

Management Review to Drive Quality and Business Improvement

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Session Objectives

1. To share how AstraZeneca has implemented, via Quality Councils, the **Management Review** aspects of ICH Q10.
2. To share three real-life examples of quality and business improvements made through the execution of decisions made at Quality Councils.

ICH Q10 – III: *Management Responsibility* – “Leadership is essential to establish and maintain a company-wide commitment to quality and for the performance of the pharmaceutical quality system”

- Management Commitment
- Quality Policy
- Quality Planning
- Resource Management
- Internal Communications
- *Management Review*
- Management of Outsourced Activities and Purchased Materials

ICH Q10 – III.F: Management Review

- (a) “**Senior management** should be responsible for pharmaceutical quality system governance through management review to ensure its continuing suitability and effectiveness.”
- (b) “**Management** should assess the conclusions of periodic reviews of process performance and product quality and of the pharmaceutical quality system.”

ICH Q10 – IV.B.4: **Management Review** of Process Performance and Product Quality

- **“Management review** should provide assurance that process performance and product quality are managed over the lifecycle. Depending on the size and complexity of the company, **management review** can be a series of reviews at various levels of management and should include a timely and effective communication and escalation process to raise appropriate quality issues to **senior levels of management for review.”**

ICH Q10 – IV.B: Continual Improvement of Process Performance and Product Quality – Pharmaceutical Quality System Elements

- Process Performance and Product Quality Monitoring System
- Corrective Action and Preventative Action (CAPA) System
- Change Management System
- **Management Review** of Process Performance and Product Quality

19 sites 15 countries



Supply Americas

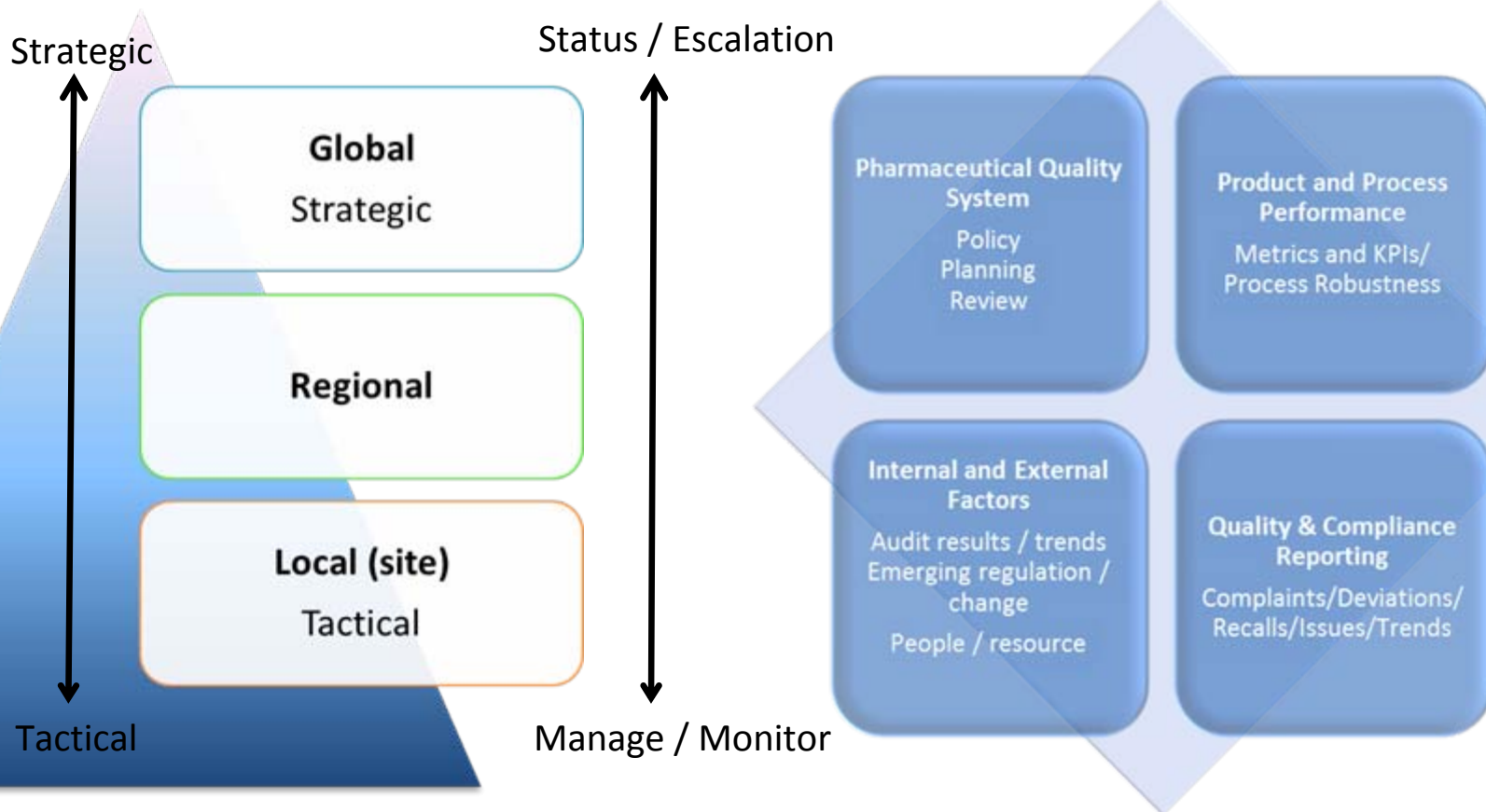
Supply Europe, Middle East & Africa

Supply Asia Pacific & Japan

Sweden Operations

Management Oversight: AstraZeneca Interpretation of Management Review Element – Three Levels of Quality Councils

Management Oversight to Quality System Health / Performance



Quality Council Membership

| Site Quality Council | Regional Quality Council | Global Quality Council |
|--|--|--|
| Site Leader (Co-chair) QA Leader (Co-chair) Production Leaders Engineering Leader Compliance Leader LEAN Program Leader Finance Leader Human Resource Leader Secretariat | Regional Operations Leader (Co-chair) Regional QA Leader (Co-chair) Site QA Leaders Site Leaders Secretariat | Global Operations Leader (Co-chair) Global QA Leader (Co-chair) Global Supply Chain Leader Regional and Global QA Leaders Regional Operations Leaders Secretariat |

Management Review Case Study: Improvement in Laboratory Operations – Site Quality Council

- Challenge:
 - Unfavorable trend in laboratory deviations
- Management Review Process:
 - Line management escalated trend data and possible root causes to site Quality Council
- Action Taken:
 - Quality Council sanctioned the formation of a cross-functional team to identify true root causes
 - Instituted awareness of lab deviations immediately to all staff, not just after investigation was completed
 - Established a visual board in lab to highlight and track all lab deviations
 - Established a team to focus on error proofing lab documentation
- Ongoing Monitoring:
 - Action plan tracked by site Quality Council
 - Performance metrics reported monthly
 - Laboratory line management accountable for sustaining and improving performance
- Business Benefit:
 - Improved cycle times/efficiency in lab
 - Reduction in site inventory costs (less stock on hold due to deviation investigations)

Management Review Case Study: Improvement of Customer Satisfaction via Complaint Process Review – Regional Quality Council

- Challenge:
 - Customer complaint profile for key product identified patient user improvement opportunities
- Management Review Process:
 - Identified within a particular region as an opportunity and also escalated to the global Quality Council as a **global opportunity**
- Action Taken:
 - Full review of customer feedback performed resulting in improved patient information and education
 - Proactive work in some regions with more extensive education
 - Product design review and improvements implemented
 - Encouragement of better customer feedback when complaints are received
- Ongoing Monitoring:
 - Product complaint process provides for evaluation of performance globally, regionally, per market, etc.
 - Complaint data is regularly reviewed and evaluated to ensure improvement measures are being realized in the field; reporting to Quality Council is routine
- Business Benefit:
 - Retention of customers
 - Reduced complaint investigation costs

Management Review Case Study: Improvement of the Primary Shipping Process – Global Quality Council

- Challenge:
 - Shipping process performance identified trend in product loss due to temperature excursions
- Management Review Process:
 - Included escalation to global Quality Council for visibility and support to drive a cross-functional **global initiative** for improvement
- Action Taken:
 - End to end review of process for improvement opportunities and introduction of more consistent processes
 - Global shipping procedure introduced resulting in clear ownership and accountabilities for execution, oversight and performance evaluation
 - Simple product protection options introduced
 - Shipping route risk assessments introduced
- Ongoing Monitoring:
 - Periodic business reviews internally and with external providers and best practice sharing introduced
- Business Benefit:
 - Reduced waste and costs
 - Improved customer service

AstraZeneca Quality Councils

Are

- A forum for leadership engagement, awareness and decision-making around quality system and process performance
- A key governance body for the Operations function to protect our license to operate and manage potential risks
- Continuing to mature as we grow and develop

Are Not

- A substitute for line management accountability
- The only forum for addressing improvements to quality systems
- A place to work or solve problems

Conclusions

- The structure and complexity of your company should be considered as you define appropriate **management review** mechanisms as required by ICH Q10
- Senior leadership support and engagement is critical for success of the **management review** process
- The ICH Q10 **management review** process helps drive continuous improvement and business benefits