STRATEGIC QUALITY MANAGEMENT

Systems Approach for Continuous Improvement

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What is SQM

➢ **Quality is an organizational skill and no longer an individualized skill**

➢ **Quality transitioned from manufacturing floor to entire organization**

➢ **Hence QM is now SQM to indicate management of the entire organization**

HOLISTIC APPROACH TO MANAGEMENT OF AN ORGANIZATION TO ACHIEVE DESIRED QUALITY OBJECTIVES

Holistic approach

➢ **Process centric company**

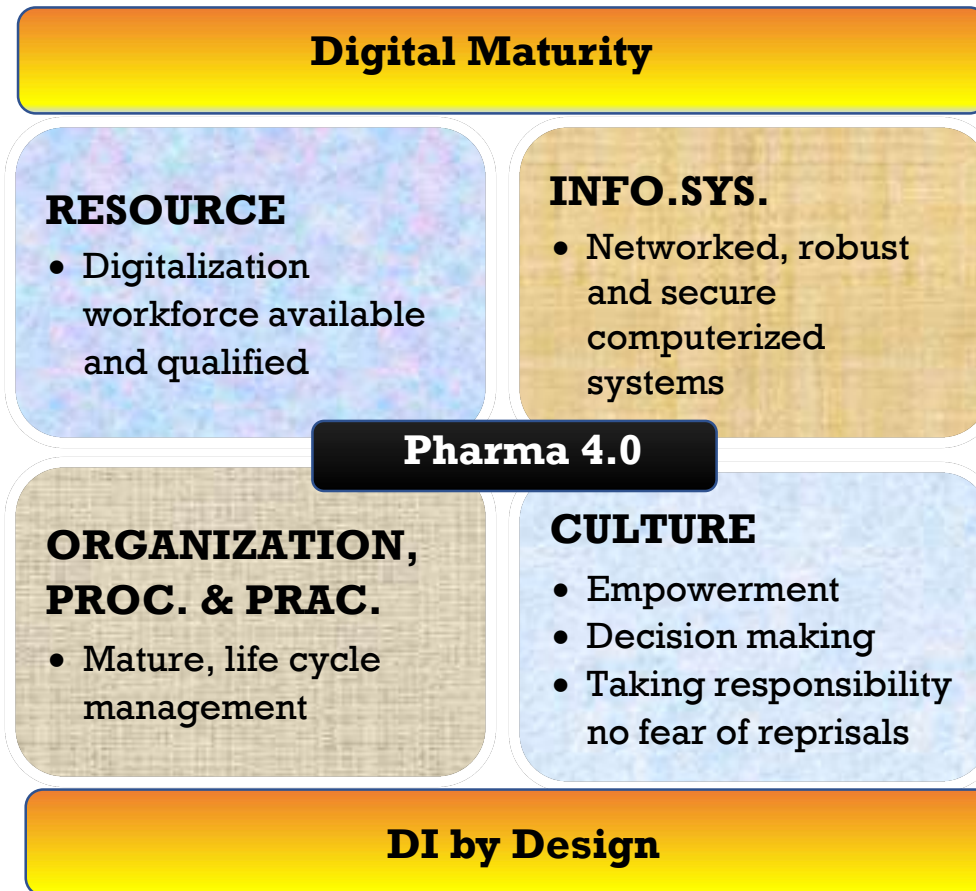*Processes consciously used to derive business outcomes: Quality*

➢ **Key attributes**

- ◆ Well defined ownership of processes

- ◆ Process development coalesce upwards instead of downwards – stakeholders involvement

- ◆ Performance measured against metrics – rework, effectiveness

- ◆ Focus is not just on tactical improvement of processes but to move them up a maturity continuum

- ◆ Business culture

Changing landscape

1. **Individualized therapies**

2. **Pharma 4.0; manufacturing floor to supply chain automation, flexibility**

3. **Designing for Quality; risk assessment & mitigation**

4. **Data analytics; AI, machine learning etc.**

5. **Managing for Quality: the 5p model**

6. **Impact of company culture**

Pharma 4.0 operating model

Digital Maturity

RESOURCE
- Digitalization workforce available and qualified

INFO.SYS.
- Networked, robust and secure computerized systems

Pharma 4.0

ORGANIZATION, PROC. & PRAC.
- Mature, life cycle management

CULTURE
- Empowerment
- Decision making
- Taking responsibility no fear of reprisals

DI by Design

Culture

1. **Value system**

2. **Value of individual components for success of the whole**

3. **Human factors; system not people**

4. **Culture of collaboration to implement holistic control strategy**
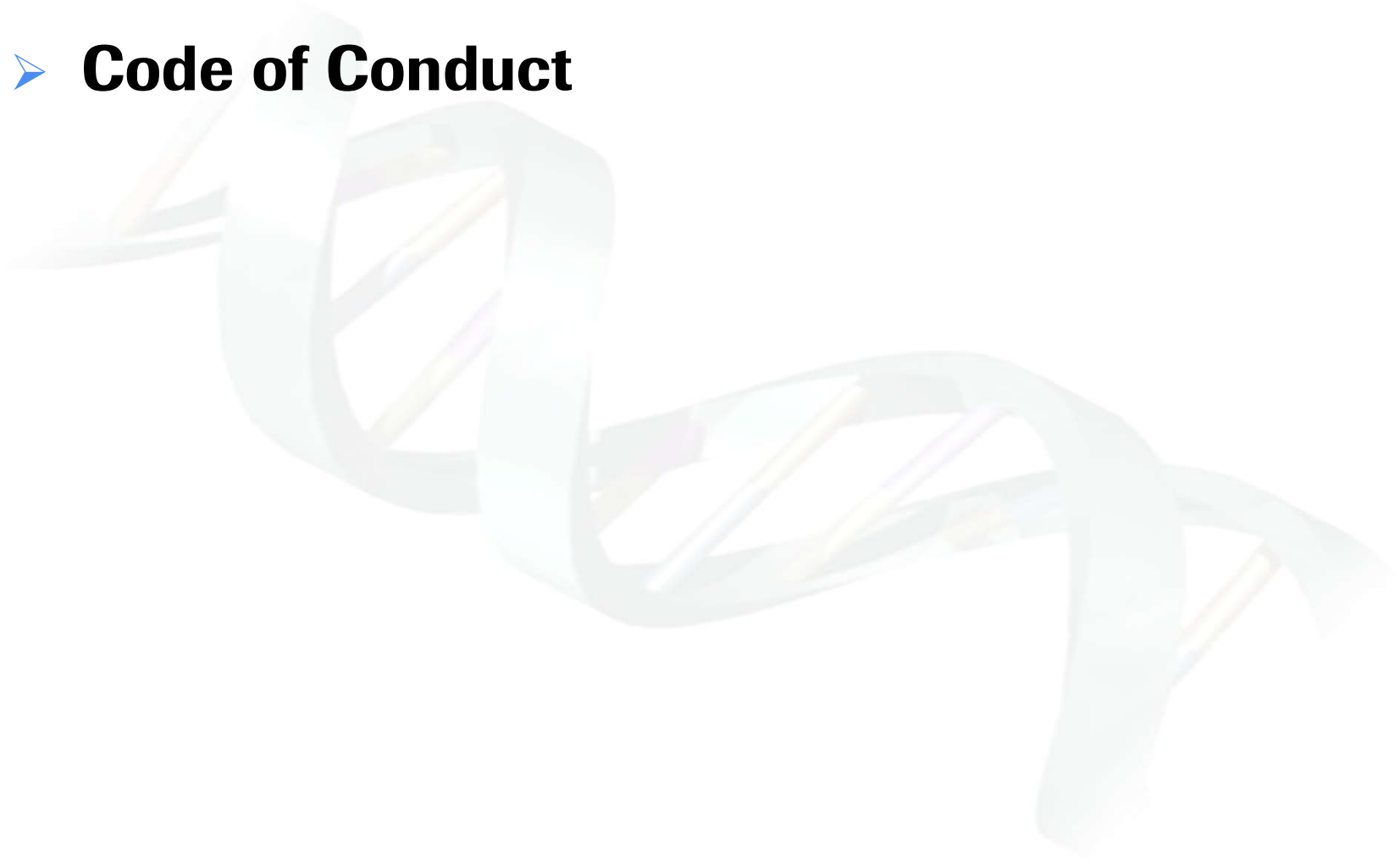
What is the 5P model

➢ **A strategic alignment model that requires alignment of all 5 variables (5-p) to improve operations**

➢ **The 5-p are:**
- ◆ Policies
- ◆ Principles
- ◆ Procedures
- ◆ Practices
- ◆ Performance (metrics)

Policy

- ➢ **Data Integrity policy**

- ➢ **VPN/Remote access policy**

- ➢ **Training policy**

Principles

➢ **Ethics Directive**

➢ **Code of Conduct**

Procedures

- Risk Assessment

- Backup and Restore

- Business Continuity

- SLA for external data store

- Raw data & metadata retention

- ERES compliance

- Instrument calibration

- Laboratory controls

- Change Management

- Raw material management

- Warehouse control
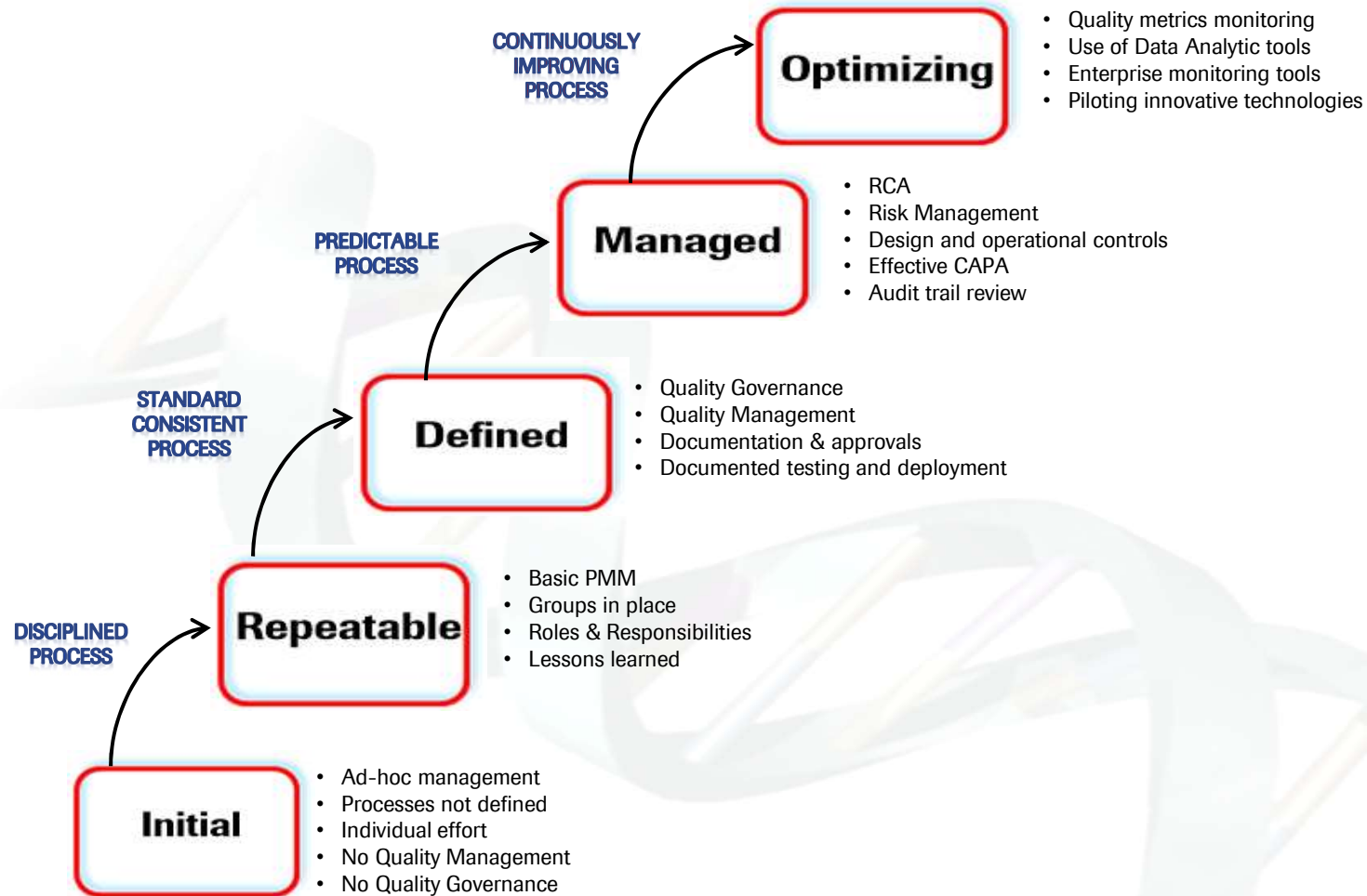
- Computer and Cloud management

Practices

- ➢ **Audit Trail reviews**

- ➢ **Batch release**

- ➢ **Issues coord. across groups**

- ➢ **OOS, Root Cause Analysis**

- ➢ **Training**

- ➢ **Design reviews**

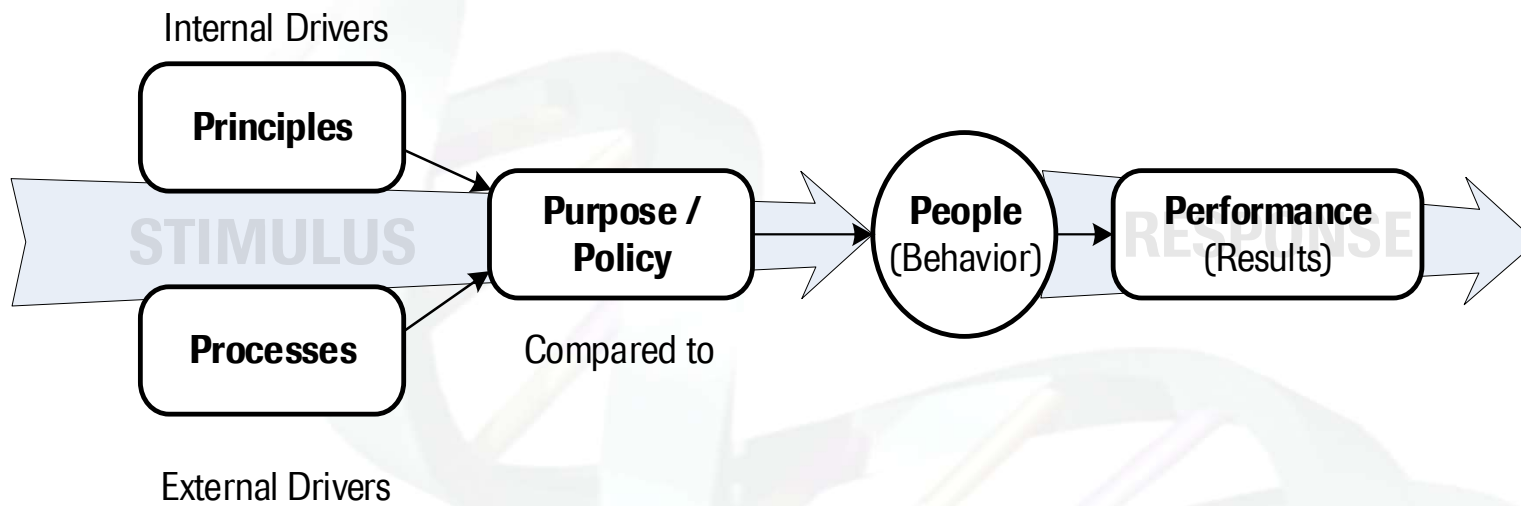- ➢ **Performance tracking**

Performance

➢ **Quality is a "continuous improvement" process**

➢ **"The continual improvement of the candle did not result in the light bulb"**

➢ **It happened due to innovation and research**

➢ **Come up with a criteria for measuring improvement**

➢ **Use Internal Audit reports to monitor progress**

Performance …. contd

Optimizing
- Quality metrics monitoring
- Use of Data Analytic tools
- Enterprise monitoring tools
- Piloting innovative technologies

CONTINUOUSLY IMPROVING PROCESS

Managed
- RCA
- Risk Management
- Design and operational controls
- Effective CAPA
- Audit trail review

PREDICTABLE PROCESS

Defined
- Quality Governance
- Quality Management
- Documentation & approvals
- Documented testing and deployment

STANDARD CONSISTENT PROCESS

Repeatable
- Basic PMM
- Groups in place
- Roles & Responsibilities
- Lessons learned

DISCIPLINED PROCESS

Initial
- Ad-hoc management
- Processes not defined
- Individual effort
- No Quality Management
- No Quality Governance

Interaction of the 5p's

Internal Drivers

Principles

STIMULUS

Purpose /
Policy

People
(Behavior)

RESPONSE

Performance
(Results)

Processes

Compared to

External Drivers

Interaction of 5Ps influencing cognitive behavior

Why People control problems occur

➤ **Presents the highest risk**

➤ **Training**

- ◆ Failure to train
- ◆ 'Read and understand' training approach
- ◆ Untrained supervisors
- ◆ Inadequate supervision on the floor

➤ **Processes**

- ◆ SOP development does not involve stakeholders and are not road tested
- ◆ Overcomplicated procedures
- ◆ Overlapping and redundant procedure

People control problems….contd

➤ **Company Culture**

- ◆ Fear of making mistakes

- ◆ Blame culture

- ◆ 'Ship the product at any cost or else' mentality

- ◆ Pressure to achieve production targets

- ◆ Over reliance on contractors

- ◆ Under resourced due to profit motive

- ◆ Failure to communicate past learnings

- ◆ Failure to maintain risk awareness/disengegement

- ◆ Yours is not reason why but just to do and die (educate)

People control solutions

➢ **Resolve people factors through:**

- ◆ Mandatory training programs on Data integrity
- ◆ Depute trainees for external training
- ◆ Sensitize employees to the culture of DI
- ◆ Ensure close supervision during increased production
- ◆ Regularly review & simplify procedures
- ◆ Required review of past learnings, DI incidents
- ◆ Not punitive but incentivize
- ◆ Open, blame-free culture
- ◆ Admit mistakes without fear of consequences
- ◆ Incident investigation; focus on process not person
- ◆ Focuses on prevention and not quick fixes CAPA
- ◆ Automate unhesitatingly, without cost consideration

People control solutions…. contd

➢ **Change training approach**

    ◆ Compliance/regulatory focus

    ◆ Personal integrity/patient focus

THE END