Advanced approaches to assure pharmaceutical product quality - Lifecycle management

Japan Pharmaceutical Manufacturers Association (JPMA)
Quality & Technology Committee
Chairman of ICH Quality Group

Kazuhiro Okochi

Agenda

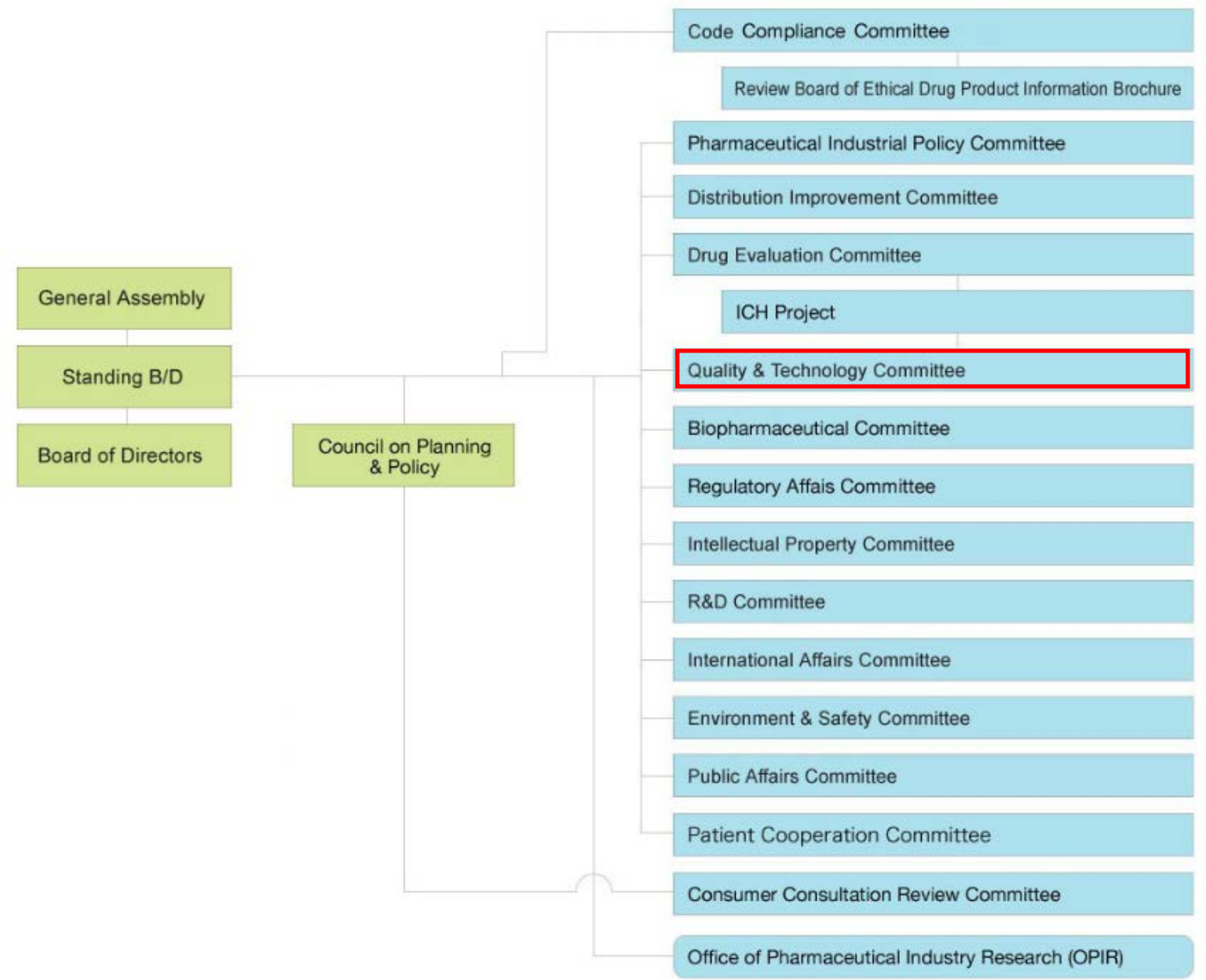
- **Japan Pharmaceutical Manufacturers Association (JPMA)**

- Pharmaceutical Quality System

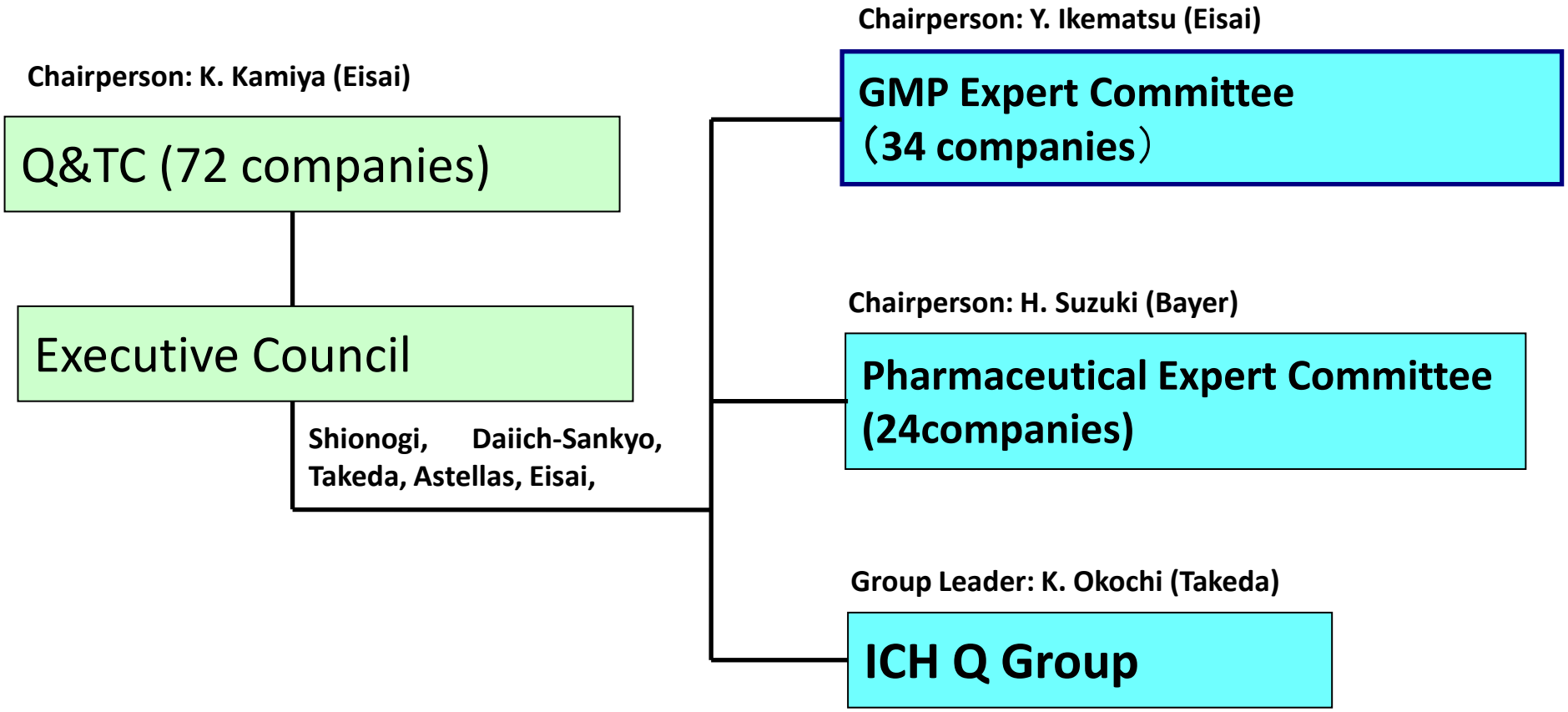
- Change Management and Continual Improvement

Structure of JPMA

As of October 2017



Quality & Technology Committee



Quality & Technology Committee

JPMA

<Key Activities>

- Established in 1973.
- Implement surveys and studies on **good manufacturing practice(GMP)**.
- Implement **pharmaceutical manufacturing technology** with subjects related to their physical properties.
- Establish and promote measures to improve reliability and quality of pharmaceutical products.
- Develop guideline(s) on quality topic(s) within the framework of International harmonization **in collaboration with ICH Project.**

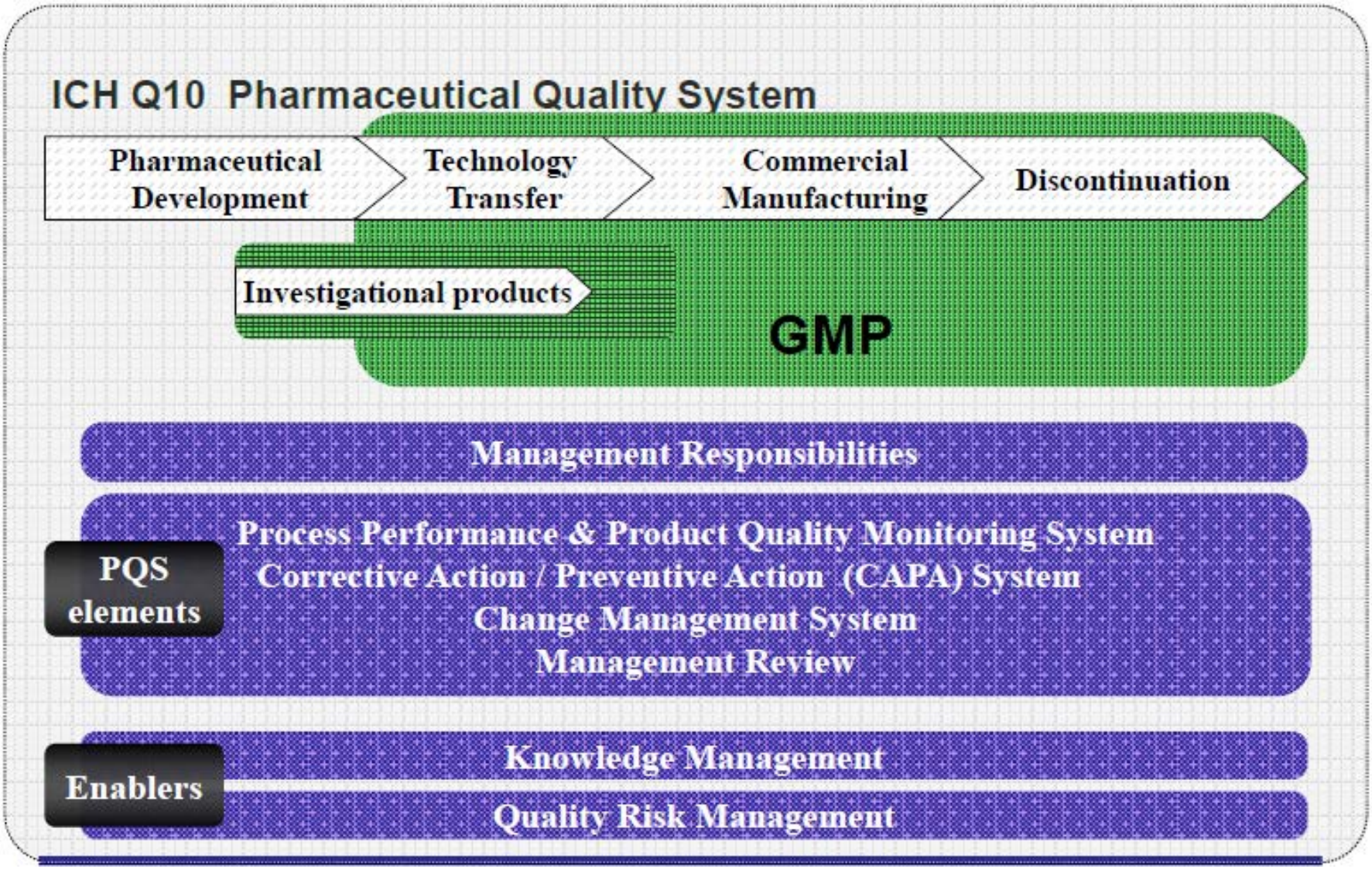
Agenda

- Japan Pharmaceutical Manufacturers Association (JPMA)

- **Pharmaceutical Quality System**

- Change Management and Continual Improvement

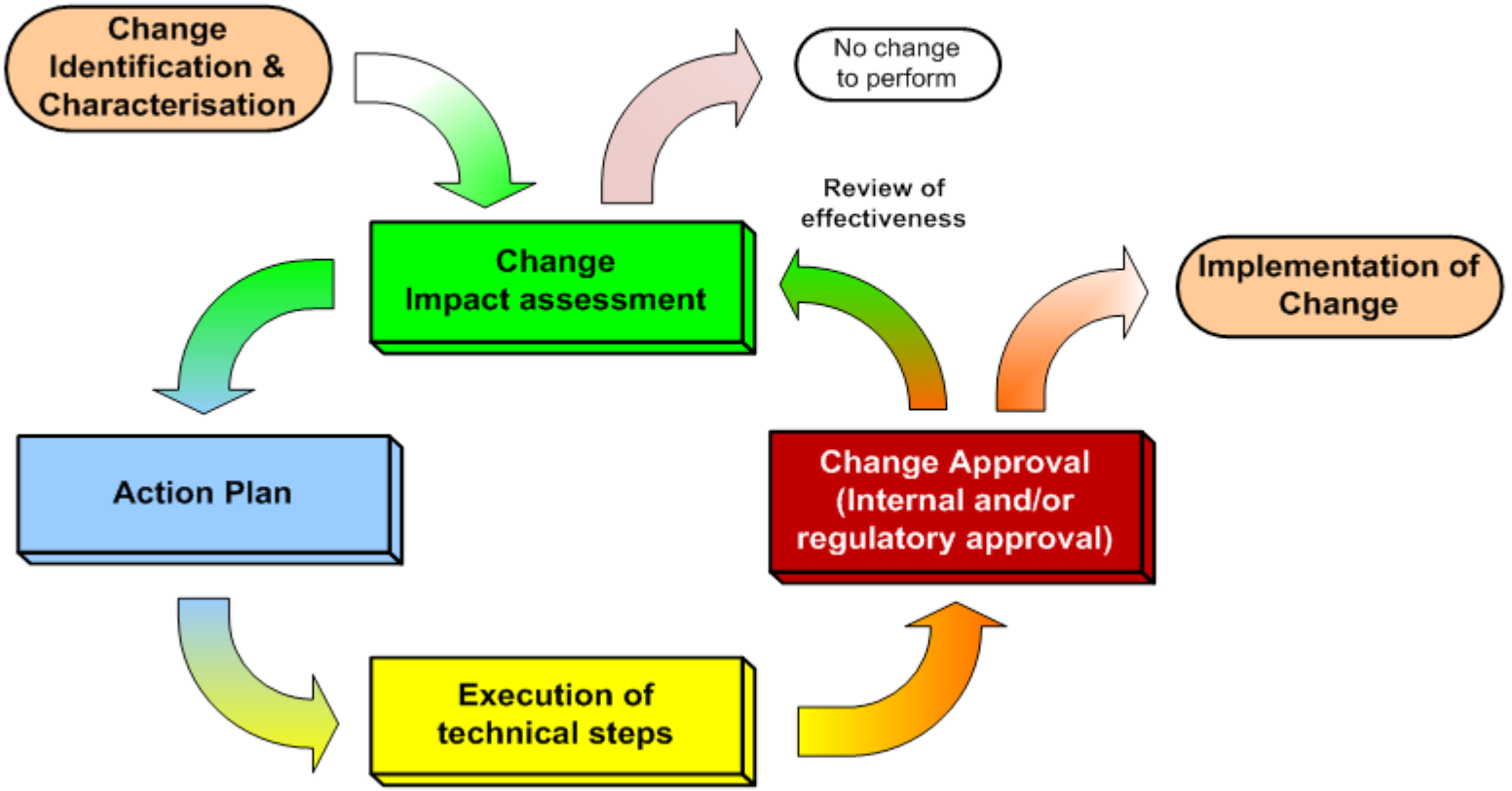
Pharmaceutical Quality System ICH Q10



Agenda

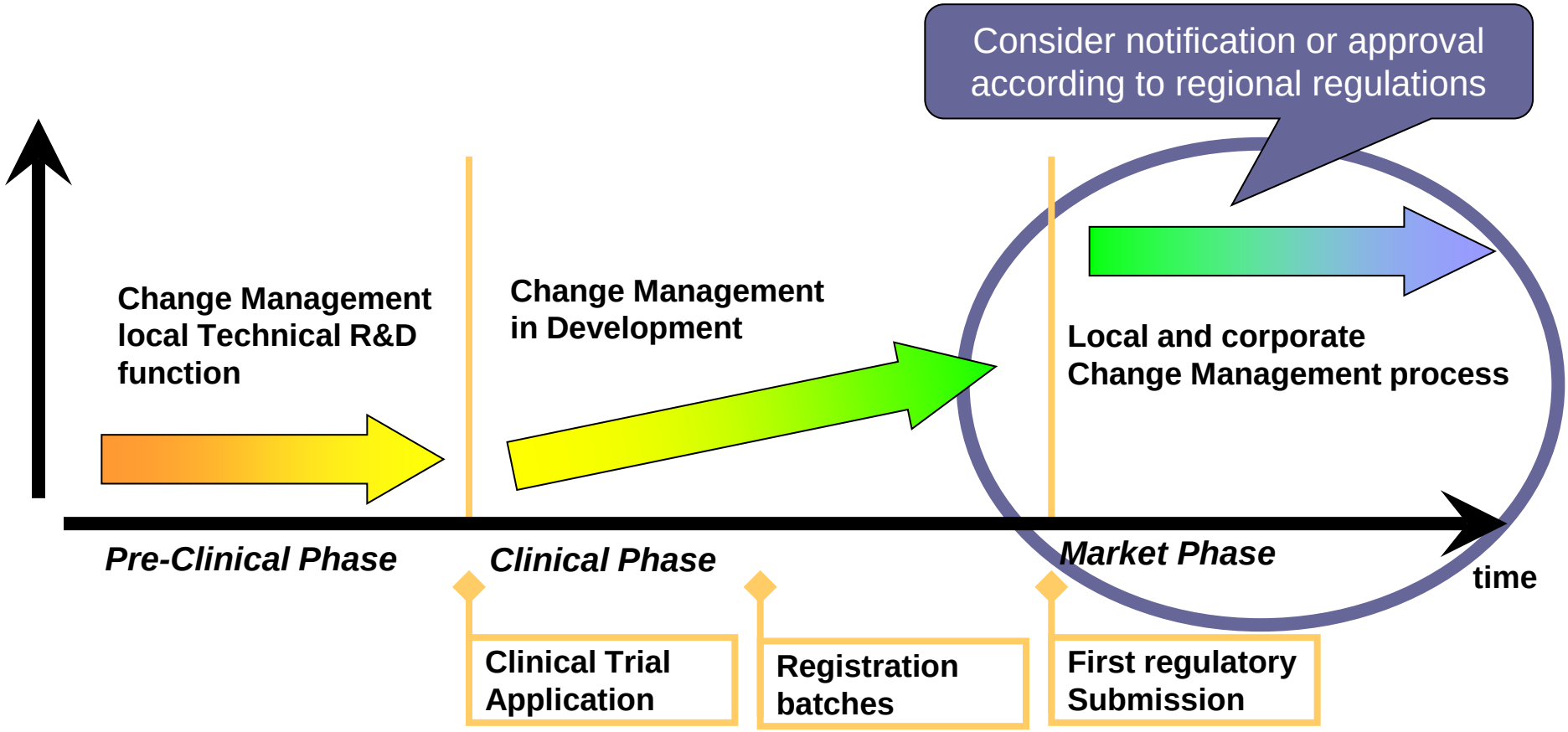
- Japan Pharmaceutical Manufacturers Association (JPMA)
- Pharmaceutical Quality System
- **Change Management and Continual Improvement**

Typical Change Management Process Map



Described in the companies PQS

Different Change Management approaches over the Life Cycle



Change Management Process

- **Verification by Quality Assurance**
  - Consider Process understanding
  - Consider Technical Regulatory Filing
  - Link to Knowledge Management
    - Knowledge management is a systematic approach to acquiring, analysing, storing and disseminating information related to products, manufacturing processes and components.
    - Sources of knowledge include, but are not limited to prior knowledge (public domain or internally documented); pharmaceutical development studies; technology transfer activities; process validation studies over the product lifecycle; manufacturing experience; deviations, customer complaint, returns, CAPA and OOS's assessments; continual improvement; and *change management* activities.

Change Management and Continuous Improvement

- Change *WILL* happen throughout the product lifecycle
  - **Proactively** due to business or technical reasons
    - Part of continuous improvement initiatives
      - e.g. new supplier, batch size change, new equipment
  - **Reactively** driven as part of CAPA
    - Due to deviations, OOS, batch rejections

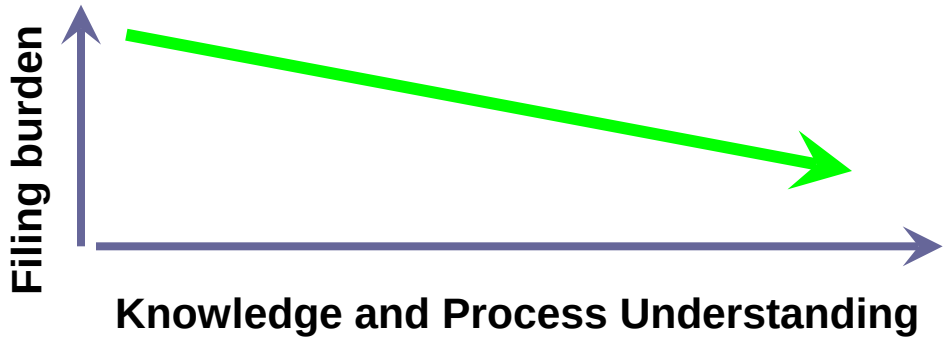
- The PQS must include a *robust* change management system
  - Use of knowledge and Quality Risk Management

- Continual Improvement must be part of our daily working lives
  - Helped by data (e.g. trend data, Statistical Process Control)
  - Driven by people - as part of the culture!

Change Management Process

Quality Assurance will:

- Verify if proposed change to operating range is within design space
- Utilise Knowledge and Process Understanding



- Ensure Manufacturing can perform the change without prior notification of health authorities

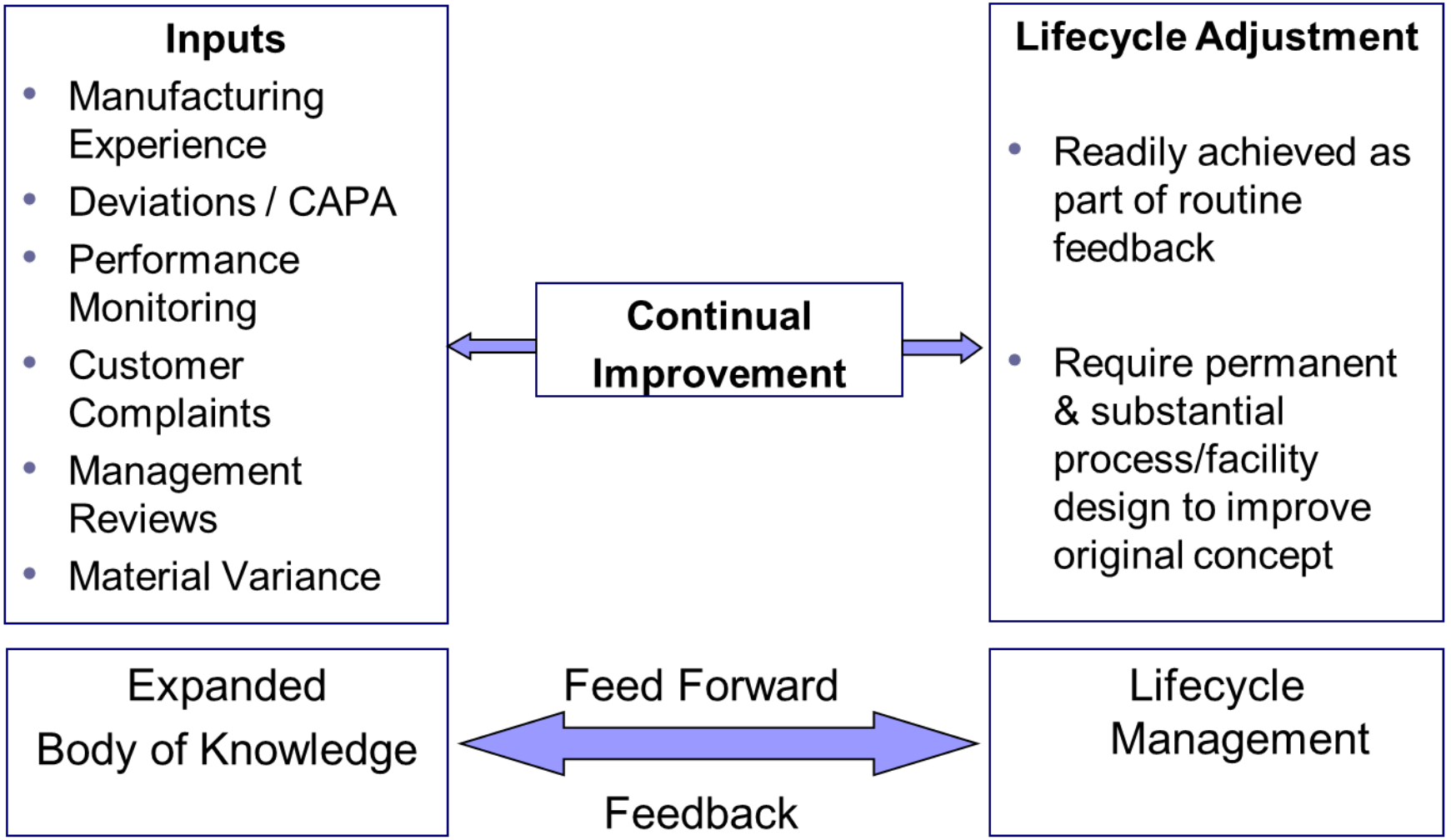
Change Management Process

- **Confirmation of successful change: e.g.**

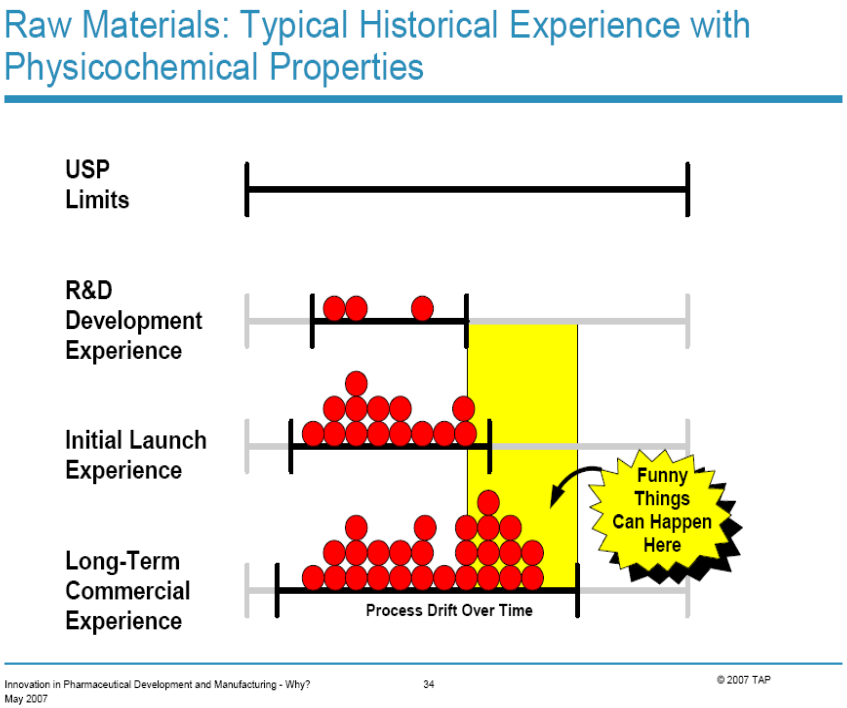
- **Process Validation**
  - Can be operated as a lifecycle monitoring i.e. ‘Continuous Process Verification’

- **Annual Product Review (APR)**
  - The effectiveness of the change is demonstrated

Continual Improvement



Change Management and Continual Improvement



Raw Materials

- Can be one major source of process variation – even if within the agreed specification limits
- Commercial manufacturing experience will increase our understanding of such raw material batch to batch variation over time

Continual Monitoring

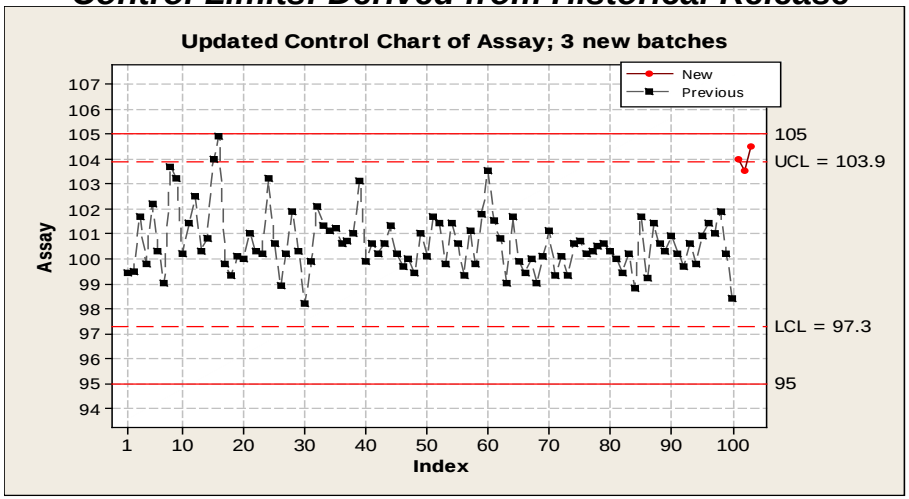
Process Tracking and Trending

- Statistical Process Control
- Address trends before they become problems

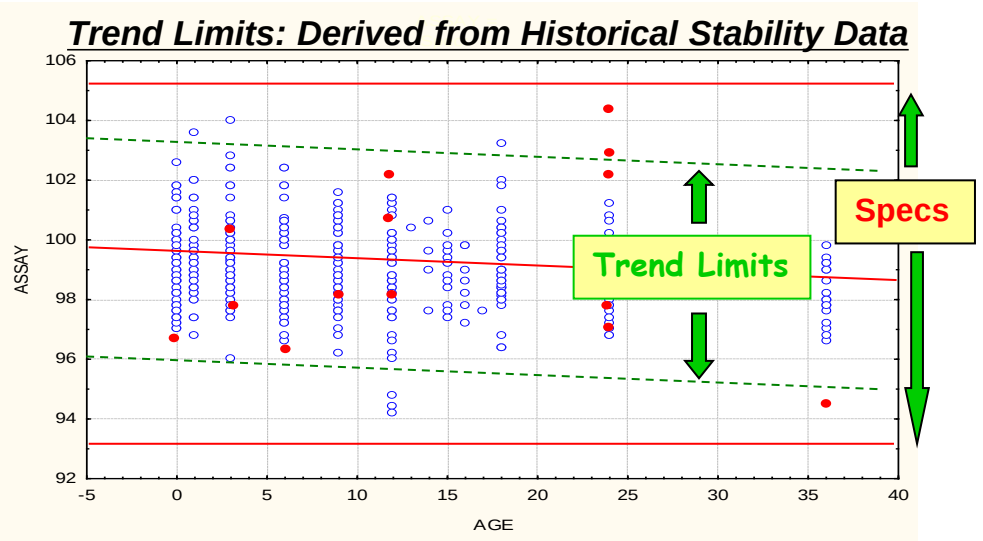
Product Quality Monitoring

- Analyze parameters & attributes in the control strategy
- Reduce sources of variation

Control Limits: Derived from Historical Release



Trend Limits: Derived from Historical Stability Data



Thank you!