

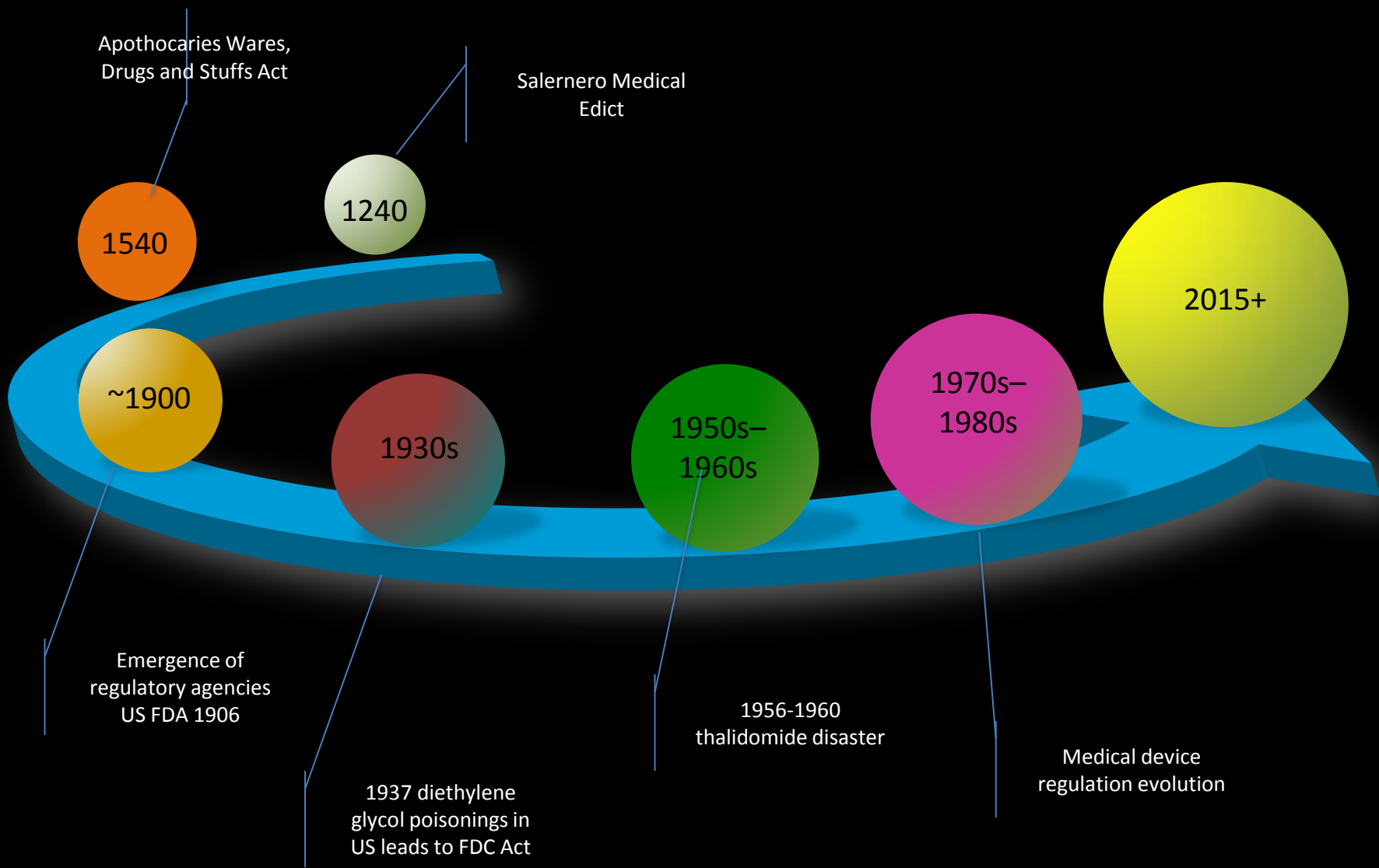
The Regulatory Profession: Opportunity Amid Complexity

Sherry Keramidas, PhD, FASAE, CAE
Executive Director
Regulatory Affairs Professionals Society



The medical products sector is a critical economic driver and social/political factor

Regulation of medical products is a
key part of public health

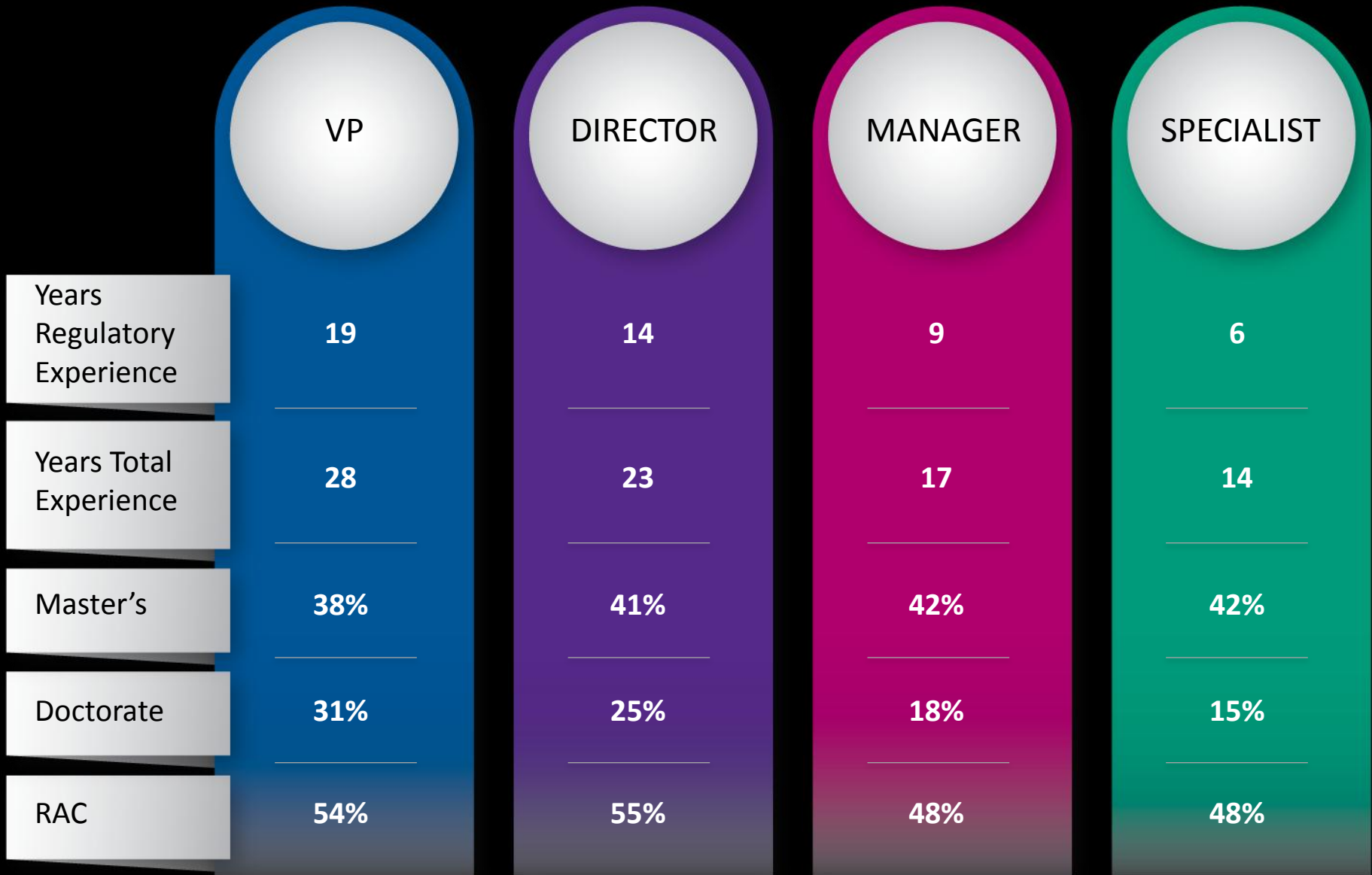


Regulatory Profession(al)

The need for a competent regulatory professional workforce, from entry level to executive level, is seen among regulators and industry around the world.

- Scope of practice based on a *body of knowledge*
- Defined competencies, knowledge and skills
- Professional qualification(s)
- Professional ethics

REGULATORY PROFESSIONAL PROFILES

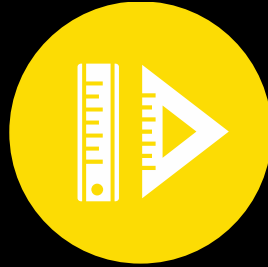




Life
Sciences
50%



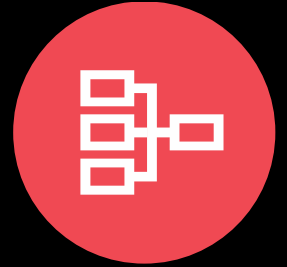
Clinical
Sciences
18%



Engineering
14%



Business
14%



Regulatory
Affairs
13%



Social
Sciences
7%



Regulatory
Science
4%



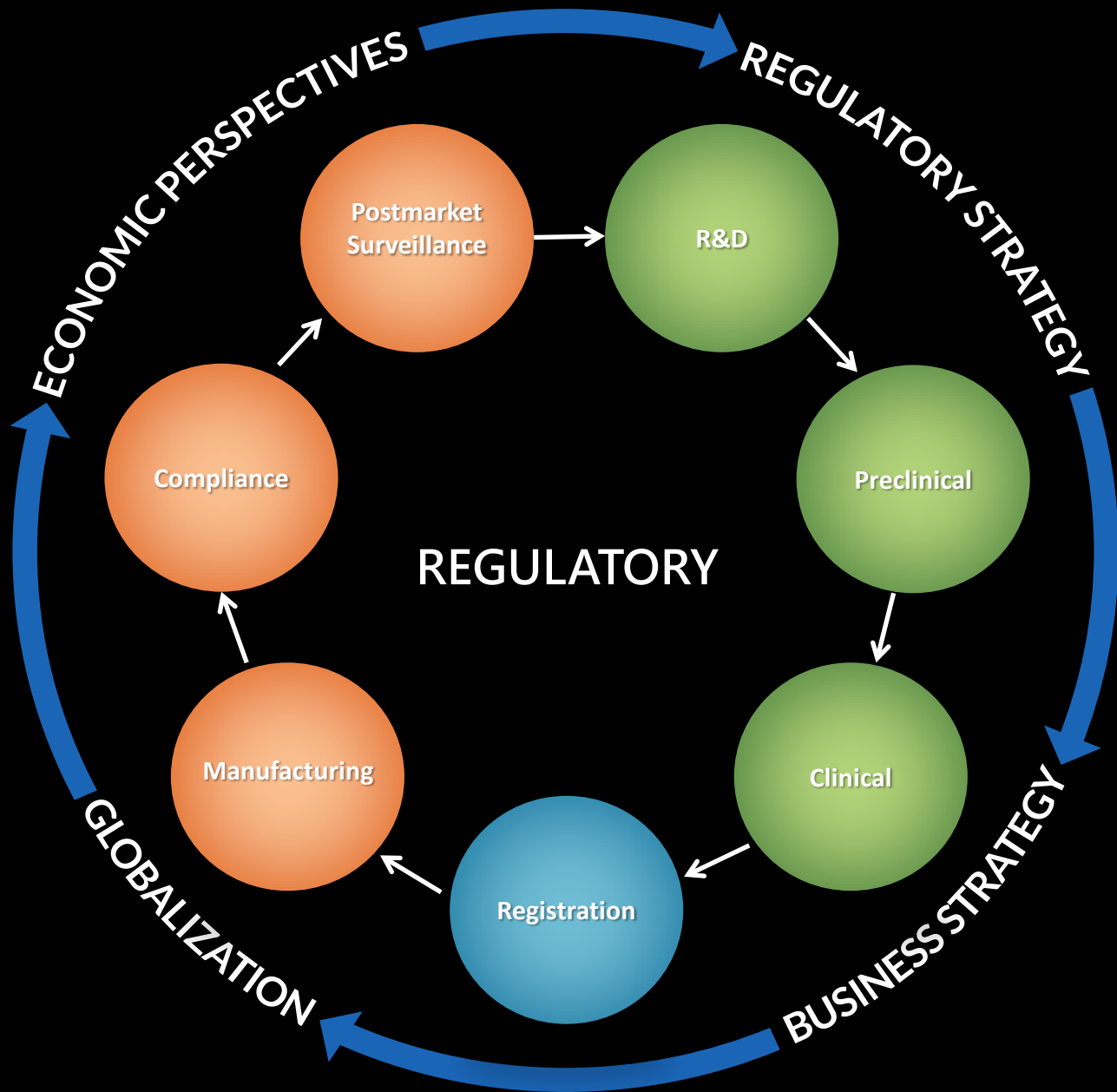
Technical
Sciences
4%



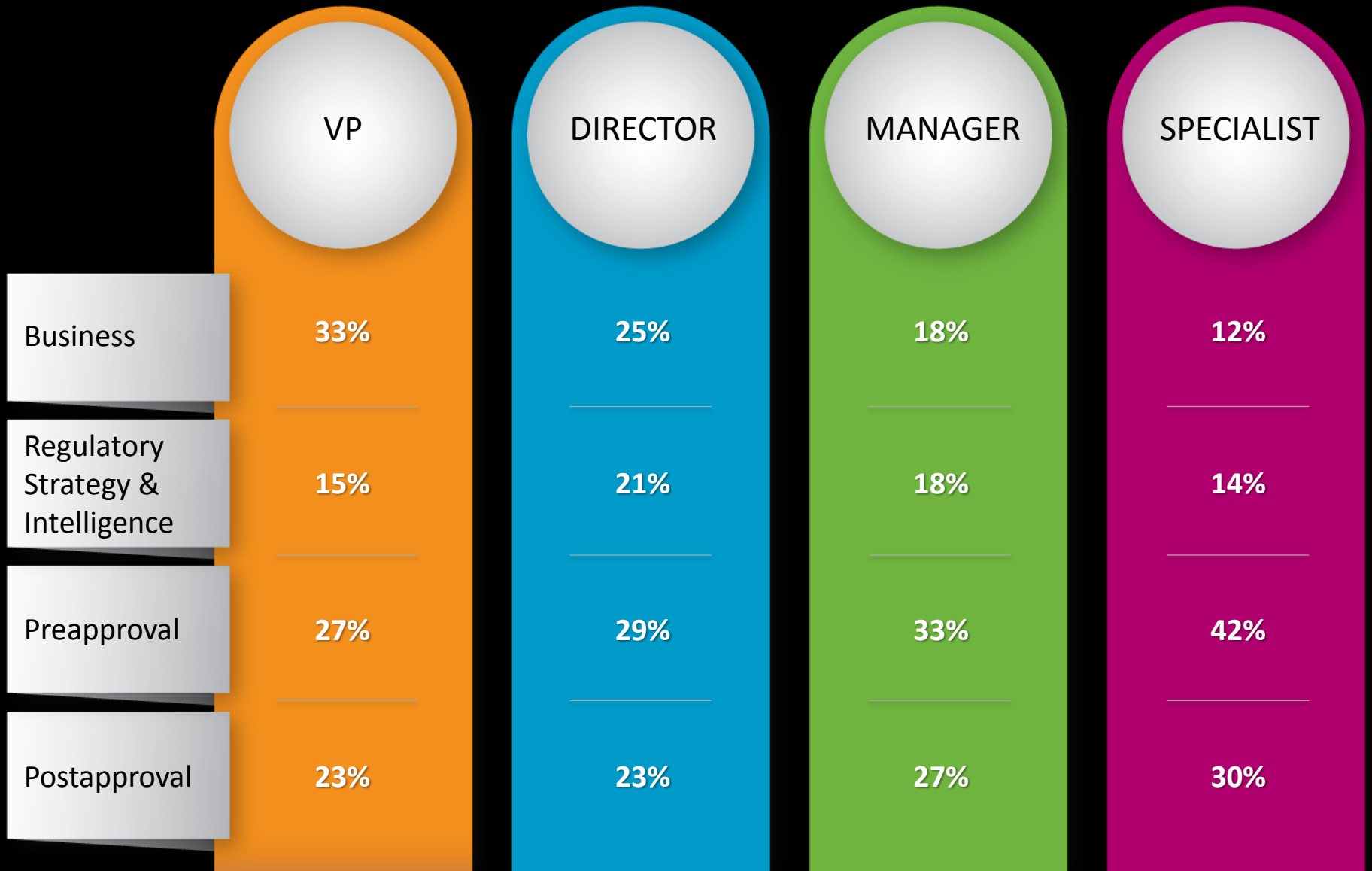
Public
Health
3%



Law
3%



SCOPE OF PRACTICE



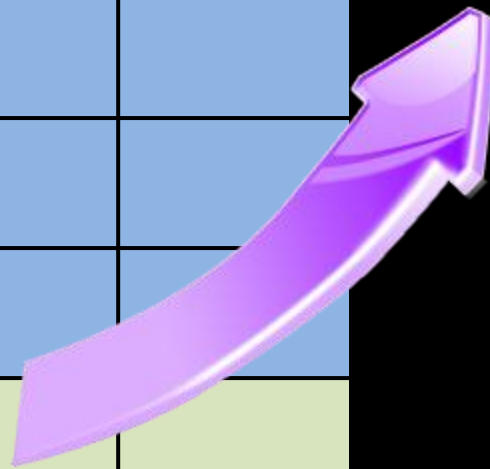
Global Regulatory Professional Competency Framework

		Novice/Entry-level		Intermediate	Advanced	Executive
		Developing systems (LMICs)	Developed Systems			
Medical Products	Information/Regulatory Strategy					
	Preapproval/Approval					
	Postapproval (Postmarket)					
Core	General					
	Technical					
Leadership						

RAC

		Novice/Entry-level
		Developing systems (LMICs)
Medical Products	Information/ Regulatory Strategy	-Describe regional and international regulatory standards and practices applicable to medical products. -Apply regulatory requirements, pathways and approaches used locally that pertain to the areas for which they are responsible.
	Preapproval/ Approval	-Apply national and international standards and requirements for product development and clinical trials. -Assess the need for potential risk management measures to assure an acceptable risk benefit profile throughout the product lifecycle.
	Postapproval (Postmarket)	-Assess the potential impact of post-approval changes to the quality, safety and/or efficacy of a product.
Core	General	-Describe the agency regulatory role and authority, including statutes, regulations, and guidelines. -Explain threats and risks to the supply chain as a result of globalization (international trade).
	Technical	-Describe the relationship between regulations, inspections, compliance and public health. -Recognize the role of international standards and standard setting organizations with regard to regulations, inspections, compliance and public health.

		Novice/Entry-level	
		Developing systems (LMICs)	Developed Systems
Medical Products	Information/Regulatory Strategy		
	Preapproval/Approval		
	Postapproval (Postmarket)		
Core	General		
	Technical		



Regulatory Framework						Product Development			Application Review & Product Registration			Compliance, Surveillance & Enforcement											
Animal Welfare	International Standards Development Organizations	Packaging	Product Classification	Product Life Cycle	Regulatory Impact Assessment	Risk Benefit	Schedule or Controlled Substances	Biomaterials	Clinical Trial Design	Naming Conventions	Shelf Life Studies	Claim Structures	Good Review Practices	Product Dating / Expiration	Product License and Registration	Shelf Life Studies	Clinical Trial Oversight	Facility Design	Good Practices (GXP)	Human Subject Protection	Marketing and Promotion	Product Dating / Expiration	Quality and Safety Monitoring

Public Health Principles					Regulatory Framework / Organizational Awareness								Science									
Environmental Health	Epidemiology	Nutrition	Personal Hygiene (GMPs)	Water and Sanitation	Zoonosis	Global Integration	Intellectual Property	International Relations/cooperation	Jurisdiction	Laws and Regulations	Policies	Principles of Quality Management Systems	Regulatory Transparency - Openness	Roles and Responsibilities	Rulemaking Process	Biology	Biostatistics	Chemistry	Ecotoxicology	Microbiology	Toxicity Testing	Toxicology

Compliance, Surveillance & Enforcement										Information Management				Professional Skills														
Adulteration	Authenticity	Complaints	Customs	Inspection & Enforcement	Sampling	Supply Chain Management	Surveillance	Third Party Audits	Traceability Systems	Trade Import / Export	Transportation	Data Management	Documentation	Literature Review	Record Keeping	Accountability	Communication Skills	Computer Skills	Confidentiality	Critical Thinking	Ethics and Conduct	Media Relations	Negotiation Skills	Personal Safety	Professionalism	Stakeholder Interaction	Teamwork	Writing Skills

Individual & workforce
assessment tools

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graph TD; A[Individual & workforce assessment tools] --> B[Alignment with regulatory system assessment & planning tools]; B --> C[Training planning tools]; C --> D[Course review tools];
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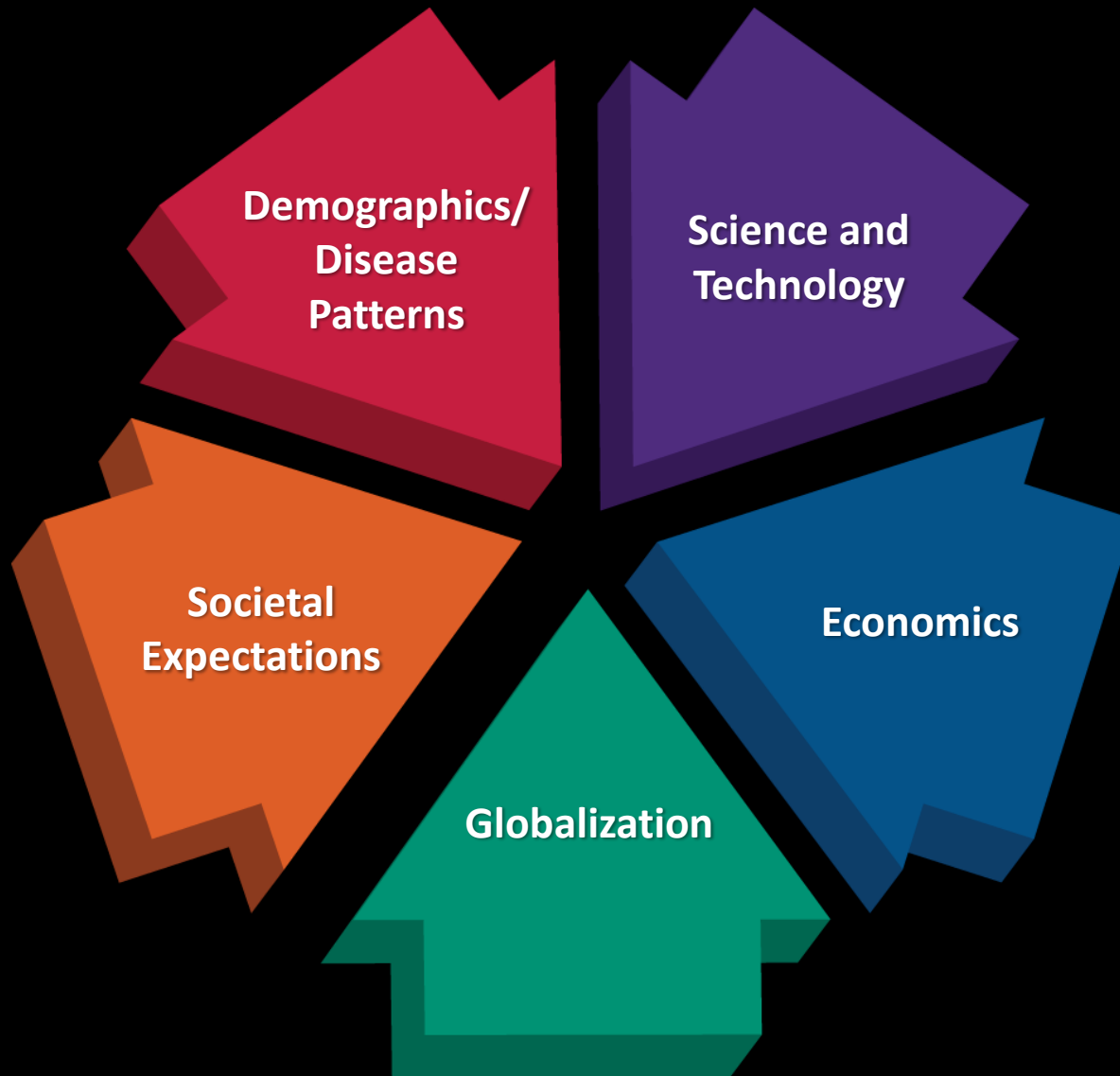
Alignment with regulatory
system assessment &
planning tools

Training planning tools

Course review tools

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EXTERNAL DRIVERS

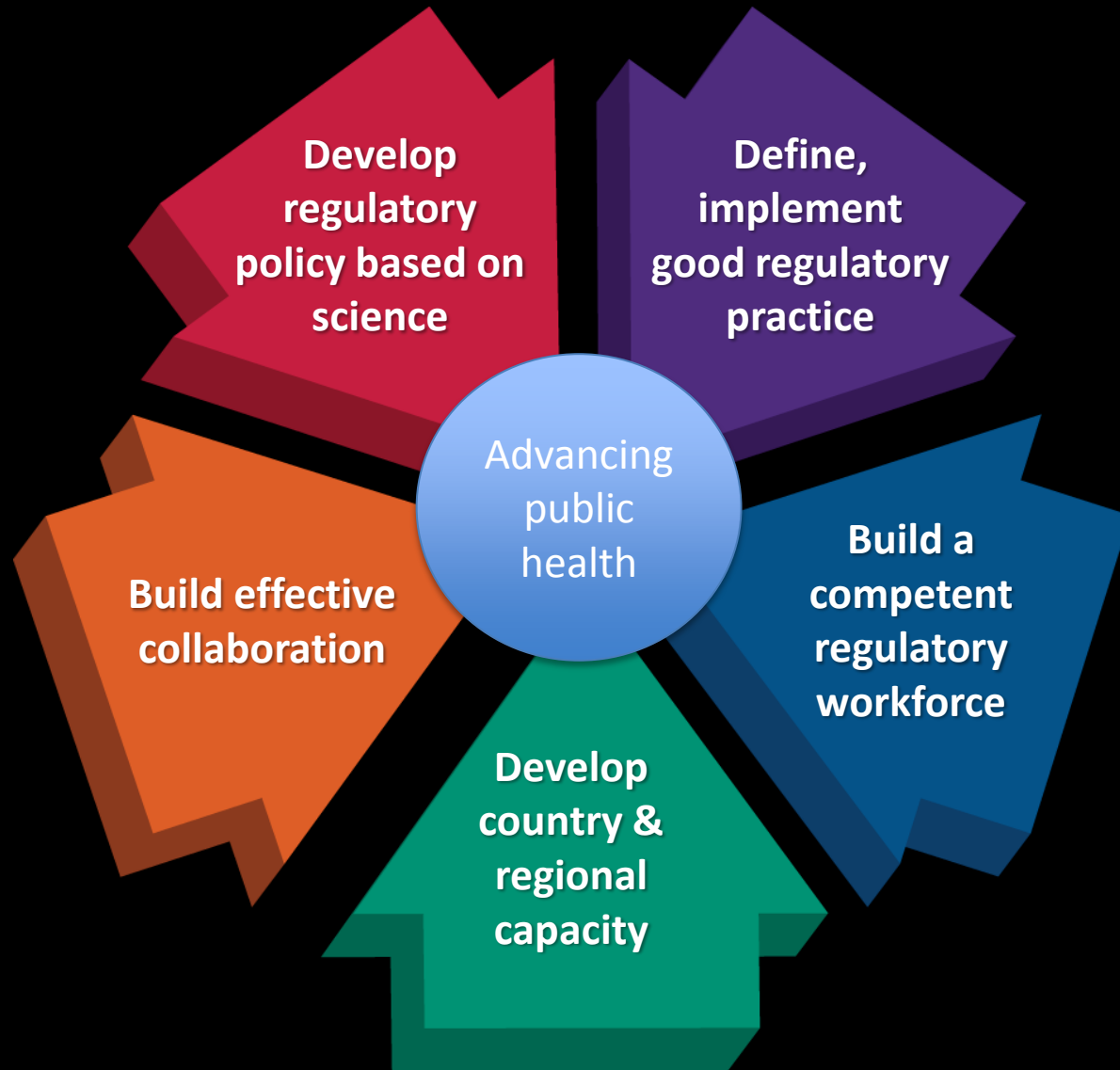


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	Technical					
Leadership						

RAC

REGULATORY CHALLENGES & OPPORTUNITIES



OPPORTUNITY

Thank you