

10-Slide Guide to BioProcess Scale-Up



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The Challenge of BioProcess Scale-Up

- ▶ It is Different
 - ▶ This is Not Discovery Research
 - ▶ This is Not Applied Research
 - ▶ This is Not Single Unit Operation Development
- ▶ It Requires a Different Set of Expertise
 - ▶ Engineering
 - ▶ Process
 - ▶ Mechanical
 - ▶ Automation
 - ▶ Mechanical Aptitude
- ▶ It is Expensive
 - ▶ So Is Failure
- ▶ It is Larger Scale
 - ▶ Don't Ignore Standard Scaling Rules to the Small Side



“Begin with the End in Mind”

Stephen Covey: 7 Habits of Highly Effective People

- ▶ What does the commercial scale look like?
 - ▶ What are the unit operations?
 - ▶ Feedstock Handling
 - ▶ Pumps/Valves/Conveyors
 - ▶ Reactors
 - ▶ Separation/Purification
 - ▶ Dewatering/Drying/Packaging
 - ▶ Waste Handling/Disposal
 - ▶ Automation
 - ▶ Environmental/Safety Features
 - ▶ What commercial type equipment is needed?
 - ▶ Water Quality
 - ▶ Feedstock Quality
 - ▶ Chemicals
- ▶ What Regulatory/Environmental Permits are Required?
- ▶ What Safety Features are Needed?
- ▶ What commercial type inputs are required and available?



Get Good Advice

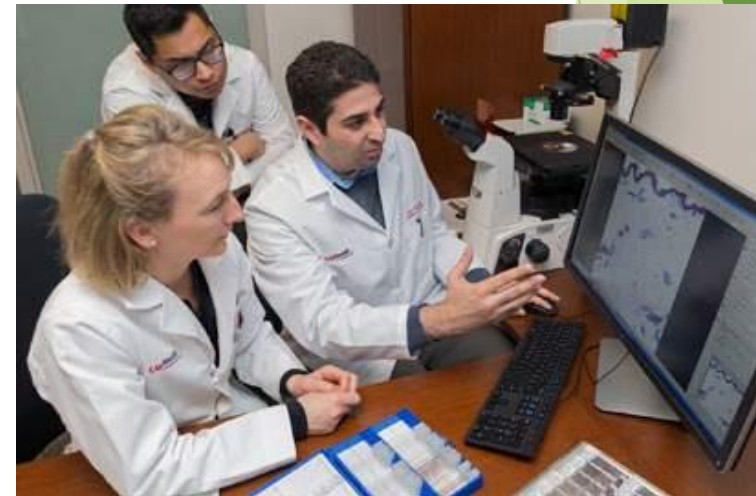
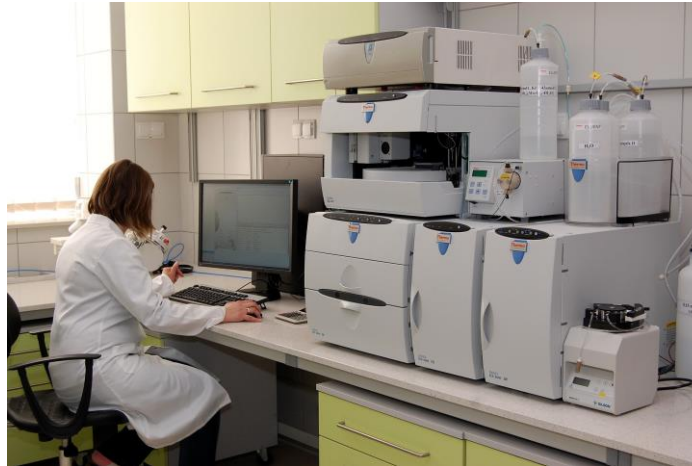
- ▶ Get Advice Early
- ▶ Internal Advice
 - ▶ Large vs Small vs Start-Up Company
 - ▶ Do you *really* have the full range of experiential expertise?
 - ▶ Theory is nice, but does it match with real world operations?
 - ▶ Successful Scale-Up/Commercial Experience
 - ▶ What are your weaknesses?
- ▶ External Advice
 - ▶ Fill Knowledge Gaps
 - ▶ Fill Experience Gaps
 - ▶ Provide an Alternative/Independent Perspective
 - ▶ Have you missed the forest for the trees?
 - ▶ Is there a different approach?
 - ▶ May provide synergistic value

Expect the Unexpected

- ▶ Development Lags
 - ▶ Production Targets
 - ▶ Recovery Targets
- ▶ Equipment Failures
 - ▶ Breakdowns
 - ▶ Alternatives Needed
 - ▶ Fabrication Delays
- ▶ Personnel
 - ▶ What is Essential: Wants vs Needs
 - ▶ Engineers/Scientists vs Real World Operators
- ▶ It Will Take Longer and Cost More Than You Expect

Develop Key Data

- ▶ Get the Right Data
 - ▶ Technical Data
 - ▶ Economic Data
- ▶ Get Data, Get Lots of Data
 - ▶ Over Sample
 - ▶ Over Instrument
 - ▶ Analyze
 - ▶ Make Data-Driven Decisions
- ▶ Fill Gaps
- ▶ Confirm Results At All Scales
 - ▶ Is the process repeatably reliable?
 - ▶ How robust is the process?
 - ▶ Can it survive process upsets?



The Integrated Pilot Plant

- ▶ How Big is Big Enough?
 - ▶ Integrate ALL Unit Operations
- ▶ Avoid Shortcuts
- ▶ Build/Operate
 - ▶ Self-Perform
 - ▶ Do you have the proven expertise?
 - ▶ Design
 - ▶ Procurement
 - ▶ Construction
 - ▶ Operation
- ▶ Pilot Plant Service Provider
 - ▶ What Unit Operations are Missing?
 - ▶ Can they be added at the needed scale?
 - ▶ Do they have the proven expertise?
 - ▶ Yes/No
 - ▶ Do you have the missing expertise?
- ▶ Complete 1,000-Hour Integrated Campaigns
 - ▶ Did They Meet Expectations?
 - ▶ Why/Why Not?
 - ▶ Were There Operational Hiccups?
 - ▶ Are They Show Stoppers?

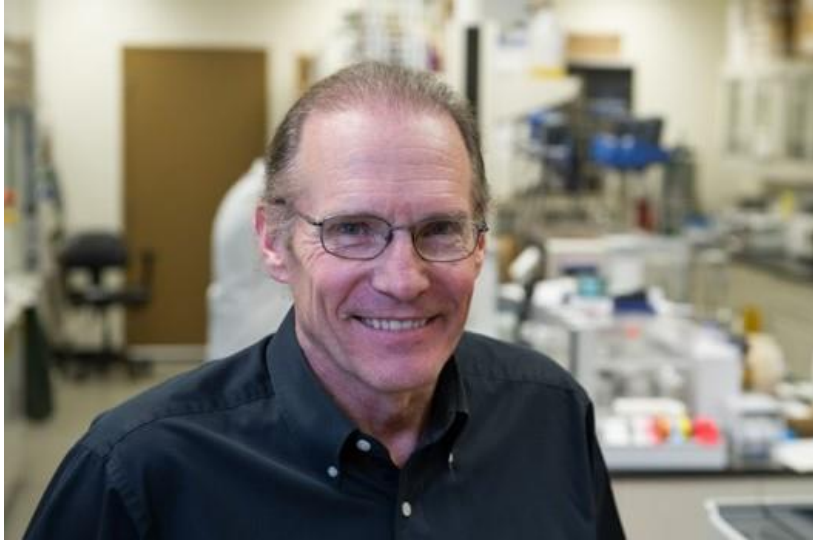
Do You Need a Demonstration Plant?

- ▶ What is the scale ratio from integrated pilot plant to commercial?
- ▶ What Unit Operations are Unproven at 1/10 Commercial Scale?
- ▶ Can a Demo Plant Have Commercial Applications?
- ▶ What is your tolerance for risk?

Conclusions

- ▶ “Begin with the End in Mind”
- ▶ Get Good Advice - Internal and External
- ▶ Expect and Prepare for the Unexpected
- ▶ Make Data-Driven, NOT Emotional Decisions
- ▶ Establish a Fully Integrated Pilot Plant with Commercial Size Components
- ▶ Scale-Up Shortcuts are often Illusions of the Solutions They Pretend To Be
- ▶ Conduct Successful, 1,000-Hour (minimum), Fully Integrated Performance Runs
- ▶ Demonstrate Unproven Unit Operations at 1/10 Scale of Minimum Commercial Scale

Thank You!



**Accredited
Member**

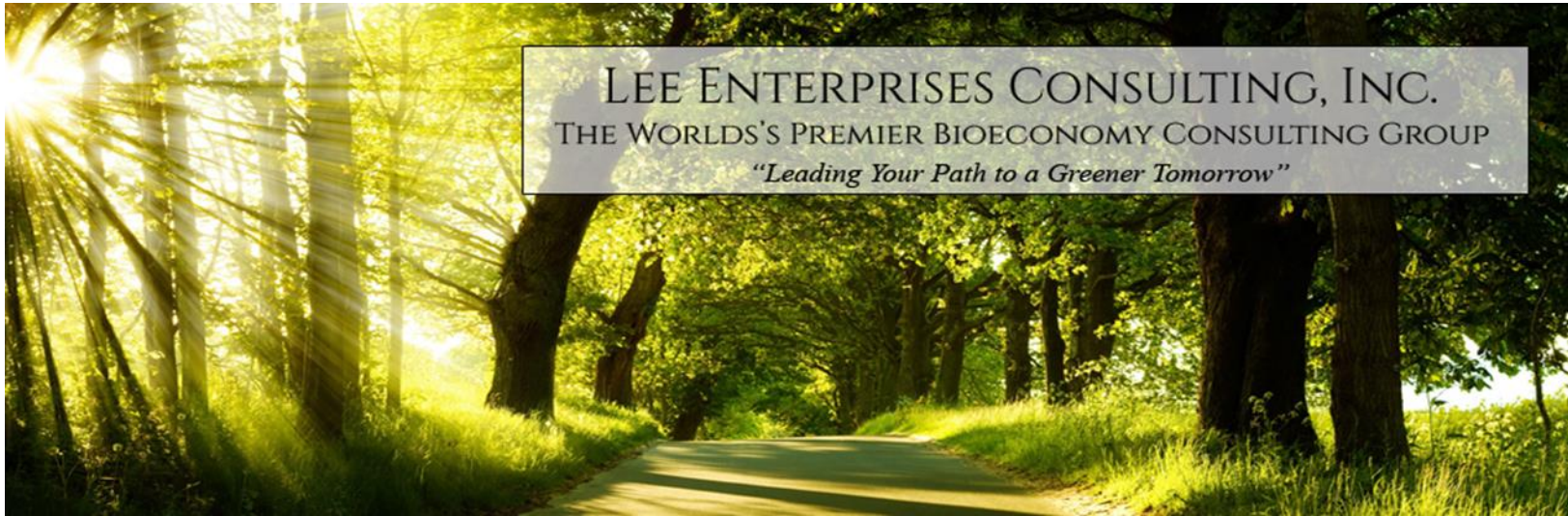


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