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.”

“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

<table>
<thead>
<tr>
<th>Site Quality Council</th>
<th>Regional Quality Council</th>
<th>Global Quality Council</th>
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<tr>
<td>Site Leader (Co-chair)</td>
<td>Regional Operations Leader (Co-chair)</td>
<td>Global Operations Leader (Co-chair)</td>
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<td>QA Leader (Co-chair)</td>
<td>Regional QA Leader (Co-chair)</td>
<td>Global QA Leader (Co-chair)</td>
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<td>Production Leaders</td>
<td>Site QA Leaders</td>
<td>Global Supply Chain Leader</td>
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<td>Engineering Leader</td>
<td>Site Leaders</td>
<td>Regional and Global QA Leaders</td>
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<td>Compliance Leader</td>
<td>Secretariat</td>
<td>Regional Operations Leaders</td>
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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)

- 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.