



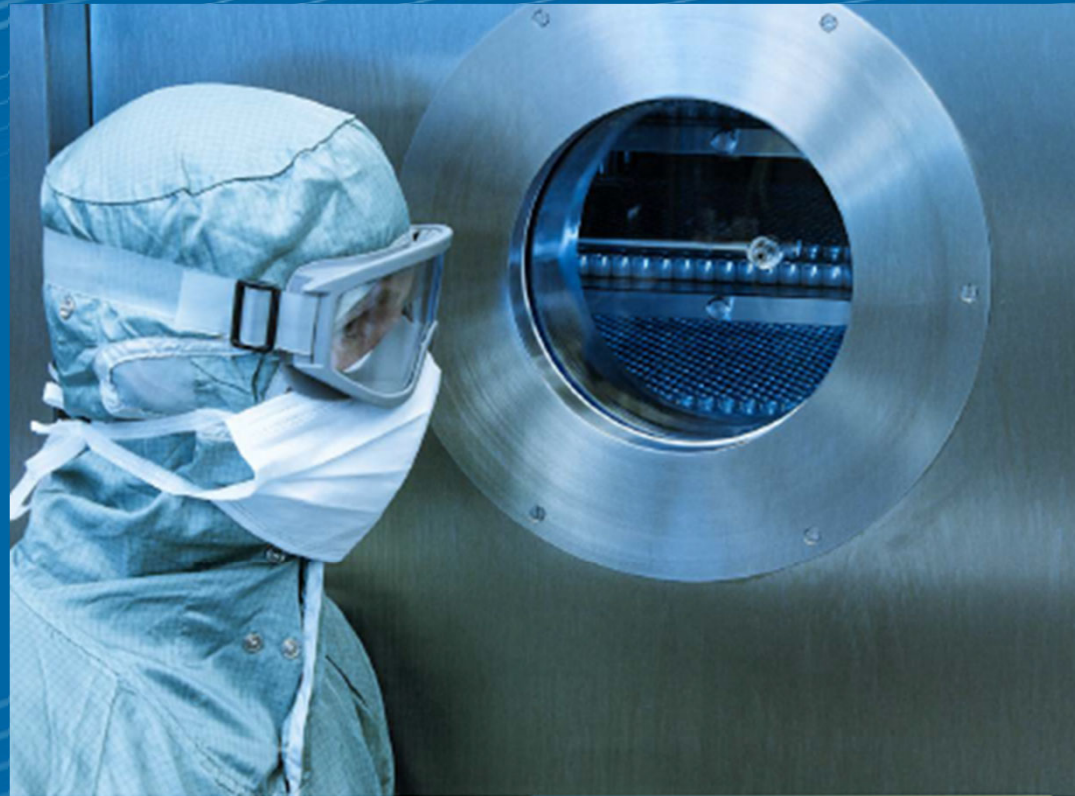
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# Theory 2

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2019 PDA EUROPE TRAINING

## Freeze Drying in Practice



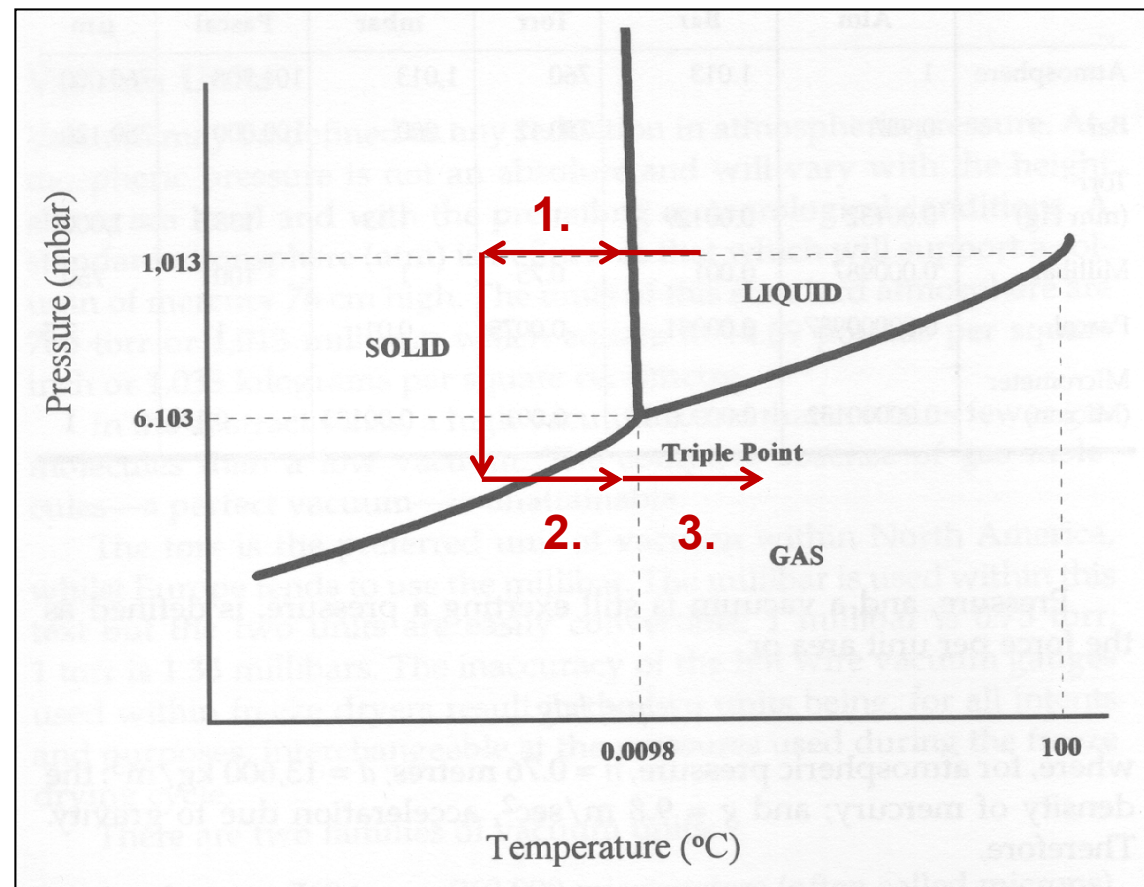
# Theory 2

- Basic principles of freeze drying processes
  - Physical understanding
  - Critical process parameters
- Primary packaging components
- Development and composition of a (biological) formulation
- Analytical characterization:
  - Product attributes for designing lyophilization cycles
  - Solid state characterization after lyophilization



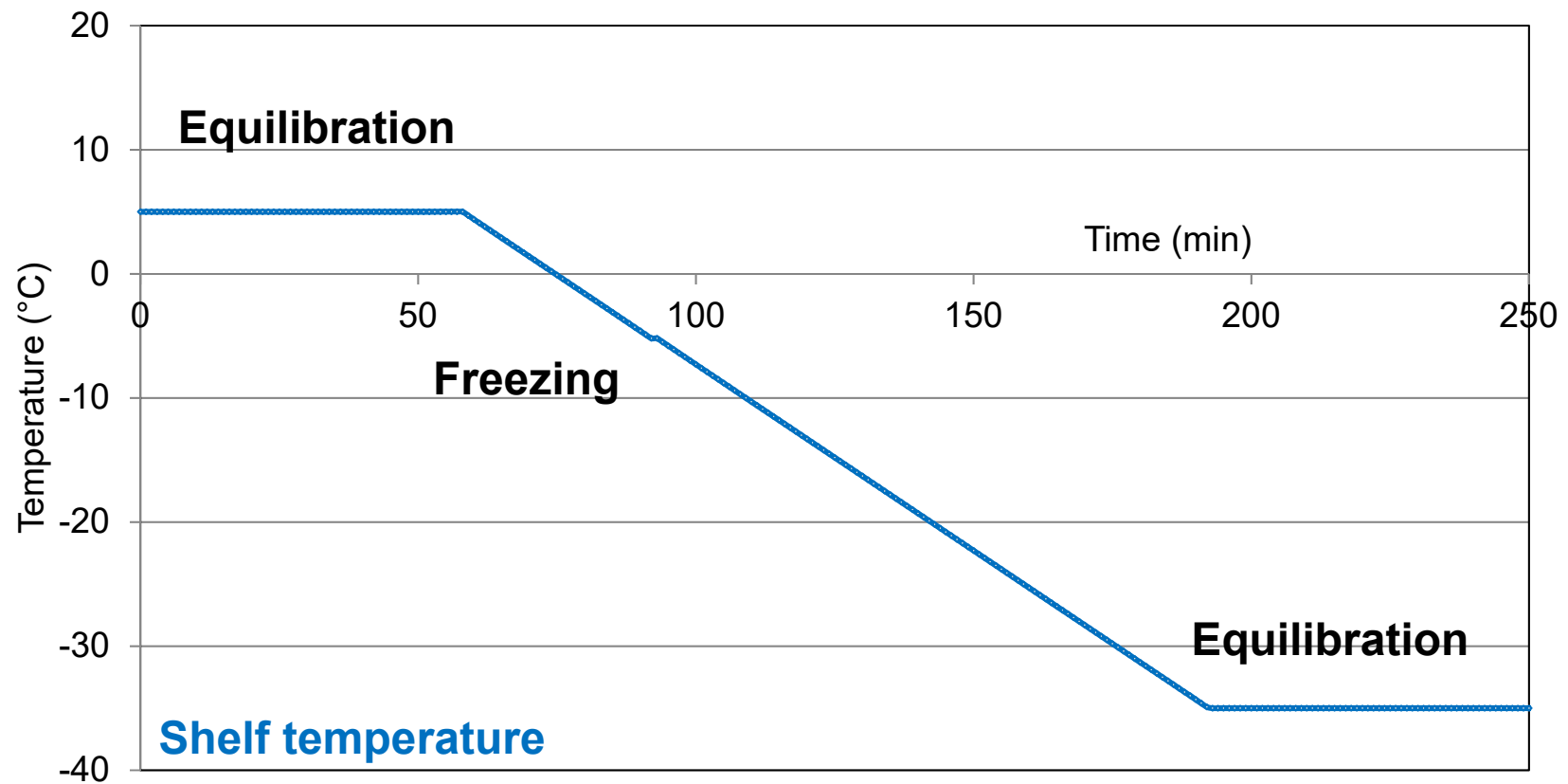
# Basic principles

- Drying by sublimation of ice (as well as desorption)
- **Phases:**
  - **1. Freezing phase**
    - ca. 2-5 h
  - **2. Primary drying**
    - ca. 5 h - 5 d
  - **3. Sekundärtrocknung**
    - bis 10 h





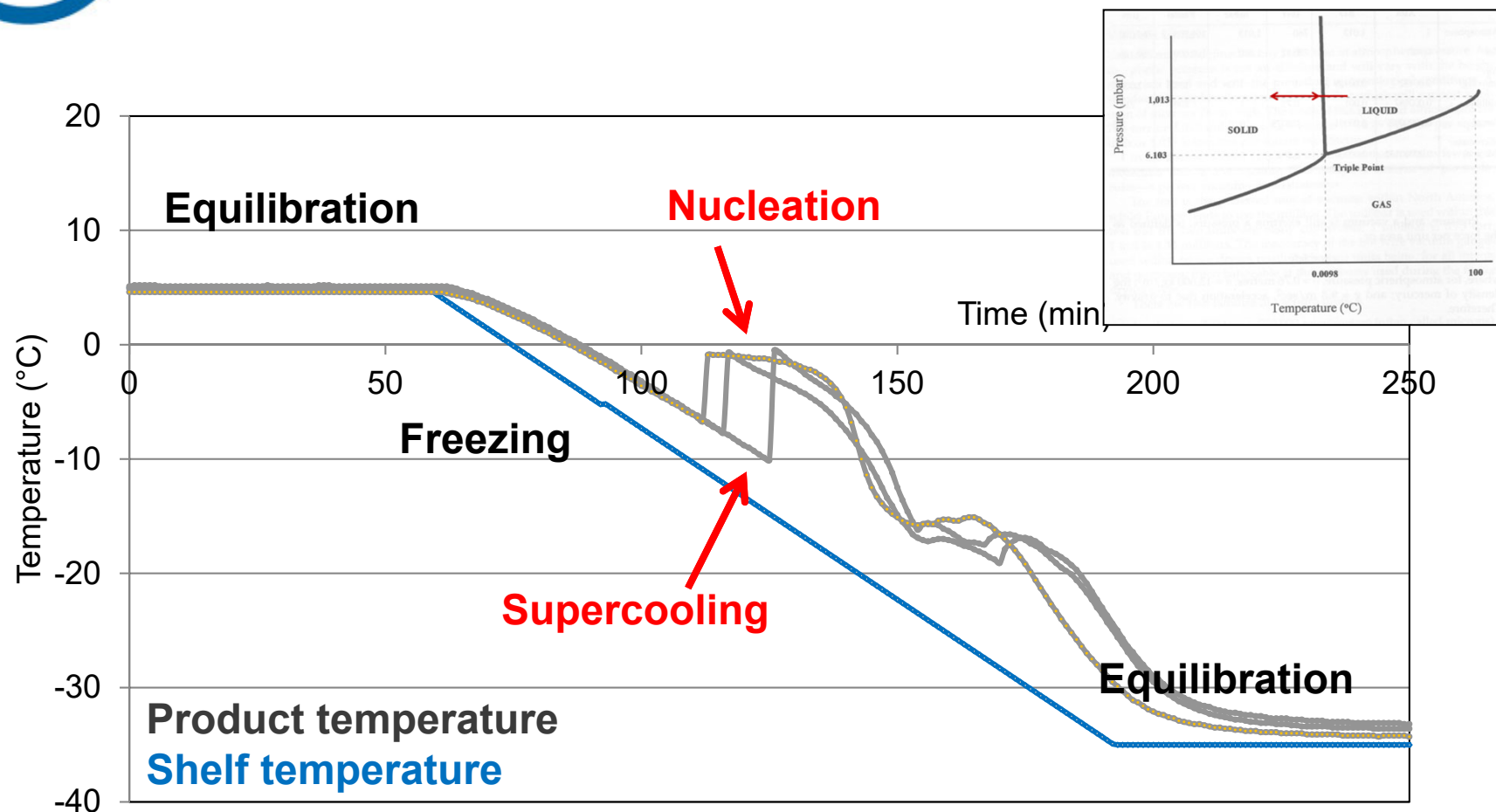
# Freezing





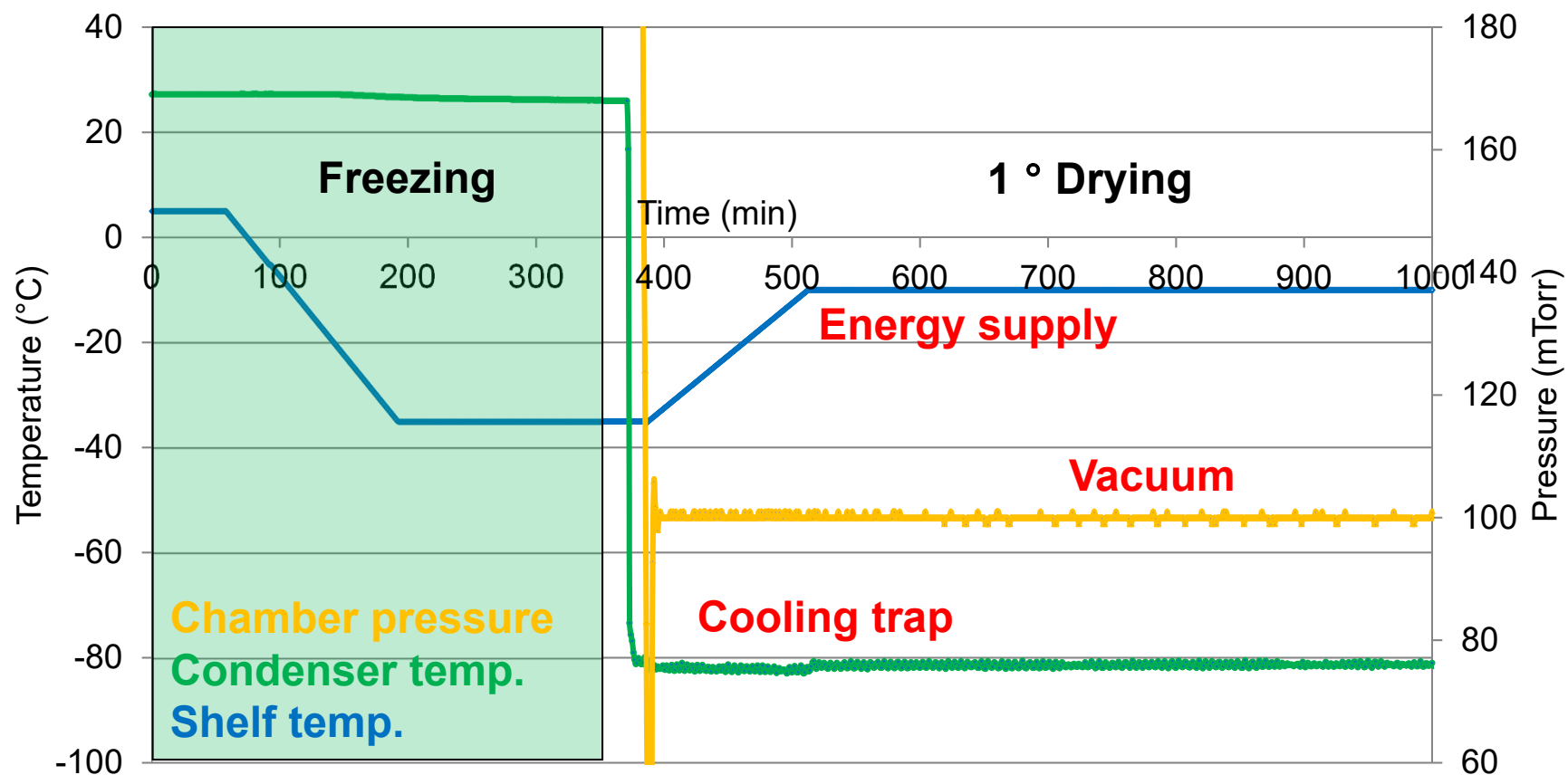


# Freezing - Nucleation



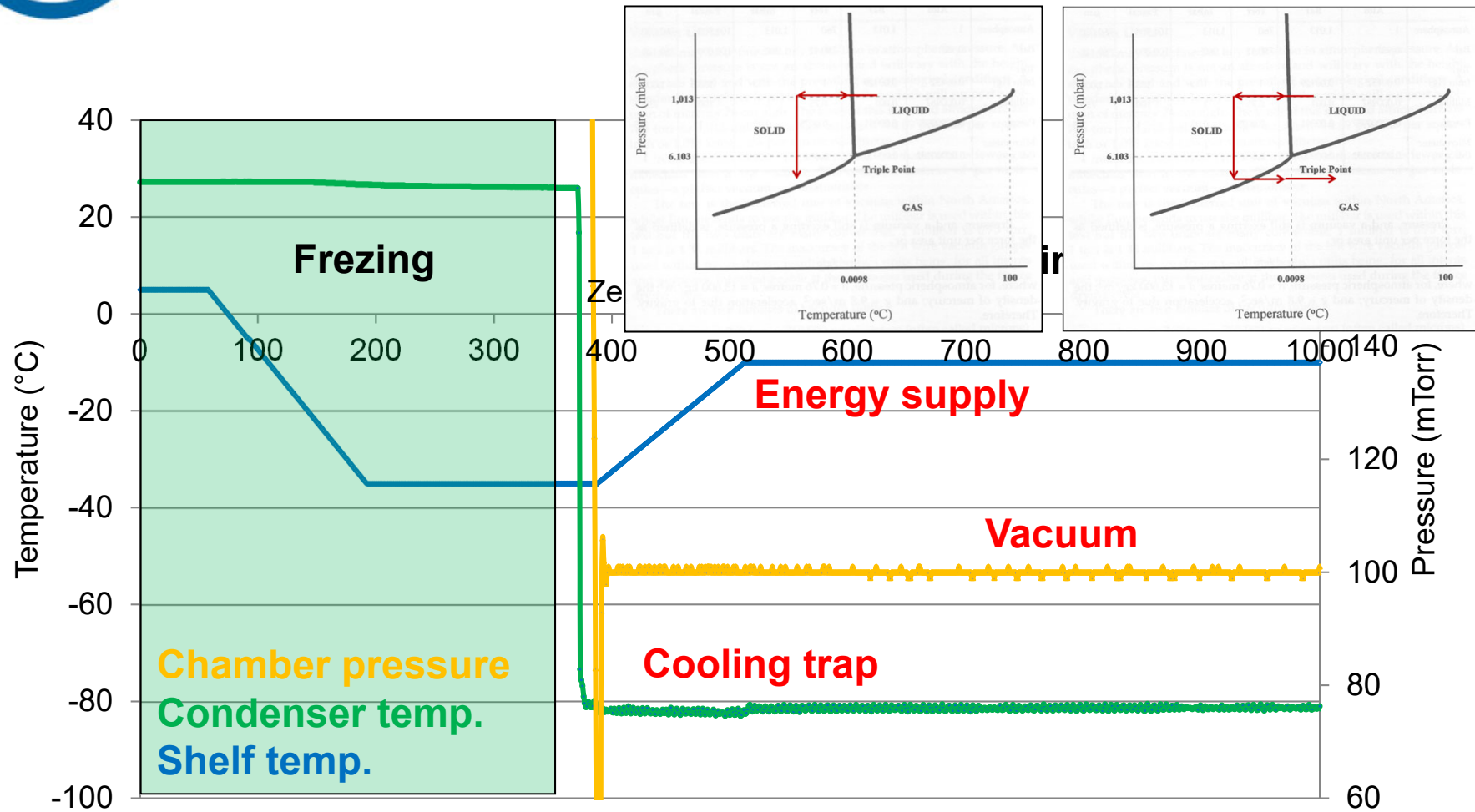


# Primary Drying



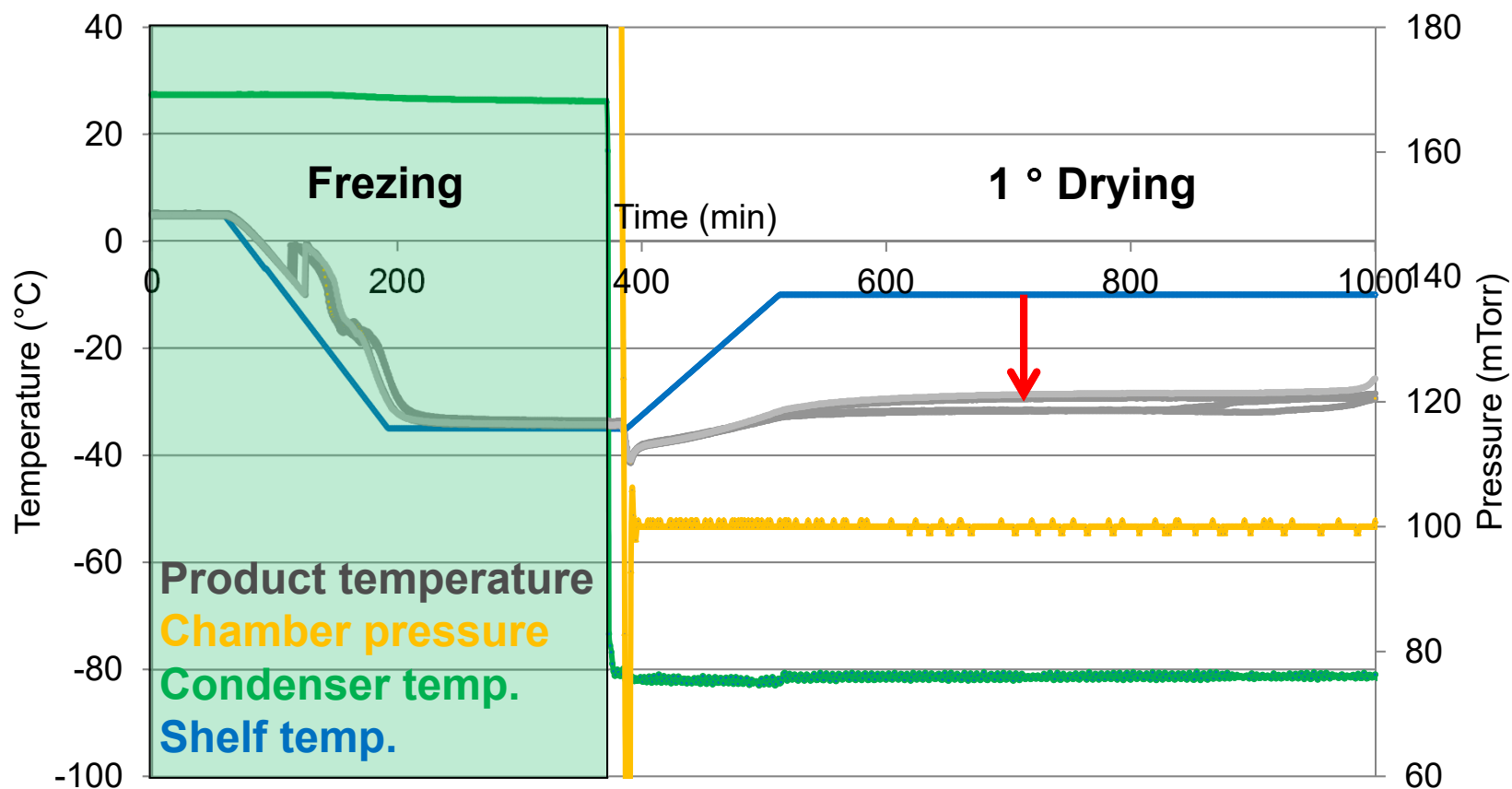


# Primary Drying





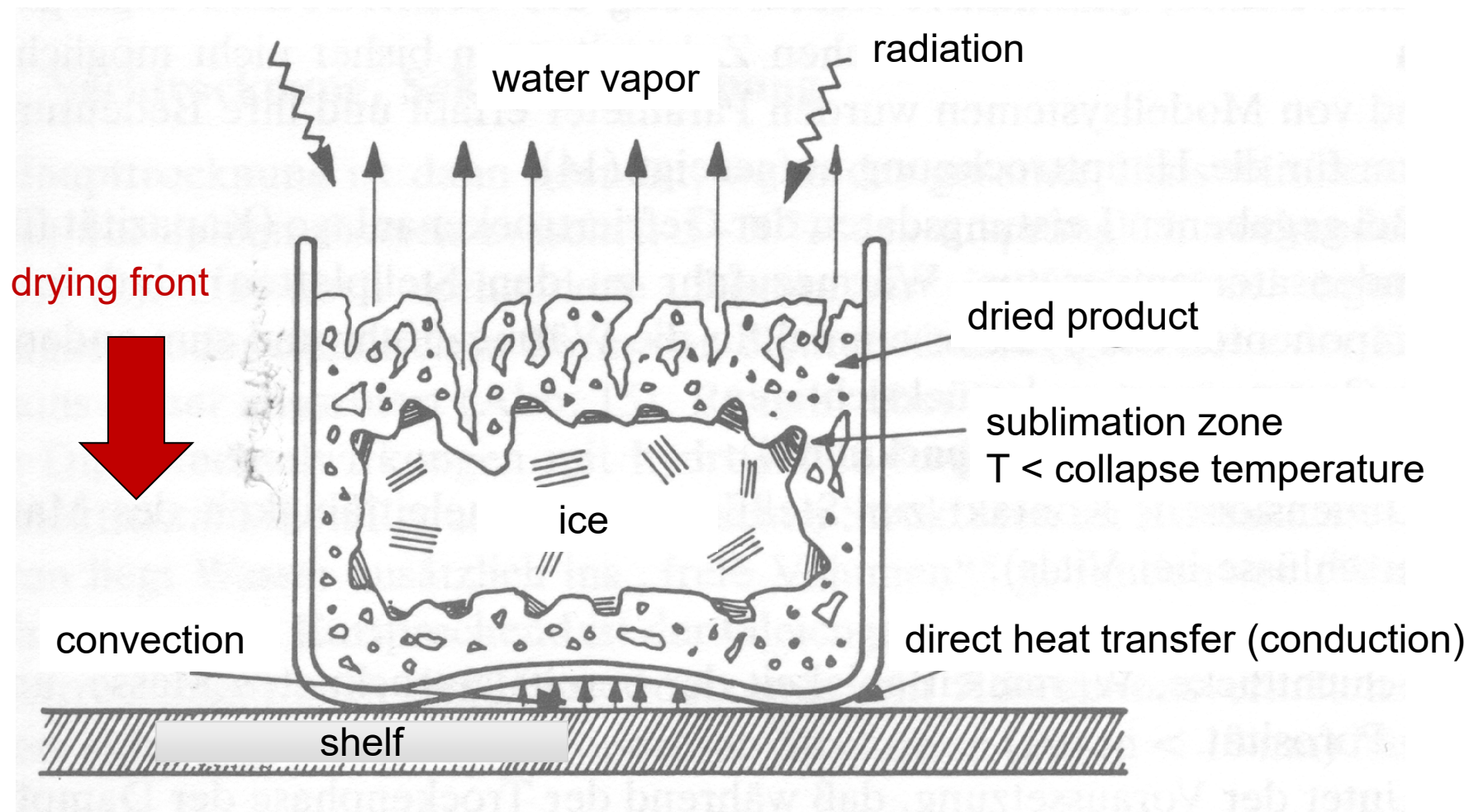
# Primary Drying - Sublimation





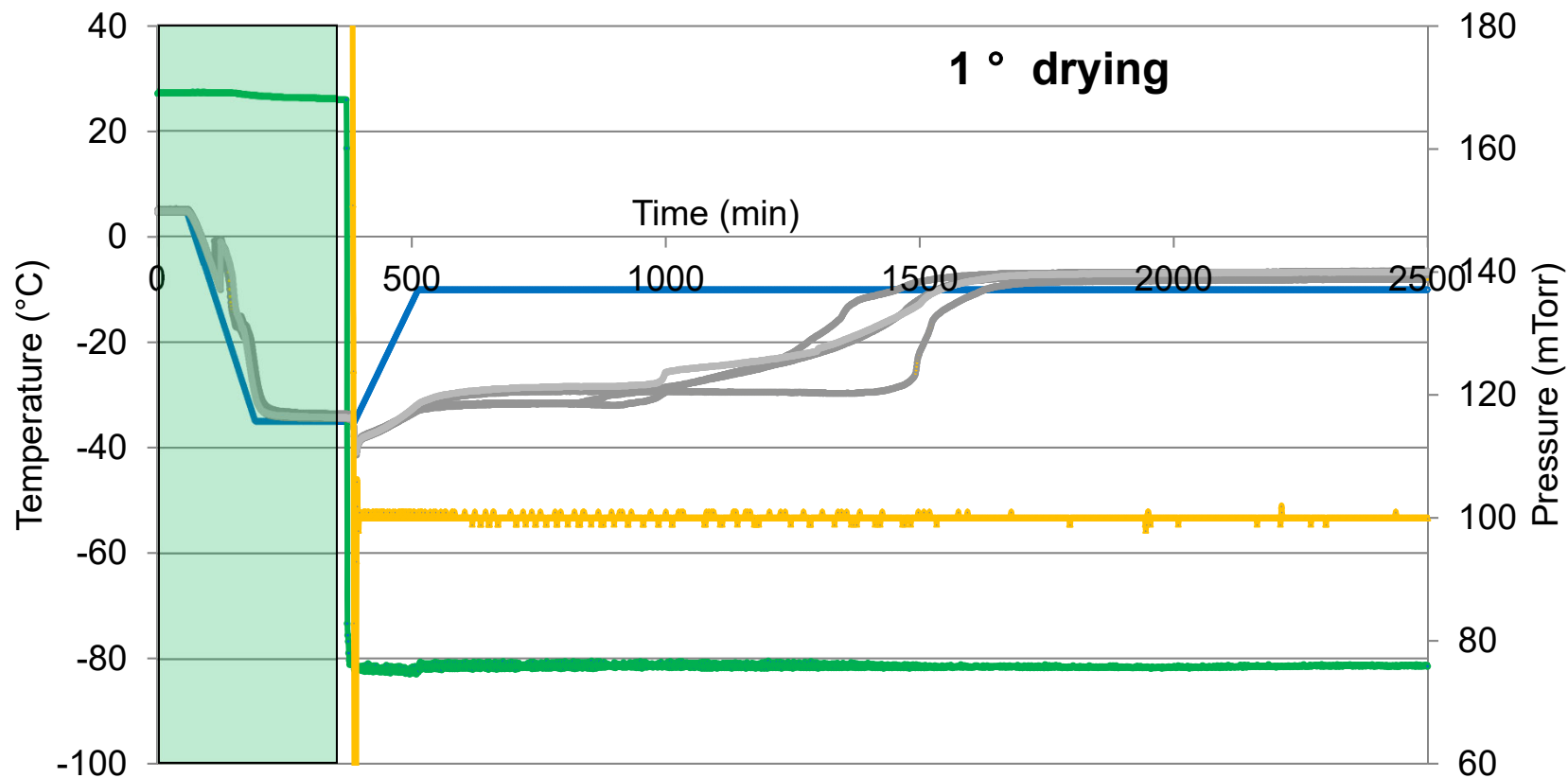


# Primary Drying - Sublimation





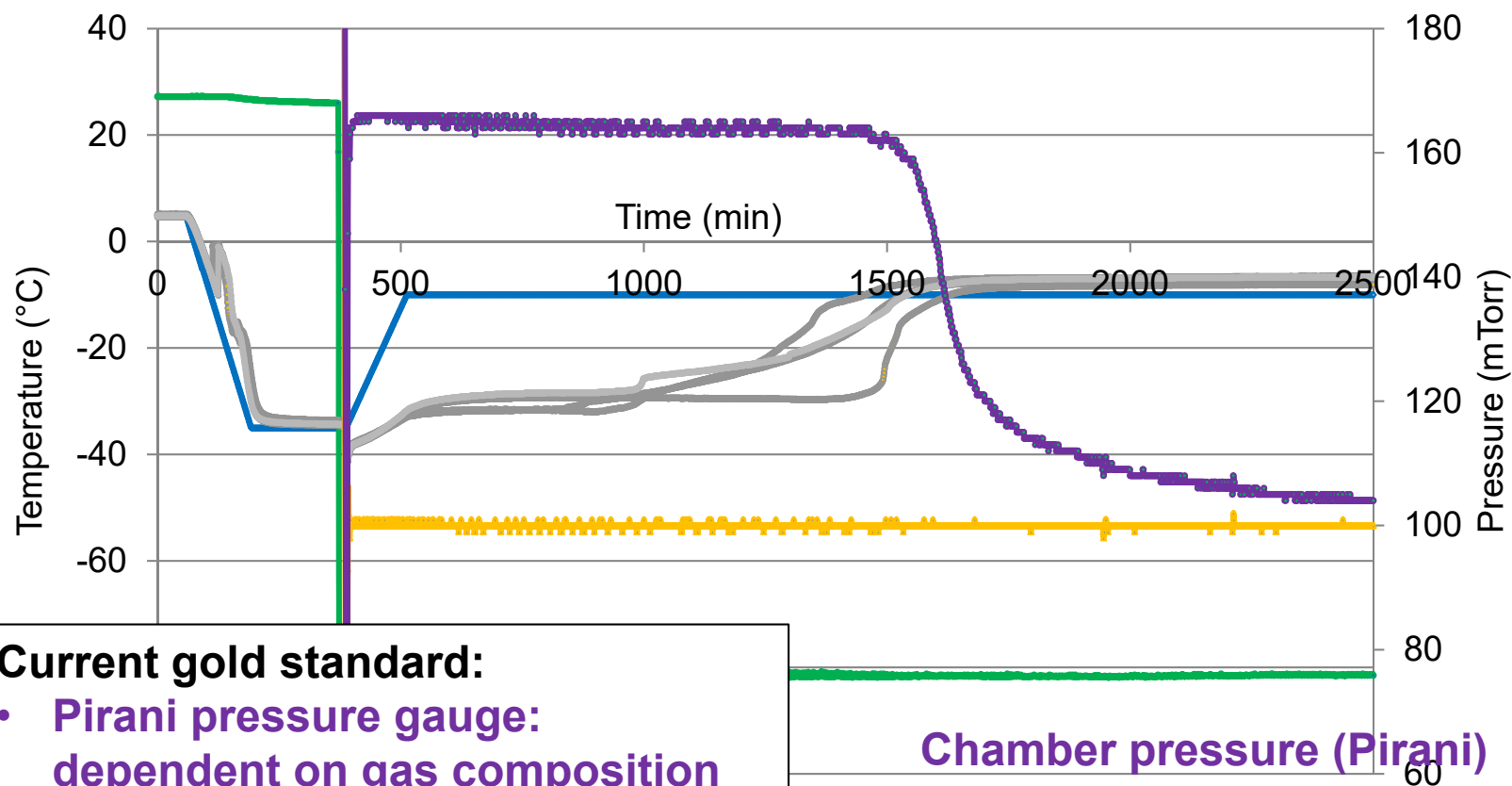
# End of primary drying: Product temperature



Product temperature  
Chamber pressure  
Condenser temp.  
Shelf temp.



# End of primary drying: Pressure gauges



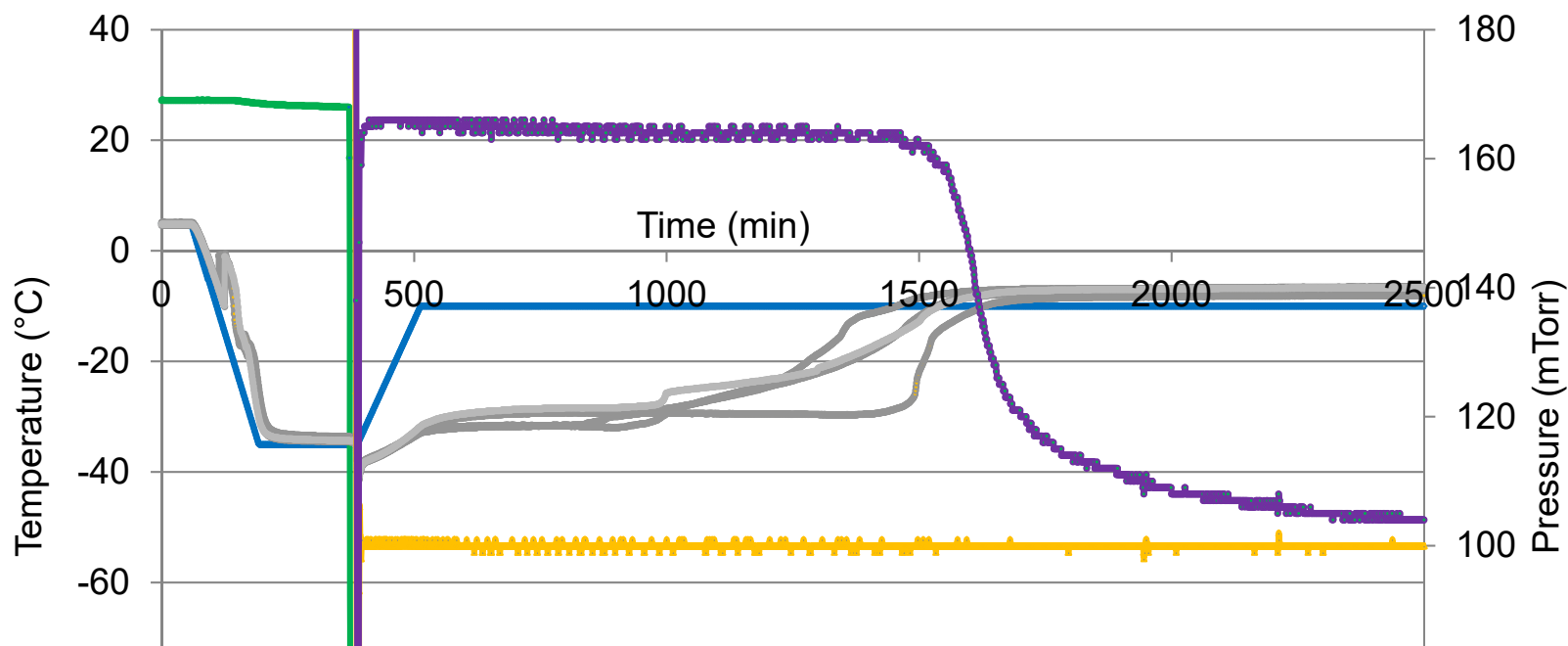
### Current gold standard:

- Pirani pressure gauge: dependent on gas composition (in the chamber)
- MKS pressure gauge: independent on gas composition

Chamber pressure (Pirani)  
Product temperature  
Chamber pressure (MKS)  
Condenser temp.  
Shelf temp.



# End of primary drying - Options

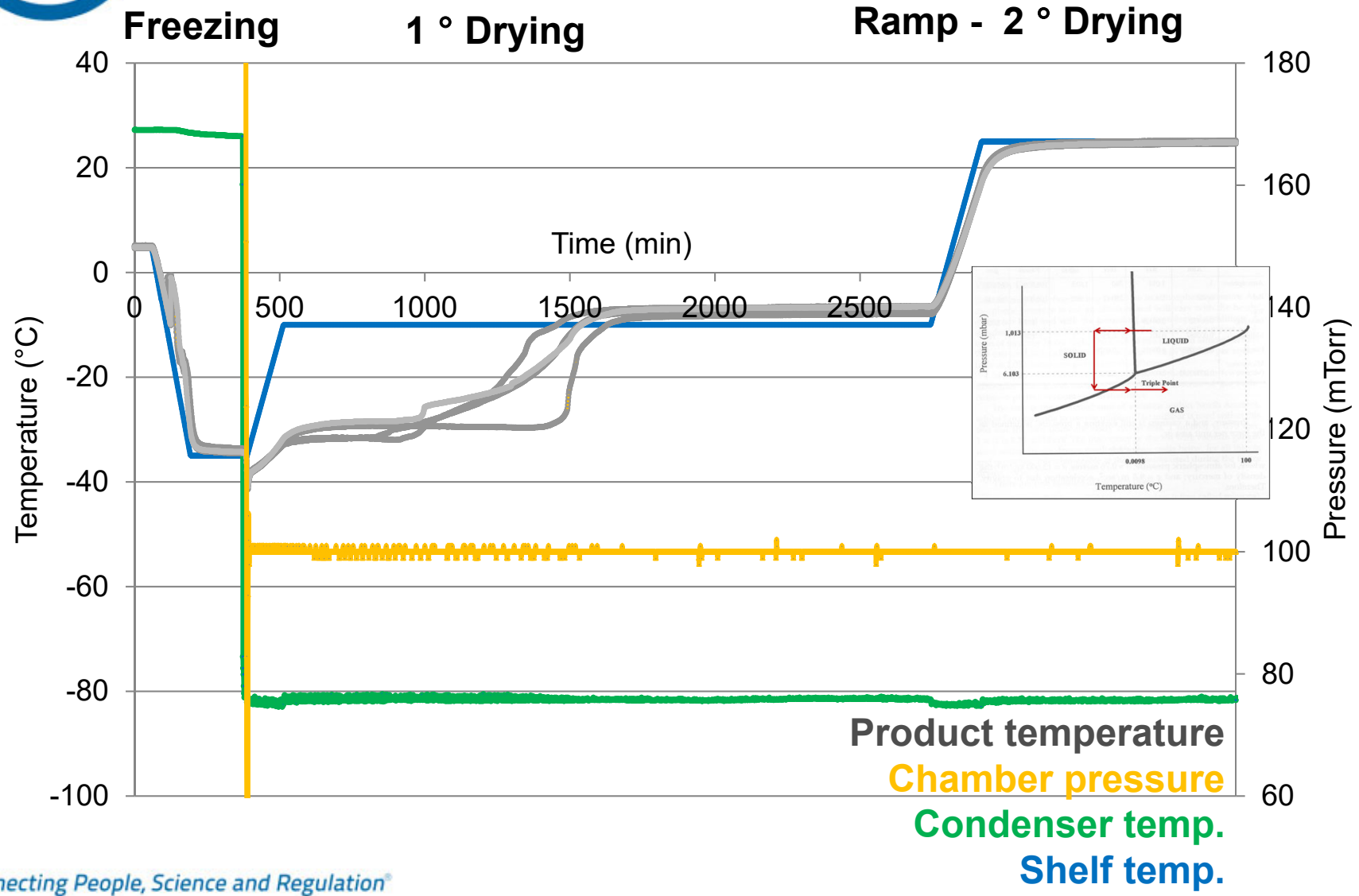


- Product temperature
- Comparative pressure measurement Pirani/MKS
- Pressure rise test

Chamber pressure (Pirani)  
Product temperature  
Chamber pressure (MKS)  
Condenser temp.  
Shelf temp.



# Secondary drying - Desorption







# Secondary drying - Desorption

