The Unique Challenges of Expansion and Retrofit Projects

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Acorda Company Overview

21 Year Old Biotechnology Company Focused on Neurology

- Headquarters in New York
- Annual Revenue of $460 million
- 600 Employees

Commercial Manufacturing Facility in Boston Area

Products

- Amprya – Walking in MS
- Zanaplex – Spasticity
- Qutennza – Post Shingles Nerve Pain
- CVT-301 – Parkinson's Disease (Ph 3)

Why are we here?

Parkinson's Video

Problem Statement

We need to double our manufacturing capacity in 3 years!

Now what?

Agenda

Key Business Drivers For Project Justification

Retrofitting vs Greenfield Construction

Extra Level Of Planning And Coordination Required For Retrofits

Balance Project Needs vs Concurrent GMP manufacturing

Case Study

Conclusions

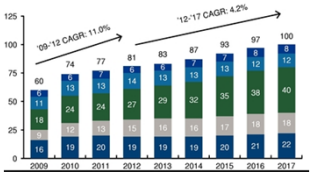
Key Business Data

Sales Projections

- High side vs Low side
- US & ROW

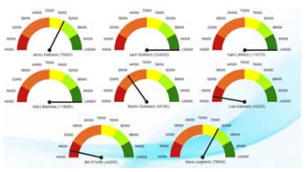
Capacity Planning

- Throughput / Debottlenecking



Success Rate / Yield

- Operational Excellence
- Advanced Analytics



Key Business Drivers For Project Justification

More Capacity

- New product launch
- Growing product sales
- Product acquisition

New Technology

- Higher Titers / Better Yields
- Efficiency / Cost reduction
- Disruptive vs. Incremental Innovation

Modernization / Replacement

- Obsolete Equipment
- Discontinued Product

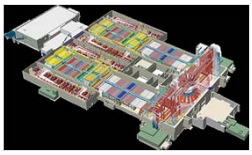
Retrofitting vs Greenfield Construction

Retrofit	Greenfield
Lower cost	Higher cost
Shorter schedule	Longer schedule
Leverage existing workforce	Recruit new workforce
Risks to existing facility / operation	No risks to existing facility / operation
Greater complexity	Less complexity
Fewer surprises (usually)	More surprises, especially if in new area/country
Predictable operating costs	Uncertain operating costs, especially if in new area/country

Planning And Coordination For Retrofits

Facility Impact

- Tie-in Points for expansion
- Demolition of existing equipment
- Isolation



Manufacturing Impact

- Ongoing production
- Regulatory inspections

Shared Resources

- Utilities
- Contractors
- Employees

Resources and Documentation

Utilities

- Load analysis / Infrastructure
- Tie-in points
- Revalidation

Contractors

- Utilize people who “know the site”
- Balance workload between expansion and ongoing work

Documents

- Change Control
- Accuracy

Site Employee Resource

Need To Involve Site SMEs

Need To Determine/Communicate Time Commitment

Site Leadership Needs To Support Resource Commitment

Temporary Backfills

Streamlines Turn Over

Cost Of Shutdown/Lost Capacity

Operating Facilities Have Operating Costs That Might Need To Be Funded By The Project

Capitalized labor

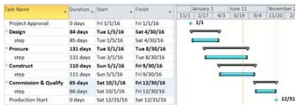
Temporary Backfills For Employees Assigned To The Project

OpEx vs CapEx

Balance Project Needs vs Existing Manufacturing

Schedule

Ongoing production vs project



Equipment/Component Selection

Match existing vs competitive bid
Fit into existing space

Contractors

Those who “know the facility” vs competitive bid

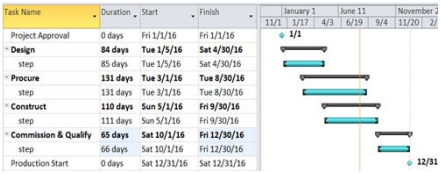
Wish Lists

Scope needs to be well defined and controlled

Planning Tools

Project Plan

Schedule



Task Name	Duration	Start	Finish
Project Approval	0 days	Fri 1/1/16	Fri 1/1/16
Design	**84 days**	**Tue 1/5/16**	**Sat 4/30/16**
step	85 days	Tue 1/5/16	Sat 4/30/16
Procure	**131 days**	**Tue 3/1/16**	**Tue 8/30/16**
step	131 days	Tue 3/1/16	Tue 8/30/16
Construct	**110 days**	**Sun 5/1/16**	**Fri 9/30/16**
step	111 days	Sun 5/1/16	Fri 9/30/16
Commission & Qualify	**65 days**	**Sat 10/1/16**	**Fri 12/30/16**
step	66 days	Sat 10/1/16	Fri 12/30/16
Production Start	0 days	Sat 12/31/16	Sat 12/31/16

Resource Plan

Department	Name	Q1	Q2	Q3	Q4
Engineering	Process Engineer	50%	50%	50%	100%
	Automation Engineer	20%	50%	80%	100%
	Facilities Engineer	30%	20%	40%	50%
Manufacturing	Upstream Supervisor	20%	30%	40%	100%
	Downstream Supervisor	20%	30%	40%	100%
	Document Specialist	0%	20%	100%	100%
Quality	QA Supervisor	20%	20%	50%	50%

RACI

Task	Process Engineer	Automation Engineer	Facilities Engineer	Upstream Supervisor	QA Supervisor	Project Manager
Project Plan	C	C	C	I	C	A
Review P&IDs	A	C	A	C	C	A
Instrument Specs	C	A	C	I	I	A
Equipment Data Sheets	A	C	C	I	I	A

Case Study

Purification Expansion - $100M & 18 months

- Add a second purification suite to large scale biologics facility
- Increase throughput
- Allow for concurrent manufacturing of 2 products
- Shell space was provided during the original construction

Execution

- Dedicated project team supplemented with site resources
- Existing equipment/components used as BOD with targeted upgrades
- Incorporate high titer upgrades from a sister site
- Existing control system expanded to include new suite
- Off-site fabrication and FAT
- Close coordination of project activities & ongoing operations

Case Study

Results

- Increase throughput and lower COGS
- End results yield a fully integrated facility
- Compressed space to allow for a 3rd purification suite

Lessons Learned

- Equipment FAT found problems early
- Remote A&E firm did not understand local construction market
- Better communication needed between project team/site leadership
- Better isolation needed between construction/commissioning & operation

Conclusions

Retrofits And Expansions Are Usually Quicker And Less Expensive

Extra Planning / Considerations Are Required For Retrofits

Site Based Resources Need To Be Carefully Managed

Communication Is Especially Important

Questions?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