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

- Deviation Management
- GMP
- Change Management

Overview – Process

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

Process Steps

Practical Considerations

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

Used Risk Management everyday

Just didn't know how

Not formally recorded

Relied upon individual approach

No formal team approach

Little evidence of consistent, scientific approach

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 into implementation

Value Adding

Team approach

Encourage the right behaviours

Empower Teams

Assuring Quality

ENVIRONMENT

MANAGEMENT

ENVIRONMENT

MANAGEMENT

NO BLAME

Safe to try new things
**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)

**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)

**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
**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 GPPRO approach**

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