Health Hazard Evaluations

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AdvaMed
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Agenda

• HHE purpose
• Ownership
• Required content
• What to do with the information
• Common mistakes
• Keys to success
Addressing postmarket device problems is the responsibility of the Firm.

The agency’s role is to review and guide. FDA monitors to assure the fix appears appropriate.

Kimber Richter, MD
FDA HHE Presentation
http://www.fda.gov/cdrh/oivd/presentations/042004-richter.html
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HHE Purpose

- Evaluate patient risk of issues affecting commercially distributed product or clinical units
- Evaluate issues that:
  - May injure patients
  - May have escaped the Quality System
- May provide rationale on why not to take further action as well as why to take action
- Cornerstone of RM files
- Reviewed at Complaint Meetings, Management Review
- Escalation, CAPA, Field Actions based on risk
Essential PMS Components for Industry

- A robust electronic system to capture and analyze events, data mining capabilities a big plus
- The right mix of people looking at the data
- A well thought out plan on what to do with the data, an escalation decision tree, encompassing actions all the way from continue to trend to recall

Dan Schultz, MD, Director CDRH
AdvaMed Risk Management Meeting May 2006
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Responsibility

“Decisions were made about how to address or disclose product problems were driven by statistical projections from engineers rather than assessments from doctors about the medical consequences of those failures.”

“Designate or hire an in-house physician whose primary responsibility is patient safety and who will participate in product performance analysis, health hazard analysis, internal communications, and external communication policies and procedures”.

Guidant Safety Independent Advisory Panel

You need the right mix of people looking at the data

Edwards Lifesciences
ISO definition of Risk:
Combination of the probability of occurrence of harm and the severity of that harm

HHE content should include:

- **Occurrence of harm**
  - Occurrence of hazard
  - Probability of harm occurring as a result of the hazard
    - likely, possibly, unlikely

- **Severity of harm**
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Factors to Consider

• Thorough complaint review
  – Communications with users, site visits
  – Have injuries already occurred?

• Detected prior to use?

• IFU review

• Align with FMEA
  – Use as an opportunity to update old/incorrect FMEAs

• Literature

• Categorize Health Risk
  – Based on occurrence and severity of harm
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Content

- Clear description of issue
  - Table-spreadsheet, summarizing complaints and other relevant sources of quality data
  - Pictures of nonconformance, confirmed malfunctions
  - Results of performance testing or failure analyses
## Health Hazard Evaluations

### Health Risk Index

<table>
<thead>
<tr>
<th>Severity of Harm (from Table 2)</th>
<th>Estimated Harm Occurrence (from Part C of Table 3)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Unlikely</td>
</tr>
<tr>
<td>Critical</td>
<td></td>
</tr>
<tr>
<td>Major</td>
<td></td>
</tr>
<tr>
<td>Limited</td>
<td></td>
</tr>
<tr>
<td>Negligible</td>
<td></td>
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</tbody>
</table>

Severity

- FMEA
  - Worst case scenario
  - Probability of Injury Occurring is key
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Table 3 – Estimated Harm Occurrence

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Likely:</td>
<td>Harm may often occur</td>
</tr>
<tr>
<td>Possible:</td>
<td>Harm may occasionally occur</td>
</tr>
<tr>
<td>Unlikely:</td>
<td>Harm may rarely occur</td>
</tr>
</tbody>
</table>

N/A: Table 3 not required when severity = Negligible in Table 2 above.

Rationale for likelihood estimate of Table 3:

- Medical input required
- Have there been any injuries?
- Support with data when possible
- Detected prior to use?
- Setting in which product used
- Be careful with this one
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HHE Triggers to Consider

- Nonconformance affecting product in the field
- Complaint rate exceeds threshold
- Confirmed manufacturing nonconformance
- Previously unidentified hazard
- Other:
“The Panel recommended greater oversight by corporate management and develop specific processes to quickly identify and act on potentially life-threatening product performance problems.“

Guidant Safety Independent Advisory Panel
Complaints
  • Trends
  • New hazards

Field non-conformances
  • Product return lab
  • Found during bounding

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CAPA?
  • Design changes
  • Manufacturing changes
  • IFU changes

Escalation?
  • Field action
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Common Mistakes

- Unclear, inconsistent triggers
- Delay in initiating
- Unclear story
- Diluting down risk with complaint data
  - Manufacture date important for denominator
- Not archiving electronically
  - CAPA, RM file
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Requirements for Success

- Tell a clear, concise story
- Timeliness (metrics)
- Consistency across documents
- Revise tool as needed
- Integration into Risk Management File
- Need buy-in from executive management
  - Get their feedback when planning
- Needs to be ingrained in the culture
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FDA

- Initiates HHEs when precedent not sufficient
- Conducted by a Medical Officer
- Used to classify recalls
- Guides FDA enforcement actions
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Summary

HHE:
- The most important document in determining patient risk of an issue
- Medical/Clinical input required
- Should be part of a company’s Postmarket Surveillance program
- Have a plan!
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References


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Role of Postmarket Surveillance

- We will assess the impact of our postmarket safety program and pinpoint areas that are in need of improvement.
- We will look at the tools we use to identify problems, analyze problems and take action.

“Ensuring the Safety of Marketed Medical Devices”
Dan Schultz, MD Director of CDRH

Appropriate recalls require solid postmarket surveillance