PROGRAMMA:

1. TEMPERATURE ISSUES
2. RISKS IN THE (COLD) CHAIN
TEMPERATURE SENSITIVITY (PRINCIPLE/EXAMPLE)

Protein Content

<table>
<thead>
<tr>
<th>Protein Gehalte (mg/ml)</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
<th>11</th>
<th>12</th>
<th>13</th>
<th>14</th>
<th>15</th>
<th>16</th>
<th>17</th>
<th>18</th>
<th>19</th>
<th>20</th>
<th>21</th>
<th>22</th>
<th>23</th>
<th>24</th>
<th>25</th>
</tr>
</thead>
<tbody>
<tr>
<td>4 °C</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>65</td>
<td>65</td>
<td>65</td>
<td>65</td>
<td>65</td>
<td>65</td>
<td>65</td>
<td>65</td>
<td>65</td>
<td>65</td>
<td>65</td>
<td>65</td>
<td>65</td>
<td>65</td>
<td>65</td>
<td>65</td>
</tr>
<tr>
<td>20 °C</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>65</td>
<td>65</td>
<td>65</td>
<td>65</td>
<td>65</td>
<td>65</td>
<td>65</td>
<td>65</td>
<td>65</td>
<td>65</td>
<td>65</td>
<td>65</td>
<td>65</td>
<td>65</td>
<td>65</td>
<td>65</td>
</tr>
<tr>
<td>35 °C</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>50</td>
<td>50</td>
<td>50</td>
<td>50</td>
<td>50</td>
<td>50</td>
<td>50</td>
<td>50</td>
<td>50</td>
<td>50</td>
<td>50</td>
<td>50</td>
<td>50</td>
<td>50</td>
<td>50</td>
<td>50</td>
<td>50</td>
<td>50</td>
<td>50</td>
<td>50</td>
</tr>
</tbody>
</table>

Time (Months)
COLD CHAIN PRINCIPLE

Data logger

CHECK

CHECK

© Pharmaceutical Consultancy Services, All rights reserved.
• Risk with products that are sensitive to temperature: they can freeze, which can lead to degradation.

Package in the wrong place: Freezes as a result of the cold air coming from the fans.

However, This should have been validated!!!
RISK MANAGEMENT

• The key to performing Risk Management:
  – COMPLETE overview of all actions/activities
• Important: Risk management may not replace GDP. It is not possible to overrule the law (guideline) with a risk assessment.
RISK MANAGEMENT

• WHOLE Supply Chain:
  – Should be mapped
  – Potential problems should be identified
    • Customs
    • Transhipment
    • Theft (risky routes)
    • Avoid intermediate stops with limited/no “security”
RISK MANAGEMENT

• Following Procedures
  – Especially when handling temperature-sensitive products:
    • Maximum load or loading pattern of cold-rooms/freezers,
    • With temperature boxing, the packaging and the “normal shipment”
    • Maximum time “out of temperature control”
  – With less sensitive products:
    • For example in the hot sun (we put it on the loading bay already because the driver will be here soon – not)
    – Prevent: the wrong product in the wrong package
RISK MANAGEMENT

• BATCH Status (Release)
  – Status may only be changed by the QP or the Responsible Person (if there has been no production).
  – Remove/Re-label identification of previous status changes.

Not ok, AND released AND quarantined
• Personnell (for the entire supply chain)
  – Well trained
  – Qualified for the activities
  – Procedures have been trained
    • On the Job for critical tasks
    • Re-train regularly
  – Behavior should be equal to the nature of the industry:
    • Always prevent risks to the “patient”
    • Following procedures is 2nd Nature