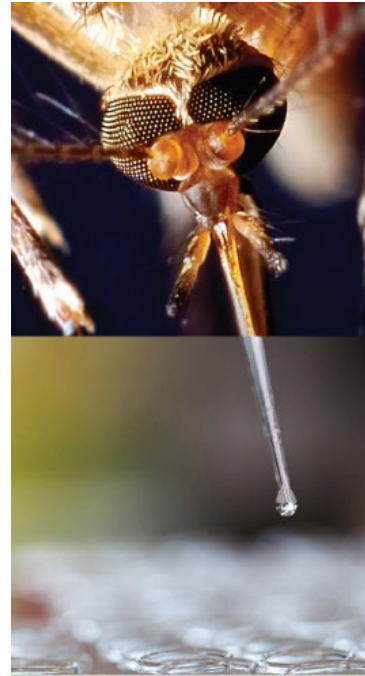
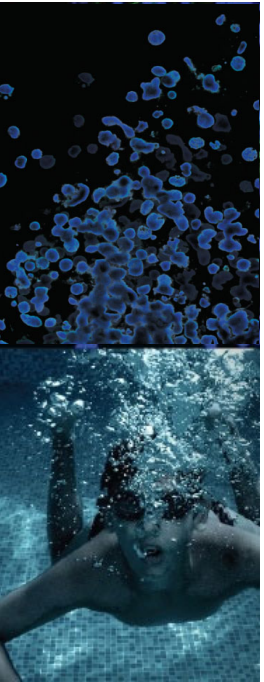




## Enable Your Drug Development with cGMP Cell Banking and Storage Services

Shalmica Jackson, PhD  
*Marketing Segment Manager, ATCC*

Credible Leads to Incredible™



# About ATCC

- Founded in 1925, ATCC is a non-profit organization with HQ in Manassas, VA, and an R&D and Services center in Gaithersburg, MD
- World's largest, most diverse biological materials and information resource for microbes – the “*gold standard*”
- Innovative R&D company featuring gene editing, microbiome, NGS, advanced models
- cGMP cell banking and biorepository services
- Partner with government, industry, and academia
- Leading global supplier of authenticated cell lines, viral and microbial standards
- Sales and distribution in 150 countries, 19 international distributors
- Talented team of 450+ employees, over one-third with advanced degrees

# Overview

- The origin of GMP
- What is cGMP and why is it important?
- cGMP regulations and drug manufacturing
- Biologics manufacturing and cell banking
- ATCC's cGMP cell banking and storage services



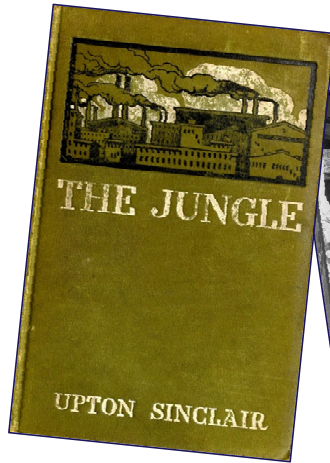


# The Origin of Good Manufacturing Practices (GMP)

1903



1906

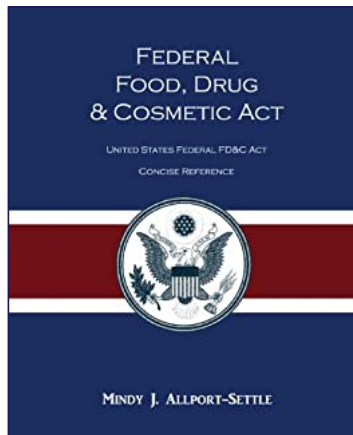


**New Drug Law!**  
As passed by Congress under the Pure Food Act of June 3, 1906, has not affected our business. We adopted our motto, "Only the Best," long before Congress thought of such an Act. Call on us for fresh Colgan's Taffy Tolu and Dr. Hass' stock and chicken powders.  
**LYNE BROS., Crab Orchard Druggists.**

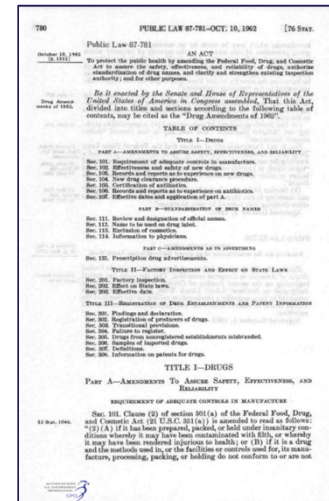
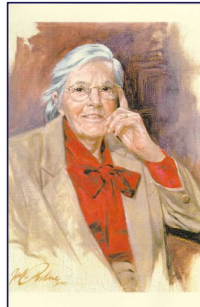
1937



1938



1957



1962



# What Are Current Good Manufacturing Practices (cGMP)?

- Requirements for methods, facilities, and controls used in manufacturing
- Ensures that products meet specifications and Quality/Regulatory standards
- Covers requirements for Quality Control and Production



## Why Is cGMP important?

- Public and consumer safety
- Minimizes risks
- Ensures safety, efficacy, and quality
- Reduces health hazards
- Improves health care economics



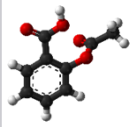
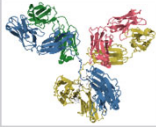


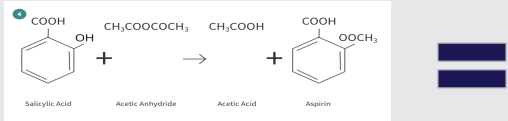

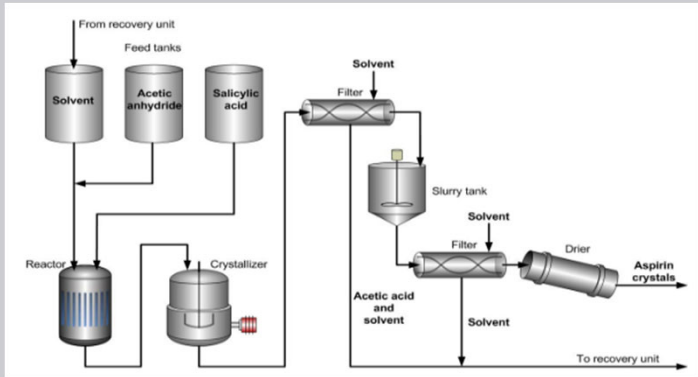
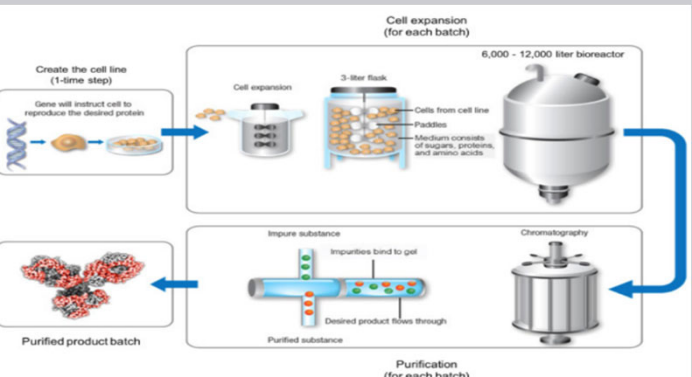
# cGMP Regulations

US FDA Title 21 Code of Federal Regulations (CFR)  
Parts:

- 11 – Establishes the US FDA regulations on electronic records and electronic signatures (ERES)
- 210 /211 – cGMP for pharmaceuticals
- 600/610 – Covers biological products (eg, mAbs, vaccines, and blood)
- 820 – Quality System Regulation (QSR) for medical devices



# Drug Manufacturing

| Drug Type              | Small Molecule Drug  | Large Molecule/ Biologic Drug   |
|------------------------|--|---|
| Example                | Aspirin                         | IgG Antibody                                 |
| Size                   | 180 Da   | 150 kDa   |
| Complexity Analogy     | Bicycle ~ 20 lbs<br>150 parts  | Private jet ~ 25,000 lbs<br>6,000,000 parts  |
| Process Flow Schematic |                                |    |
| Manufacturing Process  |                               |   |



# Challenges with Biologics Manufacturing

- Inherent biological variability
- Characterization of biological material
- Cell line development
- Process development

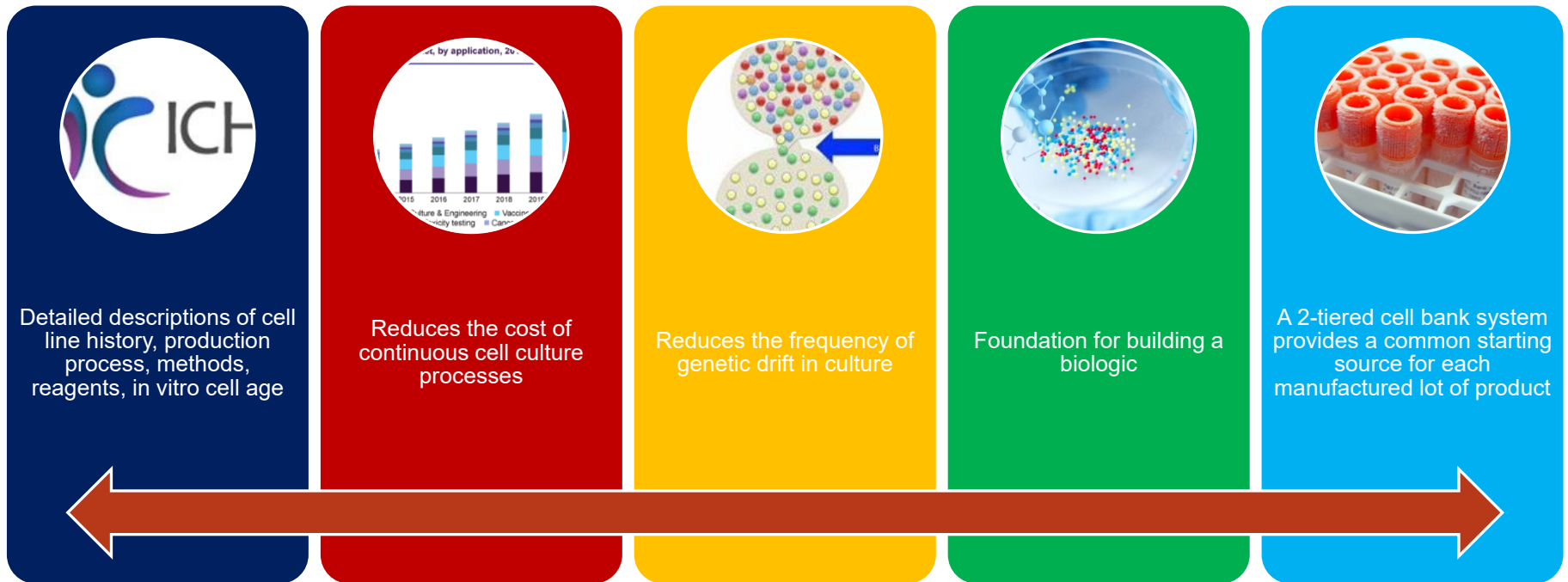
- Quality by Design (QbD)
- Robust Quality Management System (QMS)
- Validating processes
- Maintaining consistent product quality



- Raw material qualification
- Maintaining a clean hygienic manufacturing area
- Controlling environmental conditions
- Equipment maintenance
- Supply chain integrity

- Understanding guidelines
- Interpretation of guidelines
- Minimizing risks

# Importance of Cell Banking & Storage



# Cell Banking Market Drivers & Restraints

Global cell banking market is growing rapidly, but is challenged by regulatory climate and high costs

## Market Driver #1

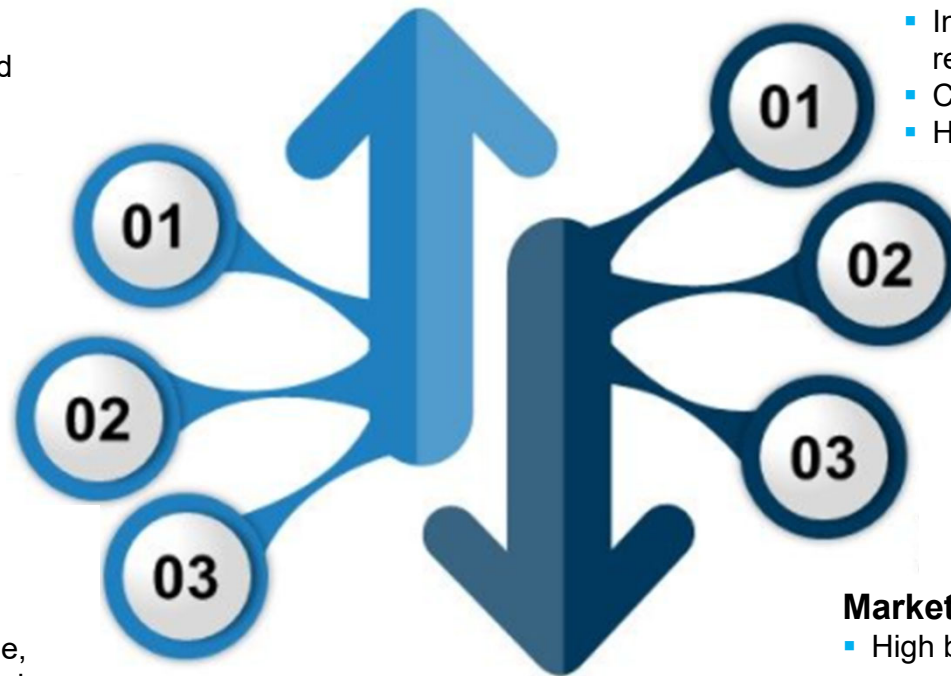
- Limited in-house storage and testing capabilities
- Full-service outsourcing

## Market Driver #2

- Improved operating efficiency
- Increased pipeline productivity

## Market Driver #3

- Increased expenditures on healthcare (biologics)
- Advancements in regenerative medicine, cell & gene therapy, and tissue engineering
- Novel cryopreservation technologies and surging research in cell line development



## Market Restraint #1

- Increasing regulatory stringency regulatory requirements
- Clonality documentation requirements
- Host cell line history traceability

## Market Restraint #2

- MCB & WCB quality control
- Increasing cell line testing demands
- Long-term continuity of production processes

## Market Restraint #3

- High barrier to entry due to operational costs
- Significant investment in infrastructure and QMS
- Complex multi-step processes

# ATCC – The Partner of Choice

- A pioneer in cell banking and storage
- Use of the most reliable and standardized procedures and equipment
- Provide critical starting materials for pharmaceuticals and biologics
- Trusted global source for cell authentication and uncompromised quality
- Avoid time and labor-intensive in-house production and eliminate associated risks and costs





# ATCC Quality Overview

## *ATCC Quality Management Systems*



- Maintain ISO 9001 certification across the broad organization
- ISO 13485 certification for synthetic standards, IVD test kits, and selected standards, controls and reagents
- Accredited for ISO 17025 and ISO 17034

# Gaithersburg MD cGMP Facility

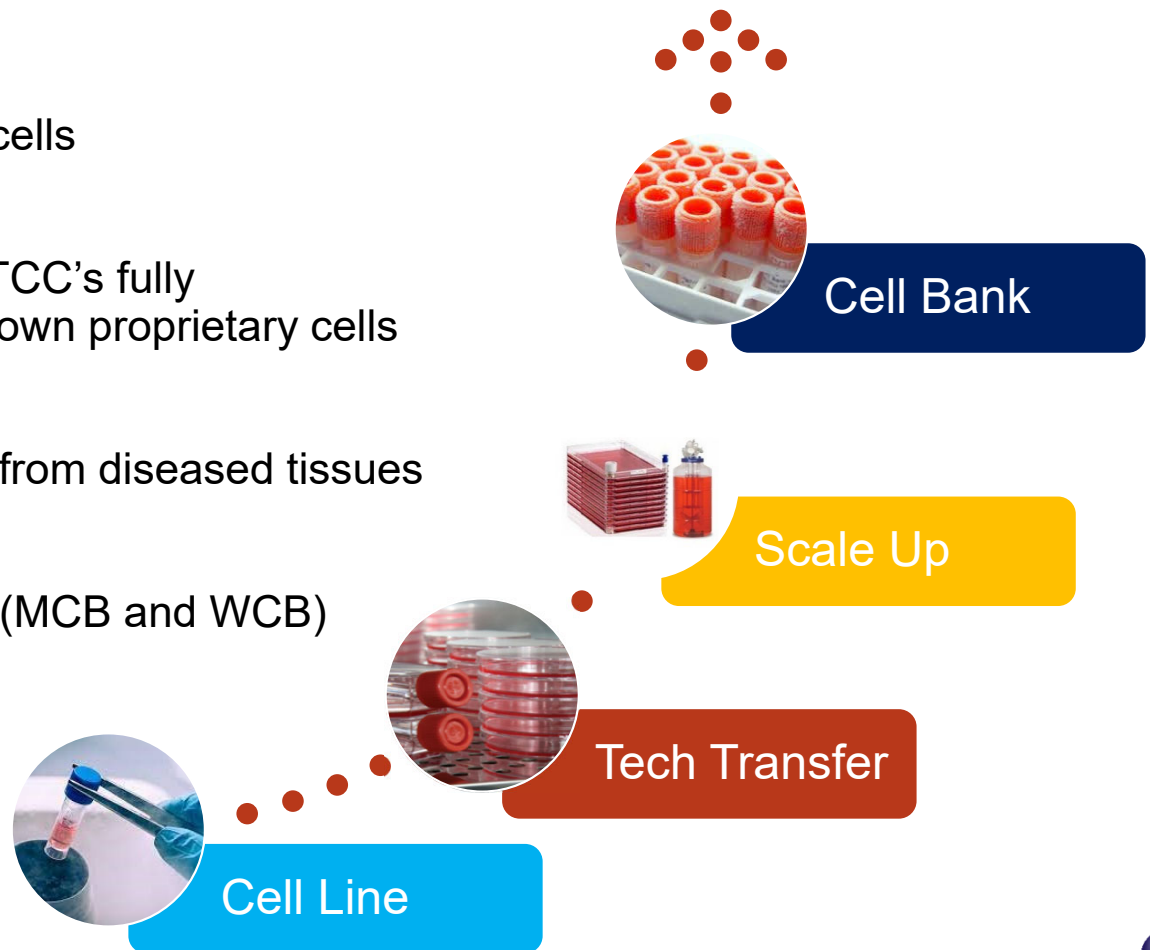
- Newly commissioned in 2021
- FDA 21 CFR part 11 compliant automated record keeping
- Our new purpose-built facility is the first to hold the distinction of being 21 CFR 600 and 610 compliant
- Examples of cGMP projects:
  - Expansion of mesenchymal stem cells, and production of exosomes (Pharma application)
  - MCB/WCB cell banks genetically modified CHO-K1 cell (Pharma application)
  - MCB/WCB KG-1A cells (Pharma application)



# Expert cGMP Manufacture

## Highlights

- Focus on Mammalian cells and stem cells
- Over 5,000 cell lines available from ATCC's fully authenticated collection -or- use your own proprietary cells
- Healthy cells, as well as cells derived from diseased tissues
- cGMP master and working cell banks (MCB and WCB)



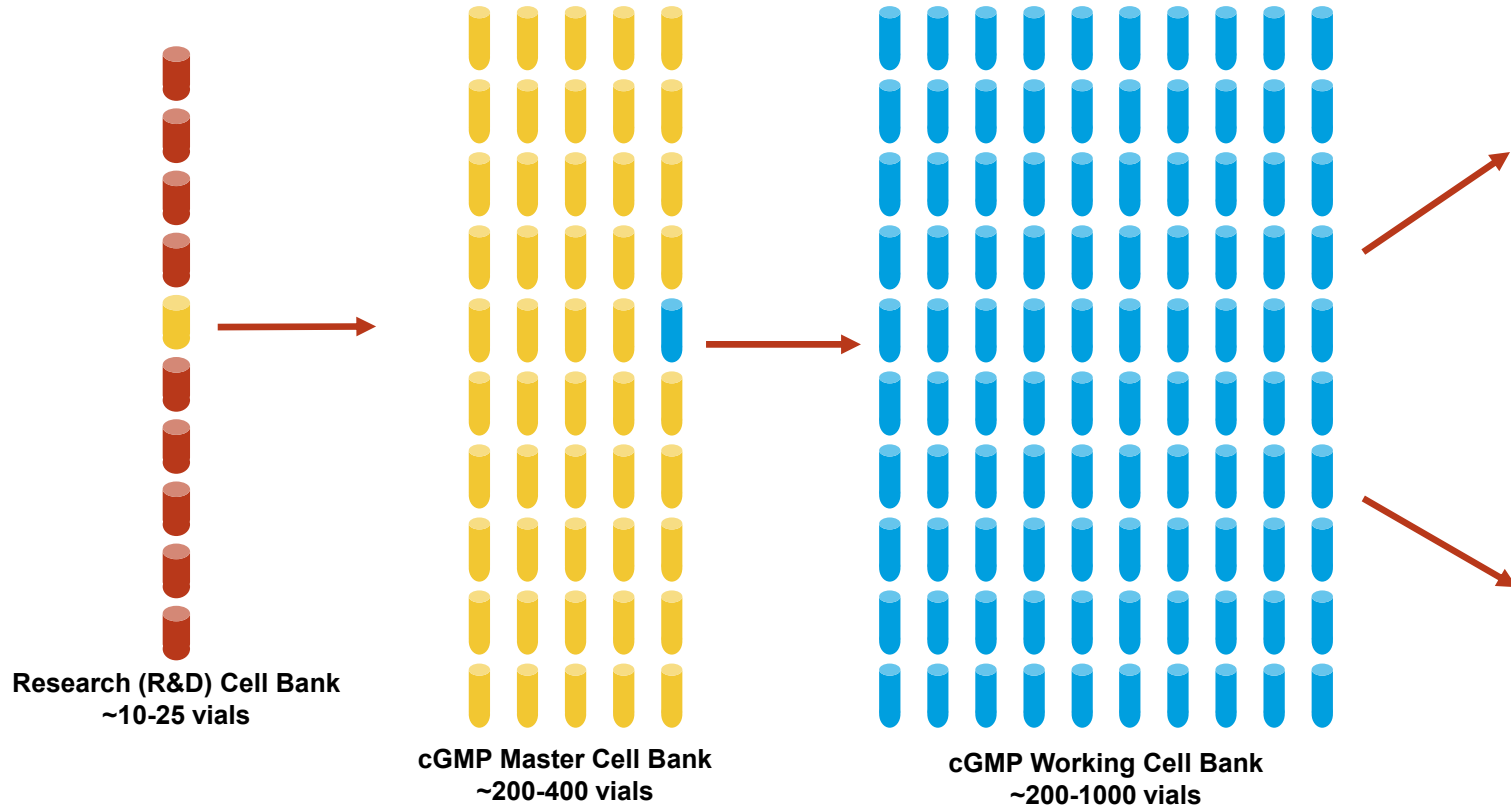
# Our Capabilities

|                     | cGMP  |  |
|---------------------|---|--|
| Compliance Standard | 21 CFR 600, 610   |  |
| Customers           | Biologics manufacturers<br>Assay developers (potency & toxicology)  | Human cells, tissues, and cellular and tissue-based product manufacturers (HCT/Ps) |
| Cell Types          | Mammalian cells<br>Stem cells<br>Primary cells  | Expansion of cells (CDU)   |
| Cell Bank Types     | <ul style="list-style-type: none"> <li>Production banks – cells will be used to make a “product” – produced in campaign “mode”</li> <li>Non-production banks - typically, bioassay banks – non-campaign – strict acceptance criteria</li> </ul>   |  |
| QC Release Testing  | <ul style="list-style-type: none"> <li>Mycoplasma testing (Direct/indirect &amp; PCR)</li> <li>Endotoxin testing</li> <li>Adventitious agents testing</li> <li>CO1 assay (interspecies testing)</li> <li>Sterility testing</li> <li>Virus panel</li> <li>Other tests as requested by customer and/or recommended for cell type</li> </ul> |  |





# cGMP Cell Banking at ATCC



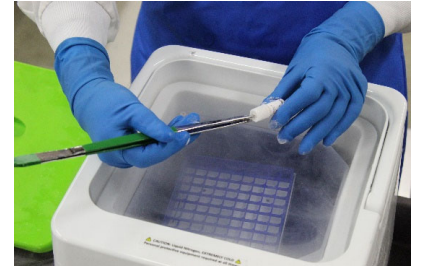
**Research (R&D) Cell Bank**  
~10-25 vials

**cGMP Master Cell Bank**  
~200-400 vials

**cGMP Working Cell Bank**  
~200-1000 vials

## Seed Stock Sources

- Over 5K ATCC cell lines
- Customer's proprietary cells



**cGMP Biorepository**  
Safe segregation of  
biological materials

# cGMP Biorepository

- Dedicated and validated units, with access restricted to cGMP-trained staff with QC and QA oversight.
- Tracking labels are supplied to ensure the proper segregation immediately upon receipt at ATCC.
- Separate storage boxes for each cell bank or multiple banks in one box (customer's option). Only one customer per storage box.
- In addition to cGMP-compliant storage we also offer ISO 9001:2008
- We have storage at LN<sub>2</sub>, -80°C, -20°C, and 2-8°C available
- Cell, microbe, protein, and nucleic acid storage options too
- Safe segregation of biological materials
- Cold-chain support and management
- On-call, after-hours personnel; 24/7 temperature monitoring
- Direct quality oversight of all unit entry and retrieval activities



# Summary

- GMP is important for consumer safety
- Ensures that products meet specifications and quality/regulatory standards
- Biologics manufacturing is complex and requires additional considerations
- Use authenticated cell lines with established pedigrees under validated cGMP cell banking procedures
- Preserve the integrity of biologics cell banks long-term with ATCC cGMP biorepository services
- For more information please visit:

**[www.atcc.org/cGMP](http://www.atcc.org/cGMP)**



# References

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- [https://commons.wikimedia.org/wiki/File:Harvey\\_W.\\_Wiley\\_%28masthead\\_picture%29.jpg](https://commons.wikimedia.org/wiki/File:Harvey_W._Wiley_%28masthead_picture%29.jpg)
- <https://www.crf-usa.org/bill-of-rights-in-action/bria-24-1-b-upton-sinclairs-the-jungle-muckraking-the-meat-packing-industry.html>
- <https://www.sciencephoto.com/media/1057609/view/sample-from-1937-sulfanilamide-poisoning-incident>
- <https://www.history.com/news/7-things-you-may-not-know-about-the-jungle>
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- Alf van Beem, CC0, via Wikimedia Commons, [https://seita.com.co/Descargas/Aplicaciones/APN\\_Aspirin\\_Crystallization.pdf](https://seita.com.co/Descargas/Aplicaciones/APN_Aspirin_Crystallization.pdf)
- [ICH Quality Guidelines \(Q5A - Q5E Quality of Biotechnological Products\)](#)



# Thank you and questions



*Coming attractions:*

**hTERT-immortalized Primary Epidermal Cells: Key Components in Complex Toxicological Models**

July 28 at 12:00 PM EST

Kevin Grady, BS

**Skin Microbiome: Considerations, Applications, and Future Directions**

August 11 at 12:00 PM EST

Tasha Santiago-Rodriguez, PhD

**Proteomic Studies Using Tumor-derived Organoids (Title TBA)**

September 22 at 12:00 PM EST

Chia-Fang Tsai, PhD

For more information about ATCC cGMP services:

**[www.atcc.org/cGMP](http://www.atcc.org/cGMP)**

