

24TH ANNUAL



24TH LCI CONGRESS
OCTOBER 18-21

LCI Manufacturing Ecosystem: Welcome

October 20, 2022

LEAN GUMBO: THE RIGHT INGREDIENTS FOR PROJECT SUCCESS



Flow of Meeting

- Welcome
- Owner Call to Action (~30min)
- EPCM Response and Further Call (~30min)
- Breakout 1 (~30min) *(then 10min Break)*
- Breakout 2 (~30min)
- Wrap Up – Next Steps, Plus/Delta (~30min)



LCI Manufacturing Ecosystem Purpose

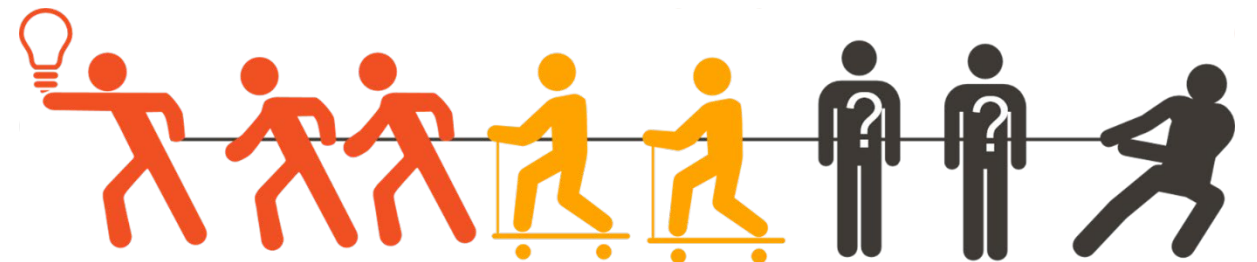
To align our efforts and work together towards a common goal and aligned strategy focused on

- maintain/increasing value
- reducing waste
- effective/efficient problem solving

...in pursuit of collective, faster success for all involved.

- A personal/company/community commitment to improving how we do our work
- Understanding group Owners' commonality and how do owners streamline/simplify
- Build engagement/sponsorship within full supply chain

(move Small L players to Big L partners; engage them to pull in No L's to make small L's)



Promoters

Provide vision to the LCI Manufacturing Ecosystem effort. Help people see WHY we want them to go on the journey

- what is in it for them
- assist in removing roadblocks
- helping with resources

- ❖ Owners sponsor Ecosystem
- ❖ EPCMs sponsor with Trades/Vendors

Community at Large

Listen, Learn, Contribute to the conversation at the level that makes sense for them

Includes:

- Lean Coaches/Champions
- Project Team members Executing LPD
- Company Leadership looking to learn not drive

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LCI Manufacturing Ecosystem: Call to Action

George Cusick, Merck
Michael Greening, Genentech
Jeffery Long, Genentech

October 20, 2022

LEAN GUMBO: THE RIGHT INGREDIENTS FOR PROJECT SUCCESS



Why Must Manufacturing Industry Change

- Internal challenges:
 - Need to increase spending in R&D to deliver unmet medical needs (new modalities)
 - Transfer spend from manufacturing to R&D by reducing manufacturing costs
- External challenges:
 - Patient/Customer needs
 - Price pressures and supply chain
 - Competition
- Company broad response:
 - Roche “3 to 5 times more patient benefit at 50% less cost to society”
 - Merck “help protect one billion more lives by being the best at supplying innovative and affordable medicines and vaccines”
 - Other Manufacturing Owners in the room: Share your Call to action in the breakouts
- Capital delivery must improve!

How is the Manufacturing Industry Responding

- Tighter controls and expectations from senior leadership
 - Safety First - zero accidents, emotional safety, wellness
 - Quality Always - zero defects
 - Lower capital cost targets versus historical benchmarks (Roche 15%, Merck 20%, others?)
 - Increased predictability on schedule to nameplate capacity
 - Sustainable construction technology throughout construction lifecycle (e.g. how much energy used to construct a facility)
- Owner project delivery response to internal and external pressures
 - Increase productivity (design & construction has lagged manufacturing significantly)
 - Realize benefits of collaboration to deliver efficiency - break the historical mode
 - Maximize standardization/productization where possible (opportunity for this group)

Project Delivery Thoughts on Meeting the Challenge

- Increase Productivity/Eliminate Waste:
 - Prefabrication (Merck seeking 80% offsite by 2025)
 - Laydowns..etc
 - Standardize non-IP across industry e.g. CIP skids, utilities
 - Automate repetitive activities in design and construction
 - Flow - 5S, Kanban, Tact Planning, JIT - applies to both design and construction
 - Adopt a common set of go-to standards e.g. ASME BPE (why does each company need a set of standards and specs)
- Quality - Zero defects
 - Digital technology to drive design accuracy into first time right installations (e.g. Trimble, Doxel, AR, “Dusty Robot”, drone/3D etc)
 - ASME BPE - adopt is the go-to standard (why does each company need a set of standards and specs)

Project Delivery Thoughts on Meeting the Challenge

- Societal/Sustainability
 - LEED Gold desire on new facilities
 - Measure and create baseline, then reduce environmental footprint in design construction e.g. measure power draw during construction, recycling technology surplants trips?
 - Leveraging diverse and inclusive talent pools
- Safety
 - Designed for safe construction?
 - Eliminate productivity impact of poor safety conditions and behaviors
- Cost and Schedule
 - Change mindset to a collaborative style to enable the above (“Scramble in Golf - Best Ball”)
 - Will meet these if we do all of the above right
 - What opportunities are we missing

Owners CTA: Address the Common Enemy “Productivity” by Behaving as Industry Partners Where IP is Not Compromised

What Owners see now and what we need to change

We recognize the value of working collaboratively in an IPD environment. It is essential that each partner know their role to make the partnership work to realize best value and to create a healthy business environment for all team members. (ie – we all make money)

Over the past several months we have experienced the following challenges from an owner's perspective:

- Low demonstration of Lean IPD experience from GCs/CMs that we look to to drive value realization
- Little experience with IFOA contracts and high-performance teaming by all parties
- Not getting the GC/CM's A-team due to competition with other industries
- Shortage of workers to safely deliver projects

Honest Reflection by Owners and AE/CM/Trade Partners Enables Us to Identify Opportunities

GES Expedition25

Vision: Safely and effectively deliver >\$15B in capital to enable 1B more patients served.



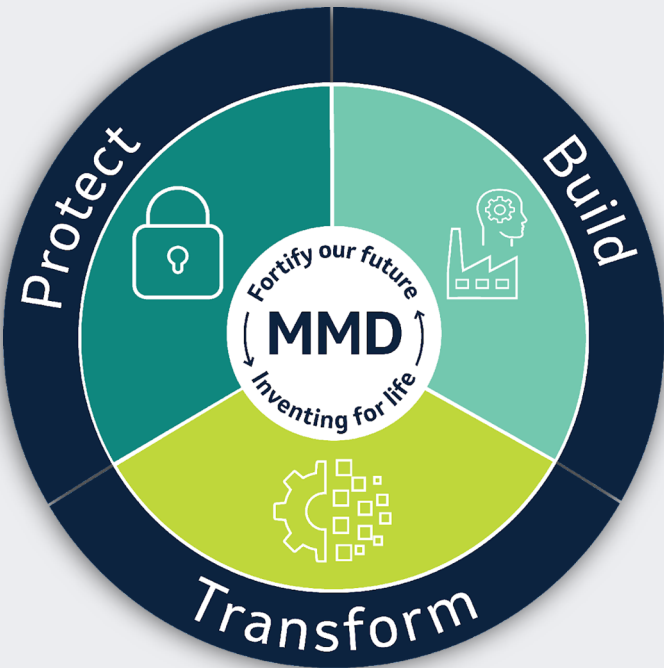
Fortify our Future



Ways of Working:
Mindsets and Behaviors



Inventing for Life



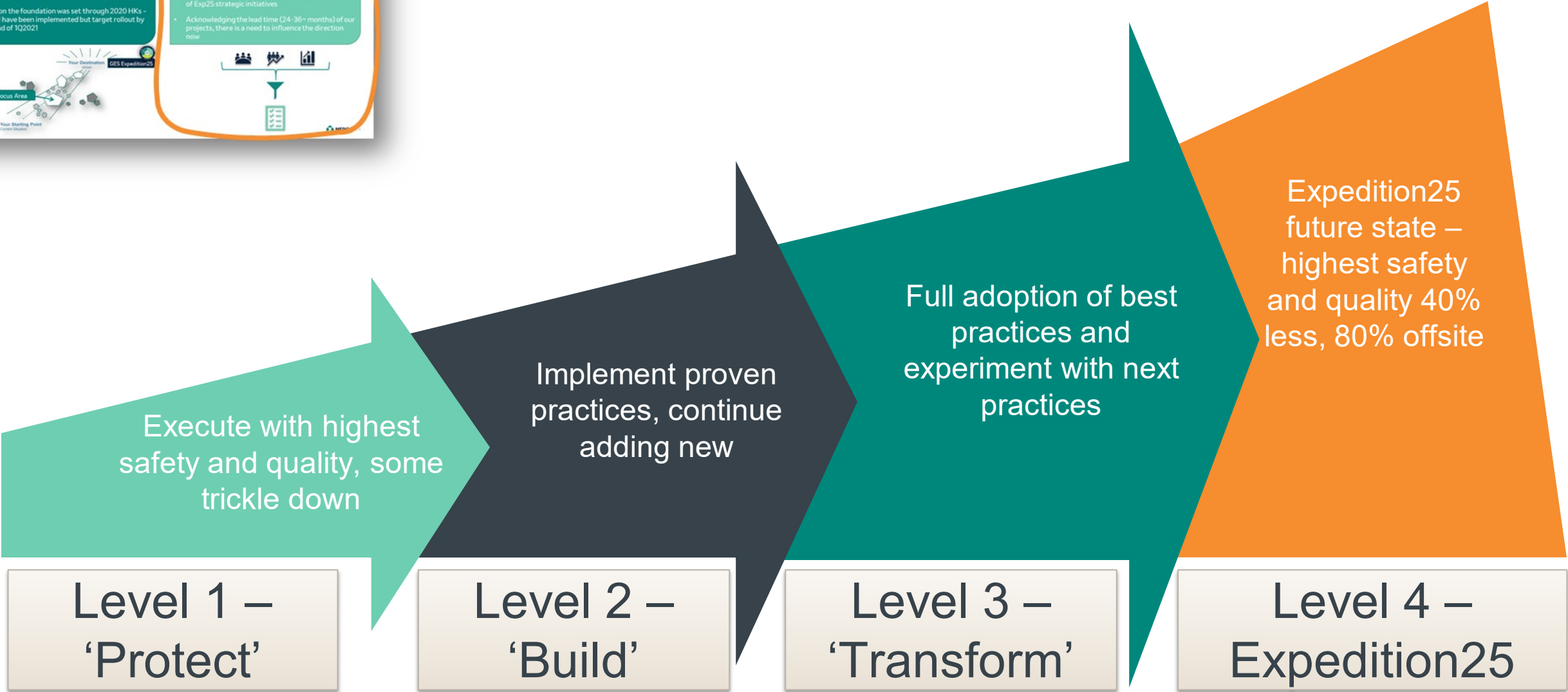
2025 Strategic Imperatives

Protect Safety First, Quality Always
0 Incidents, 0 Defects

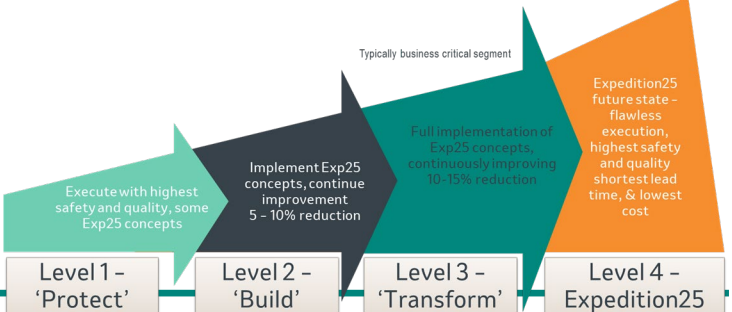
Build Agility- Workforce and Facilities
Develop forward-looking and agile growth network.

Transform our Business
40% Less, 80% Offsite – Capital Effectiveness

Levels of Transformation



Levels of Lean



Lean focus	People: Integrated Project Delivery	Safety: Variability Red.	Digital; Stds, Data & Digital	Delivery: Flow, PPM	Quality	Cost: Target Value Delivery
Level 4 Expertise, Realization.	Collaboration: Embraced Mission and behaviors include CofS, Boundaryless with R/R shared among 8-10 key partners, HI >80%, integrated form of contract or poly party contracts and team formed in FEL2.	Generative: World Class Safety, >90, trades 80% SOR, Hearts & Minds deeply imbedded, effective training, invest in PPE, Health and logistics.	Design: 7D*, LOD 500 minimum, Interactive VR/AR (Oculus/HoloLens); BIM to Field; Delivery: Digital Twin, As-Built BIM model; Asset Data for Ops	Lean Fast Track: Milestones, committed to Takt & pull >60% offsite. JIT design and delivery linked to takt. Decisions are timely, minimum change	Generative: work is expected to be RFT and is 90%+ RFT. Digital twins are used to release work with ongoing checks between models. No changes after FEL2.	Experienced TVD: WBS, suite team leads own costs, priority and A3 tradeoff process <2 weeks. IPD team experienced with TVD and trades imbedded in CDP.
Level 3 Ongoing Experimenting, Adopting	Coalition: Embraced mission and behaviors, reimbursable with risk/reward with Tier 1 partners, Health Index>70%, trades onboarded during BOD as partners. Build trust among team and risk/reward at Tier 2.	Proactive: Very good safety >85, built in, trades >60% SOR, Hearts & Minds and safety training paper based. Typical PPE and C19 programs.	Design: VDC Initiated; 5D implementation; LOD 400 minimum; Visualization (AR) for Design (Holobuilder); BIM Big Room Delivery: Real-time Collaboration (Construction Cloud); Record BIM model; BIM Kiosk (site)	Uninterrupted flow: Teams experienced with practice 5.7.1, >50% offsite with Manf and Assembly mindsets, first or second full use of Takt on project.	Proactive Quality: RFT is a clear expectation, systems to build in quality are used. Errors or omissions are not passed to next phase. No change after FEL3.	TVD Learning: WBS, suite team leads technical with need for estimate support, A3 tradeoffs process, trades active during BOD and project life cycle.
Level 2 Positive Perception, Experimenting	Coordination: Mostly top down, mission and behaviors communicated, some bottom up, HI >60%, trades onboarded after BOD. Boundaries from multiple transactional contracts.	Calculative: Good safety, checked in, >75 score, 50% trade SOR, training and permits paper based, traditional PPE.	Design: BIM Enabled Software; 4D implementation; LOD 350 minimum; Reality Capture Visualization > Laser Scan(Doxel), 360 Photo(Matterport) Delivery: Design Collaboration/Clash Reporting (Navisworks); Cloud Collaboration (BIM360); Paperless	First Fast Track or Last Planner: Practice 5.7.1 used but still learning, 30 - 50% offsite and some standards/reuse , not yet fully using Takt.	Inspected: errors are identified and corrected prior to passing along to next phase. RFT is expected and measured. Changes minimized after FEL3.	TVD New: Batch estimating by EPCM with risks/opportunities log, 10% ranges, tradeoffs take > 4 weeks. TVD new to team and primarily by CM.
Level 1 Traditional	Cooperation: Top Down MSD, EPCM with fixed price contract. Independent decisions and RFI common. Bidding trades after DD. No Team Health Index (HI)	Reactive: Top down safety, PSM checked in, <80 safety score.	Design: 3D Enabled; LOD 300 minimum; Model Viewer (Navisworks) Delivery: Execution Plans (BxP) 2D Drawing files; PIMS for Collaboration; Follow GES Procedure 2.0	Critical Path: Led by EPCM, Earned Value, <50% offsite with batch shipping, not JIT. Schedule bought from subs. <30% offsite, primarily stick built.	Punchlisting: Errors and omissions are captured and corrected at end of work. Late changes common.	Batch estimating: EPCM uses typical range estimates, value engineering, risk registers. EPCM manages costs.

Our North Star: Connecting the dots with PT Strategy

Pharma Vision Deliver 3 to 5 times more patient benefit at 50% less cost to society

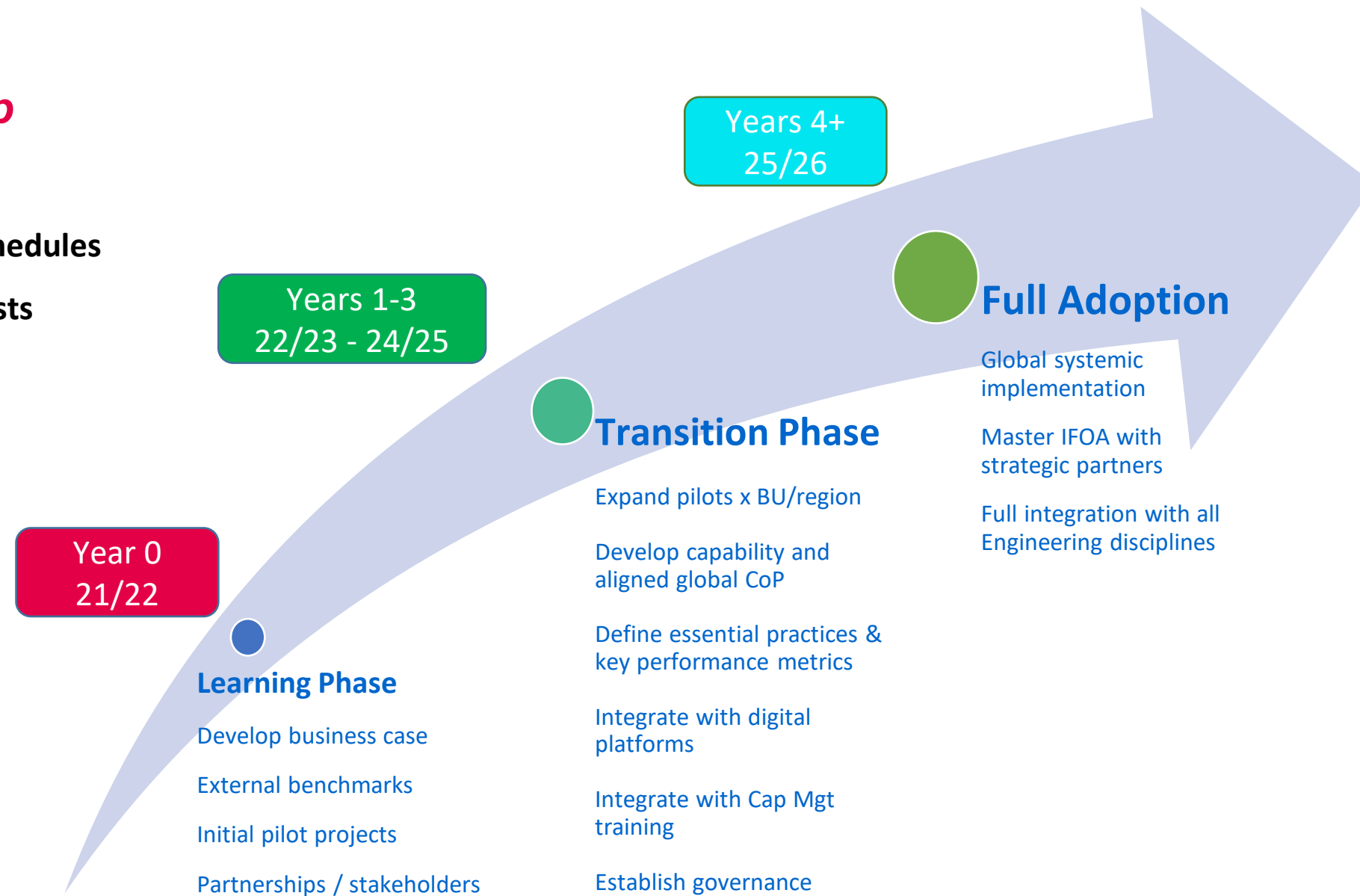


Our Vision - Moving to Lean Integrated Project Delivery



Lean Roadmap

- ❖ Up to 30% Faster Schedules
- ❖ Up to 15% Lower Costs
- ❖ Quality & Safety



Lean Advantages

Safety
Quality
Value
Cost
Time
Culture
Capability



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LCI Manufacturing Ecosystem: Response to Call to Action

Brad Kraus, DPR
Tammy McConaughy, CRB
Catherine Myers, SSOE

October 20, 2022

LEAN GUMBO: THE RIGHT INGREDIENTS FOR PROJECT SUCCESS



Why EPCM , Trade Partners, and Supplier must change?

- 68% of US companies are outsourcing to control costs of operations
- Rising material and labor costs are increasing over projects costs, consequentially preventing projects from moving forward
- Team's need to find ways to offset.
- Safety – craft are getting hurt/injured at work(avg. 10 days/yr)
- Productivity Issues
- Labor Shortages- Aging work force and skills shortages(professional and craft)
- Technology adaption- Relative to other industries, Construction progresses slower.
- Gender Diversity



Challenges to EPCM/GC/Designers to Lean Transformation

- Inconsistencies within the construction industry.
 - Not all customers are driving lean philosophy and behaviors
 - Lack of inconsistencies creates a lack of professionals with lean experience
 - Supply chain
- Completeness of Design Documents
 - Compressed Design Durations
 - Lack of timely information during design period
- Understanding Value of Good Work
- Safety-compressed schedules present challenges with craft management in the field. (overtime, trade stacking)

Challenges to EPCM/GC/Designers to Lean Transformation

- Quality-Procurement delays and a stressed labor market has significantly impacted trade partners ability to consistently hit quality benchmarks.
- Cost and Schedule – Market instability due to world pandemic and other has significantly impacted ability to accurately to predict final overall cost and schedule
- Labor shortages - Supplier market is stressed with more work than labor available which impacts schedule and quality.
- Coordination with specialized/custom equipment vendors
- Low quantity of trade partners that can “fill the gaps” in drawings to provide all in budget and schedule.

Opportunities for EPCM/GC/Designers to Lean Transformation

- Bringing teams on-board at the right time
 - ONE team from the start focused on one goal, one outcome.
 - Projects have multiple customer that include the Designers/Engineers, construction team and suppliers
 - Design for off-site manufacturing and prefabricated assemblies
- Clear direction on program
 - Take time to perform initial positioning/programming well
 - Understand there will be some change but work as a team to get best program definition possible
 - Understand the project cost implications of change later in the program
 - Our employees certainly prefer value-added work--want to avoid superfluous work

Opportunities for EPCM/GC/Designers to Lean Transformation

- Use available tools
 - Revit models with enhanced data(contains spec, design criteria, 1 model)
- Transparency for all team members
 - Business case – the why
 - Risks, Constraints, Problems are treasures
 - True Budget and schedule milestones
 - Understanding and keeping the current constraint at top of mind
- Open learning and support
 - Coaching and learning for the whole team
 - Support when falling into traditional behaviors
 - Be open learners, it is not going to be perfect

Conditions of Satisfaction

These Conditions of Satisfaction were created in April 2022 from a full team survey and subsequent workshop with representation from the stakeholders on the project. The outcome was a commitment to use as the project definition of success and to guide decision making. We will verify at different stages that the expectations remain relevant and are being upheld by all team members.

Conditions of Satisfaction Definition: Measurable goals and objectives created by a team that define success for the project and inform decision making.



Critical to Success Factors	Factor	Criteria
	Lifespan	
	Operations	The new facility will be flexible, modular, and fit for purpose, allowing the building to change with the needs of the discovery pipeline, external acquisitions, and company strategic initiatives.
	Cost	
	Schedule	Certificate of Occupancy is December 2023, occupancy by 2024; faster is better.
	One Team	Create individual ownership to succeed as one team through balanced participation and a commitment to the broader project journey.
	Safety	Zero incident mindset with actions that are people focused, embrace mentoring, and for incident free environment.
	Sustainability	Achieve LEED/WELL Gold, Universal Design while supporting Carbon Neutrality by 2030.
Project Goals	Quality	Right first time execution using standard work that will drive intentional behavior that produce predictable results.

Project Goals	Behavior	Criteria
	Inclusion	Each team member is empowered to have a valued voice and share openly without fear of criticism or backlash.
	Reliability	The team makes reliable and realistic commitments and will operate and function with culture of respect and learning.
	Work/Life Balance	The project is staffed properly, overtime work is shared and managed fairly by team to mitigate burnout. Actions are taken when excessive levels of overtime are incurred. For our team building get-togethers focus on improving team relatedness and health.

Desired Behaviors	Behavior	Criteria
	Individual Development	We are continuously promoting individual development with many opportunities to learn about personal and professional skills / knowledge.
	Listening	We all will be active listeners to fellow team members and provide support and ideas.
	Decision Making	We work to identify issues early, use collaborative, sound decision making methods to get innovative resolution in a timely manner as to not adversely affect deadlines or cause fire drills. We use a "Problem Solver" mentality to improve all processes.
	Continuous Improvement	We are embodying new methods and collecting lessons learned for continuous improvement on this project while maintaining the team's commitment to Merck's Expedition25, Level 3 Lean.
Desired Behaviors	Accountability	We hold ourselves accountable, do not blame others, admit mistakes, and give the benefit of the doubt to fellow team members.

Examples of Lean Strategies for Project Alignment

Project Lonestar/
Taysha Gene Therapies

SCOPE AND GOALS

Project Lonestar is the allocation, fit-up, commissioning, and qualification of a gene therapy manufacturing facility supporting patients with monogenic central nervous system diseases and other rare genetic disorders.

The facility is fit-up of an existing warehouse located in Patriot Park of Durham, NC which will be built in phases. This project, Phase 1, will fit-up approximately 130,000 square feet to include manufacturing as well as office, warehouse, quality control laboratories, technical development laboratories, and utility spaces.

The major project goals are to provide an engineering lot ready facility by the end of 2023 within a target value of \$104MM.

PROJECT CHARTER

CONDITIONS OF SATISFACTION

- Safety – Zero recordable and lost time incidents.
- Quality – Right first-time quality as demonstrated by minimal punch list and no schedule impacts due to construction quality.
- Cost – Cashflow no more than \$50MM before end of 2022 with Project Max Allowable Cost of \$107MM.
- Schedule – Engineering Lot Ready by 12/31/2023.
- Efficiency – LastPlanner® Plan Percent Complete > 75% with 100% success on Top 10 critical milestones.
- Fun – Everyone meets their financial goals. Celebrate successes along the way.
- Trust – Maintain healthy conflict resolution. Foster problem-solving, plus/delta culture vs blaming.
- Communication – Empower a "see something, say something mindset."
- ONEteam – Minimize RFIs, gaining clarity through open collaboration.
- Innovation – Use area based (TAKT) design and construction sequences. Maximize PPMOF opportunities.

MILESTONES

28 Jan 2022	Design IFC
02 May 2022	Start Building Fit-up
06 Sep 2022	CUB Delivery
05 Dec 2022	Electrical Energized
03 Feb 2023	CUB Start-up
01 Apr 2023	Stocking Permit
03 Apr 2023	1st Process Equipment Set
11 May 2023	Certificate of Occupancy - Warehouse
10 Jun 2023	Certificate of Occupancy - Building
26 Dec 2023	Engineering Lot Ready

WHY

Be an ally to the rare disease community, letting the patients inspire us to achieve great things.

COLLABORATION & COMMITMENT

We will schedule milestones that we will celebrate as a team!

EMBRACE NEW IDEAS AND EXPLORE OPPORTUNITIES

We will embrace new ideas and explore opportunities that promote innovation and sustainability.

OPENNESS TRANSPARENCY PARTNERSHIP

We will maintain a culture of openness, transparency and partnership with a focus on shared success.

HEALTH & WELL-BEING

Everyone goes home safe. EVERY DAY!

ONE

We speak and ask as one.

Breakout Sessions



Breakout Session #1

Discuss each topic for 5 minutes

Identify one person per table to “champion” each topic

A.Capabilities Development

B.Procurement/Contracting

C.High Performance Team Development

D.Partner and People Selection

E.What’s in it for my team/company/self on manufacturing projects

Identify a Champion for Focus Forward

No report out! Your Champion will take the team’s notes / comments on to the next breakout session!



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Identify a Champion for Focus Forward

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Take a break! Be back at. . .



Breakout session 2

Each topic “Champion” move to the corresponding table

Not a champion? Vote with your feet for the topic you would like to discuss

Each table will provide a two-minute recap at the end of the session – the team will collect all notes on the flip charts (or elsewhere!)

A.Capabilities Development

B.Procurement/Contracting

C.High Performance Team Development

D.Partner and People Selection

E.What’s in it for my team/company/self on manufacturing projects

F.Focus Forward



Section Divider



What happens next?

More ideas / questions? Want to be more involved?

Contact:

Shannyn Heyer

Jessica Kelley

Tammy McConaughy

Annmarie Thurnquist

You will receive an email with today's PowerPoint and their contact info by the end of the week.

The sponsor team will review information received from this event and schedule follow-up discussions.

