The J&J Risk Based Exposure Assessment Process

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ONE TEAM Making the Difference for Patients WORLDWIDE
Risk Based thinking

- **Risk** drives the decision, **hazard** is considered
- Prioritize activities, use of resources and future investments based on risk
- Risk Based thinking assumes that
  - Consider realistic scenarios
  - Integrates approach with QA, engineering and manufacturing
  - Relies on facts and data in the decision making process
- Without Risk Based Thinking
  - Infinite resources will be required to achieve objectives.

Where we were yesterday?
- Former J&J guidelines recommended containment specifications and controls based on OEL and Toxicity levels API.

Where we are Today?
- Recommends containment specifications and controls based on risk. Introduction of Risk Based Exposure Assessment Process (**RBEAP**) and Risk Based Exposure Assessment Control Guideline (**RBEAC**)
Risk Based Exposure Assessment Process (RBEAP)

- Tool created by cross functional team, **IH Steering Team**
  Janssen Supply Chain
- Process to systematically **assess** inhalation exposure **risks** of activities with Active, Pharmaceutical Ingredients and solvents
- Tool introduced step-by-step in Pharmaceutical Production, Chemical Production and R&D (training program, metrics)
- **Team Approach:** Use of stakeholders, involvement operations.
Risk Based Exposure Assessment Process (RBEAP)

Provides a **lean, systematic and pragmatic methodology** to:

- **Identify** the chemical **hazards** for each unit operation
- Identify **priorities** for air **sampling** based on those products that have the potential to generate the highest airborne particulate concentration.
- Organize the data so that **Similar Exposure Groups** can be established.
- **Communicate** results to employees, medical and management using a transparent format.
- Understand future IH air sampling needs and managing changes, i.e., impact of introducing new products.
- RBEAP is used to **understand exposure risks** to be able to make **data driven decisions** to prioritize **containment projects**.
Risk Based Exposure Assessment Process
Six Steps

1. Create a Unit Operation Inventory

2. Identify Risk Factors Compounds
   - Batch Size, % active ingredient or quantity, etc
   - Solvents – Vapor Pressure, temperature

3. Prioritize compounds UO sampling
   - Assign High, Medium or Low risk to prioritize activities

4. Personal Sampling if required
   - Based on the qualitative risk assessment and respiratory protection requirement.

5. Analyze & Communicate Data

6. Periodic Re-Sample
   - Periodic re-sampling according to specified criteria

Analyze using Bayesian Statistics

The J&J Risk Based Exposure Assessment Process
May, 14th 2013
## Risk Based Exposure Assessment Process

### Create inventory of Unit Operations

<table>
<thead>
<tr>
<th>Location</th>
<th>Unit Operations</th>
<th>SEG</th>
<th>Risk</th>
<th>Sampling complete reference last IH report</th>
<th>RBEAP date</th>
<th>APF1</th>
<th>APF2</th>
<th>APF3A</th>
<th>APF3B</th>
<th>APF4</th>
<th>Remarks</th>
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<tbody>
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Document all information for each Unit Operation

General Information

Active compounds involved

Selection compound greatest potential airborne exposure

Respiratory protection required (based on analysis below)

Document results personal sampling

Analysis of the IH sample data for ‘worst case’ compound
Risk Based Exposure Assessment Process

Conclusion

Former Approach

Not Risk Based.
Beyond Compliance
More resources and IH Costs.
(Need to sample for each API and process)
IH method required for every chemical
Sampling criteria were hazard based

Current Approach

Risk Based
Full regulatory compliance
Sampling criteria based on worst case scenario
Eliminates need to have IH method each API
Cost avoidance with resources and air sampling
Supports new product introduction, sourcing decisions and product transfers
Streamlining medical surveillance, All IH information in one document
Generates statistical data to drive risk based decisions investments
One format to share and communicate results (Internal + Ext)
Thank You

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