Partnerships in Achieving Manufacturing Excellence

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International Workshop on "Vaccine Quality Management"
July 10 - 11th 2013 – Hosted by Birmex, Mexico D.F.
PATH’s vision

A world where innovation ensures that health is within reach for everyone.
PATH’s mission

Improving the health of people around the world by:

- Advancing technologies
- Strengthening systems
- Encouraging healthy behaviors
PATH’s vaccine development projects

- Pneumococcal disease
- Diarrheal disease
  - Rotavirus
  - Enterotoxigenic *E. coli* and *Shigella*
- Influenza/RSV
- Polio
- Malaria
- Meningococcal disease
Role of product-development partnerships

Development risk vs. Potential returns

- Developing world risk/return
- Private sector
- Risk-return threshold
Role of product-development partnerships

- Mitigate risk
- Share costs
Global access: critical terms

- Ensuring product supply
  - Impact requires scale
- Making products affordable
  - Market segmentation enables tiered pricing structures
- Managing intellectual property
  - Relative value of supply and price concessions vs royalties
  - Reserve rights if supply/pricing commitments not met
Product development partnerships and global access

• Expand the risk/return threshold for the private sector

• Identify unique partnership characteristics

• Negotiate global access consistent with partnership
Mutually beneficial, collaborative partnerships

WHAT PATH BRINGS
- Expertise in developing country health systems
- Presence in poor countries
- Ability to strengthen clinical trial capacity
- Financial support
- Technical expertise
- Strategic relationships
- Intellectual property

WHAT PARTNERS BRING
- Expertise in product development
- Scientific and technical capacity
- Intellectual property
- Manufacturing facilities & equipment
- Large-scale distribution systems
- Market-based approach
PATH support to manufacturing

- Vaccine product support
  - Meningococcal Type A conjugate
  - Pneumococcal polysaccharide conjugate*
  - Japanese Encephalitis
  - Influenza
  - Rotavirus*
  - Polio / hexavalent

- Country-level support
  - Brasil
  - China
  - Viet Nam
How do you manage?

ICH Q10 says, “Performance indicators should be identified and used to monitor the effectiveness of processes within the QS.” and “Performance indicators that measure progress against quality objectives should be established, monitored, communicated regularly, and acted upon as appropriate.”

• Management needs to establish the metrics, act on them to improve the QS and communicate the results and goals to everyone.

• QA needs to facilitate the collection of the data, its analysis (root cause and risk analysis) and present the data in a usable form to top management.
How do you measure performance?

• The ICH Q10 Quality System consists of these four key elements:
  • Process Performance and Product Quality Monitoring,
  • Corrective Action and Preventive Action (CAPA),
  • Change Management, and
If you don’t measure, how can you improve?

An example of a process performance and product quality monitoring system are Key Performance Indicators (KPIs):

- Corrective Action Preventive Action (CAPA) System
- Deviation/Investigation System
- Change Control System
- Training Program
- Internal Audit Program
- Documentation Management System
- Supplier Control Program
- A KPI can also be defined at any level. For instance, as part of a manufacturing process, yield at a particular step or the performance of a cleanroom during aseptic operations can be KPIs on the shop floor.
Management support

- Clear definition of responsibilities within the organization – this includes global, regional, and/or local, as appropriate for the business
- Sufficient qualified resources to perform tasks and activities associated with processes and systems
- Clear definition of information and communication flow within all levels of the organization
- Integration of risk management into all activities, particularly design and process operations
- Support of initiatives for continuous improvement throughout the organization
Managing the Quality System using Performance Indicators

10 – 11 October 2013 in Hanoi

This two-day workshop is intended for senior manufacturing and quality management executives. A key to successful to effective quality management knows what to manage; which data to gather and how to assess the risk to the product, the company and most importantly, the patient.
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