

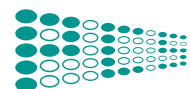
PHARMACEUTICAL  
CONSULTANCY  
SERVICES

# VALIDATION

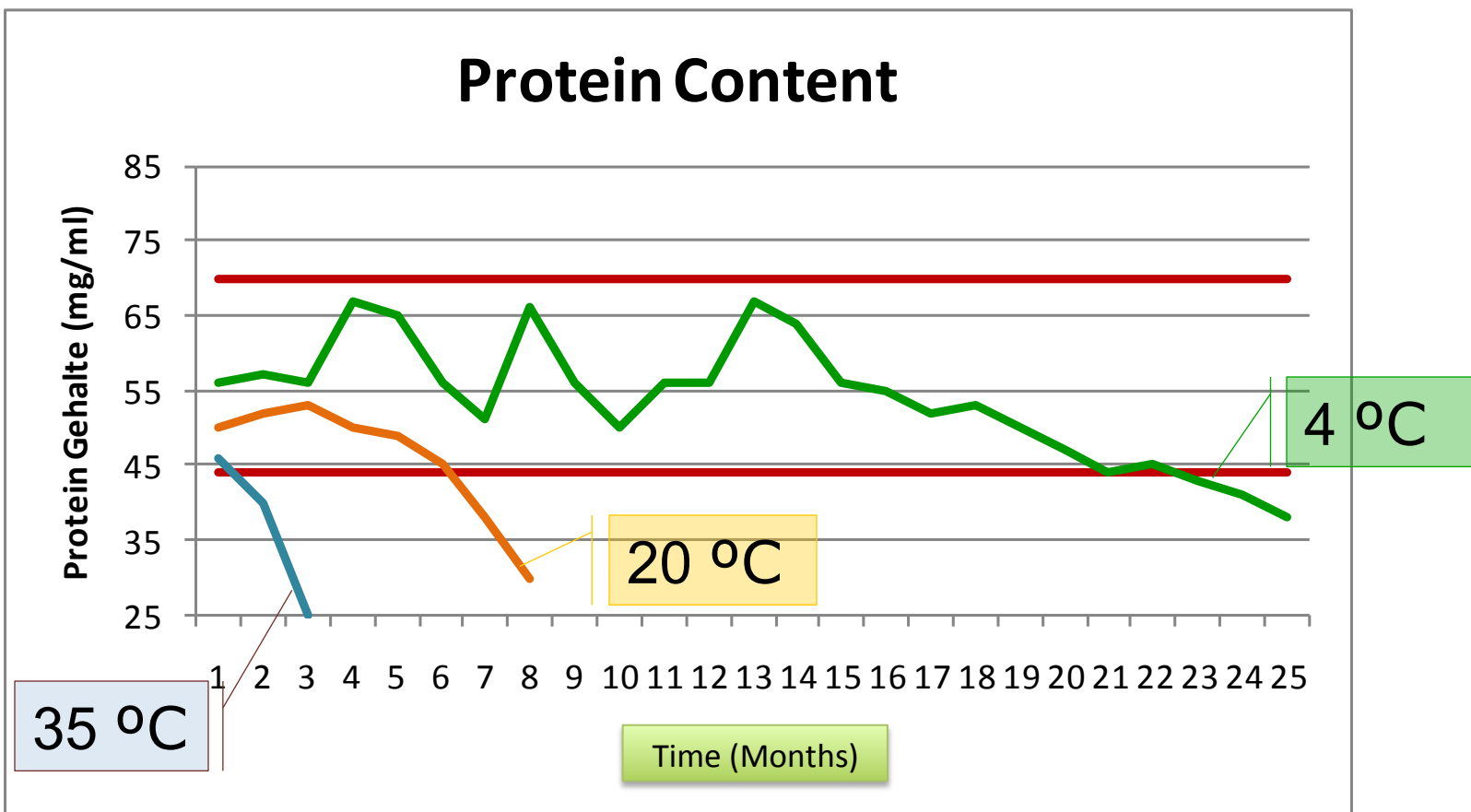
## Jaap Koster

# PROGRAMMA:

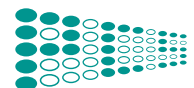
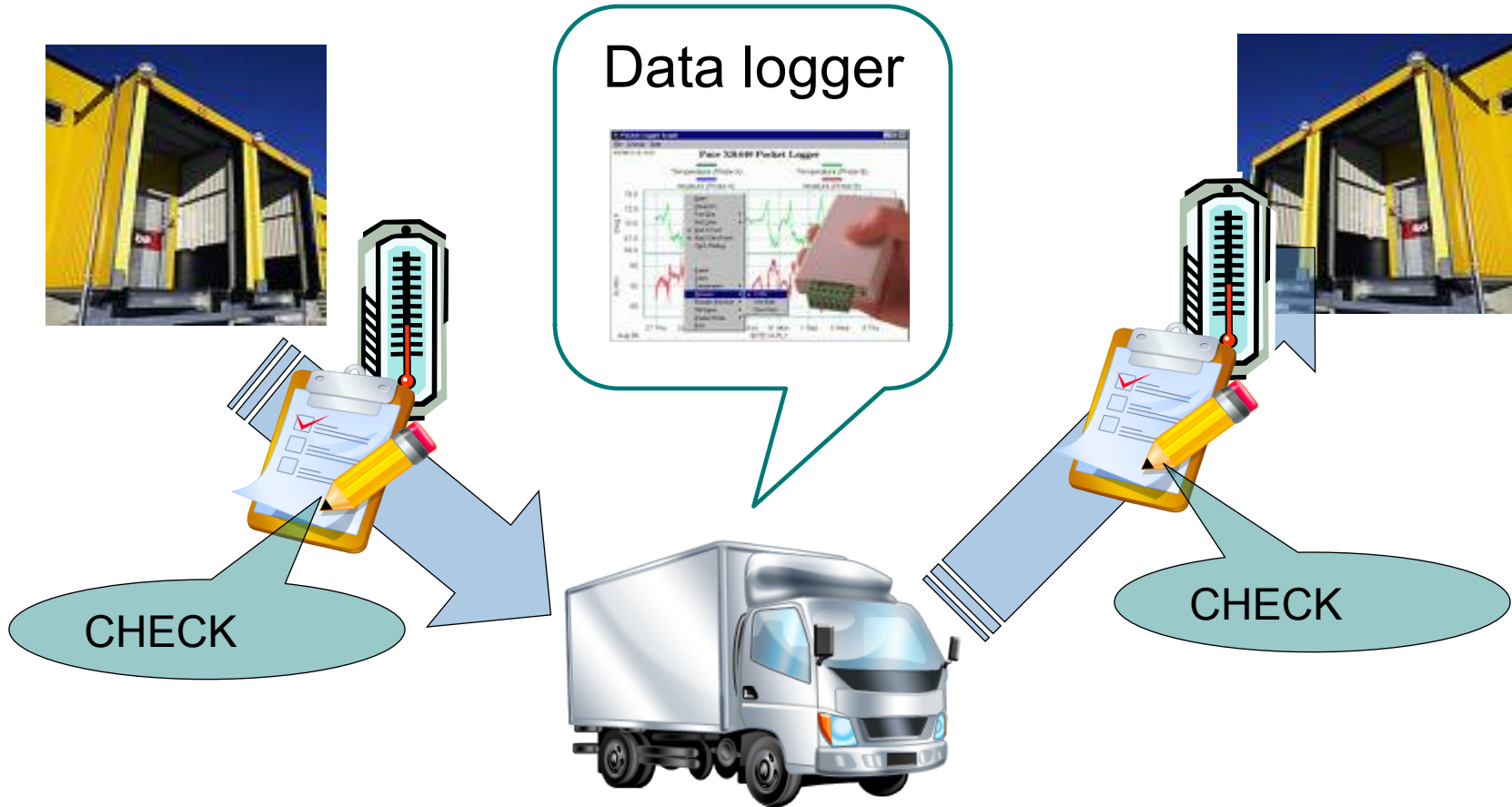
1. TEMPERATURE ISSUES
2. RISKS IN THE (COLD) CHAIN



# TEMPERATURE SENSITIVITY (PRINCIPLE/EXAMPLE)

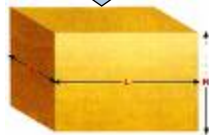
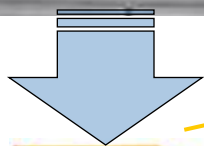


# COLD CHAIN PRINCIPLE



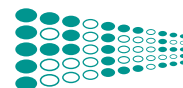
# TEMPERATURE SENSITIVITY (PRINCIPLE/EXAMPLE)

- Risk with products that are sensitive to temperature: they can freeze, which can lead to degradation.



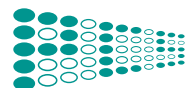
Package in the wrong place:  
Freezes as a result of the cold air coming  
from the fans.

However,  
This should have  
been validated!!!



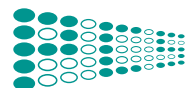
# RISK MANAGEMENT

- 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
    - Transshipment
    - Theft (risky routes)
    - Avoid intermediate stops with limited/no “security”





# RISK MANAGEMENT

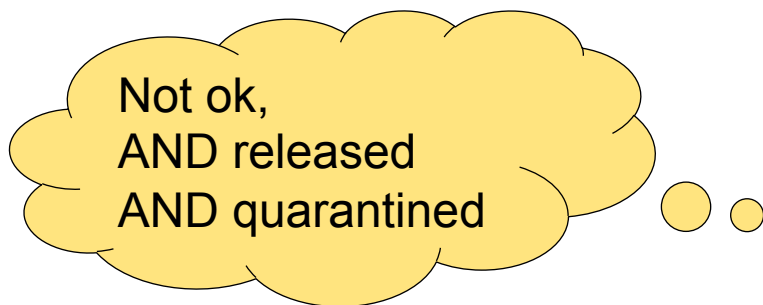
- Following Procedures
  - Especially when handling temperature-sensitive products:
    - Maximum load or loading pattern of cold-rooms/freezers,
    - With temperature boxing, the packaging and the “normal shipment”
    - Maximum time “out of temperature control”
  - With less sensitive products:
    - 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.



# RISK MANAGEMENT

- Personnell (for the entire supply chain)
  - Well trained
  - Qualified for the activities
  - Producedures 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
- .....

