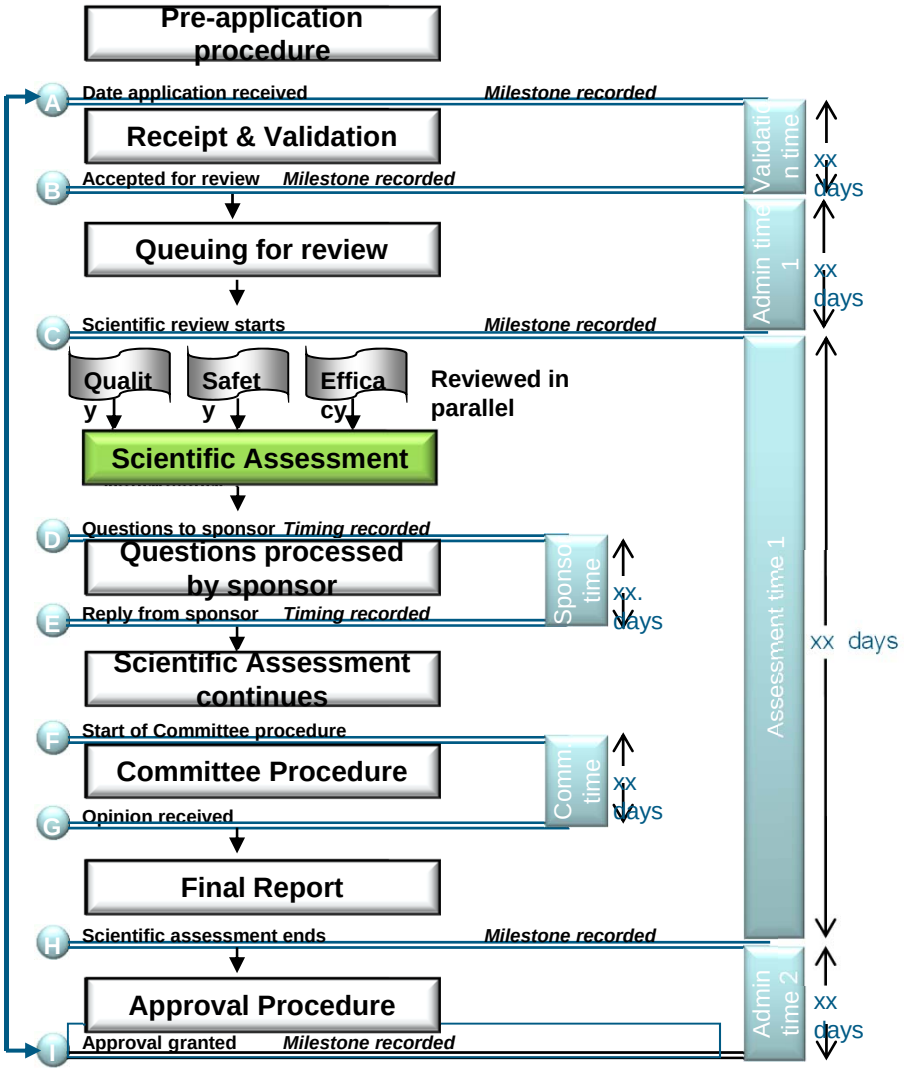
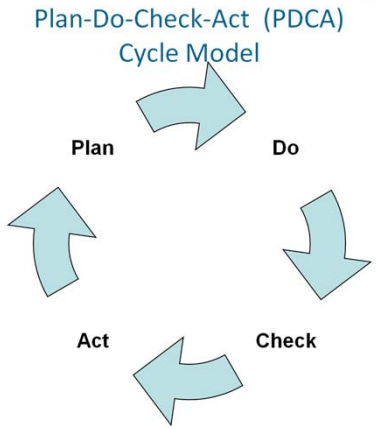




Practical Next Steps: ***Break Out One***

Goals/Standards/Common Elements

Background: What is a Quality System?

- A Quality System sets out the standards that you are working to, and how you are going to meet them.
- The system should define what people, actions and documents are going to be employed in order to carry out the work in a consistent manner, leaving evidence of what has happened.
  - It may include manuals, handbooks, procedures, policies, records and templates.
- The fundamentals of a Quality System are the same regardless of what your work is.
  - The same principles can be applied whether you are an academic research, a medical device regulatory or a medical product regulator

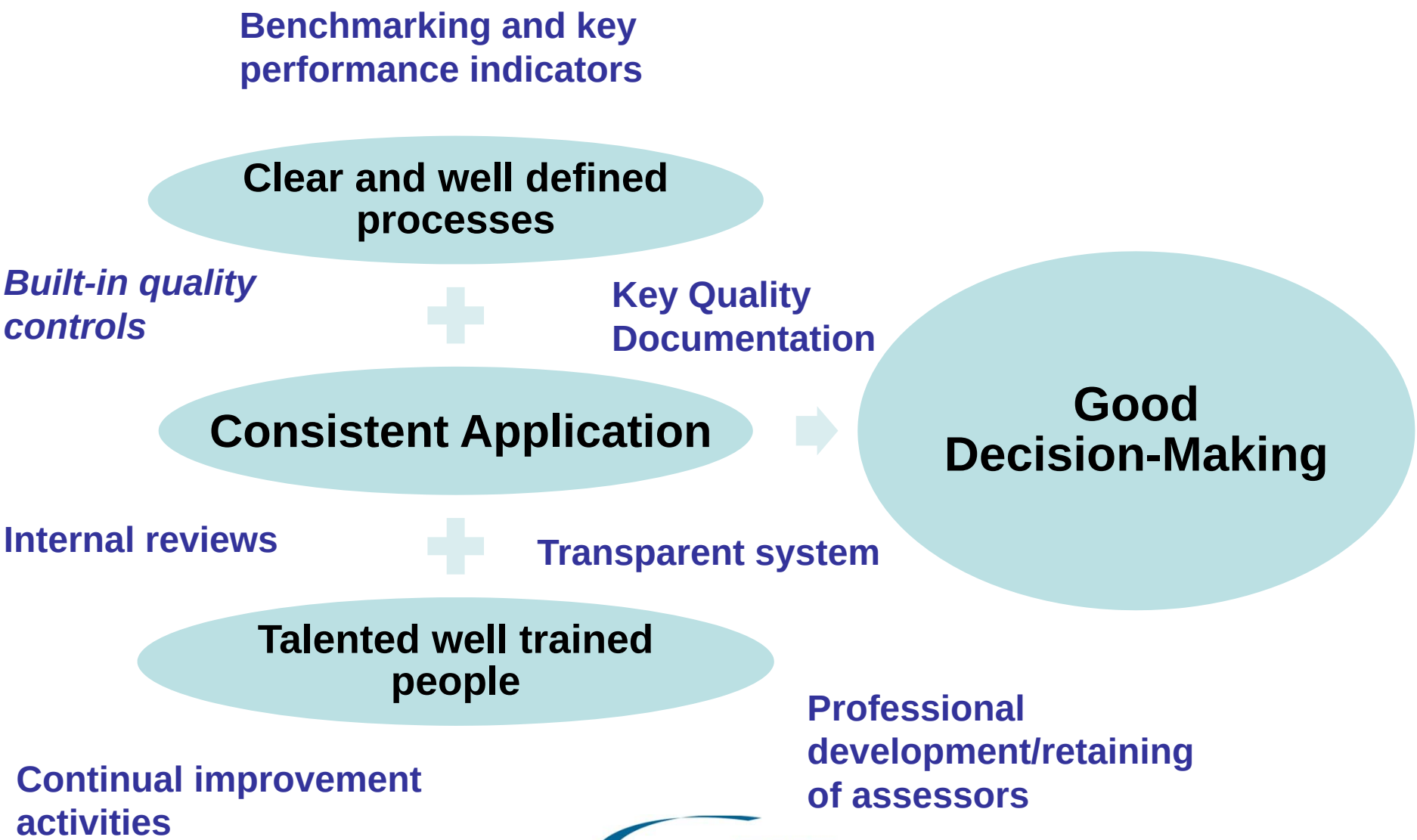
Source: BARQA The Research Quality Association

Exercise : Goals and Standards

The following Table will be completed as part of a group exercise

Question	Participants' Views EMA, Hong Kong, Indonesia, Japan, Singapore, CDE/TFDA, Thailand, FDAAA	Range of Agencies' Rating: Overall Good, Fit for purpose, Needs to improve, Poor
What is (are) the Goal(s) of your quality system?	Q T Tr P Consistency of activity Need management support and staff buy-in	**Need to improve:** Tracking, auditing systems, formalise systems/goals /standards, need to encourage staff participation, implementing a quality department , to be done with limited resources to implement quality systems, improving feedback (on assessment reports); customer feedback (two-way)
What is the scope of an agency's quality systems?	Should: •Relate to the entire agency •Cover all activities based on remit (responsibility and accountability)	
What activities are to be covered by the Quality System?	Review, inspections, feedback,	
What regulations or standards need to be complied with?	Jurisdictional specific, based on remit and legal boundaries	

Elements of a Quality Process



Exercise : Common Elements of Quality Systems

Elements of a Quality System	What are the key components/systems/ processes/documentation	What activity does such system drive eg Transparency/ accountability Consistency of process Effectiveness of process	Range of Agencies' Rating: Overall Good, Fit for purpose, Needs to improve, Poor
Key Quality Documentation	SOPs, Assessment Templates, Overall quality policy, job descriptions		FFP: Medicines NTI: Devices
Built-in quality controls	Peer feedback, internal meetings, management checks using core templates		
Internal reviews	Independent Quality department, peer reviews of reports; legal review of a reg decision		
Transparent system	Internal and external information availability, accountability, timeline publication, Summaries of approval	**Stakeholder feedback**: periodic industry association meetings; public forums/panels for further actions	NTI: Not consistent across agencies
Professional development/retaining of assessors	Ongoing training		
Continual improvement activities	Internal audits, stakeholder feedback, analysis of decisions		
Benchmarking and key performance indicators	Independent metric assessment		