

Theory 2

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2020 PDA EUROPE TRAINING COURSE

Freeze Drying in Practice



9-13 MARCH 2020 | OSTERODE AM HARZ | GERMANY



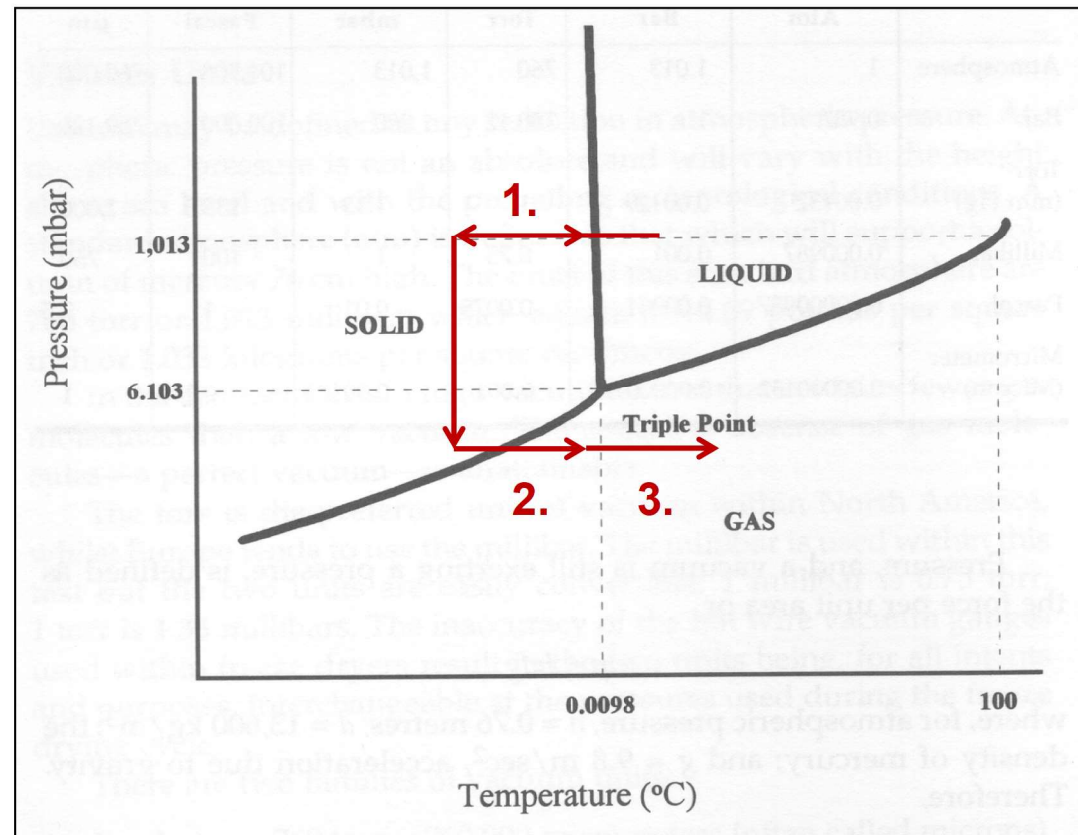
Theory 2

- 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



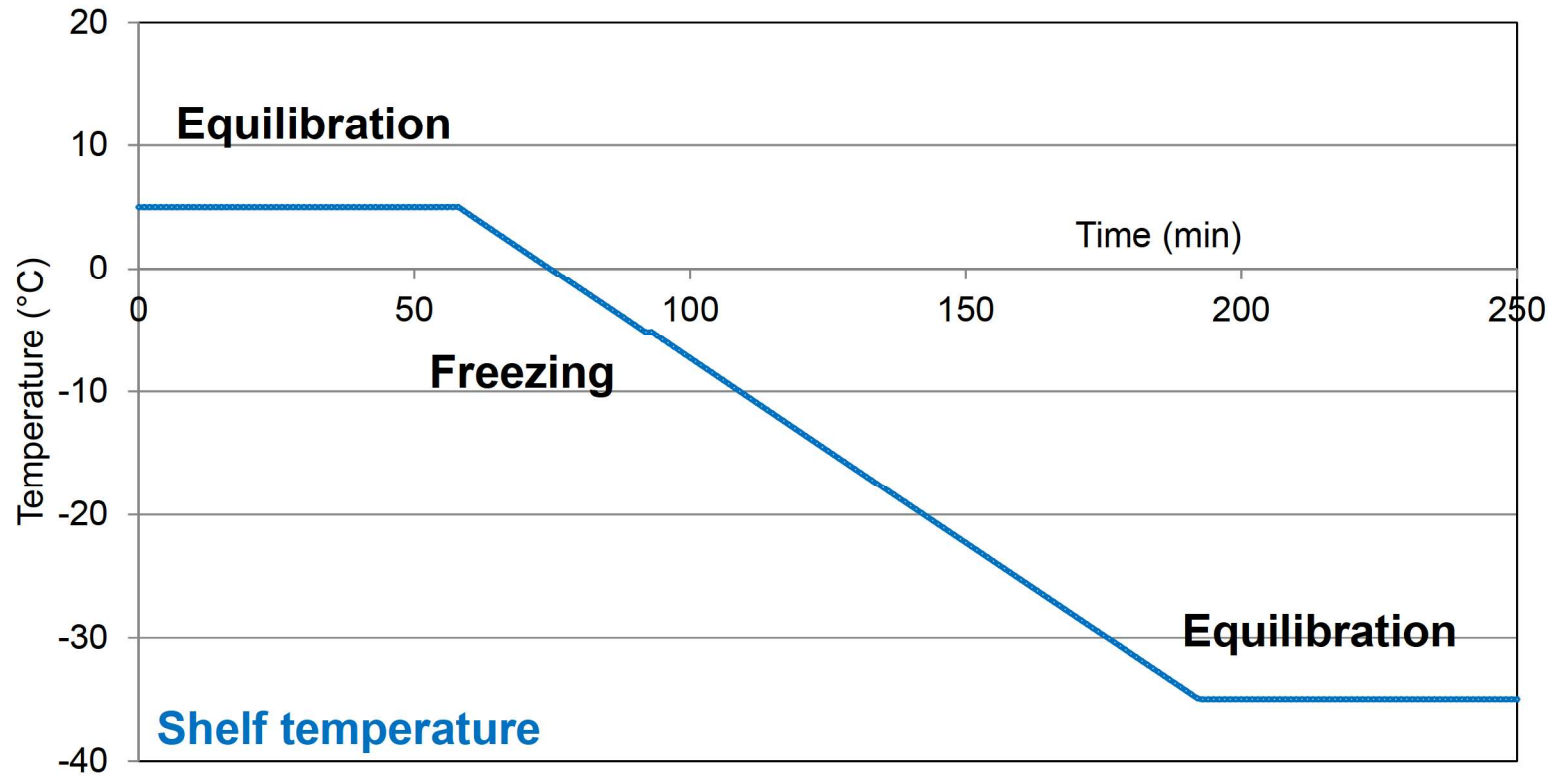
Basic principles

- 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



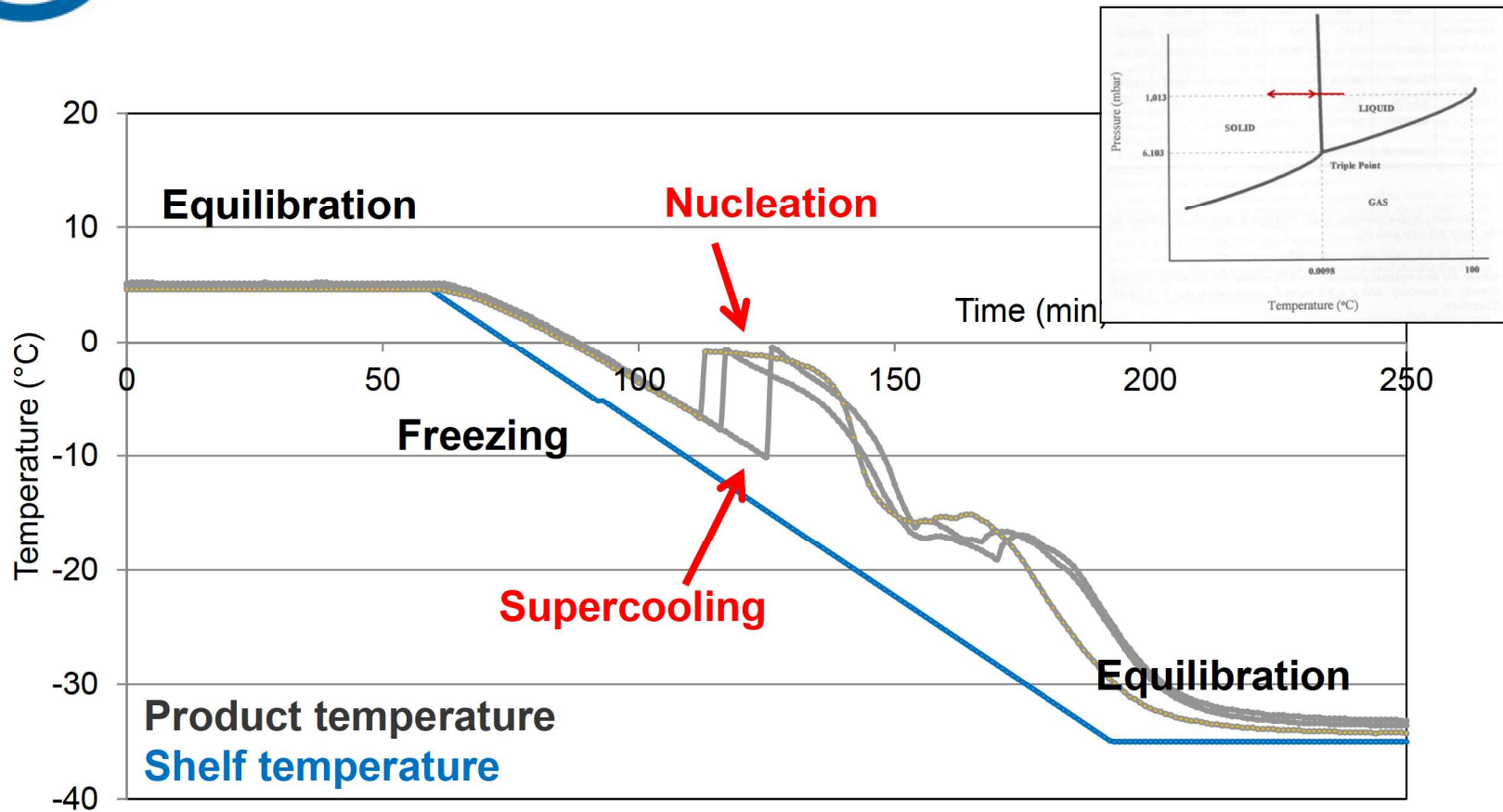


Freezing



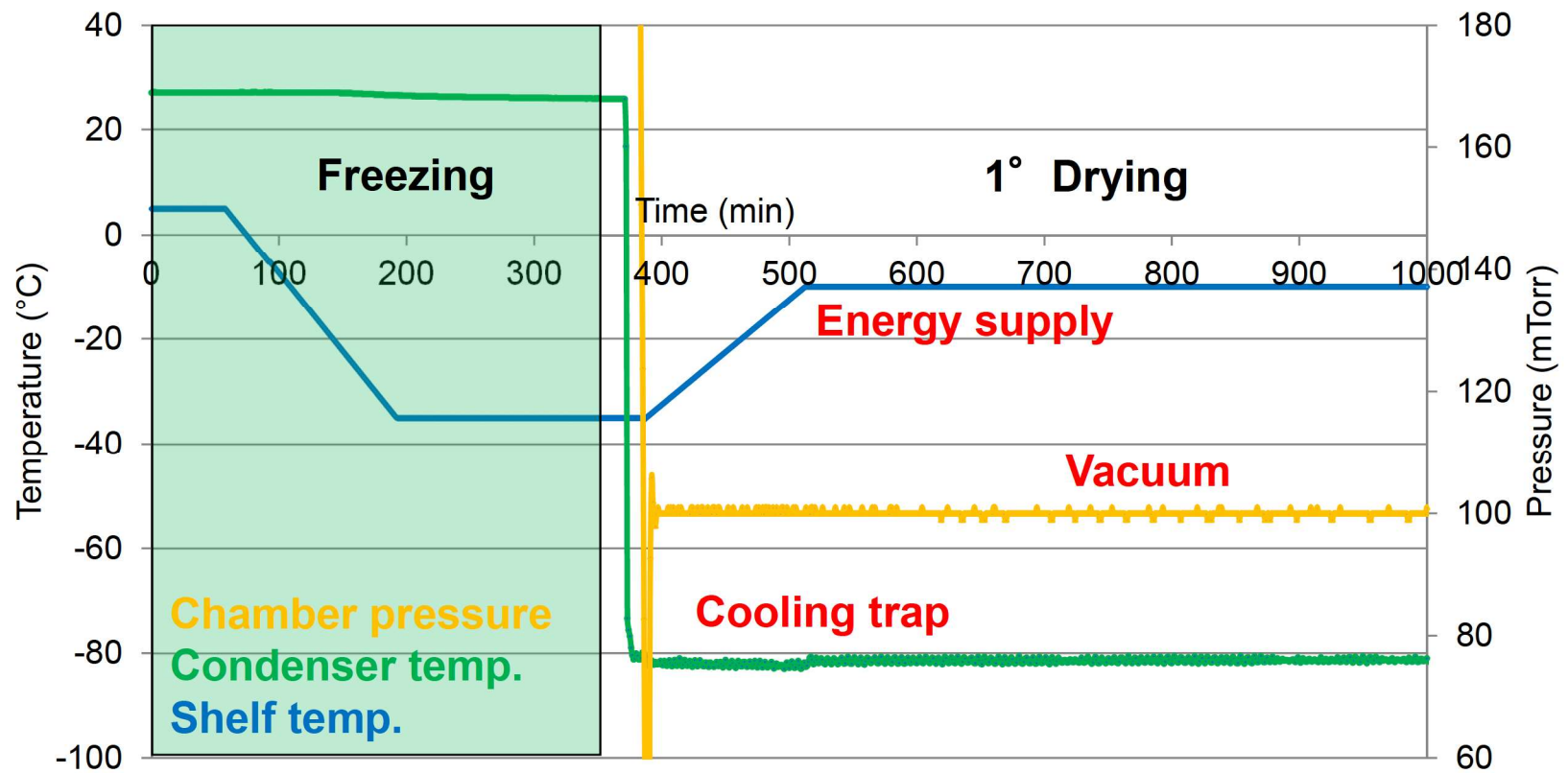


Freezing - Nucleation



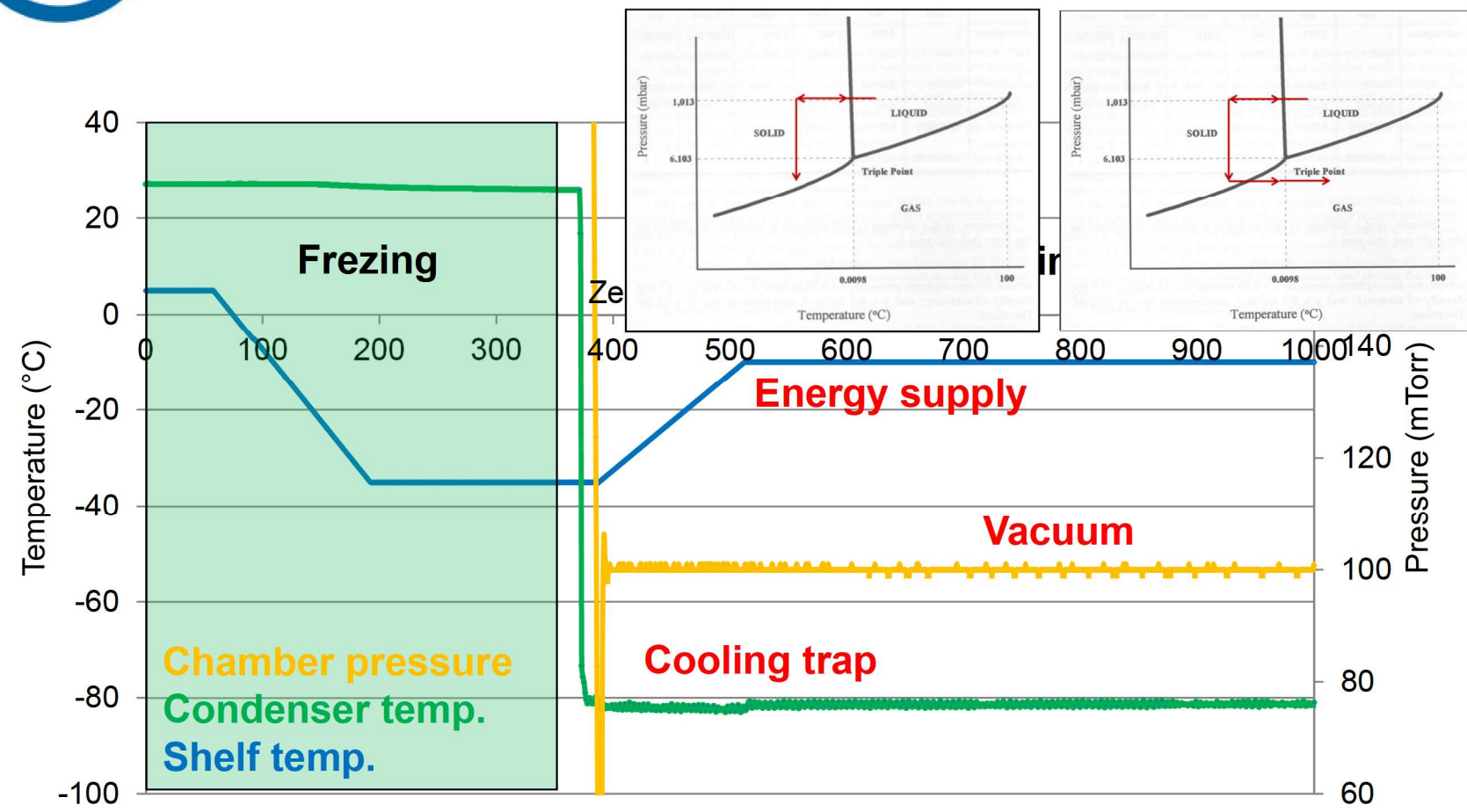


Primary Drying



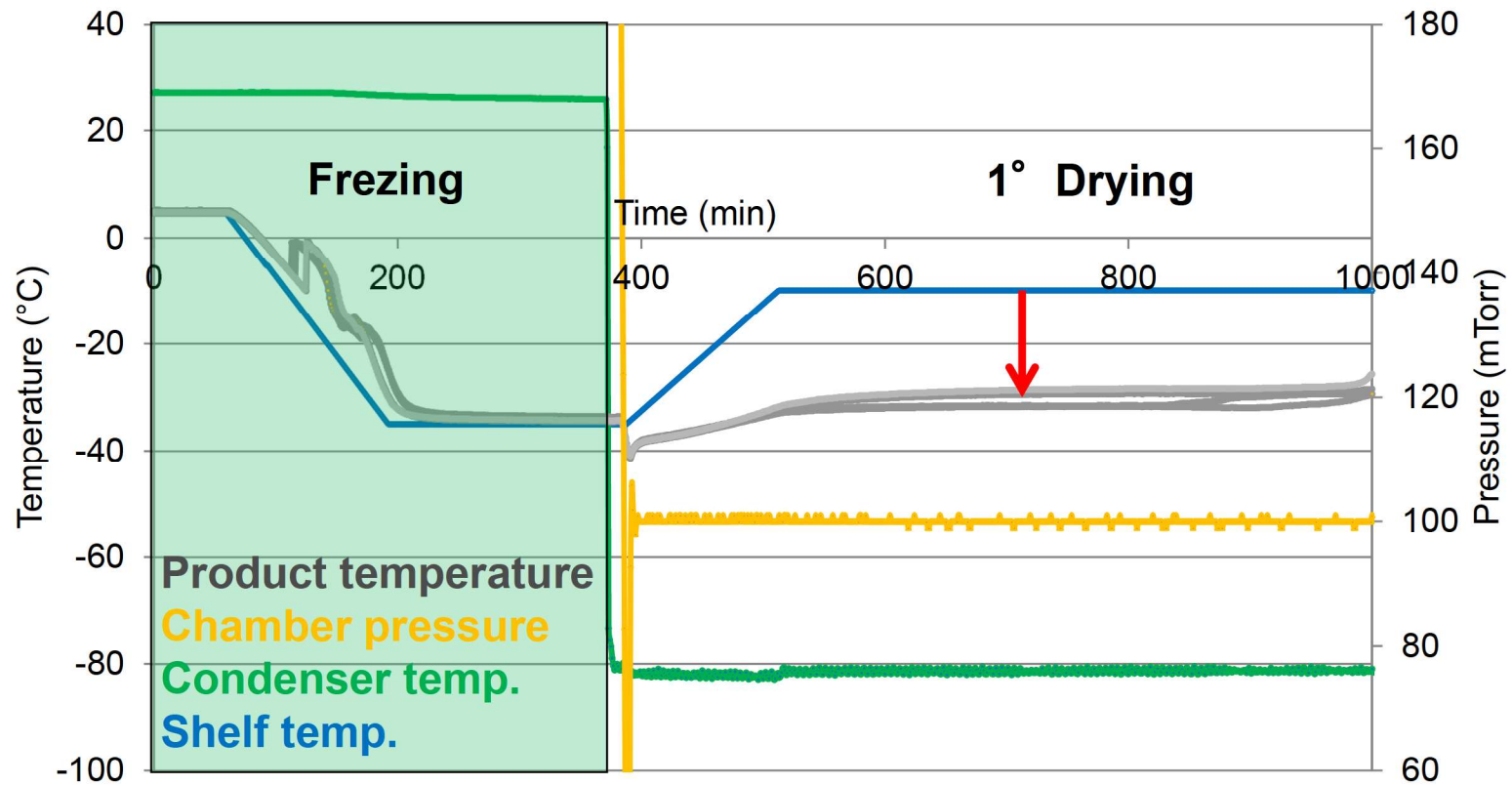


Primary Drying



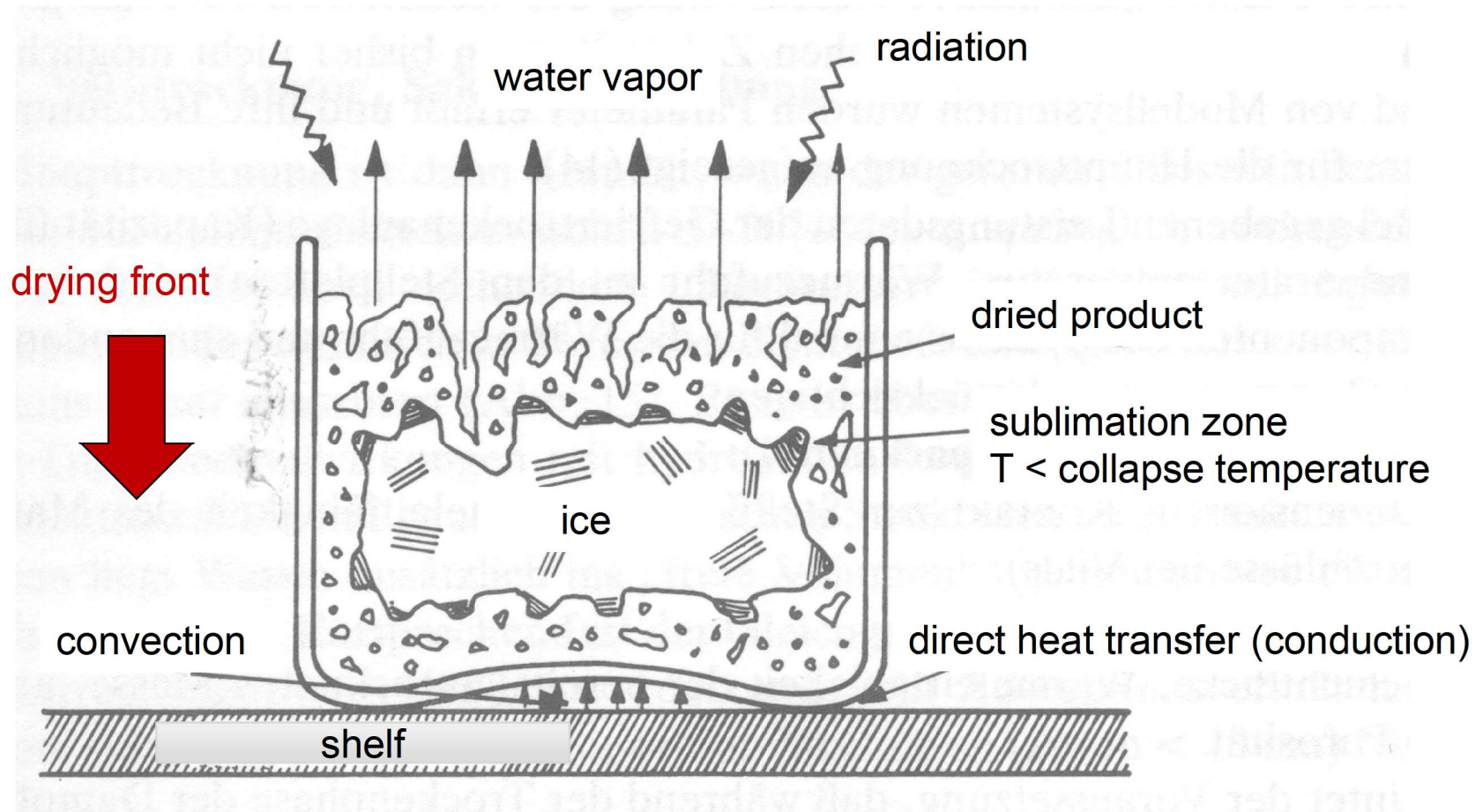


Primary Drying - Sublimation



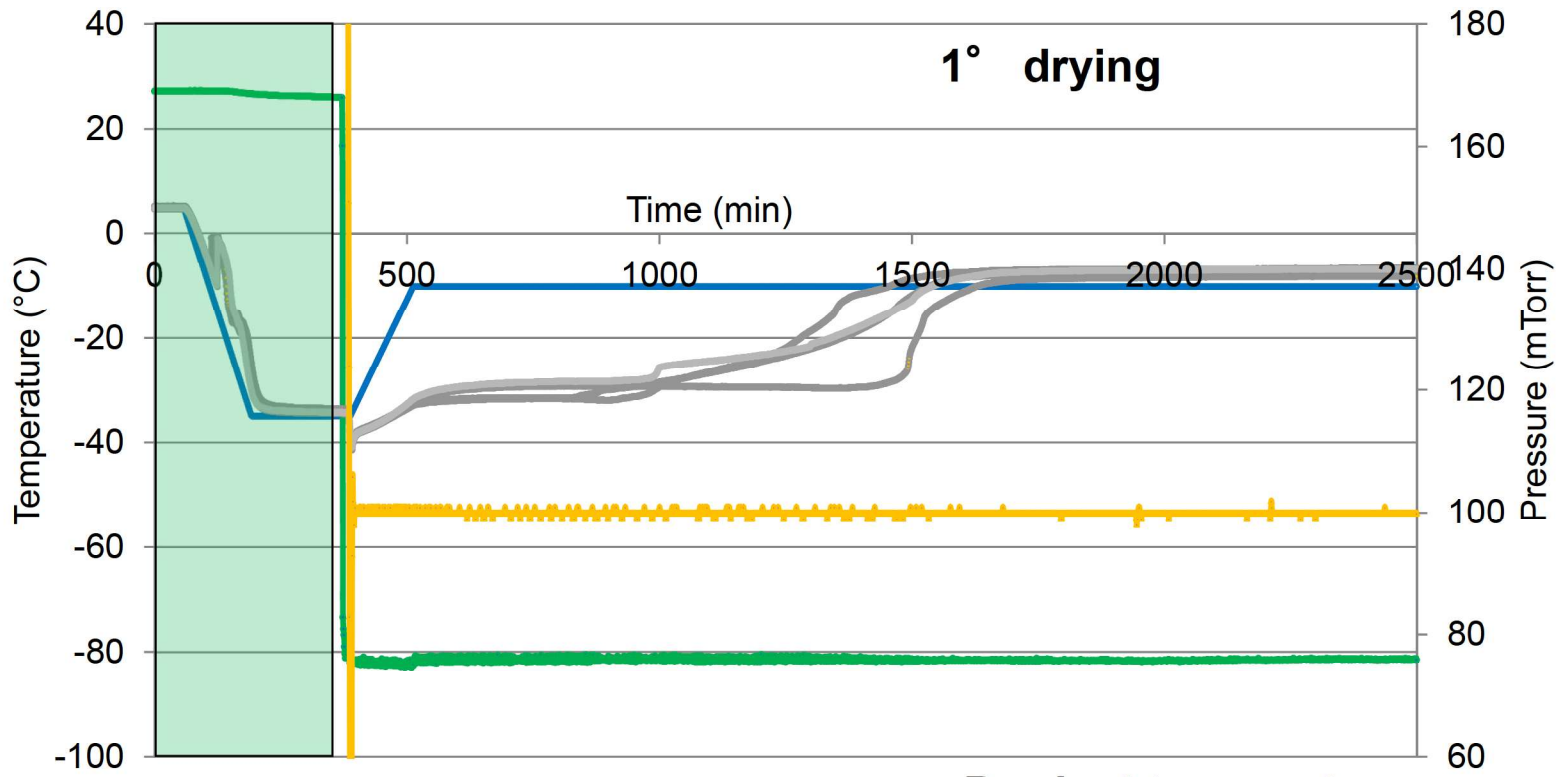


Primary Drying - Sublimation





End of primary drying: Product temperature

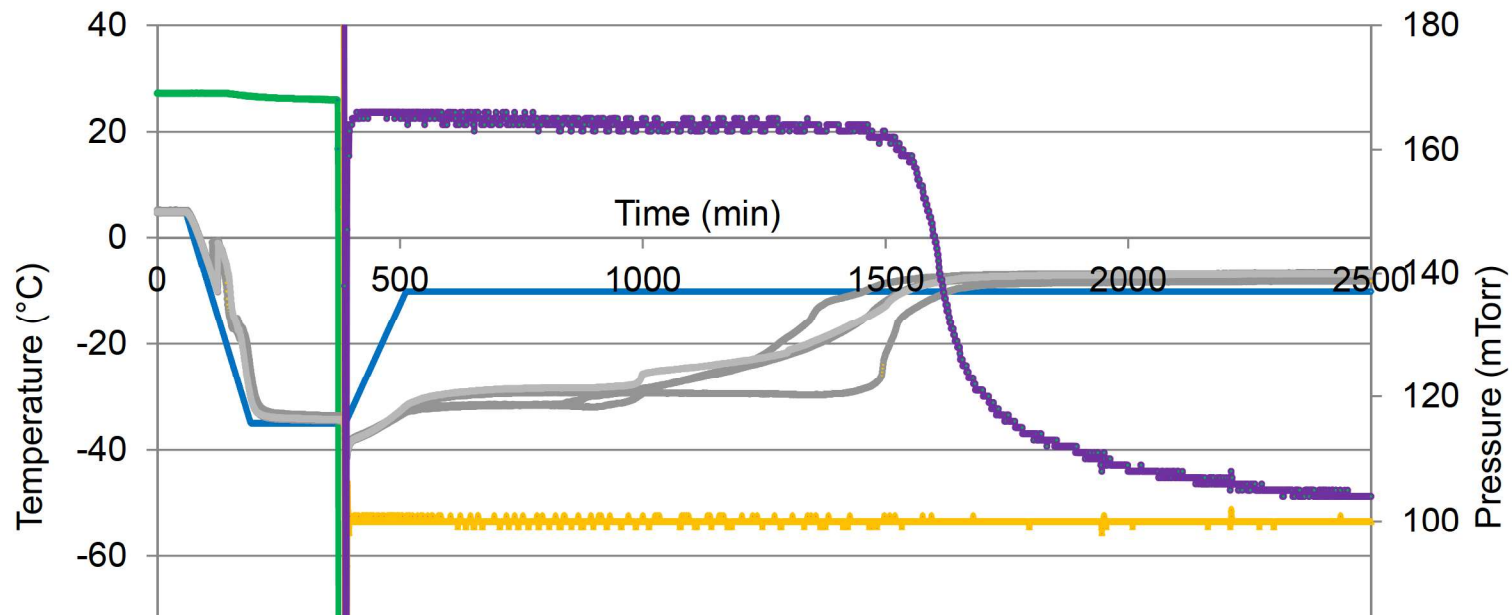


Freezing

Product temperature
Chamber pressure
Condenser temp.
Shelf temp.



End of primary drying: Pressure gauges



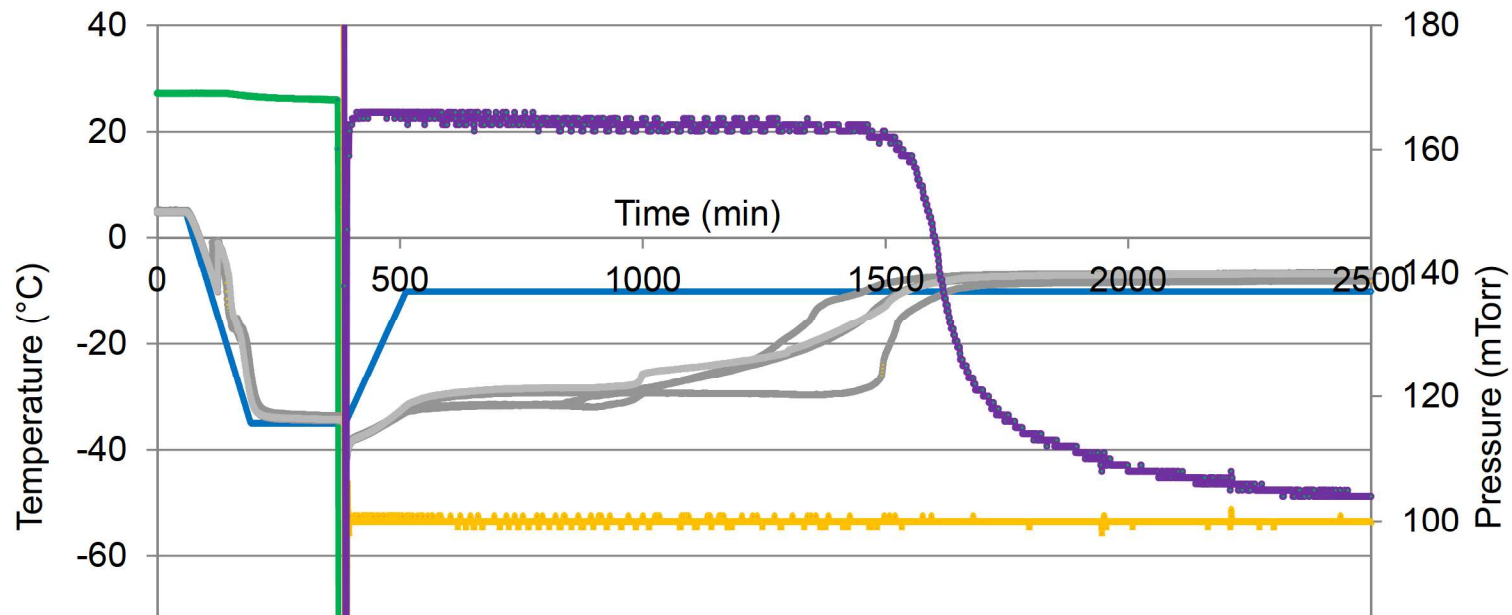
Current gold standard:

- 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

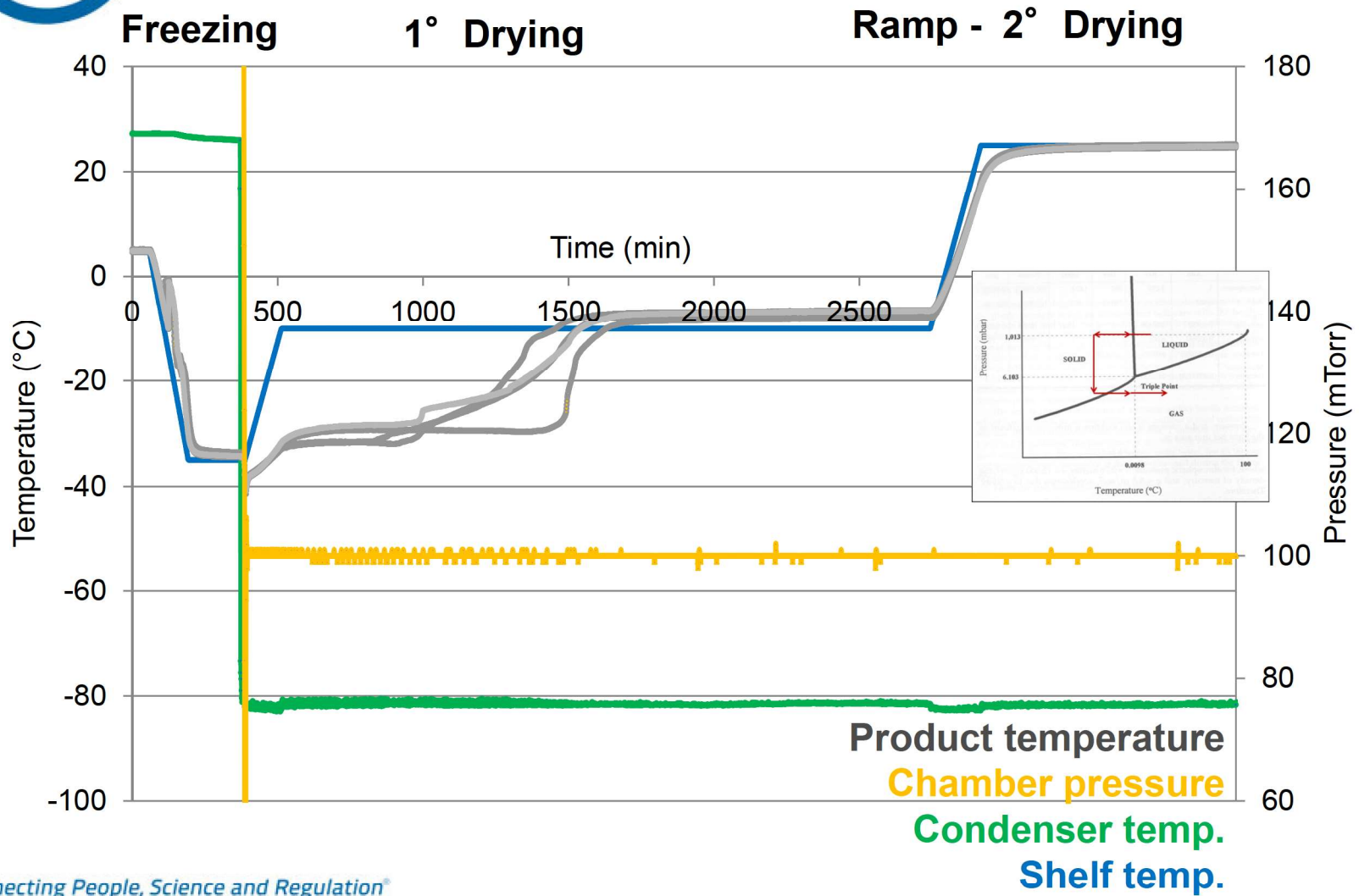


- Product temperature
- Comparative pressure measurement Pirani/MKS
- Pressure rise test

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



Secondary drying - Desorption





Secondary drying - Desorption

