QUALITATIVE RISK ASSESSMENT (API & CHEMICALS), RBEAC GUIDELINE

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INTRODUCTION

of the presenter:

Marcel Buehrer

Organic Chemist 24 years
EH&S / Industrial Hygiene 7 years

Working for J&J 25 years
For other pharmaceutical companies 3 years
Scope of this Presentation

- Tool & guideline: Risk based thinking
- Qualitative Risk Assessment
- Implement selected solutions
- Share solutions - Communicate
RBEAC-Process

• Tool & guideline: Risk based thinking
• Qualitative Risk Assessment
• Implement selected solutions
• Share solutions - Communicate
Tool & Guideline

• Created by cross functional team, IH Council Johnson & Johnson

• The guideline defines the hazards and provides guidance for selecting controls based on exposure risk

• Team Approach: engineering, maintenance, operations quality and EHS

• Provides a step by step process
Step by step process

• Assess exposure risks of all activities related to operations, maintenance and cleaning of new or existing installation

• Understand and implement appropriate exposure controls strategies

• Select controls that manage the risks (not the hazards)

• Prioritize projects where greatest exposure risk is given the highest priority

• Stimulate communication between the different stakeholders

• Allows flexibility for each site to make selections based on internal possibilities

• Documentation of assessments and decisions so these can be understood now and in the future
Risk Based Thinking

**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
Cost avoidance with resources and air sampling
Streamlining medical surveillance
Generates statistical data to drive risk based decisions investments
One format to share and communicate results (Internal + Ext)
All IH information in one document
Risk Based Thinking

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
   - Analyze using Bayesian Statistics
   - IHDataAnalyst.Ink

6. Periodic Re-Sample
   - Periodic re-sampling according to specified criteria
Process Flow
Risk Based Exposure Assessment Control Guideline (RBEAC)

- A navigation map
- 3 sections:
  - overview for first time reader
  - risk based exposure assessment
  - list of exposure control options
Process Flow
Risk Based Exposure Assessment Control Guideline (RBEAC)
Qualitative Risk Assessment
Process Flow
Risk Based Exposure Assessment Control Guideline (RBEAC)
Quantitative Risk Assessment
Process Flow
Risk Based Exposure Assessment Control Guideline (RBEAC)
Exposure Control Project
Process Flow
Risk Based Exposure Assessment Control Guideline (RBEAC)
Post control Quantitative RA

Quantitative Risk Assessment
Personal Exposure Monitoring; Statistical Analysis of IH Data;

Is Statistical Analysis of IH Data greater than (>?) the OEL?

Yes
Is Statistical Analysis of IH Data greater than (>?) the Assigned Protection Factor of the Respirators?

No

Is reliance on respiratory protection acceptable?

Yes

No

Document Risk Management:
Qualitative Risk Assessment; Quantitative Risk Assessment (if required); Control Technology Utilized
Starting the Process

• For existing processes the EHS professional can initiate and execute the assessment.

• For new processes it is necessary to set up a team of stakeholders so that all aspects of the proposed process can be assessed.

• Additionally, for technology transfers or external manufacturing processes, a team approach is preferred as it lends itself to a clear understanding of the risk assessment scope and the exposure risk management conclusion.
RBEAC-Process

- Risk based thinking: tool & guideline
- Qualitative Risk Assessment
- Implement selected solutions
- Share solutions - Communicate
Qualitative Risk Assessment

• At this point a qualitative risk assessment analysis is undertaken. This process has two distinct phases; gathering information and evaluating that information.

• Data on such items as the products and chemicals used are gathered to understand their potential risks. For example: liquid vs. powder, % active, dustiness, OEL/TLV, dilution of blend, etc.
Qualitative Risk Assessment

• In addition, a full description of the processes/tasks and equipment are gathered so that the exposure risks inherent in the process, its interventions, transfers, and cleaning can be understood.

• Obviously for a new process the information may be preliminary in nature.

• It is also important not to rush to solutions before all the relevant details have been gathered.
Qualitative Risk Assessment

- It is best to design a practical solution and then undertake the assessment rather than incorporating a wide range of engineering controls that may not be necessary and/or could add considerable cost.

- For new processes where historical IH data have not been collected, a qualitative assessment can be made of the potential exposure risk.
Qualitative Risk Assessment

Evaluation criteria

<table>
<thead>
<tr>
<th>No.</th>
<th>Description</th>
<th>Abbreviation</th>
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<tbody>
<tr>
<td>1 A</td>
<td>Health Hazard</td>
<td>HLTH HD.</td>
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<tr>
<td>1 B</td>
<td>PB-OEL classification</td>
<td>PB-OEL CLASS</td>
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<tr>
<td>2</td>
<td>Additional Information</td>
<td>ADD. INFO</td>
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<tr>
<td>3</td>
<td>Dustiness of solids</td>
<td>DUST</td>
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<tr>
<td>4</td>
<td>Volatility of liquids</td>
<td>VAPOR</td>
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<tr>
<td>5</td>
<td>Documented adverse effects</td>
<td>ADV. EFF.</td>
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<tr>
<td>6</td>
<td>Process temperature [°C]</td>
<td>PR. TEMP.</td>
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<tr>
<td>7</td>
<td>Exposure Time [h]</td>
<td>EXP. TIME</td>
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<tr>
<td>8</td>
<td>Frequency</td>
<td>FREQUENCY</td>
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<tr>
<td>9</td>
<td>Amount of handled substance [kg]</td>
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<tr>
<td>10</td>
<td>Concentration [%]</td>
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<tr>
<td>11</td>
<td>Route of exposure</td>
<td>EXP. ROUTE</td>
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<tr>
<td>12</td>
<td>Number of exposed persons</td>
<td>PERSONS</td>
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<tr>
<td>13</td>
<td>Existing kinetic impact</td>
<td>KIN. IMP.</td>
</tr>
<tr>
<td>14</td>
<td>Relevant installed Engineering controls</td>
<td>ENG. CONTR.</td>
</tr>
<tr>
<td>15</td>
<td>Relevant surface of the source</td>
<td>SURFACE</td>
</tr>
</tbody>
</table>
## Qualitative Risk Assessment

**Use your own tool**

| IT-CODE | HEALTH HZRD. | PB-OEL CLASS | MAK-VALUE | OEL TLV | ADD. INFO | FORM | DUST | VOLATILITY | VAPOUR PR. | DOC. ADVERSE EFF. | TEMPERATURE | EXPOSURE TIME | FREQUENCY | QUANTITY | CONCENTRATION | EXPOSURE ROUTE | EXPOSED PERSONS | KINETIC IMPACT | ENG. CONTROLS | SOURCE SURFACE | RISK VALUE | HAZ. EXPOSURE RISK |
|---------|--------------|--------------|-----------|---------|-----------|------|------|------------|-----------|------------------|-------------|---------------|-----------|---------|-------------|----------------|----------------|----------------|---------------|--------------|--------------|---------------|----------------|
| 465612  | 3            | 2            | --        | 280     | --        | --   | L    | M          | Y         | 125              | 0.3         | d              | 512.0     | 100    | A           | 1              | L              | CLS           | P             | 6            | L           |               |
| 465612  | 3            | 2            | --        | 280     | --        | L    | L    | L          | N         | 115              | 1           | d              | 512.0     | 100    | A           | 1              | M              | CLS           | P             | 22           | L           |               |
| 465612  | 3            | 2            | --        | 280     | --        | L    | L    | M          | Y         | 125              | 1           | d              | 512.0     | 100    | A           | 1              | L              | CLS           | P             | 22           | L           |               |
| 465612  | 3            | 2            | --        | 280     | --        | L    | L    | M          | Y         | 125              | 0.1         | h              | 0.01       | 100   | A           | 1              | L              | LEV           | P             | 1            | L           |               |
| 465612  | 3            | 2            | --        | 280     | --        | L    | M    | M          | Y         | 125              | 0.1         | h              | 0.5        | 100   | A           | 1              | L              | LEV           | P             | 1            | L           |               |
| 3849    | 1            | 0            | --        | --      | --        | --   | P    | F          | --        | RT               | 0.5         | h              | 1.0        | 100   | A           | 1              | L              | FLX           | P             | 0            | L           |               |
| 465612  | 3            | 2            | --        | 280     | --        | L    | M    | Y          | Y         | 115              | 0.3         | d              | 1.0        | 100   | A           | 1              | L              | CLS           | P             | 6            | L           |               |
| 465612  | 3            | 2            | --        | 280     | --        | L    | M    | L          | Y         | 115              | 4           | d              | 512.0     | 100    | A           | 1              | L              | CLS           | P             | 43           | M           |               |
| 465612  | 3            | 2            | --        | 280     | --        | L    | M    | N          | N         | 125              | 0.3         | d              | 250.0     | 10    | A           | 1              | L              | CLS           | P             | 1            | L           |               |
| 465612  | 3            | 2            | --        | 280     | --        | L    | M    | L          | Y         | 115              | 4           | d              | 512.0     | 100    | A           | 1              | L              | CLS           | P             | 43           | M           |               |
RBEAC-Process

- Risk based thinking: tool & guideline
- Qualitative Risk Assessment
- Implement selected solutions
- Share solutions - Communicate
Process Flow
Risk Based Exposure Assessment Control Guideline (RBEAC)
Exposure Control Project
Implement selected solutions
High Risk activities
Reactor Charging – isolator technology
Implement selected solutions
High Risk activities
Reactor Charging – flexible containment
Implement selected solutions

High Risk activities

Reactor Charging – drum charging system / powder transfer system
Implement selected solutions
High Risk activities
Reactor Charging – adaptor sleeve  FIBC long neck – delumper/powder transfer
Implement selected solutions
High Risk activities
Reactor Charging – contained dump station bags
Implement selected solutions
Discharging centrifuge/dryer
Implement selected solutions
Weighing Warehouse: down flow booth / weighing isolator
Implement selected solutions
Weighing Quality Control
Process Flow
Risk Based Exposure Assessment Control Guideline (RBEAC)
Post control Quantitative RA
IH-Sampling

• Confirm your decisions with sampling data
• Underline your judgement with science
RBEAC-Process

• Risk based thinking: tool & guideline
• Qualitative Risk Assessment
• Implement selected solutions
• Share solutions - Communicate
Share solutions - communicate
Containment solution guides – example
Share solutions
Communication channels

• IH Steering Team Janssen Supply Chain: cross functional team
  - Industrial Hygienists
  - Engineering
  - Toxicology
  - Occupational Health
  - Corporate IH
  - Operations

• Engineering Competence Groups

• IH network meetings

• Sharepoint folders
Conclusions

• Advantages Risk Based Thinking
• Prioritize implementation containment projects
• Document & share solutions
• Stimulate communication stakeholders
QUESTIONS ?