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## AVOIDING COLD CHAIN LOGISTIC CHALLENGES BY USING SPIN FREEZE-DRYING TO STABILIZE GENE THERAPIES

### Freeze-drying: a solution for cold chain logistics challenges

- Maintaining the integrity of temperature-sensitive gene therapy products during transportation and storage is a critical challenge in the distribution chain.
- **Spin Freeze-Drying** increases the thermostability of ATMPs by removing water from the product. Hence, it eliminates the need for temperature-controlled transport and simplifies the distribution chain accordingly.
- All products are optimally dried via spin freeze-drying ⇔ Not possible via conventional freeze-drying.

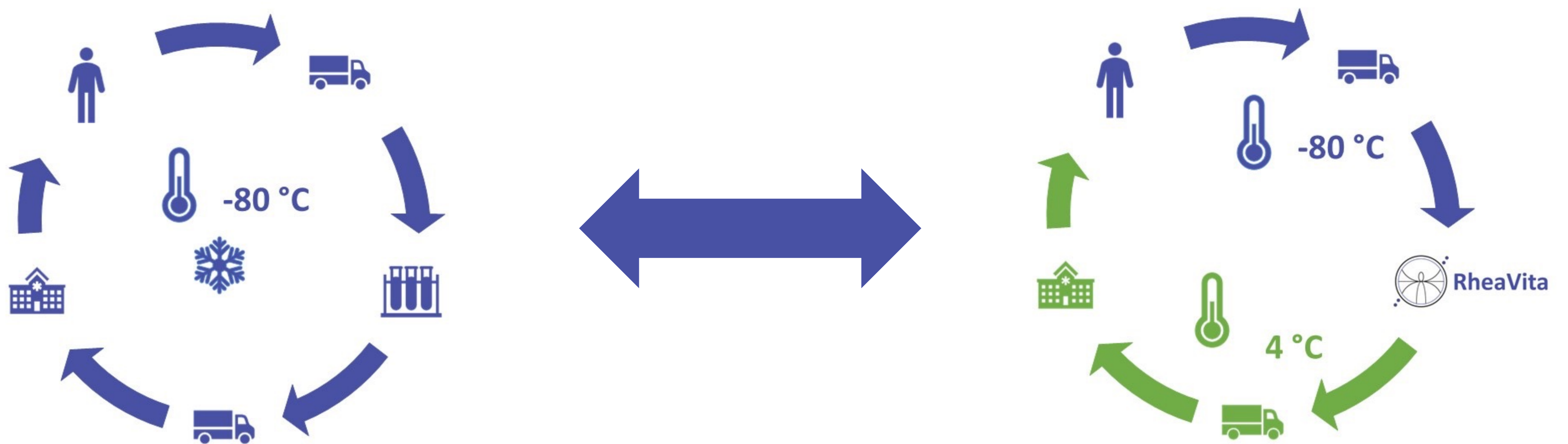


Figure 1: Freeze-drying can be used as a process step to simplify cold chain logistics

### Controlled spin freeze-drying

- **Spin freezing** of vials; cooling via cold gas (Figure 2)
- Infrared-assisted primary and secondary drying
- Thin product layer leads up to **40x shorter processing time**
- Contactless temperature measurement
- **Closed feedback-loop** freezing and drying (Figure 3)

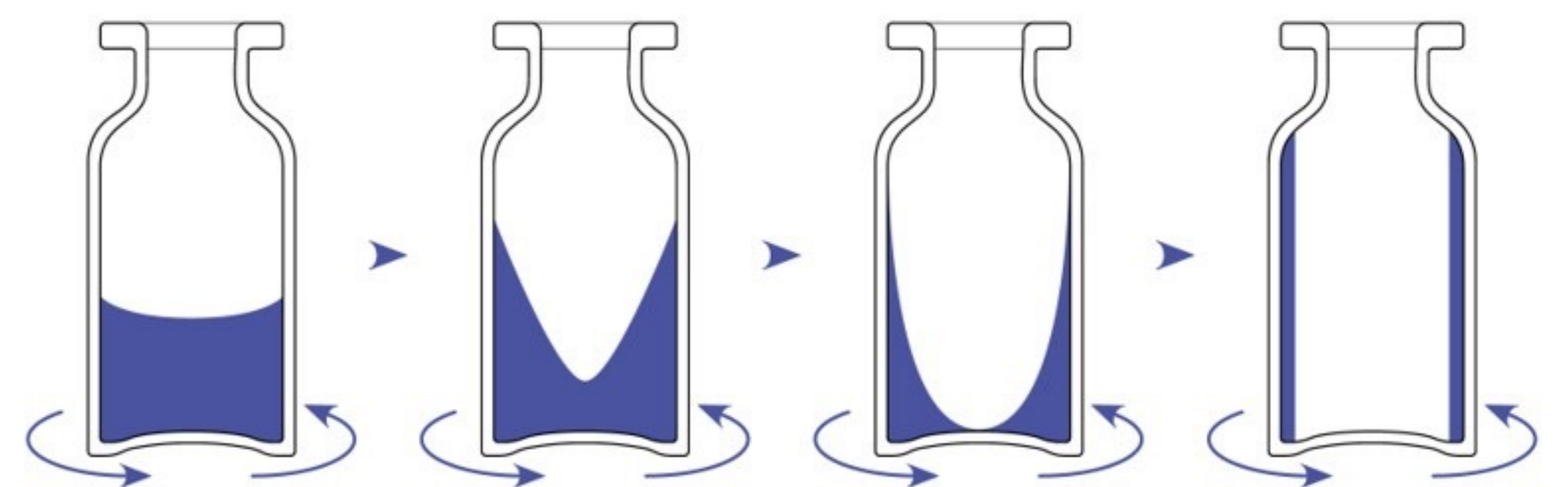


Figure 2: Illustration of spin freezing - Vials rapidly rotated to create a thin frozen product layer spread over the entire vial wall

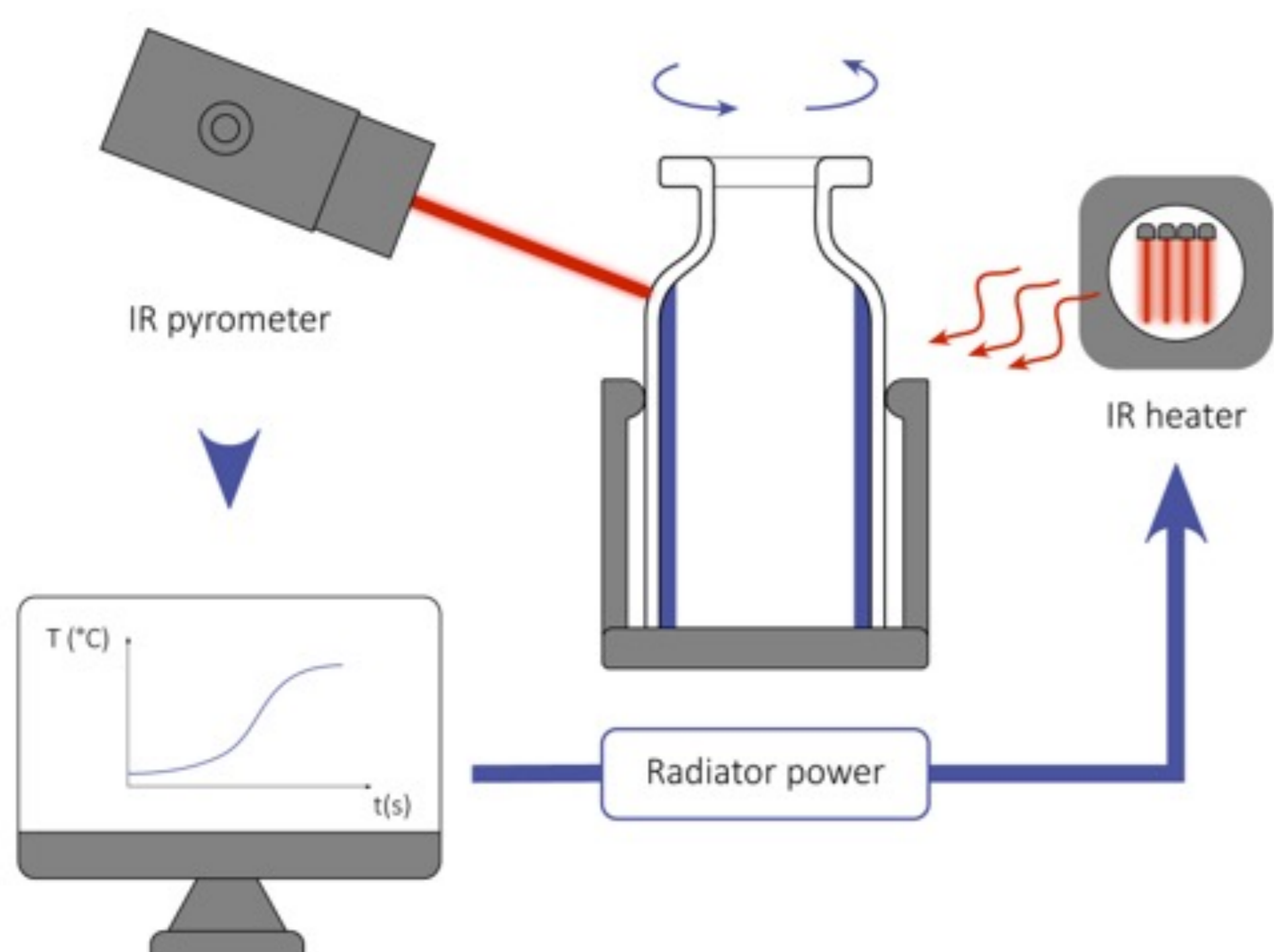


Figure 3: Closed feedback loop to control the freezing and drying cycle

### Opportunity

- Minimal amount of resources for process and formulation development
- **Simplifying cold chain logistics by freeze-drying gene therapy products without altering CQA's**
- Same quality from pre-clinical to production – **no scale-up issues**
- **Scaling out** instead of scaling up
- **Fast formulation and process development**



Figure 4: Closed feedback loop to control the freezing and drying cycle

**Continuous spin freeze-drying enhances the thermostability of ATMPs. This simplifies the distribution chain and avoids cold chain logistics.**

Questions?

