

# BUILDING IT IS THE EASY PART

CASSS VIRTUAL SUMMIT · MAY  
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*Lilly*

# The Promise

## **>\$350 billion pledged US manufacturing and R&D across the industry**

14+ companies since April 2025. The largest capital deployment in pharmaceutical manufacturing history.

## **Every investment is a tech transfer**

New API synthesis, new fill-finish, new OSD capacity. Processes that worked at established sites must now work at sites that do not yet exist.

## **The capital is committed. The approach has not changed.**

We are about to execute the largest wave of transfers in pharmaceutical history using the same playbook that produces CRLs 74% of the time.

## **THE PATTERN**

**The biggest preventable barrier  
between a medicine and a  
patient is not clinical data. It is a  
facility that fails inspection.**

# What the Data Shows

**202 Complete Response Letters (2020–2024)**

**74% Manufacturing Deficiencies**

**>50% PAI Failures**

FDA could not complete the inspection  
or found conditions requiring remediation

Source: FDA openFDA CRL Archive (July 2025); Pharma Manufacturing; RSM US

# Where the Findings Cluster

## Process Validation

PPQ too small or compressed.  
Cleaning validation untested  
at the receiving site.

## Data Integrity

Audit trail gaps. Access controls.  
These findings increased  
in frequency.

## CMO & Supplier Oversight

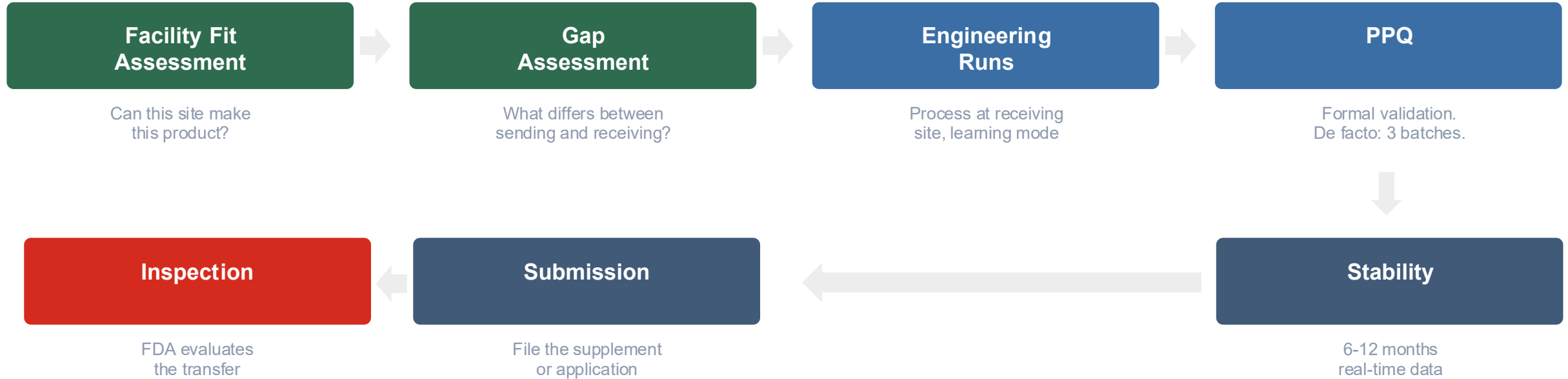
Inadequate oversight of CDMOs.  
Quality agreements that existed  
on paper only.

## Personnel Qualification

Trained on paper.  
Competency not demonstrated  
under real conditions.

**85% of small biopharma outsource API. 77% outsource finished dose. A single facility CRL triggers a domino effect.**

# Anatomy of a Technology Transfer



**Every step is designed around the sending site's process. The inspection evaluates the receiving site's reality.**

## What Transfers on Paper

Methods and specifications  
Process parameters

## What Does Not

Tacit process knowledge  
Site-specific interactions

# Reality of a Technology Transfer

Process Performance	Deviations & CAPAs	Training	Quality System
<b>THE PROTOCOL</b>			
3 PPQ batches all meet spec ✓	Zero open deviations ✓	All personnel completed training ✓	SOPs approved and in place ✓
<b>THE INSPECTION</b>			
More variability than sending site ⚠	2 open investigations root cause pending ⚠	Competency not demonstrated ⚠	Untested under real pressure ⚠

Same transfer. Two realities. The protocol passed. The inspection did not.

## **THE UNCOMFORTABLE TRUTH**

**Nothing about the current wave suggests we have changed the approach. The capital is new. The playbook is not.**

# A Playbook That Has Not Changed

## Qualification Lots

### WHAT WE DO

3 PPQ batches at the receiving site.  
De facto standard.

### WHAT WE COULD DO

Use the 2,000 batches already manufactured.  
Process knowledge exists.  
The framework cannot use it.

## Stability

### WHAT WE DO

6–12 months real-time data at the new site.  
Same formulation.  
Same container closure.

### WHAT WE COULD DO

Predictive models from historical data.  
Higher confidence.  
Faster.

## Analytical Transfer

### WHAT WE DO

Full revalidation at every receiving site.  
Months of work.

### WHAT WE COULD DO

Verification, not validation.  
Same method, same platform.  
Weeks, not months.

**ICH Q8 introduced enhanced process understanding in 2009. We are still re-proving what we already know.**

# The Replication Paradox

We solved the scale problem through platform replication. The question is whether the regulatory framework has caught up.

## 1 Platform replication is the manufacturing innovation.

The ability to build the same facility anywhere and produce the same product at the same quality. That took decades to achieve. It is a genuine accomplishment.

## 2 The regulatory framework does not recognize it.

The fifth identical site is qualified the same as the first. Three PPQ batches. Twelve months of stability. Full analytical revalidation. Demonstrated knowledge is treated as irrelevant.

## 3 The framework selects against novelty.

Because replication carries the same regulatory burden as innovation but less technical risk, the rational choice is always to replicate. Innovation becomes impossible when replication is this inefficient.

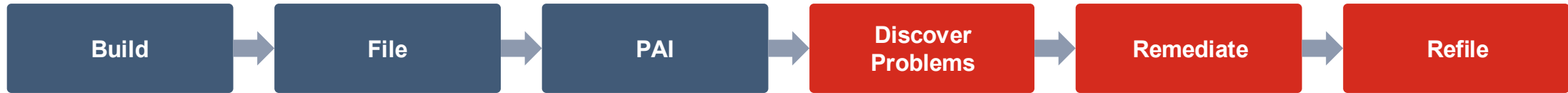
**If we want this wave to advance manufacturing, we have to make replication fast enough that companies have room to try something new. But speed needs to be balanced with strategic and scientific approaches to validation and stability.**

## **WHAT WOULD BE DIFFERENT**

**Inspection readiness is not something you achieve at the end. It is something you design from the beginning.**

# PreCheck and the Decoupled Model

## OLD MODEL



Coupled. Sequential. One shot.

## PRECHECK MODEL



**Two independent clocks. Use the window to build operational maturity.**

PreCheck is a pilot. Seven slots. The principle is right. The scale question is open.

# Three Shifts

Not incremental improvements. Fundamental changes.

## INDUSTRY

### Transfer as Translation

**We own this.**

Treat knowledge transfer as the deliverable. The batch record is the transcript, not the translation.

Invest in it. Resource it. Stop pretending documentation is sufficient.

FDA does not need to change anything for us to do this better.

## INDUSTRY + FDA

### Predictive Evidence Over Physical Proof

**Neither side can do this alone.**

Industry must generate the data: platform knowledge, multivariate models, predictive stability.

FDA must create clear pathways for sponsors to use accumulated process knowledge in tech transfer filings.

ICH Q12 started the conversation.

It needs to go further, faster.

## REGULATORY FRAMEWORK

### Make Replication Efficient

**The framework drives this.**

If FDA recognizes platform replication as a demonstrated, characterized system, the fifth site qualifies differently than the first.

PreCheck is the start. It needs to scale toward platform-level recognition, not just individual facility assessment.

**CHANGING THE PLAYBOOK IS HARDER**

**Let's not waste this >\$350 billion  
opportunity.**

Thank  
you