

BIOTECHNOLOGY COMMERCIALIZATION ROADMAP

Mark Warner, PE
Founder, Warner Advisors LLC

As the next wave of first-of-a-kind biorefineries ramps-up, the subject of project engineering once again comes to the forefront. Questions about the overall process, why it takes so long and costs so much abound, all capped off by the realization that an EPC solution counted on is not always the reality. An understanding of the entire process is key for those heading down the commercialization path. The graphic at the end of this document is a concept to commercial operation roadmap, with detailed descriptions that follow.

Project Development

Front-end loading (FEL) is the engineering development process to take a concept from the idea stage to the point that funding sources (banks or governmental agencies) and/or company boards of directors can make decisions to move forward on the project. It is structured in a stage-gated process, with each step targeted at developing adequate information to make an informed go/no-go decision on the path forward. The process is typically broken into 3 phases (FEL1, 2 and 3) that collectively represent what is referred to as Front End Engineering Design (FEED). This process usually costs 2-3% of the total cost of the project and needs to be funded by the company before project financing can be secured.

Execution Phase

The execution phase is the period from the start of detailed engineering to the end of construction (mechanical completion). Detailed design converts the concepts of the FEED package into documents that can be used by contractors to build the facility. Major focus is on developing drawings and specifications for civil, structural, mechanical, architectural, electrical and control systems. Construction begins with the site being prepared, utilities are brought in and foundations prepared. Equipment is placed on foundations and connected with pipes, power and controls. The construction phase is complete when mechanical completion is reached. This is the point where the facility has been constructed, but not tested or operated.

Commissioning and Start-up

Once the plant reaches mechanical completion, the process of commissioning and startup begins. This is a structured process that verifies the operability of each component before operating them individually, then in groups, then as a full process facility. Start-up is the point when raw materials are introduced to the process with the intent to make product.

The technology commercialization process can appear very structured, but is based on decades of best-practice learnings from the process industries. Some key perspectives, applicable to industrial biotechnology commercialization, are as follows:

FEL is different than facility construction documents – The development stage of the project is more strategic than operational, with the goal being to set the framework that the project can be built within. It's focused more on the operational specifications of the process (temperature, pressure, fermentation time, etc) than the equipment details (how thick is the tank wall, what type of concrete foundation). I often describe this as the “interior design” phase of the project, with construction being when the “sheet-rockers” start their work.

The world of engineering firms that are good at FEL is getting smaller – As an alumni of the engineering services industry, I can attest to the fact that few firms do both FEL development work and design/build very well, as they are dramatically different. The development phase is where multiple options are considered, tweaked and morphed into a final project concept. By contrast, detailed design is a very structured process, guided by governmental regulations and requirements. The slowdown in all process industries over the last 5-10 years has impacted the number of firms that have extensive FEL expertise and this is often the more challenging support to find.

EPC is not what you think – Quite simply, EPC stands for Engineer, Procure and Construct, the primary phases of project execution. Unfortunately, over the years it has become synonymous with an integrated “turnkey” project execution, hiring a firm that can build a fully operational facility and guarantee its performance. This has been common in industries with fully proven technology, such as corn ethanol, but is rare to non-existent in emerging technologies. You can find qualified firms capable of both engineering and building a facility, but unless you have other operational facilities that have passed a performance test, it is very unlikely that any performance guarantee will be provided.

Understanding engineering industry terminology and typical path forward is a key to ensuring the process meets time, quality and cost expectations.

Mark Warner is a registered professional engineer with 30 years of experience in process commercialization, focusing for the last 10 years on taking first-of-a-kind-technologies from bench-top to commercial operation. He is the founder of Warner Advisors, providing consulting services and acting in interim engineering leadership roles for advanced bioeconomy clients. He can be reached at mark@warneradvisorsllc.com or visit www.warneradvisorsllc.com.

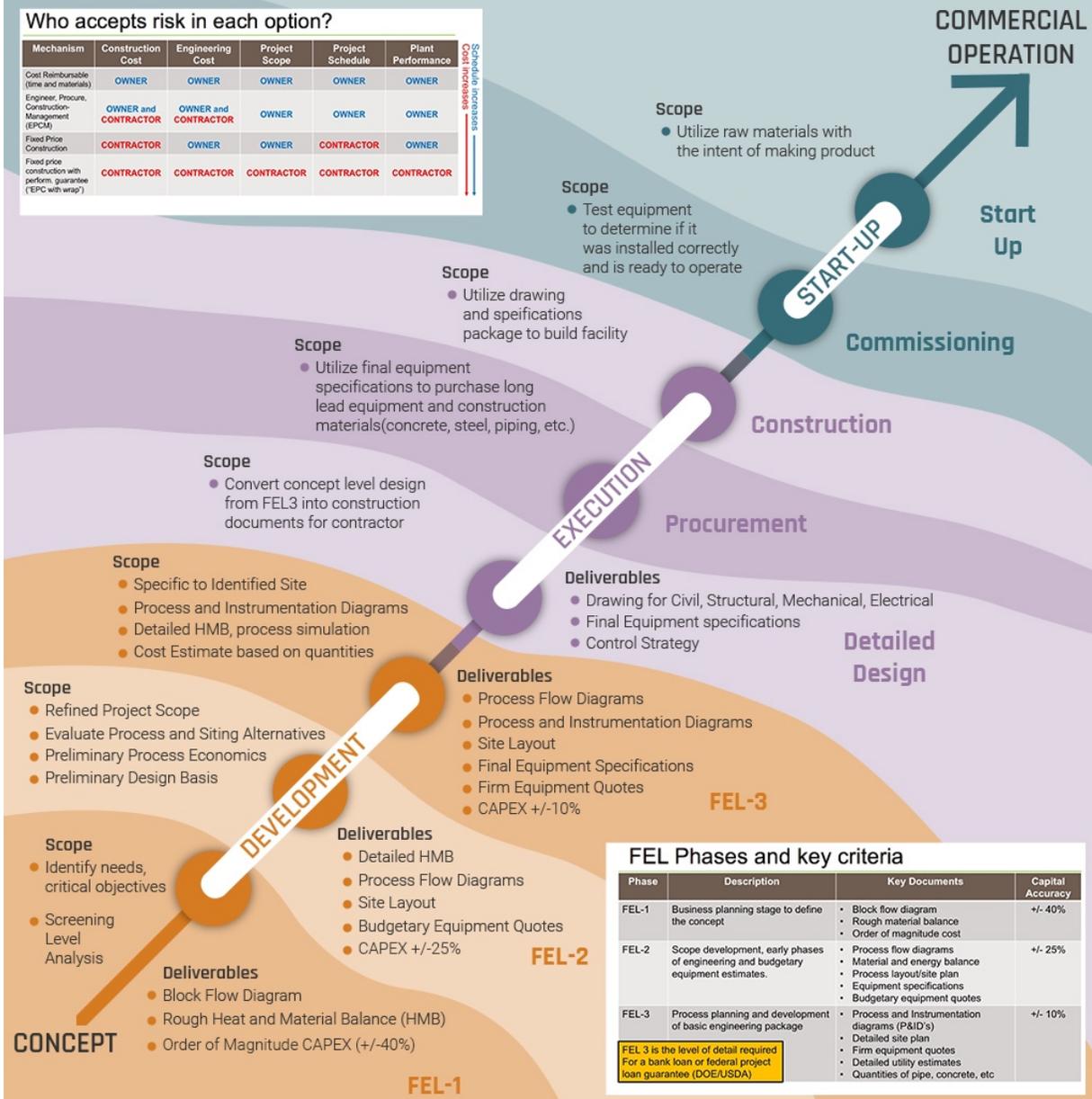
COMMERCIALIZATION ROADMAP

From Concept to Commercial Operation

Who accepts risk in each option?

Mechanism	Construction Cost	Engineering Cost	Project Scope	Project Schedule	Plant Performance
Cost Reimbursable (time and materials)	OWNER	OWNER	OWNER	OWNER	OWNER
Engineer, Procure, Construction-Management (EPCM)	OWNER and CONTRACTOR	OWNER and CONTRACTOR	OWNER	OWNER	OWNER
Fixed Price Construction	CONTRACTOR	OWNER	OWNER	CONTRACTOR	OWNER
Fixed price construction with perform, guarantee (EPC with wrap)	CONTRACTOR	CONTRACTOR	CONTRACTOR	CONTRACTOR	CONTRACTOR

Cost increases (vertical arrow on right)



FEL Phases and key criteria

Phase	Description	Key Documents	Capital Accuracy
FEL-1	Business planning stage to define the concept	<ul style="list-style-type: none"> Block flow diagram Rough material balance Order of magnitude cost 	+/- 40%
FEL-2	Scope development, early phases of engineering and budgetary equipment estimates.	<ul style="list-style-type: none"> Process flow diagrams Material and energy balance Process layout/site plan Equipment specifications Budgetary equipment quotes 	+/- 25%
FEL-3	Process planning and development of basic engineering package	<ul style="list-style-type: none"> Process and Instrumentation diagrams (P&ID's) Detailed site plan Firm equipment quotes Detailed utility estimates Quantities of pipe, concrete, etc 	+/- 10%

FEL 3 is the level of detail required For a bank loan or federal project loan guarantee (DOE/USDA)