QUALITY RISK MANAGEMENT (QRM)

Just another regulation?

GXPPRO

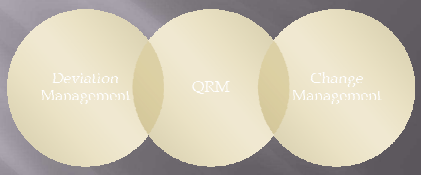
in Partnership with

Torbay NHS

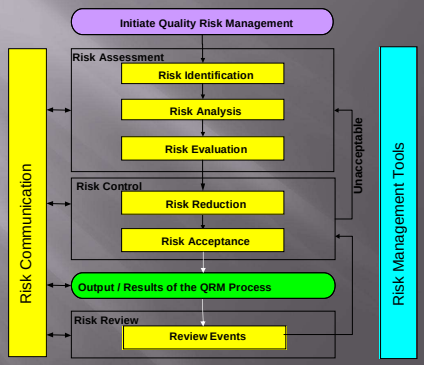
Quality Management

The basic concepts of Quality Assurance, Good Manufacturing Practice, Quality Control and Quality Risk Management are inter-related.

QRM Relationships



Overview – Process



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Process Steps

1. Organise available information/assemble team
2. Define the risk question
3. Choose tool
4. Determine risk factors
5. Define the scales for the risk factors
6. Define the risk terms and/or develop matrix
7. Determine the threshold for action
8. Apply the tool
9. Define risk mitigating measures
10. Document and Approve

plus Ongoing Risk Review

Initiation and Risk Identification

Risk Analysis

Risk Evaluation

Risk Reduction

Output & Risk Acceptance

Risk Review

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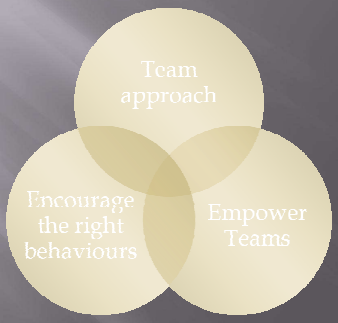
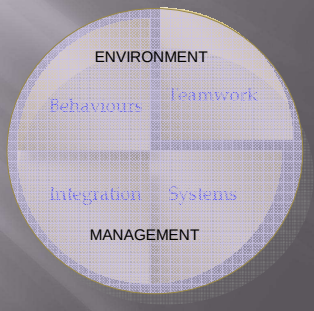
Practical Considerations

- Identify QRM Coaches
- Develop in-house experts
- Develop standard documents
- Qualify your Risk Assessment Outcomes
- Integrate with current Quality system

Value Adding



Assuring Quality



ENVIRONMENT & MANAGEMENT

NO BLAME → *Safe to try new things*

SUPPORTIVE → *Rewarding right behaviours (Teamwork?)*

COACHING & MENTORING → *Developing Skills, Knowledge & behaviours*

CASE STUDY

- Torbay PMU
  - Wanted to integrate QRM into critical GMP functions
  - Focus on Patient, Business and Compliance risks
  - Encourage quicker/ scientific decision making
  - System that added value
  - Include all critical functions in decision making
  - Didn't know how to achieve this

Current System

- Used Risk Management everyday
  - Just didn't know it
  - Not formally recorded
  - Relied upon individual approach
  - No formal team approach
  - Little evidence of consistent/ scientific approach

Getting Started

- External assistance
  - 2 day hands-on training course
  - External consultant (GXPPro)
  - Run at our location
  - Using actual local examples as case studies
  - Recommended tools to use (e.g. FMEA/ risk ranking)
  - Focus on cross function interaction and adding value
  - Didn't want just box ticking exercise
  - Gave a lead in to implementation

SOP

- First requirement of system
- Covers where and when to use
- Recommends what tools to use
- Stresses the need for cross function support
- Details requirements for report writing
- Embeds in rest of Quality System

Where did we want to use QRM

- Deviation reviews
- Customer complaints
- Change requests
- OOS investigations
- Process reviews
- Process efficiencies

Implementation

- Identified one current area of concern
  - Issue with Low volume vials
  - Automated system (high throughput)
- Decided to use as part of Initial training with Consultant
- Used a 10-step format
- Could be used for any process

10- Step Process

- Step 1: Preparation
  - Select project team (internal and external)
  - Information gathering
- Step 2: Risk Question
  - Define, Outcomes/ Scope and Factors
  - Agree before starting (difficult)

10 – Step process (cont)

- Step 3: Tool Selection
  - What tools are you going to use (don't have to be formal)
    - Brainstorming
    - Information gathering
    - Risk Ranking and filtering
    - FMEA
  - Can use more than 1

10 – Step Process (cont)

- Step 4: Risk Factors
  - Usually
    - Severity
    - Probability / Likelihood of occurrence
    - Detectability
- Step 5: Scales
  - What scoring system are you going to use
  - 1-3/ 1-5/ High/ Medium / Low etc….

10 – Step process (cont)

- Step 6: Risk terms/ Matrix
  - Which of the Risk factors are you going to use
  - Are you going to use a matrix (3x3 or (3x3)x3 etc…)
- Step 7: Action Threshold
  - What level of Risk are you happy to accept
  - Action limits
  - Triggers for Risk reduction strategies
  - Must agree before scoring (and use!!!!)

10 – Step process (cont)

- Step 8: Perform Risk assessment
  - Input from ALL members of the team
  - Get more info if you need it
  - Bring different team members in (if required)
  - Record all potential risks (even if discounted)
  - Score every risk (don't presume anything)
  - Don't change scoring system during Risk assessment

10 – Step Process (cont)

- Step 9: Risk Identification
  - Identify all Risks above pre-determined threshold
  - Discuss ways of reducing risk and record
  - Reduce risks to below Threshold (if possible)
  - Can you live with Risk??
- Step 10: Document
  - Document outcomes/ CAPA
  - All team members to sign up to plan
  - Circulate summary to all critical parties
  - Implement actions (Change Control/ CAPA)

Review

- Once actions implemented perform RA again
- Have Risks been eliminated/ Reduce
- Comfortable with Risks
- Have actions added value
- Ensure reviews on-going
- Identify any new risks

Benefits of Approach

- Emphasis on team working
  - Brings together Prod/ QC/ QA/ maintenance etc..
  - Draws on everyone's knowledge
  - Builds trust and respect
  - No individual knows everything
- Systematic
  - Can be used for prospective (Process review) and Retrospective (Customer complaint)

Results from Trial

- Identified Risks not previously thought of
- Showed how many preconceived ideas held
- Showed where the highest risk sources of error were
- Led to additional validation work on equipment
- Identified in-process checks to improve performance
- No subsequent instances of problem (so far)

Where else have we used it

- Customer complaints
- Maintenance operations
- Process reviews (lean/ efficiency savings)
- Identifying Critical control points in a process

Future developments

- Audit schedule review
  - Where should audit resource be targeted
  - Don't use fixed frequency scheduling
  - Critical process done more frequently, others less
  - Used for both Internal and Supplier audits
- In-process monitoring
  - Use critical control points to reduce finished product testing
  - Continuous monitoring (water system)

Future Developments (cont)

- Process reviews
  - Highlight process efficiencies
  - Justified approach (reduce historic processes)
  - Combine with lean
  - Target resource to high risk areas (based on Risk assessment)
  - Identification of CCPs (Critical Control points)

Conclusion

- Big benefits if used correctly
  - Enhanced team working
  - Improved compliance
  - Better understanding of processes
  - Greater emphasis of risks
  - Target resource
  - Efficiency savings

Adding Value – *The GXPPRO approach*

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