

# Regulatory Competency Framework

---

**Suchart Chongprasert, Ph.D.**

**Director, Bureau of Drug Control**

**Food and Drug Administration, Thailand**

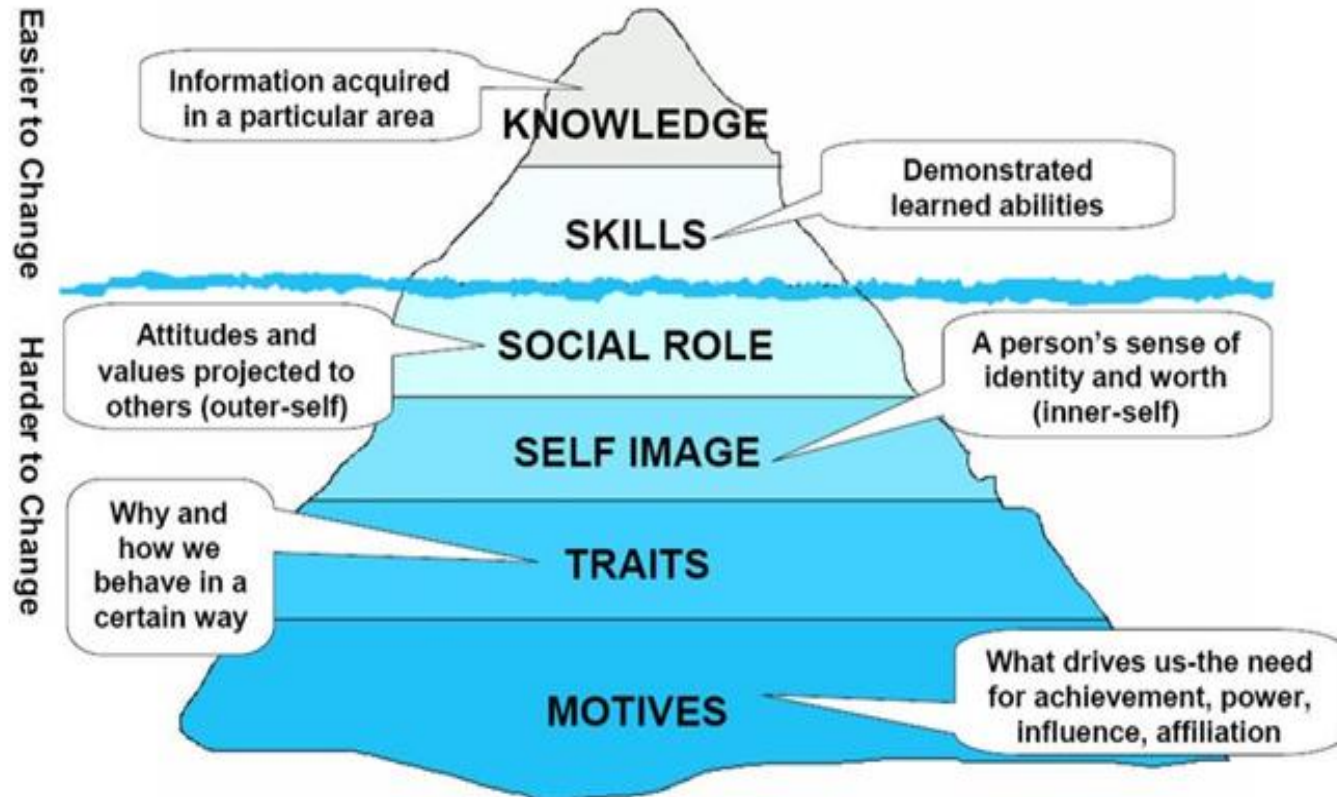


# WHAT IS A COMPETENCY ?

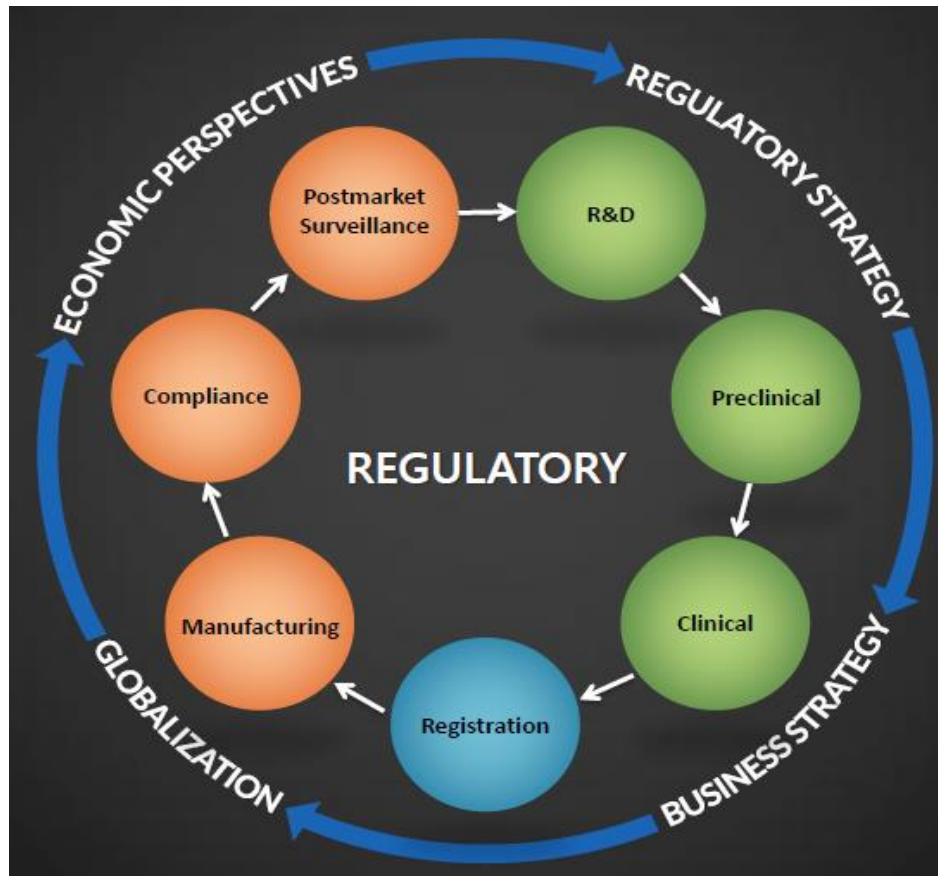
- A competency is a cluster of related knowledge, skills, abilities, and characteristics that are related to the performance of a significant aspect of the practice of a profession. (HPRA, 2014)



## ICEBERG MODEL OF COMPETENCIES



# Regulatory Competency



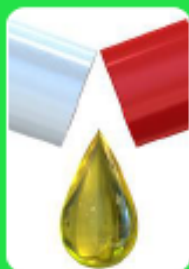
Regulatory competency of personnel is involved in all stages of **drug product life cycle**

# Regulatory Competency – Reviewer



## Core competency

- Evaluation, comparative analysis
- Critical thinking
- Data organization
- Interpersonal communication
- Conflict management



## Functional competency

- Types of submissions / Drug classes
- Clinical trial design and protocols
- Drug development process
- FDA regulation
- Discipline-specific data



## Technical competency

# Competency Building – Reviewer

## Training for Reviewer

- Drug law, regulations, and policy
- Relevant Guidelines for Drug review
- *Training for Good Review Practices (GRevPs)*
- *Hand-on training*

# Competency Building – Reviewer

## Training based on Good Review Practices (GRevPs)

- Fundamental Values and Principles of a Good Review;
- Managing review;
- Communication in review process (Written and Oral);
- Critical thinking development;
- How to conduct a review (Review strategy)

# Competency Building – Reviewer

## Mentoring System

- On-the-Job training
- Case-based learning
- Consultation





# Competency Building – Internal Reviewer

Internal  
Reviewer



Biologist  
Chemist  
Pharmacologist  
Medical officer  
Microbiologist  
Statistician  
Etc...



## Quality

- Formulation & Manufacturing
- QC : Micro biology
- QC : Chemistry

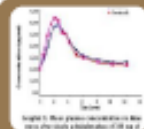


## Non clinic

- Pharmacology
- Toxicology



## Clinic



## BA / BE

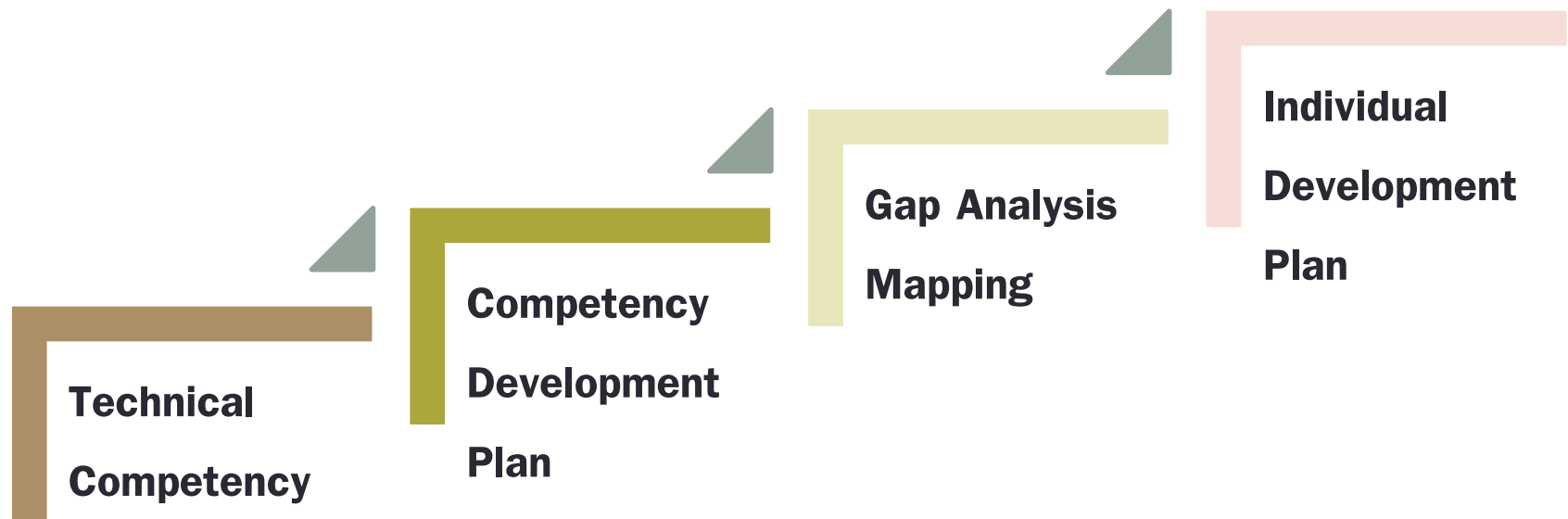


## Biotech

# Competency Building – Internal Reviewer

## Internal Reviewer Roadmap

---



A black and white portrait of Albert Einstein, showing his characteristic wild hair and mustache. The image is dark, with the subject's face and hair highlighted. On the left side of the image, there is a quote in white and orange text.

**A person who  
never made a  
mistake never  
tried anything  
new.**

**- Albert Einstein**

**“Thank You”**