



vitrafy^o

**Smarter Cryopreservation Freezing and
Data-Driven Intelligence for Regulatory
Readiness, Clinical Development, and
Commercialization.**

Regulatory Notices

Guardion Regulatory Notice

Guardion is intended for General Laboratory Use. It is the customer's responsibility to ensure that the performance of the product is suitable for customer's specific use or application. Guardion may be used within validated cGMP environments as part of a facility's broader quality management infrastructure, subject to the customer's own validation and qualification requirements.

Customers are responsible for validating Guardion in accordance with their applicable regulatory requirements.

LifeChain Regulatory Notice

LifeChain is general-purpose workflow management software. It is not cleared or approved by the U.S. Food and Drug Administration as a medical device, and it is not intended for use as Blood Establishment Computer Software (BECS) as defined under 21 CFR 606.

LifeChain may be used within validated cGMP environments as part of a facility's broader quality management infrastructure, subject to the customer's own validation and qualification requirements. Customers are responsible for validating LifeChain in accordance with their applicable regulatory requirements, including 21 CFR Part 11 compliance where applicable.

LifeChain is not intended for compliance with 21 CFR 606 blood establishment requirements.

Email sales@vitrafy.com should you have a enquiries about our first generation unit, VCU1.



**Cryopreservation hasn't
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**But cell and gene
therapies have.**

If cryopreservation was fashion, it would be vintage.

Isolated Technology

Stand-alone unit not integrated into the process is the current gold standard.

Lacks Intelligence

Data capture and analytics to support GMP compliance and FDA approvals uncommon.

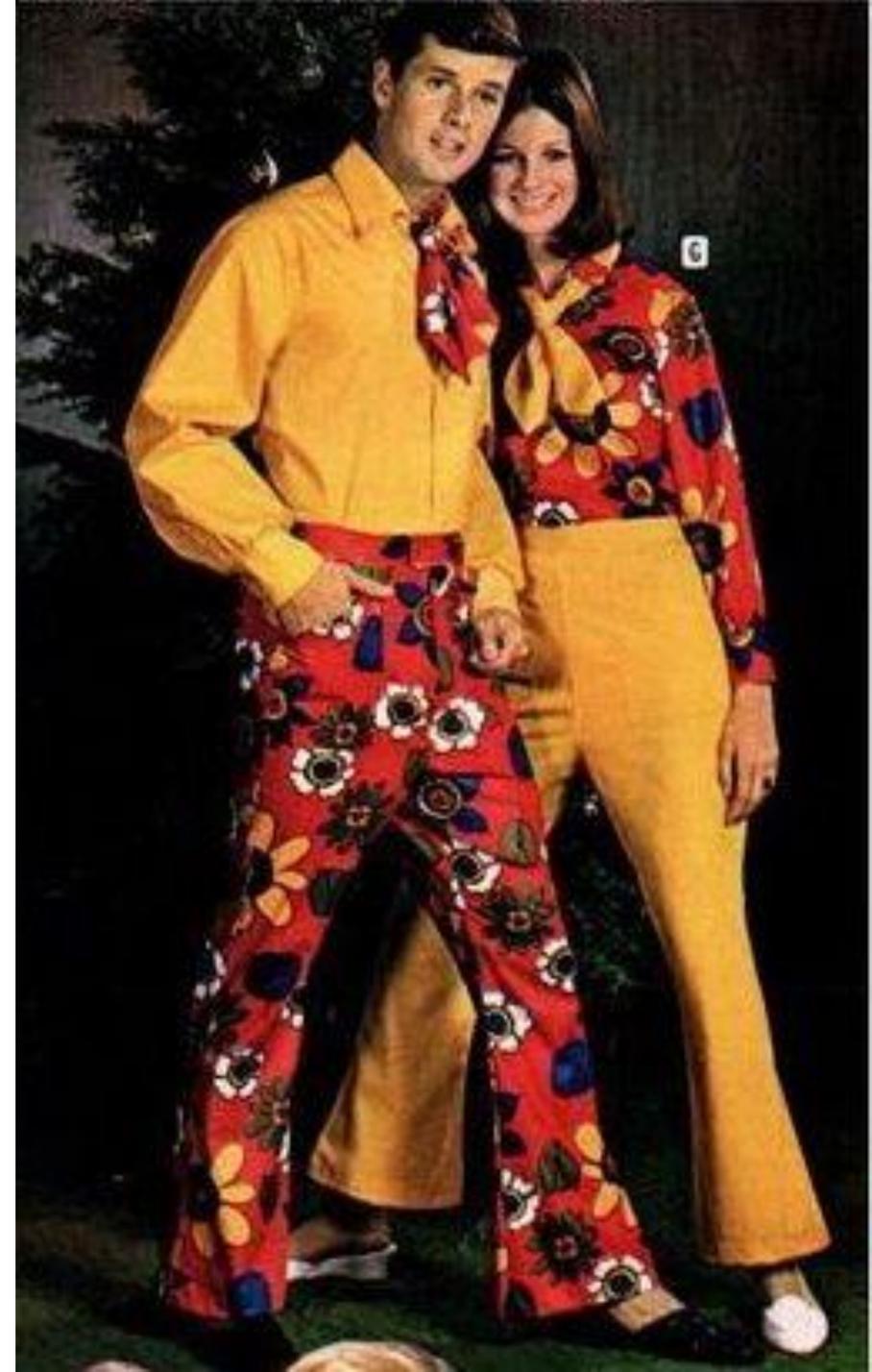
Damaging

Liquid nitrogen and harmful toxins are mandatory throughout the process.

Hidden Costs

Variability in outcomes, manual handling and regulatory overhead impact momentum.

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Legacy cryopreservation shifts the burden onto researchers.



Freezing variability negatively impacts viability and usability.

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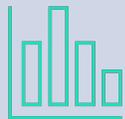
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Data gaps prevent scaling from research to commercial.

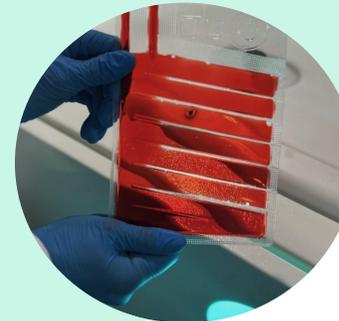
Vitrafy cryopreservation ecosystem reduces burden on researchers.

**Guardion
Cryopreservation
Freezer Unit**



**LifeChain Software
Orchestration**

**Vitrafy Thawing
Units**



**Vitrafy Smart
Consumables**

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Freezing Quality

Acceptance of hidden costs of what happens at the freezing stage.



Batch Time

Batches processed in minutes, not hours so you can focus on what's important.



Orchestration Software

Delivers data packages that support standardization and transparency.

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**Cryopreservation is a process.
Not a step.**

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Booth 241

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Irvine, California

