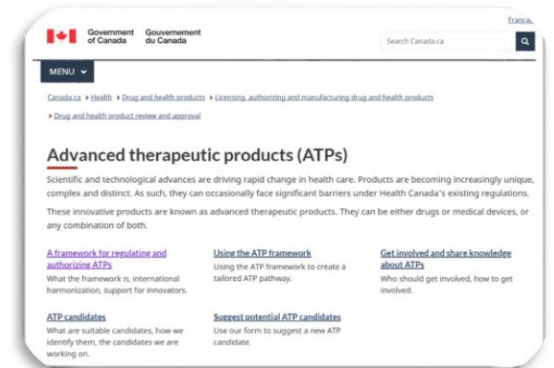


Health Canada Regulatory Innovation and Implementation

- Agile regulations
 - Public Health Emergencies
- Regulatory Modernization continues
 - Div 1, 3, 4, 5, 8
- Ministerial Order
 - Reliance
- Use of Foreign Information



Advanced Therapeutic Products (ATP)



Enabling Regulatory Innovation

- tailored oversight for novel health technologies

Adapting to Scientific Advances

– addressing increasingly complex therapeutic products

Breaking Regulatory Barriers

– creating pathways where existing frameworks may not fit

Operationalizing



Health Canada Experience: Innovation · Implementation · Operationalization

Prior Knowledge

- mAbs, multivalent vaccines, mRNA vaccines, strain changes, annual strain updates

Modelling

- predictive stability, shelf-life extension

Master Files

- adjuvants, intermediates

Artificial Intelligence

- review tools / aids, guidance documents (in development)

Operationalization: Institutional and Cultural Challenges

Inconsistency

- Within-Agency
 - Nature versus Nurture
 - Reviewer Variability
 - "Reviewer Roulette"
- Interpreting modern regulatory concepts
 - Reg flexibility, science-based, risk-proportionate, evidentiary standards etc

Risk-benefit

- Preference for certainty
 - What is scientific-certainty?
- Fear of unintended consequences
 - Is there evidence to support regulatory concerns/questions/requests?
- Difficult to quantify risk of delaying potential benefit

Operationalization: Organizational Challenges

Governance

- Improved communication regarding expected outcomes
- Processes to define measures of operationalization
 - KPIs
- Improved effectiveness review
- Sharing/aligning best-practices

Workforce & Expertise

- Turnover and reductions
 - Sub. Mtr. Knowledge: long to develop, easy to lose, hard to replace
- Subject Matter Knowledge
 - Sources of new knowledge/expertise?
 - Challenge function?
- Succession planning and knowledge transfer

Shared Responsibility for Regulatory System Strengthening

Regulators and industry share responsibility for enabling innovation.

- ✓ Constructive feedback on implementation challenges/inconsistencies
- ✓ Early engagement on innovative approaches
- ✓ High-quality, science-based submissions including relevant supportive data not just required data
- ✓ Open dialogue between regulators and stakeholders

Areas for Continued Attention

Accountability	Strengthen internal and external accountability mechanisms to identify and address inconsistencies.
Expertise	Recruit, develop, and retain specialized scientific and regulatory expertise.
Global Collaboration	Strengthen international partnerships to advance regulatory innovation, alignment, sharing of best practices.
Knowledge Sharing	Leverage global best practices, case studies, and lessons learned to support continuous improvement.

Conclusions



Innovation delivers shared benefits for patients, regulators, industry, and health systems.



Modernized regulatory pathways provide the foundation for regulatory innovation.



The next challenge is operationalization; translating policy into consistent practice.



Sustained collaboration and feedback are critical to achieving harmonization, consistency, and continuous improvement.

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