

## **PROCESS DESIGN: SCIENTIFIC CONCEPT TO ENGINEERING REALITIES**

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## **BIOTECH PROCESS DESIGN**

- Cell Culture – Dr. Anton Edmund
- Clarification – Raj Beri
- Purification – Chris Lim
- Facility and Equipment Design – Judy Bodette



# PROCESS DESIGN?

LAB → PRODUCTION



# PROCESS DESIGN?

LAB → PRODUCTION

- Time
- Money
- Science
- Regulation
- Politics



**WITH  
MORE  
TIME,  
\$,  
AND  
KNOW-  
HOW**



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# ADD REGS AND POLITICS

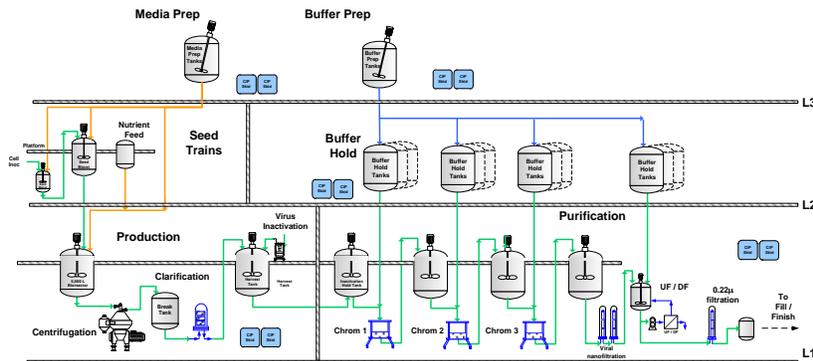
# ADD REGS AND POLITICS



# REAL WORLD PROCESS DESIGN

- What goes right
- What goes wrong
- What you can do about it

## ACTUAL EXAMPLE



## PROBLEM AREA

- Bioreactor used microcarriers
- Process did not use centrifuge prior to filtration
- Cleaning Standard Changed
- Stray bits of microcarrier now seen in equipment
- No CIP process to eliminate