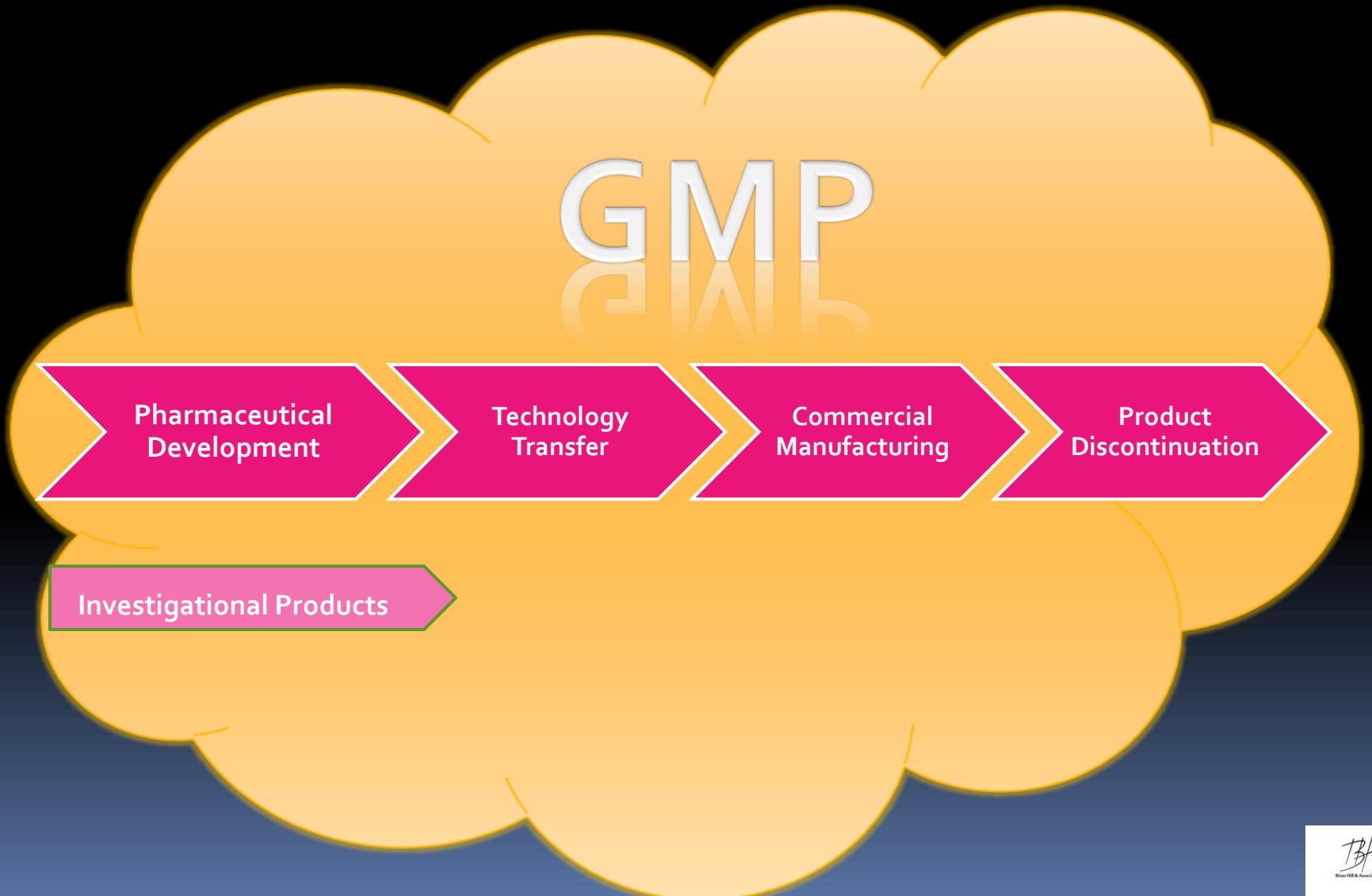
Implementing and Maintaining an effective Quality System

LEADERSHIPS ROLE

4 Key Elements to support an Effective Quality System

1. Product Life Cycle



2. Maintaining a State of Control

How do you know that you are in a state of control?

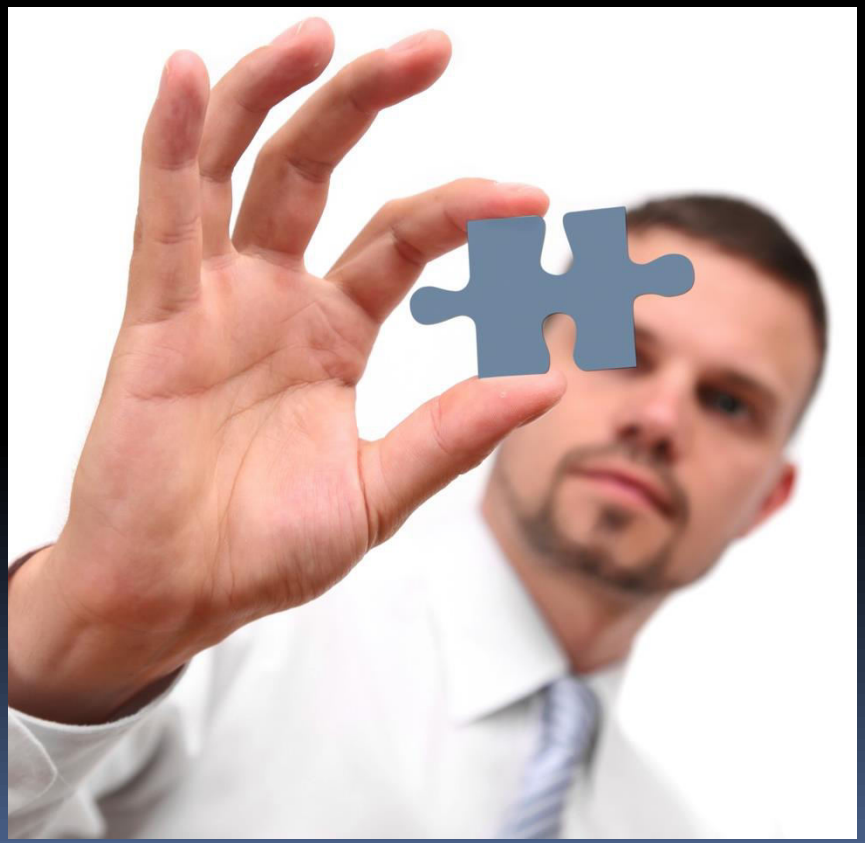


3. Learning Organization

Learns from Mistakes



Connects



4. Organization Capable

Communicates, Interconnected



Supportive

Action oriented



Your role as a Leader

Championing Knowledge in your Organization

- Your Products
- Your Processes
- Your People

Managing Complexity

Operations
- Systems
- Facility, Equipment and Infrastructure

Tasks
- Number of Products & Product types
- Product technology & Demand

Decisions
- Operational Structure & Relationships
- Critical Thinking

Personnel
- Organization Capability
- Knowledge, Skills & Training

Managing Risk



Managements Role

- Participation
- Ongoing support
- Communication
- Cross functional Interrelationships
- Measuring health of Organization
- Advocating continual Improvement
- Resource allocation

Cost of Non Compliance

- Rejected Materials
- Rework
- Recalls
- Plant Shutdown
- Loss of Sales
- Loss in Markets
- Delayed New Product Approvals
- Product Liability
- $ Fines

Cost

- It costs you significantly more being in a state of non compliance than it does to remain within a state of ongoing compliance!



Implementing an Effective Quality System

- **KISS** – Keep It Simple and Sustainable

Which do you think your organization would prefer?

Complex Systems **with** **Conflicting Messages**





Or

Clear Instructions plus a Clear Future Direction





Your Role as a Leader is to:

Assure predicable outcomes that support the business goals and instill…

…the right beliefs and behaviors throughout your organization and …

…Champion Quality beyond Compliance

Reference Materials

- ICH Q8 - (R2) Pharmaceutical Development
- ICH Q9 - Quality Risk Management
- ICH Q10 – Pharmaceutical Quality System

For more information

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