The Unique Challenges of Expansion and Retrofit Projects

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Acorda Therapeutics

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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
Quettanza – 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
- Lower cost
- Shorter schedule
- Leverage existing workforce
- Risks to existing facility / operation
- Greater complexity
- Fewer surprises (usually)
- Predictable operating costs

Greenfield
- Higher cost
- Longer schedule
- Recruit new workforce
- No risks to existing facility / operation
- Less complexity
- More surprises, especially if in new area/country
- 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

Resource Plan

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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

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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