14. Building A Robust Quality Management System

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Presenter’s note

• Please note, the slides contained herein, along with the narrative, are of a generic nature. These have been created in order to promote the general understanding of legislation surrounding EU Good Distribution Practice for Medicinal Products, and not with specific scenarios in mind.

• The author and presenter does not accept any liability for any inappropriate action taken or misinterpretation of legislation.
LEARNING OBJECTIVES

• Quality System Requirements

• Design Criteria, for an effective QMS

• Interpersonal skills necessary to implement an effective QMS.
Quality Systems.. Some Thoughts!

• Quality

“Quality is never an accident, it is always the result of intelligent effort”

  – John Ruskin

• Systems

“The trouble is, companies have either lots of passion but no systems, or too many systems and no passion”

  – Tom Peters

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Quality System Requirements

• Critical Success Factors

• What are the benefits of a QMS

• Effective Operation of the QMS
Critical Success Factors

• My QMS:
  – How effective is it?
  – How embracing is it?
  – How passionate is it?
  – Are we an effective distributor?
What Are The Benefits?

- System Control
- Process Control
- Customer Focus
- Employee Focus
- Systematic Approach
- Supplier Relationship

- Patient Safety
- Economic Benefits
- Business Focus
- Marketing Benefits
- System Development and Improvements
- Increase in Effectiveness and Efficiency

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Effective Operation of The QMS

• Establishment and operation of an effective Quality Management System requires:
  
  – Appropriate Design and development
  – Effective implementation
Design Criteria for an effective Quality Management System

• Based on business need
  – Objectives cascade from the business plan
  – QMS seen as a business driver

• Incorporates legal/regulatory requirements

• Incorporates appropriate quality standards
  – GDP
  – ISO 9000
  – Corporate requirements (if applicable)
Design Based on 10-point GDP Structure

- Quality Management
- Personnel
- Premises and Equipment
- Documentation
- Operations
- Complaints, Returns, suspected falsified Medicinal Products and Medicinal Product Recalls
- Contract Operations
- Self Inspection
- Transportation
- Brokers

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Compatibility of System

• A system will have been designed and developed for you

• It will probably be based around GDP, ISO or Corporate

• Does it provide the necessary assurance that you need?

• Can the system evolve?

• Is there compatibility between different systems?
GDP Structure Based as a Model

System Control
- Quality Management
- Key personnel
- Documentation
- Complaints & Recalls
- Self Inspections

Operations
- WDL
- Validation/
- Qualification
- Processing
- Quality Control
- Warehousing
- Distribution

Resources
- Packaging Materials
- Personnel Training & Hygiene
- Premises & Equipment
  - Calibration
  - Maintenance
  - Security
  - Pest Control

Quality Data
- Batch Records
- Reference samples
- RP Releases

Products

Customers
Documentation Structure

- Policies
  - Managing SOPs
  - Operating SOPs
  - Work Instructions - Records

Very top-level/almost Generic
Foundation of QMS
Training Structure

- Make improvements to procedures
- Read Procedures
- On the job training
- Competency assessment
- Qualified to perform task

New Starter
An Effective QMS

- Documentation Structure
- Personnel Structure
- Training Structure

QMS

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Maintaining an Effective QMS (1)

• Deviation/Incident Reporting
  – Document departure from SOP/WI
  – Investigate
  – Identify root cause

• Continuous Improvement
  – CAPA
  – Based on factual reasons
  – All personnel involvement
Maintaining an Effective QMS (2)

• Change Control
  – Document any change impacting product
  – Involve relevant personnel
  – Rational for change
  – Perform and test the change
  – Evaluate and conclude in change control report

• Self Inspection
  – Involve all departments
  – Test SOP/WI
  – Review records
  – Training
Warehouses: What to Consider for your QMS

- Pest control
- Quarantine
- Security
- Inventory Control
- Goods in
- Complaints/recalls/counterfeits
- Goods out
- Stock rotation
- Internal/External
- Training records
- Cleaning
- Transportation
- WMS
- Destruction
- Temperature control/monitoring
- GDP Training
- Technical Agreements
- Despatch note
- Returns
- Picking face
Affiliate Distribution Management (1)

- Orders from Customers/distribution partners (Wholesale Dealers)
- Coordination of returns from Customers/distribution Partners; Reconciliation of return (complaint, etc)
- Orders & returns mgmt
- Invoicing of customer
- Invoicing of customers for orders
- Procurement
- Procurement of inventory – inglasia operations requests from manufacturer inventory to be shipped over to contract warehouse
- Product is brought into the EU using the contract warehouse Import License and stored & distributed using the Contract warehouse WDL

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Affiliate Distribution Management (2)

• Procure and sell medicinal products;

• Outsource warehousing and storage to outside business partner/Contract warehouse;

• Outsource any rework of product (secondary packaging/labelling) to outside business partner;

• Outsource despatch of product to outside courier service
Affiliate Distribution Management (3)

• Quality Systems
  – Management Review Process;
  – CAPA Process;
  – Complaint Handling & Recall Process;
  – Regulatory Approvals Process;
  – Supplier Evaluation and Monitoring Process;
  – Internal Audits (self-inspection) Process;
  – Records

• Contracts and Agreements with Business Partners
  – Service contracts;
  – Technical agreements
What If There Is Already A QMS In Place?

• Does it comply to ISO and GDP Guidelines?
• Does it comply with the old or new GDP Guidelines?
• What techniques can I use to evaluate my existing QMS?
• Just satisfying the inspectors is not good enough!
The Quality Management Role

• Developing a quality culture
  – Promoting the importance of Quality
  – Promoting Quality in Development/Organisational Plans

• Supporting Your Organisation’s Quality Vision
  – Quality policies and strategy
  – Quality Processes and Systems

• Assuring Quality
  – Supporting Quality Measurement
  – Evaluation of Quality
  – Supporting Continuous Improvement.
Old Culture

- Quick fix
- Major breakthrough
- Quality on the agenda
- Talk about Quality
- Will this improve profit
- Keep my head down
- Put others work right
- Spend company money
- Look for good feedback

New Culture

- Right first time
- Continuous small improvements
- Quality first on the agenda
- ‘Walk about’ Quality
- Will this improve customer service
- Show interest in helping others
- Make sure they know you had to put it right
- Spend it as if it were your own
- Welcome feedback both good and bad
Required Behaviours - Quality Personnel

- Seeking to add-value through process ownership
- Active promotion of continuous improvement
- Focus on effectiveness and efficiency
- Focus on the internal and external customer
- Implementation and development of management principles.

- Process understanding and mapping
- Through objectives, KPIs, Effectiveness and efficiency measures
- Through SWOT and GAP analysis
Required Behaviours From Leaders

- Promoting unity and direction
- Upholder/maintainer and initiator of policies
- Hierarchy of needs
- Action centred leader
- Continuum of leadership
- Team development and sustainability
- Belbin/Myers-Briggs indicators
Support Mechanism

• The training system
• The internal audit system
• The communication system
• The continuous improvement system
Personnel Behaviour Reinforcement (1)

The Training System

- Adequate job analysis
- Design focusing on mental and physical skills, knowledge and attitude
- Adequate execution and monitoring
- Devolution of training responsibilities
- Monitoring of on-site training and reinforcement of learning
- Career Development to support process owners

Model for training execution

- Analyse
- Design
- Evaluate
- Execute
Personnel Behaviour Reinforcement (2)

The Internal Audit System
- Adequate planning – embracing system based on status and importance
- Conducted by trained, competent, personnel
- Issue of report
- Corrective action follow up – root cause
- Involve all personnel

Internal audit mechanism
- Plan
- Conduct
- Report
- Follow up

Annual Review

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Personnel Behaviour Reinforcement (3)

The Communication System

- Eliminate blame culture
- Effective cascade of strategy and responsibility by management
- Effective cascade to workforce – Team objectives etc.
- Operational management – Briefing, job description, training, objective setting

Mechanism for feedback
- On-going reinforcement

Communication Mechanism

- Strategy
- Employee feedback
- Cascade to workforce
- Operational management

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Personnel Behaviour Reinforcement (4)

- The Continual Improvement System
  - Annual review
  - Corrective and preventative actions
  - Use of CI tools
  - Analysis of data
  - Management review
  - Audit results

Continual improvement mechanism

- PLAN – Set required objectives
- DO – Implement processes
- ACT – Take action to CI process
- CHECK – M&M Against objectives

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Something to think about...

• *It is better to like what you do, than to do what you like.*
Q&A

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