

26<sup>TH</sup> ANNUAL



26<sup>TH</sup> LCI CONGRESS  
OCTOBER 22-25, 2024

# Going IPD in Biopharma Project

Frank Wilde, Genentech, Inc.  
Andres Robles, DPR Construction  
Stephen George, Southland Industries

SURFING THE WAVE OF LEAN DESIGN AND CONSTRUCTION

24-Oct-2024

# Overview of Project and IPD Setup

Frank Wilde - Genentech/Roche





# Introduction

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Considered the founder of the biotech industry (1976), Genentech has been delivering on the promise of biotechnology for more than 45 years.

## Genentech

- Founded in 1976
- Headquartered in South San Francisco, CA
- 13,500 employees in the U.S.



## Roche

- Founded in 1896
- Headquartered in Basel, Switzerland
- 90,000 employees in over 100 countries

### Frank Wilde

Senior Project Manager  
Project Delivery  
Global MSAT & Engineering  
Genentech / Roche



### Problem Statement:

Deliver the biomanufacturing facility project OSUT as first IFoA project for Genentech/Roche

# Genentech/Roche Project Execution Strategies

- The Roche/Genentech contracting strategy is based on evaluating project complexity and business impact
- In Europe typically **lump-sum or EPCMQ**<sup>1</sup> not-to-exceed contracts, with Roche holding all contracts
- In the US simple and low impact projects could be **Design-Bid-Build**
- Other US contracting formats include EPCM, or split A/E-CM-Q etc.
- US projects with higher complexity and higher potential business impact could benefit from the value created by **IFD**<sup>2</sup> **behaviors**
- IFoA contracts can be used in between these two bookends

→ In summary, we evaluate each project on it' s merits

<sup>1</sup> Engineering Procurement Construction Management Qualification

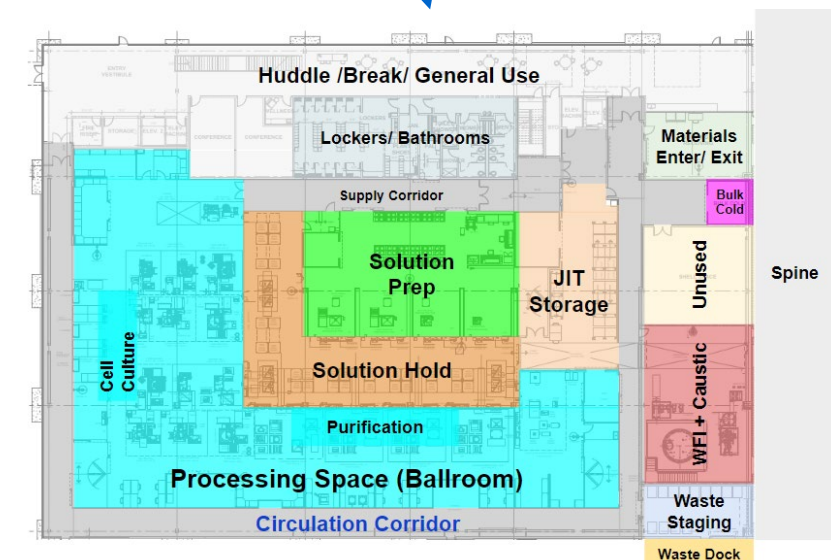
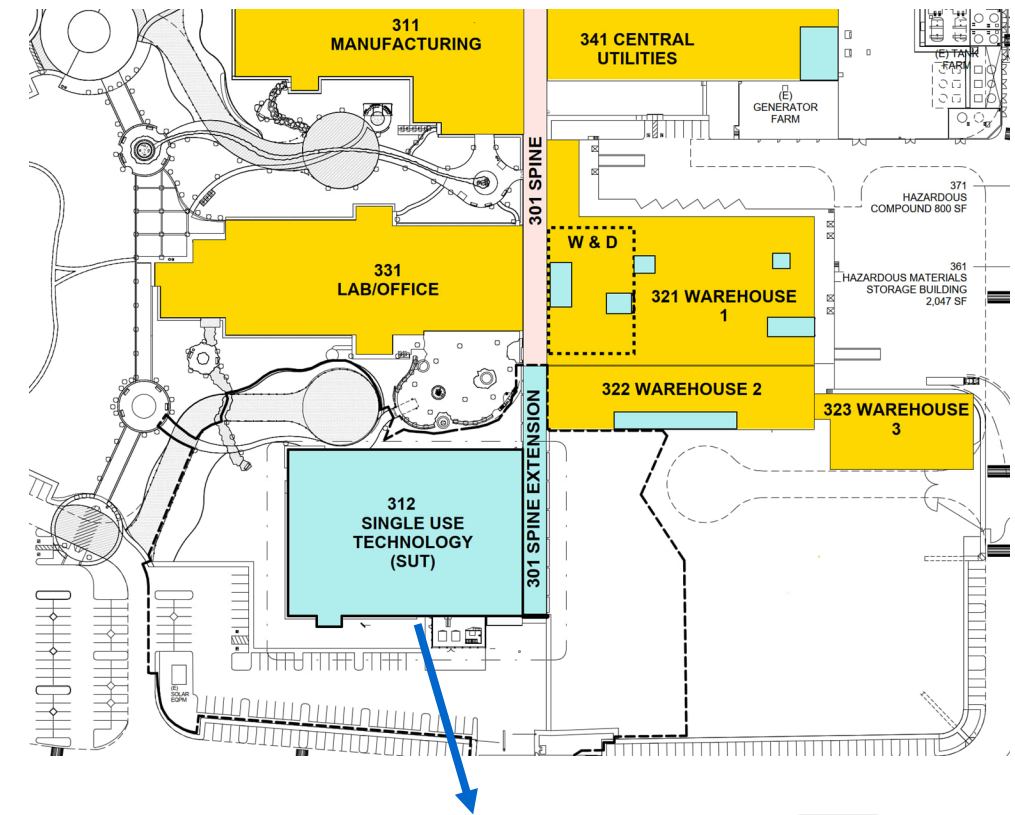
<sup>2</sup> Integrated Form of Delivery

## Background to Roche / GNE Approach on IPD

- Multi year approach examining the best contract forms, types of agreement to execute work, change to internal standard documents and procedures
- IFoA at OSUT part of a deepening initiative that started in 2021 to execute larger scale work with IFoA / IPD
- Combined with prototyping digital methods, updating technology used to increase work output predictability, shorten execution time, increase quality in delivery
- No one size fits all, we are a global engineering organization, have to flex to local markets conditions in a variety of countries
- IPD elements now form part of our execution methods in all locations
- Brings the entire team together to deliver on one goal

# OSUT Project Overview

- **OSUT** Oceanside Single-Use Technology Project
- **Location:** Oceanside, CA
- **Project Driver:** Expand commercial drug substance capacity
- **Timeline:** Project Initiation Dec-2021 to Handover Jan-2025.  
Groundbreaking Feb-2023 to TCO<sup>1</sup> Aug-2024 (19 months)
- **Investment:** ~\$280M (incl. start-up and qualification)
- **Scope:** Build a “copy/ paste of the process core”, at the same scale, from the SSF B50 Clinical Supply Center (CSC) to allow rapid and seamless tech transfer of products from the CSC for clinical and commercial production. OSUT will be 6x2kL SUB capable (4 x 2kL installed), 1x Purification train.



<sup>1</sup> Temporary Certificate of Occupancy



# OSUT Project Highlights enabled by IPD






If a partnership created a highly collaborative cross-discipline environment to:

- Install, test & commission the process systems in parallel to the building construction
- Target LEED Platinum (Gold is confirmed)
- Install propane heat pumps for HHW and process cooling
- Install a photovoltaic facade system



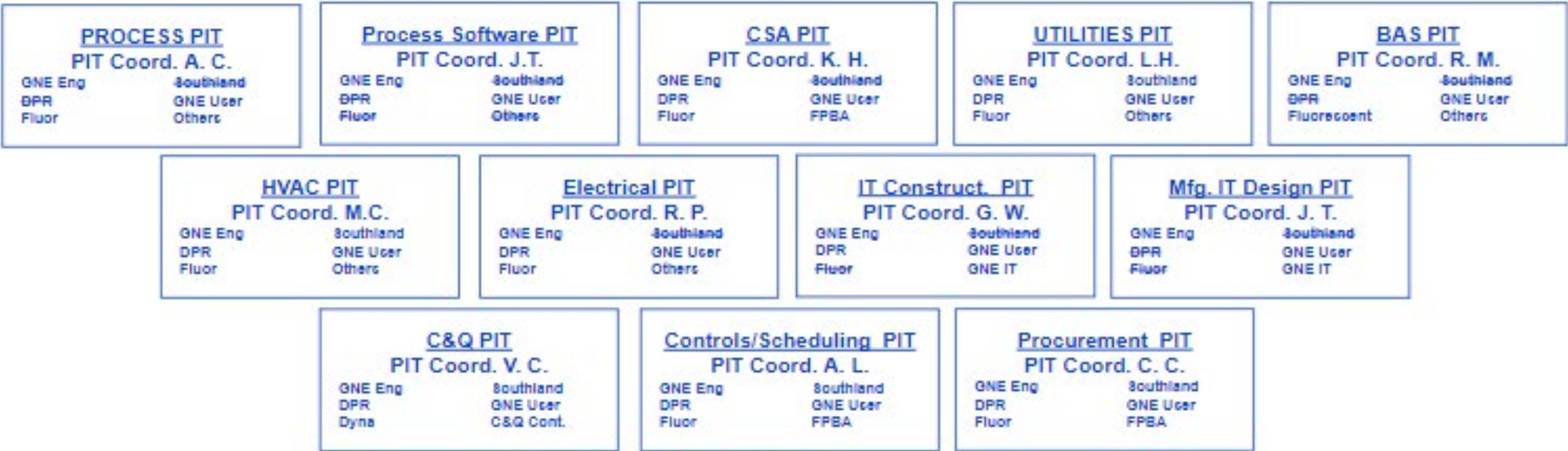
# OSUT Project IPD Organization

- **5 IPD partners** in an Integrated Form of Agreement contract (IFoA)
- **Genentech** owns all of the manufacturing scope (process, automation, GMP C&Q) issuing ~240 PO's and service contracts
- **IPD partners** own the building scope (CSA, electrical, utilities, HVAC, BAS, security)

	SUT Process & Auto.	CSA/Bldg. Design	CM / GC	Mechanical (D&B)	Electrical (D&B)
<b>IPD Partner Level - IFoA</b>					
<b>Scope</b>	SUT equipm., incl. automation & IT	CSA, architecture, landscaping,	All other building & constr. trades	HVAC, plumbing, ss piping, utilities	Electrical, I&C, BAS, low voltage
<b>Design</b>	GNE with Fluor & Emerson	FPBA with specialist consultants/designers	n/a (constructability)	Southland inhouse and Fluor for hyg. piping (tbc)	Dynalectric with Genesis
<b>Procurement</b>	GNE with Fluor	n/a (review & oversight)	DPR	Southland	Dynalectric
<b>Construction</b>	Suppliers & DPR erection support	n/a (review & oversight)	DPR with suppliers	Southland with suppliers	Dynalectric with suppliers
<b>C &amp; Q</b>	Commissioning of all GMP systems, comm. of special non-GMP systems tbd *	n/a (review & oversight)	Commissioning of non-GMP systems *	Commissioning of non-GMP systems *	Commissioning of non-GMP systems *
<b>Permitting / Certifications</b>	Leed certification, Building Owner	Architect of Record, Building permitting	Certificate of Occupancy	Engineer of Record	Engineer of Record

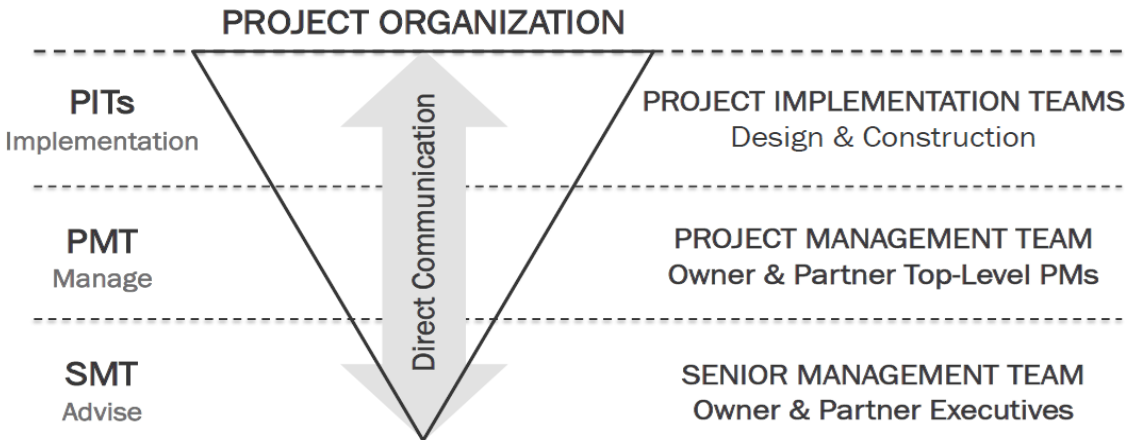


# OSUT Ways of Working- PITs



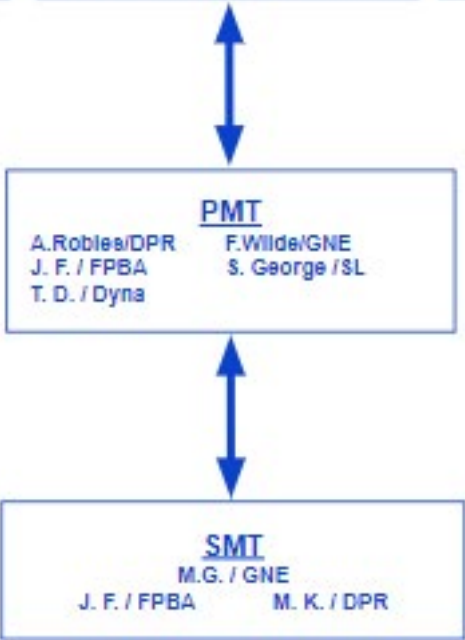
## THE INTEGRATED ORGANIZATION

Clear responsibility • Rapid communication • Workflow



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# OSUT IPD Contract

Remember to distinguish delivery methods vs. contract types ...

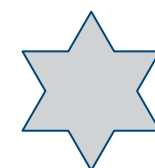
<u>Project Delivery Method</u>	<u>Contract Type</u>
Design/Bid/Build, CM as Agent	Guaranteed Maximum Price (GMP)
Integrated Project Delivery (IPD)	Integrated Form of Agreement (IFoA)

The intent of an IFoA is shared risk, shared rewards amongst multiple contract parties, with highlights ...



## Contract Price

Includes cost of work, project contingency, allowances, and the “Incentivized Compensation Layer”



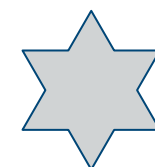
## Incentivized Compensation Layer (ICL)

Shared profit pool amongst contract parties; profit removed from cost of work, including profit in labor rates



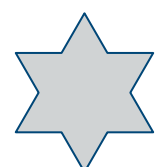
## Contingency

The base contract price typically includes contingency to cover unknowns. Contract terms and teams should align on proper utilization of contingency.



## Achievement Events

Profit is paid to non-owner parties when pre-defined milestones called Achievement Events in the project schedule are met.



## Project Management Team (PMT)

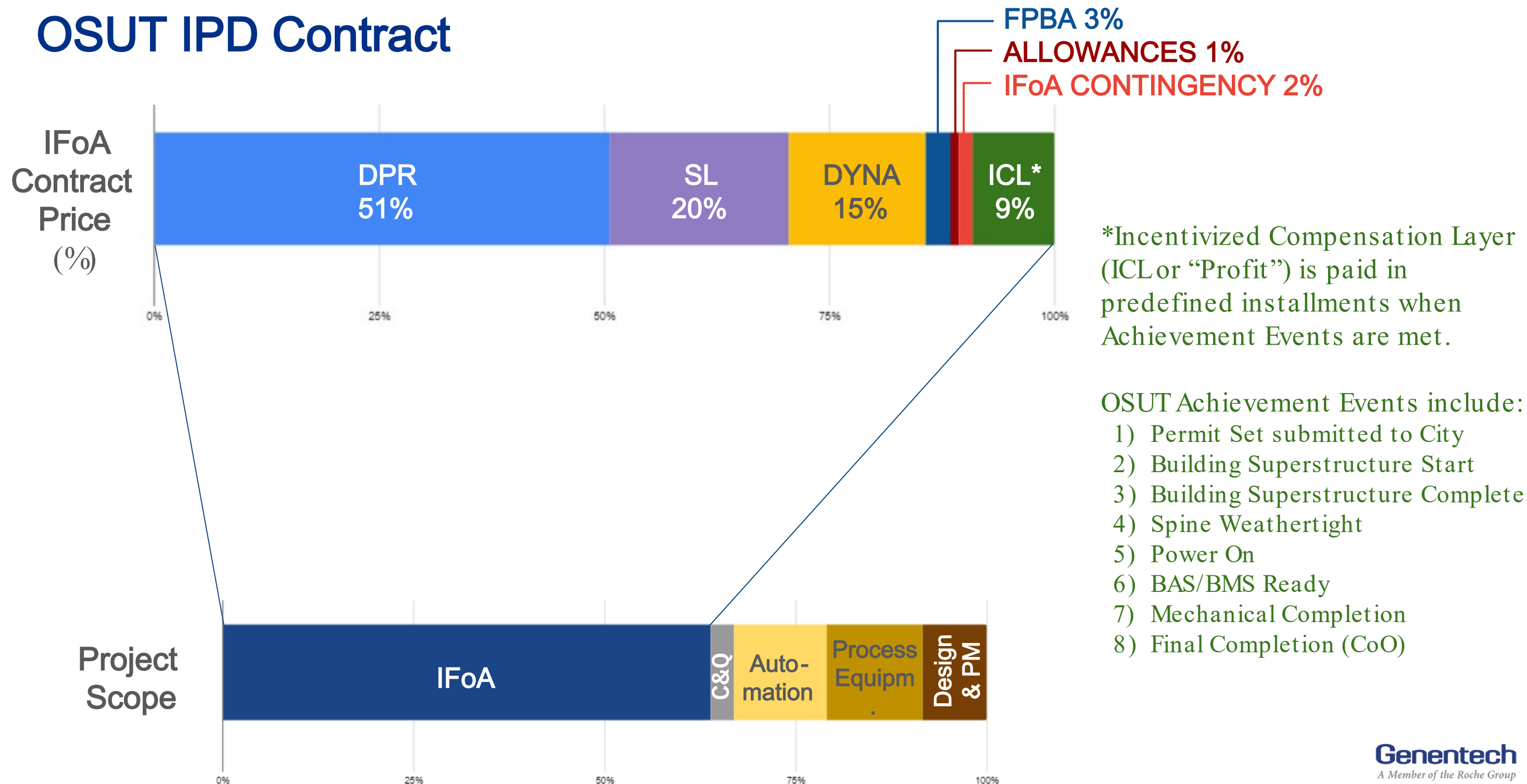
PMT will provide management-level guidance for planning, design, and construction to achieve the project reqs; chaired by a person designated by the Owner.



## Senior Management Team (SMT)

When PMT cannot agree on project decisions, the SMT serves as an escalation point. Each contract party has a vote, and the Owner has additional votes.

# OSUT IPD Contract





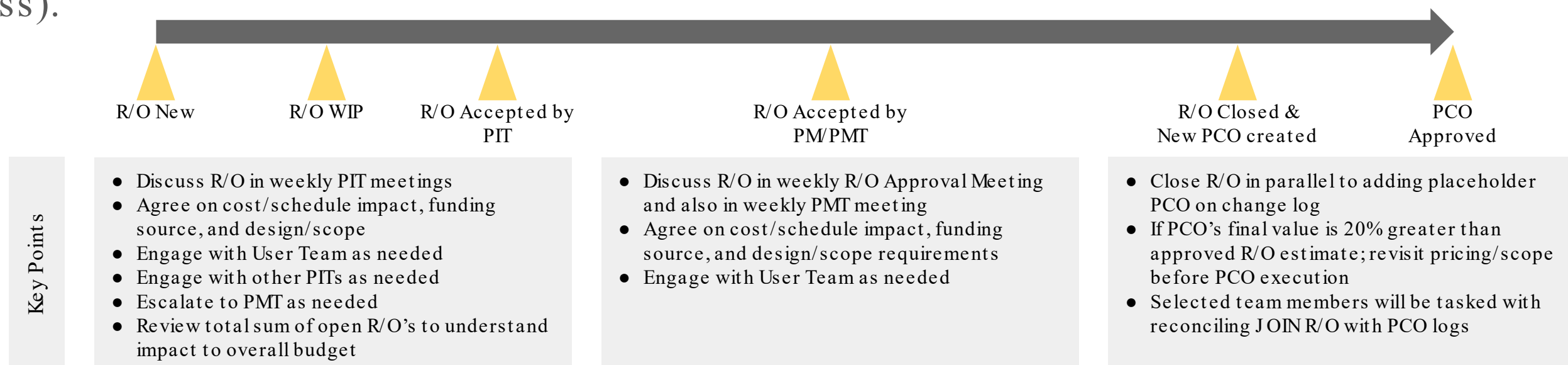
# OSUT Target Value Delivery (TVD)

## What is Target Value Delivery?

“A disciplined management practice to be used throughout the project to assure the facility meets the operational needs and values of the users, is delivered within the allowable budget, and promotes innovation throughout the process to increase value and eliminate waste.”

- Lean Construction Institute

For OSUT, the team agreed on a process workflow to help drive TVD by gaining team consensus across IFoA partners on design or scope decisions at the front end (where on typical projects design decisions are made in silos and schedule/cost impacts are identified during the change order process).



R/O = Risk/Opportunity  
PCO = Project Change Order

# Perspective from General Contractor going IPD

Andres Robles - DPR



# Introduction



\$15.5B

Value of Life Sciences  
Projects Successfully  
Completed by DPR

#1

PHARMACEUTICAL  
CONSTRUCTION  
Since 2017

DPR ranked #1 in  
pharmaceutical construction  
by ENR magazine every year  
since 2017.

#1

DPR's rank on BD+C's 2023  
list of top science and  
technology sector  
construction firms

Andres Robles  
Project Executive  
Life Sciences Core Market  
DPR Construction





# Set-up from IFoA GC Partner



- ~60% of cost of work completed directly by IPD Partners
- Over 40 subcontractors and one key designer on traditional lump-sum contracts

# Re-aligning communications and changing behaviors

- Challenge the traditional Owner-GC-Subcontractor dynamics
- Rethink the decision-making process (Cluster/PIT teams)
- Internal/external alignment on desired project outcomes



# Pros & Cons from GC in IFoA to a conventional GC setup

## *Pros*

- Early construction start
- Increased productivity on fieldwork execution
- High level of transparency on project costs
- Innovation was rewarded
- Target value delivery created budgetary benefits
- Fewer change orders and RFIs

## *Cons*

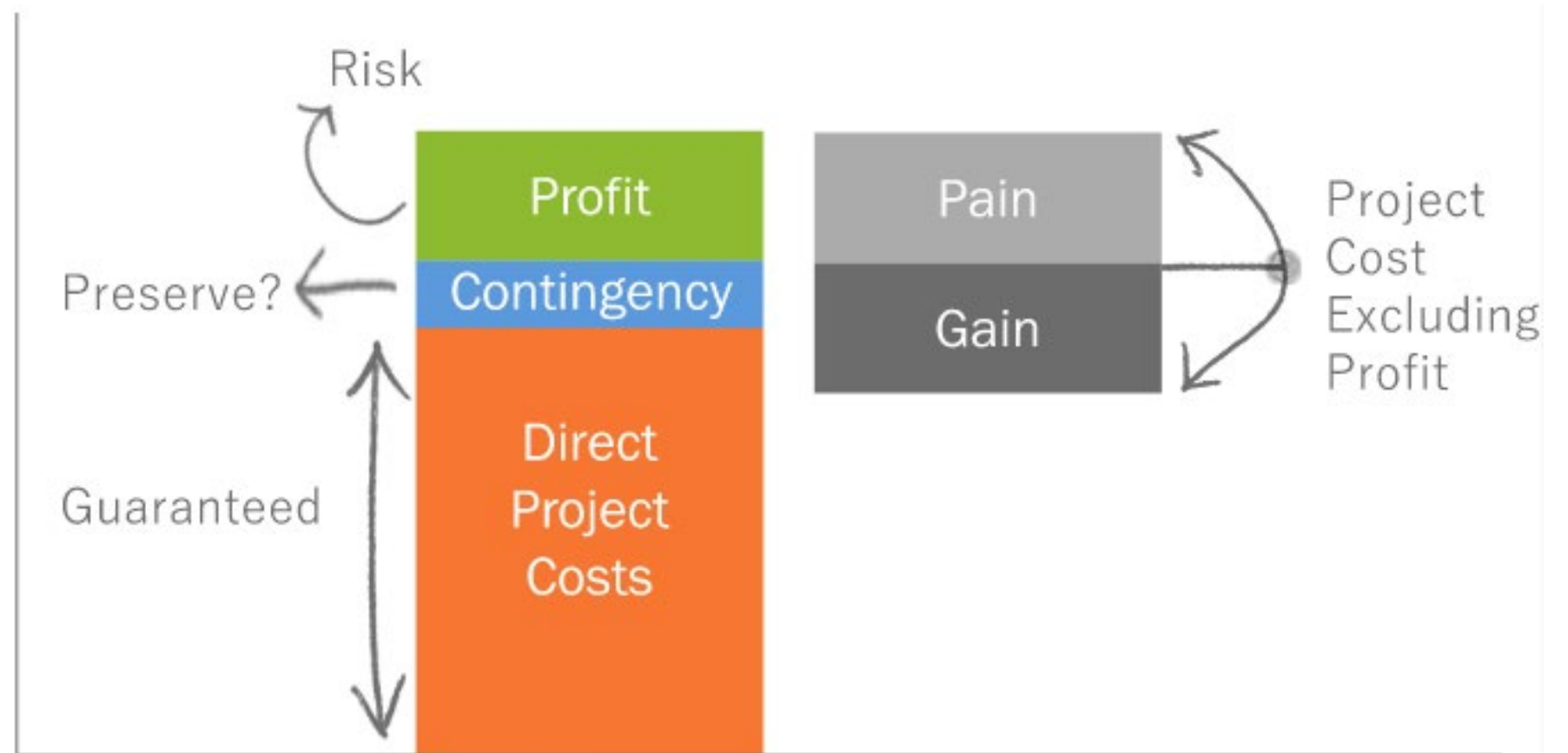
- Each partner taking on additional risk based on the performance of each individual
- Group decision-making can slow the process
- Additional staff needed on both the owner and contractor side
- cGMP projects tend to be very prescriptive. This limits the team's opportunities to generate budget/schedule reduction solutions





# Cost & Schedule view from IFoA

- Over 5% on total cost of work due to field productivity increases
- Over six weeks of schedule delays absorbed while maintaining key owner validation dates
- Sustainability goals for the project exceeded with little budget impact



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# Perspective from Subcontractor going IPD

Stephen George - Southland



# Introduction



**Stephen George**  
Project Executive

As an MEP building system expert, Southland Industries provides integrated, full lifecycle solutions that optimize the design, construction, operation, and efficiency of buildings.

Through collaborative partnerships with our clients and the collective expertise of our people, we create premier environments and future-ready spaces where communities and business can thrive.



**#21** ENR Top 600  
Specialty Contractors

**#26** Consulting-Specifying  
Engineer MEP Giants  
2023

Great Place to Work®  
Certified

Lean Construction  
Institute (LCI)  
Founding Member

**#4** Mechanical Contractor





# Set-up from IFoA Trade Partner



- DB HVAC (In-House, Copy/Paste)
- DB Plumbing (In-House)
- DB Dirty Utilities (In-House)
- DB Clean Utilities (Subcontracted)
- 85% of Contract Value Self Performed

# Construction Coordination - Prioritizing Efficiency



- It's a Culture, Not a Checklist
- What is Best For the Project Goals
- Simple Changes Matter
  - Pathways into the Building
  - Group Layout / Inserts
- Shared Resources / People



# Pros & Cons From a Trade Partner Perspective

## *Pros*

- Collaboration Contractually Supported
- Reduction of Paperwork Waste
- Group Goal on Budgets

## *Cons*

- Invent Every Wheel As We go
- Design Flow Interruptions
- Risk with cGMP Process Layouts





# Project Owner Summary and Way Forward

Frank Wilde - Genentech/Roche





# Owner's Project Outcome & Lessons Learned

- IPD gives flexibility on the scope distribution, supports the interest of all parties to “Get it Done!”
- IPD can help drive challenging schedules and to keep target budgets
- Owner team needs to be adequately set up, covering all disciplines
- Changing the client / contractor relationship is challenging for owner teams
- When things fall behind or uncomfortable the “IPD democracy” can be challenging
- Continual training, helps prevent falling back to transactional contract methods
- Project success always goes back to how the team works and IPD can further improve outcomes

## Genentech/Roche Way Forward with IPD

- We believe that high performing teams will deliver the best results:
  - Team alignment to a common set of objectives is fundamental
  - Highly collaborative behavior generates innovation and flow
  - Shared risk and reward creates ownership
  - IFoA/ IPD puts a collaborative framework / operational structure around the team
- IPD is one of the tools that enables these characteristics
- Consider the application on each project based on potential to add value

Thank you for your attention



We are happy to answer any questions that you may have...

# Contact Us

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**Frank Wilde**

Genentech, Inc.

wilde.frank@gene.com

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**Andres Robles**

DPR Construction

andresr@dpr.com

**Stephen George**

Southland Industries

sgeorge@southlandind.com





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Thank you for attending this presentation. Enjoy the rest of the 26<sup>th</sup> Annual LCI Congress!