TECHNOLOGY TRANSFER BEST PRACTICES IN THE ERA OF COVID-19

Charlie Maher
Global Director, Process & Manufacturing Technology
CAI

Eric Felz
Head of Facilities Engineering and Validation QMS
Takeda

TECHNOLOGY TRANSFER → PRODUCT REALIZATION

The goal of technology transfer activities is to **transfer product and process knowledge** between development and manufacturing, and within or between manufacturing sites **to achieve product realization**.

This knowledge forms the basis for the **manufacturing process**, **control strategy**, **process validation** approach and ongoing **continual improvement**.

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TECH TRANSFER VARIABLES

Lifecycle Phase

Development - Clinical

Clinical - Commercial

Commercial - Commercial

Regulatory Domain

- Same
- New

SU & RU Site Type

Internal - Internal

Internal - External

External - Internal

External - External

SU & RU Site No.

- One - One
- One - Many
- Many - One

State of Product & Process Knowledge

- In development
- Out of date
- In people's heads
- Change in process
- Change in equipment
- Change in materials
- Change in scale
- Change in language
- Change in people

COVID-19: TECH TRANSFER CHALLENGE

- Large number of new products at once
- Compressed timelines
- Novel technologies
- Many startup companies launching their first product
- Focus on re-purposing existing facilities
- High visibility

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PLAN FOR TECH TRANSFER SUCCESS

Planning Milestone

- Program Charter
- Technology Transfer Report from Sending Unit
- Plant Fit Assessment (facility, process equipment, lab, warehouse, etc.)
- Overall Risk Assessment
- Project Plan

Knowledge Management Milestone

- Lab Runs
- Product & Process Characterization
- Control Strategy
- Detailed Process Risk Assessment
- Detailed Analytical Risk Assessment
- Cleaning
- Packaging
- Stability
- EHS Requirements

Process Readiness Milestone

- Equipment qualification
- SOPs approved
- Personnel trained
- Supply chain ready to support
- Batch records approved
- Analytical methods qualified
- Engineering Runs results
- Changes needed
- Documentation completion
- EHS Review

Process Qualification Milestone

- PQ Runs performed, evaluated
- Deviations
- Change Control
- Reports Drafted

Program Handover

- Transition to ongoing manufacturing operations
- Continuous process verification
- Technology Transfer Program Assessment and Lessons Learned

PLAN FOR TECH TRANSFER SUCCESS

- Partnering Strategy
- Partner Selection
- Due Diligence
- Program Charter
- Team Formation
- Risk Assessment
- Tech Transfer Project Plan

1. STRATEGY: PARTNER FOR SUCCESS

- Rapid access to technology, capacity, markets, supply chain
- Approach:
  - Define your partnering strategy
    - In-house: Activities that are a core source of value creation or essential to product quality
    - Outsource: Activities that can be done better/faster/cheaper by others
  - Successful partnerships:
    - Commitment to a common vision
    - Complementary strengths
    - Culture and values ‘fit’
    - Respect and trust
    - Defined responsibilities (business & quality)
    - Governance

1. PARTNER FOR SUCCESS

bpl Biotest CSL Behring LFB octapharma

CoVIg-19 PLASMA ALLIANCE

Working Together to Fight COVID-19 with Immunoglobulin (Ig) Therapy

Takeda Better Health, Brighter Future

Global Plasma Leaders Collaborate to Accelerate Development of Potential COVID-19 Hyperimmune Therapy

April 6, 2020

- Partnership brings together world-leading plasma companies to focus on developing and delivering a hyperimmune immunoglobulin in the global fight against COVID-19

Osaka, JAPAN, and King of Prussia, PA, USA – April 6, 2020 – Biotest, BPL, LFB, and Octapharma have joined an alliance formed by CSL Behring (ASX:CSL/USOTC:CSLLY) and Takeda Pharmaceutical Company Limited (**TSE:4502/NYSE:TAK**) to develop a potential plasma-derived therapy for treating COVID-19. The alliance will begin immediately with the investigational development of one, unbranded anti-SARS-CoV-2 polyclonal hyperimmune immunoglobulin medicine with the potential to treat individuals with serious complications from COVID-19.

Oxford Covid-19 Vaccine Shows Promise In Early Stage Trial, Generates 'Double Defence' Against Coronavirus: Report

by IANS - Jul 16, 2020 11:13 PM

UNIVERSITY OF OXFORD

AstraZeneca

moderna

Moderna Partners with Takeda and the Government of Japan to Supply 50 Million Doses of mRNA Vaccine Against COVID-19 (mRNA-1273) to Japan

October 29, 2020

MHLW and Takeda will import and distribute mRNA-1273 in Japan starting in the first half of 2021

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Oct. 29, 2020-- Moderna, Inc. (Nasdaq: MRNA), a biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines to create a new generation of transformative medicines for patients, today confirmed that the Ministry of Health, Labour and Welfare of Japan (MHLW) and Takeda Pharmaceutical Co., Ltd (NYSE: TAK) have agreed to purchase and distribute 50 million doses of mRNA-1273, Moderna's vaccine candidate against COVID-19, to support Japan's aim of providing vaccines to the Japanese public as soon as

Humanigen and Lonza Announce Collaboration to Expand Manufacturing of Humanigen's COVID-19 Therapeutic Candidate Lenzilumab

Published: Sep 15, 2020

Lonza Humanigen

Sept. 15, 2020 05:00 UTC

Catalent Signs Agreement With Johnson & Johnson to be US Manufacturing Partner for Lead COVID-19 Vaccine Candidate

Catalent, Inc. recently announced a collaboration with the Janssen Pharmaceutical Companies of Johnson & Johnson, whereby Catalent's Biologics business unit will accelerate availability of manufacturing capacity and prepare for large-scale commercial manufacturing of Johnson & Johnson's lead vaccine candidate for COVID-19 at its facility in Bloomington, Indiana.

REGENERON

Back

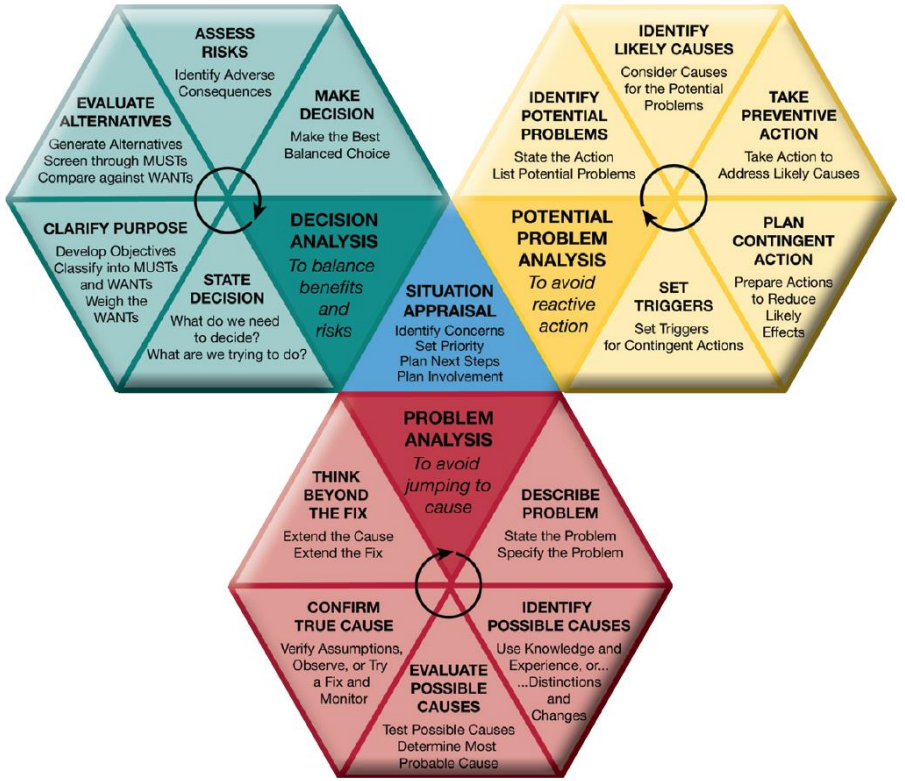
August 19, 2020 at 1:00 AM EDT

REGENERON AND ROCHE COLLABORATE TO SIGNIFICANTLY INCREASE GLOBAL SUPPLY OF REGN-COV2 INVESTIGATIONAL ANTIBODY COCKTAIL FOR COVID-19

2. PARTNER SELECTION

- Approach:
  - Identify partner requirements (cross-functional)
  - Develop decision support tool
  - Partner search
  - Short list for detailed due diligence

  - No ‘good’ partner options?
    - Consider phased approach
    - Consider modular solutions



https://www.kepner-tregoe.com/

3. DUE DILIGENCE

- Approach:
  - Go to site & meet the team
  - Supplier qualification process
  - Process-focused gap assessment
  - Walk the facility, watch operators
  - Review batch records & CAPAs

- Input into decision support tool
- Select a partner

4. PROGRAM CHARTER

- High-level coordinating document – agreed by all parties
- Key elements:
  - Business objectives
  - Intended markets
  - Regulatory strategy
  - Schedule
  - Budget
  - Resources
  - Governance
  - Stage-gate reviews

5. TEAM FORMATION

- Approach:
  - Tech Transfer is a team sport
  - Cross-functional
  - Both SU & RU represented
  - Ensure team members have bandwidth
  - Led by Tech Transfer PM

PM	PROCESS	FACILITY	OPERATIONS	QUALITY, COMPLIANCE & REGULATORY
• Tech Transfer PM • Knowledge Management	• CMC • Process Engineering • Analytical Methods	• Facility & Utility Eng • CQV	• Manufacturing • Supply Chain • Procurement	• Quality • Regulatory • EHS

6. TECH TRANSFER RISK ASSESSMENT

- Cross-functional Deep Dive
  - SU: Product/Process Info – CQA, CPP, CMA
  - RU: Programs, capabilities, facility, personnel
  - Detailed risk assessment for each functional area
  - RA Report → foundation for Tech Transfer Project Plan

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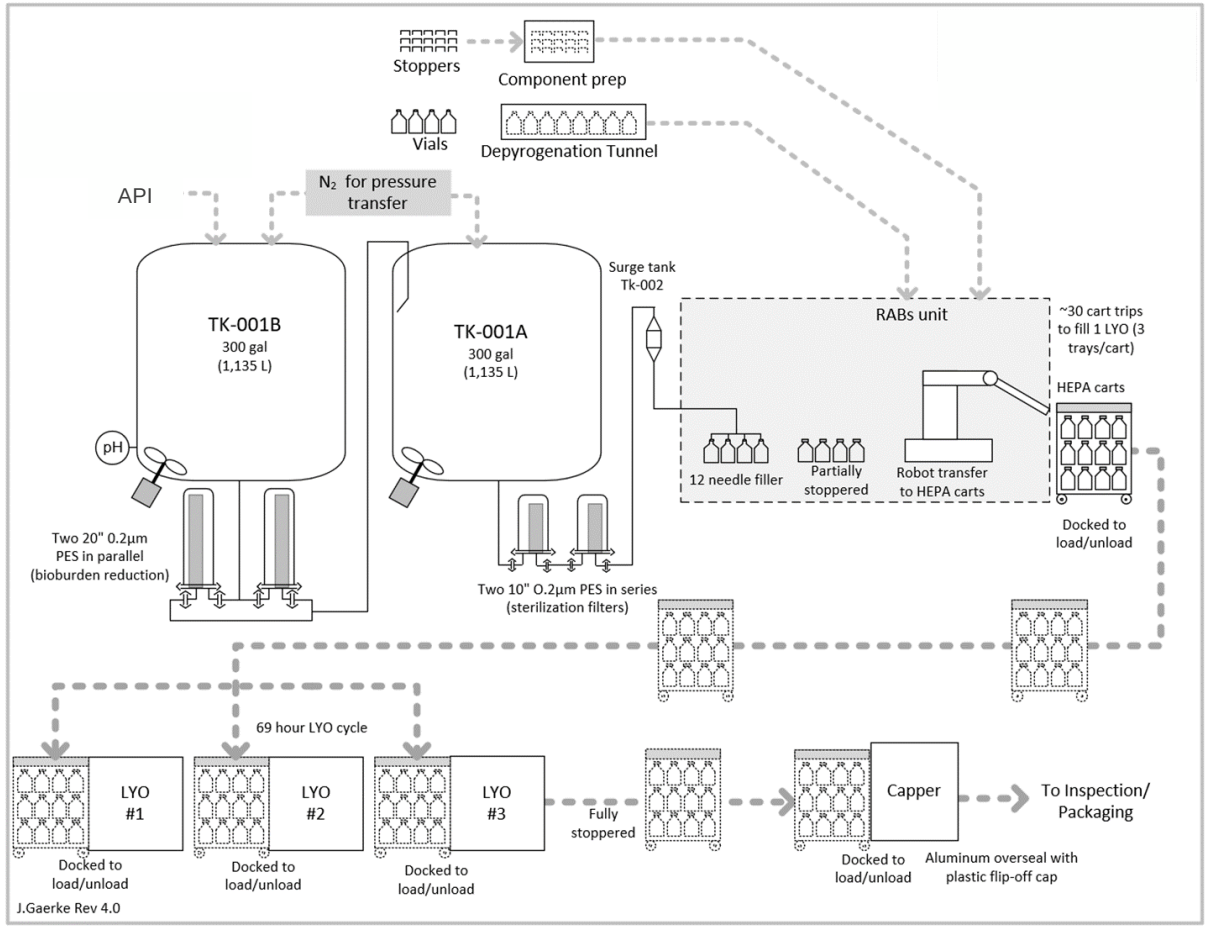
6. TECH TRANSFER RISK ASSESSMENT

- Example: Process Equipment
  - System/equipment design comparability
  - As-built P&ID review
  - CIP/COP/SIP comparability
  - Maintenance and calibration records
  - Detailed list of required modifications
  - Small differences → big impacts
    - Mixing impeller
    - Product filter
    - CIP cycle / agents
    - SIP sequence
    - Filling needles
    - Vial size
    - Lyophilizer configuration



7. TECH TRANSFER PROJECT PLAN

- “The plan”
  - Detailed project schedule
  - Work breakdown structure
  - Resource plan
  - RACI
  - Risk register
  - KPIs & reporting
  - Issue resolution
  - Continuous improvement

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END IN MIND:

PRODUCING QUALITY MEDICINES TO MEET PATIENT NEEDS

QUESTIONS?

Charlie Maher
Global Director, Process & Manufacturing Technology
CAI
Charliemaher@cagents.com

Eric Felz
Head of Facilities Engineering and Validation QMS
Takeda