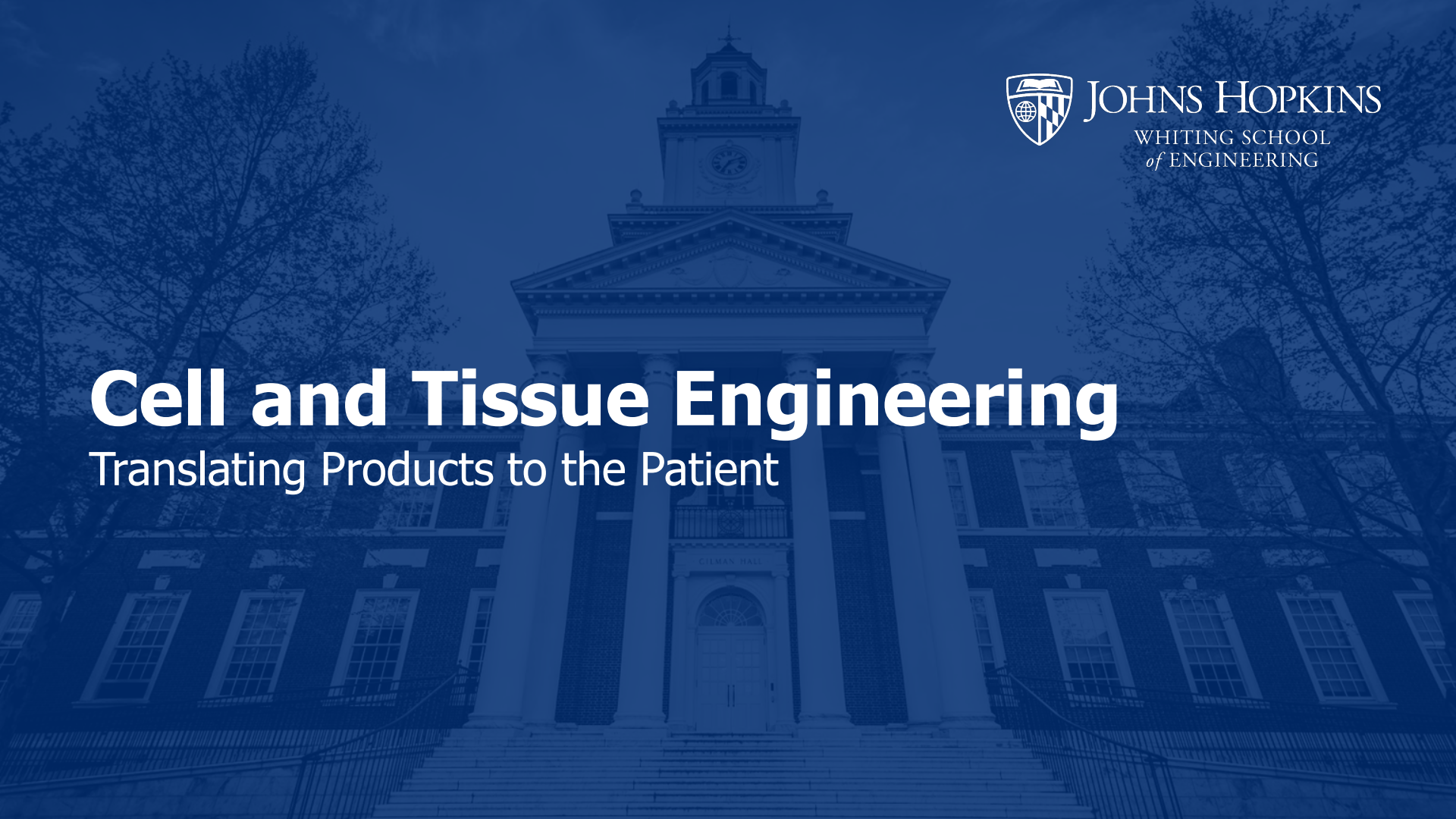


Cell and Tissue Engineering

Translating Products to the Patient

Key determinants for translating science to products

Science

Market Opportunity

Public & Private Funding

Regulatory Approval

Public Sector Perception

Replace
Repair
Restore
Regenerate

Schematic edited from *Topics in Tissue Engineering*

Product characterization – cellular

Cellular Components

- Pathogen testing
- Species
- Gender
- Age
- Weight
- Surgical procedure

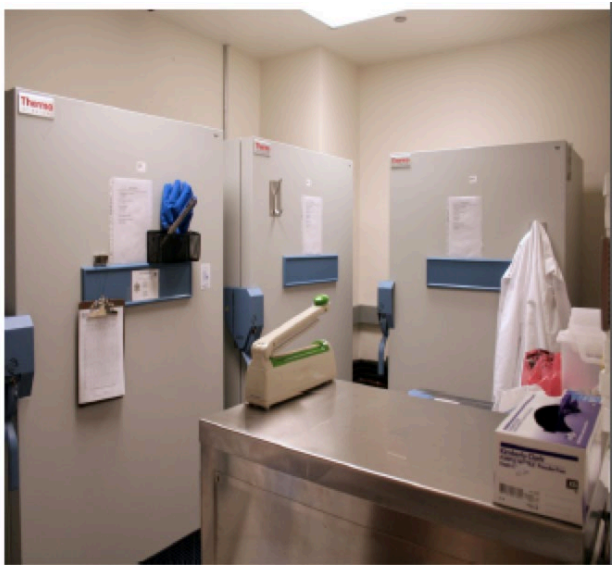
	Passage 2	
	Excision	Liposuction
CD11a (alphaL integrin)	1.1 ± 1.1	1.1 ± 0.8
CD11b (alphaM integrin)	0.8 ± 0.7	0.5 ± 0.6
CD18 (beta2 integrin)	0.4 ± 0.4	0.5 ± 0.4
CD29(beta1 integrin)	97.0 ± 1.5	96.6 ± 1.4
CD49d (alpha4 integrin)	64.6 ± 24.0	88.4 ± 9.2
CD49e (alpha5 integrin)	97.8 ± 1.2	97.9 ± 1.4
CD51 (alphaV integrin)	97.8 ± 0.8	97.3 ± 3.3
CD61 (beta3 integrin)	29.7 ± 33.2	40.5 ± 21.5
CD49b (alpha2 integrin)	72.6 ± 12.4	88.7 ± 11.1

Katz et al., 2005; Amos et al 2008

Product characterization – non-cellular

NonCellular Components

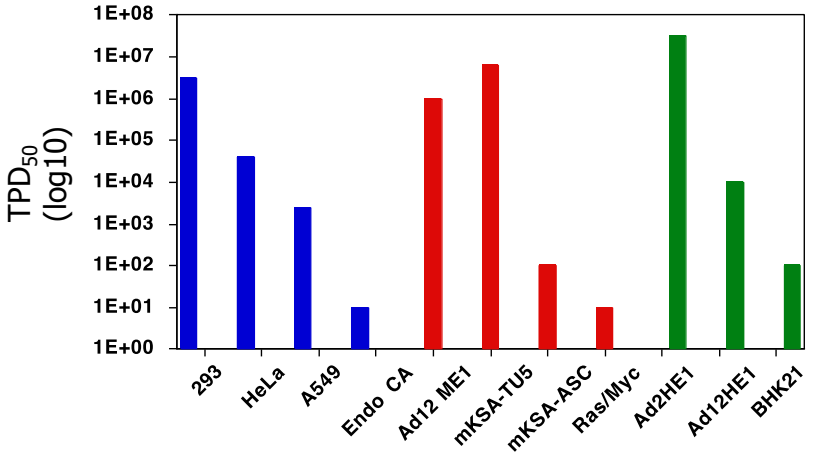
- Purification techniques
- Production methods
- Degradation rate
- Consumption rate
- Contaminants
- Storage history



Product characterization - safety

Safety

- Toxicity
- Physiologic effects
- Tumorigenicity

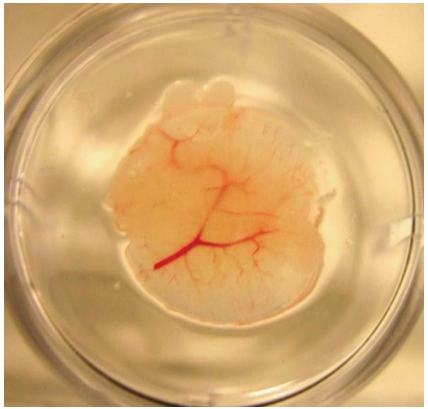


TPD_{50} values for cell lines of human, mouse and hamster origin

Product characterization - efficacy

Efficacy

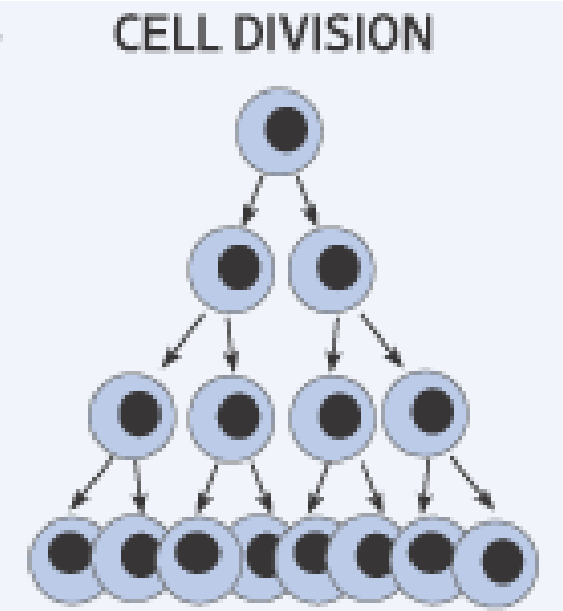
- Number of cells
- Type of cells
- Fate of cells
- Behaviors: adhesion, migration, production…
- Clinical endpoints: wound closing, protein expression…
- Product parameters: in vivo survival, growth rates…



Human Ectopic Artificial Livers

Product preservation

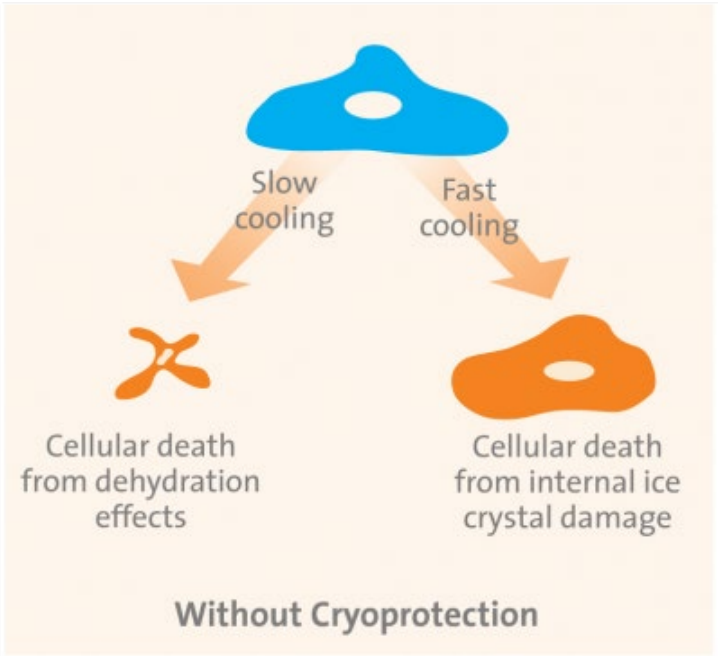
1. Freezing
2. Dehydration



Aging Ills Reversed in Mice, Naik, WSJ online

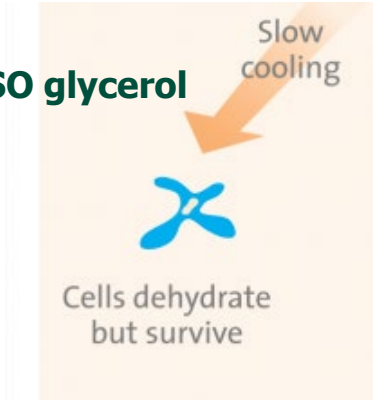
Product preservation - freezing

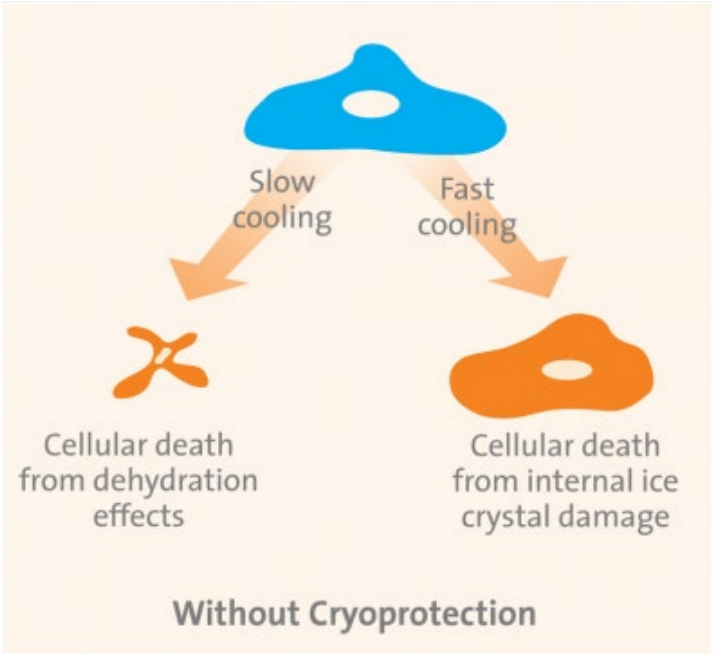
- Freezing < -130oC



Product preservation - cryoprotection

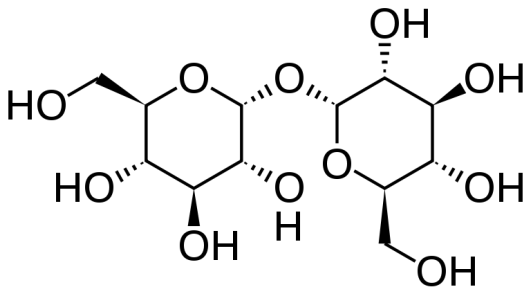
- Freezing < -130°C



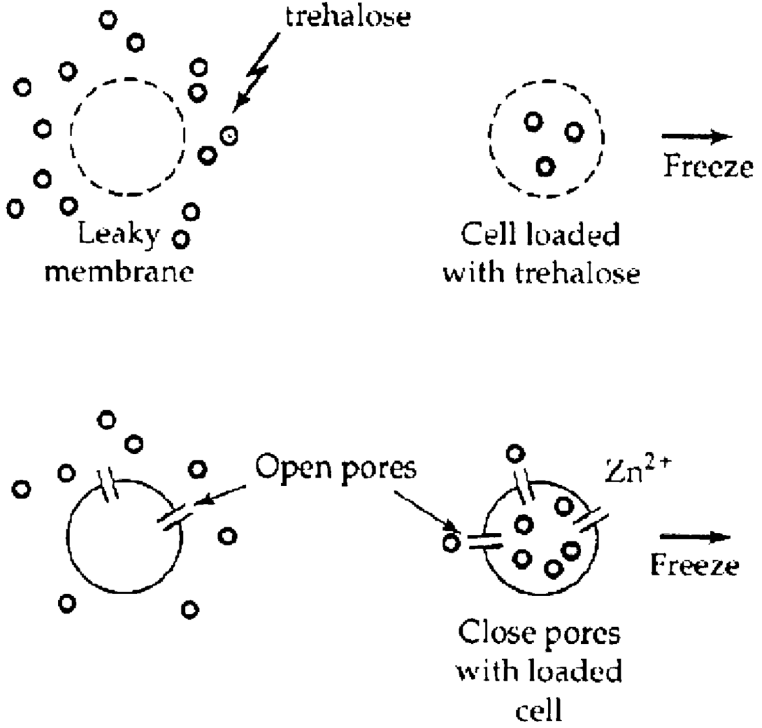


Product preservation - dehydration

- Dehydration



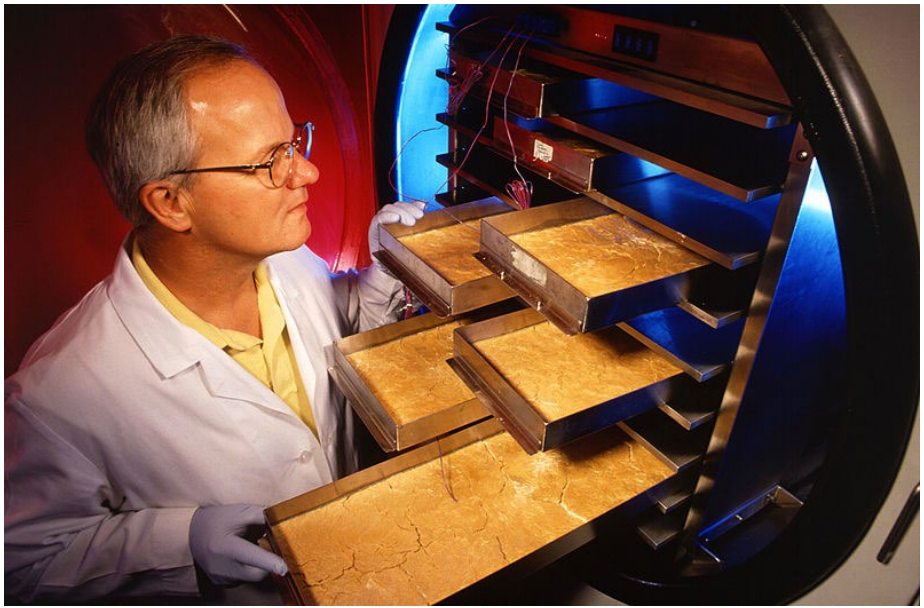
Trehalose

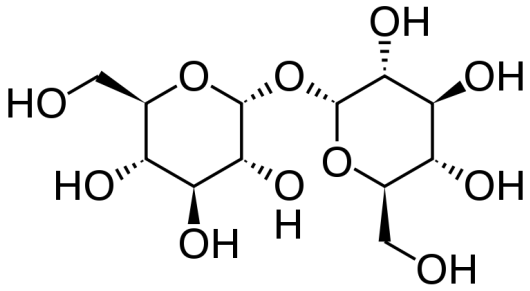


Wikipedia; Tissue Engineering, Palsson & Bhatia

Product preservation - lyophilization

- Dehydration





Trehalose

Lyophilization