A Unified Product Structure for Innovative Product Development and Manufacturing of Reference Biomaterials in a Regulated Environment: The MicroQuant™ Case Study

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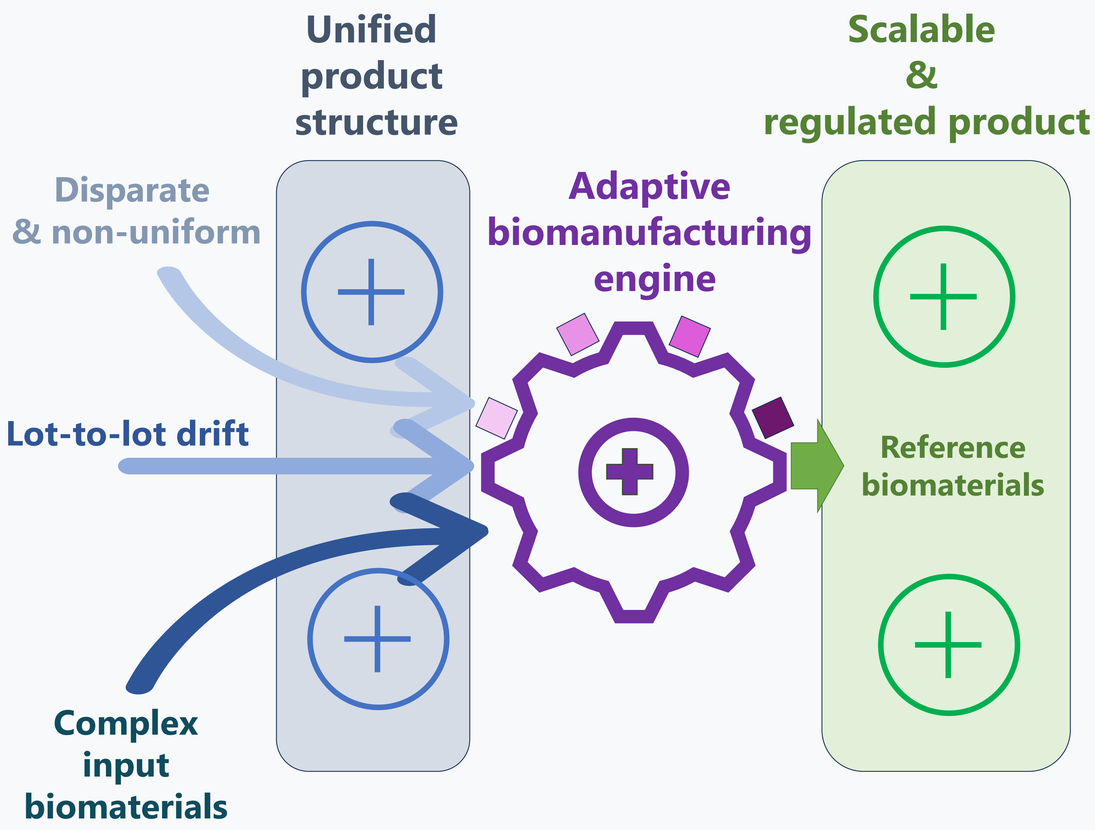
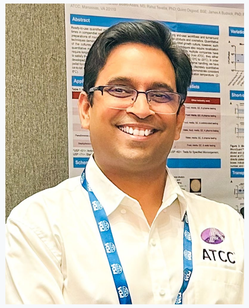
Introduction

Problem:

- Translating novel biomaterials from R&D to regulated manufacturing is **slow and risky**
- Misalignment between innovation, development, manufacturing, and quality leads to:
  - **Process inefficiencies**
  - **Variability and rework**
  - **Delayed timelines and regulatory risk**





Rahul Tevatia, PhD
I am a Senior Scientist in the Cryobiology Department at ATCC. I have PhD in Chemical and Biomolecular Engineering and over 10 years of experience in solving complex problems in regulated biotech development and biopharmaceutical manufacturing.

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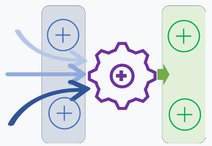
Introduction | Methods | Results | Discussion

Materials & Methods



Quality-by-design control strategy

Critical quality attribute (CQA) and critical process parameter (CPP) mapping
Aligned with ICH Q8(R2), Q9, Q10, and Q11 as well as ISO 17034, ISO/IEC 17025, and ISO 9001

CONTROL STRATEGY — In-process monitoring · Specification limits · Risk-based decision gates · Deviation management · Change control

	Stage 1	Stage 2	Stage 3	Stage 4	Stage 5	Stage 6
CQAs	• Organism identity (ATCC® Seed-stock: Passage zero) • Supplier-certified traceability • Inventory management	• Sterility of growth-medium and buffers • Target colony forming units (CFU) • No contamination	• Pellet integrity index • Water activity (AW < 0.2) • CFU/pellet is in intended use	• CFU/vial release criterion • Strain identity confirmed • Pellet specification met	• Certified property value • Shelf-life statement • Identity statement	• Temperature-controlled transit • Customer feedback • Customer complaints assessment
	Material procurement →	**Culture & preparation** →	**Lyo-casting & packaging** →	**Quality control** →	**Value assignment (CoA)** →	**Distribution** Customer relation management (CRM)
CPPs	• Seed-stock storage (Liquid N_2 vapor phase) • Growth-media composition • Lyo-formulation • Expiry / usable window	• Incubation temperature & time • Aseptic handling / dispensing	• Lyophilization profile • Inert gas purge & fill • Cold-chain storage (4°C)	• Incubation conditions • MALDI-TOF / 16s rRNA / ITS • Plate count enumeration method	• Statistical analysis (GUM) • Values reported: Mean, St dev., 95% CV • Identity confirmation • CoA issuance	• ISTA-aligned pack configuration • Domestic: 4°C packaging overnight shipping • International: dry ice shipment

QMS DOCUMENTATION — MasterControl SOPs / Work Instructions · Batch Records · Training & competence records · Calibration (IOQ) · CAPA / deviations · ISO 17034 compliance

CQA – A physical, chemical, biological, or microbiological property or characteristic that should be within an appropriate limit, range, or distribution to ensure the desired product quality. (ICH Q8(R2))
CPP – A process parameter whose variability has an impact on a CQA and therefore should be monitored or controlled to ensure the process produces the desired product quality. (ICH Q8(R2))
Process bands represents the validated process of MicroQuant™ production (ATCC®, Germantown, MD) and QC-value assignment-distribution (ATCC® , Manassas, VA)

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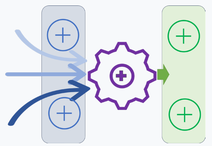
Results

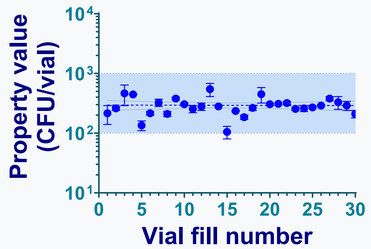


ATCC® MicroQuant™ (ATCC® 16404-LQ-PACK™)

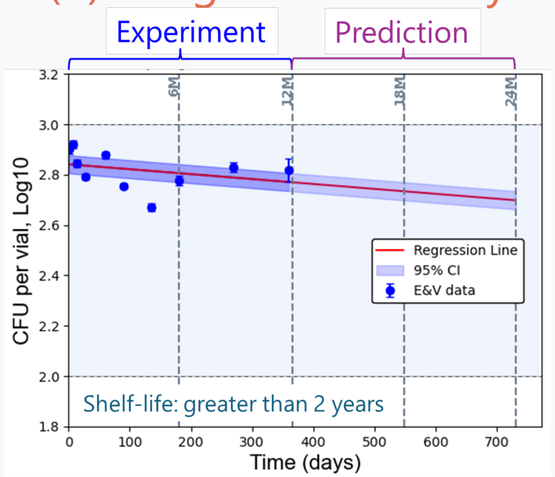
(A) Homogeneity

Random Vial Filling trend

Parameter	Best fit values	95% CI
Slope	-5.077	-11.82 to 1.66
Y-intercept (CFU/vial)	756	656 to 856
R^2 value	0.0456	
Deviation from zero	Not significant (p > 0.05)	

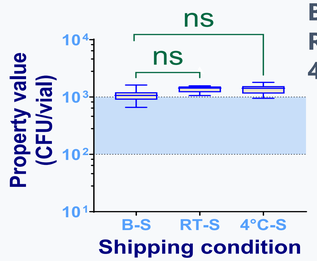


(B) Long-term stability



Storage temperature: 4±2°C
Testing temperature: 22.5±2.5°C (room temp.)

(C) Transport stability



B-S: Before shipping
RT-S: Room temperature shipping
4°C-S: 4°C Shipping

Shipping studies shows no significant difference (p > 0.05) in the property value of MicroQuant™ products before and after shipping.

ISTA aligned pack configuration

Domestic
2-8°C shipping

International
-80°C shipping

(D) Scalable Model

Replicable blueprint for ISO 17034-compliant RM development and manufacturing

	1. Feasibility Scope & Design	2. Execute & Verify Characterize batch	3. Production Scale & Release	4. Monitor Post release
Homogeneity Between / within units	Not Applicable	✓	✓	✓
Stability Long-term / shelf-life	Not Applicable	✓	✓	✓
Transport Domestic & International	Not Applicable	✓	Not Applicable	✓
Use stability End-user stability	Not Applicable	✓	✓	Not Applicable
Characterization Property value & traceability	✓	✓	✓	✓
Uncertainty GUM propagation	Not Applicable	✓	✓	✓

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(A) Unified product structure enabling translation of novel biomaterials into regulated manufacturing

R&D-Manufacturing Misalignment

Innovative product development

- **Rapid iteration**
- **Novel architectures**
- **Limited regulatory structure**

- Process inefficiencies
- Batch variability
- Extended timelines
- Regulatory risk

Regulated Manufacturing

- **Precision & consistency**
- **Compliance driven**
- **Change-averse systems**

Unified Product Structure ATCC® MicroQuant™

Validated, Scalable Manufacturing

MicroQuant™ Reference Biomaterials

- 36 authenticated & quantitated products
- Easy-to-use QC format
- No culture time

- **Homogeneity**
- **Stability**
- **Traceability**
- **Batch comparability**

A cohesive product structure bridges innovation and compliance, enabling scalable, accredited production of next-generation reference biomaterials.

(B) R&D to Manufacturing: Process and Quality Maturation

R & D	Manufacturing
Process Control Exploratory, operator-led	**Process Control** Critical Quality Attributes (CQA) / Critical Process Parameter (CPP)
Documentation Lab notebooks, presentations	**Documentation** Quality Management System (QMS) SOP/WI
Quality Assurance (QA) Spot check, no ISO framework	**Quality Assurance (QA)** ISO 17034 / 17025 / 9001
Stability & uncertainty Not characterized	**Stability & uncertainty** GUM budget, shelf-life
Batch release Not required	**Batch release** Quality Control (QC) + Certificate of Analysis (CoA)