Overview

Project lifecycle stages:
Design – Planning – Execution – Completion
Key Considerations for each

Areas for Special Focus
Actionable Information
‘War Stories’
Q & A
'Retrofit' Project?

Any project executed post-licensure

whether the Plant is....

more Currier & Ives...
Retrofit Projects are executed:

- During Plant-wide Shutdowns
- Concurrently with manufacturing

Presentation focus: Concurrent with Operations
So what?

Project Management is a Mature Science

I MEAN, HOW HARD CAN IT BE?
Procure Services and Equipment...

Install, Qualify...
Principal Concerns of Retrofit Projects

Manufacturing:
"When can we return to production?"

Quality:
"How can we prove no adverse effect on:
- Work In Process?
- The processes under modification"

Regulatory:
"How can we prove no adverse effect on regulatory filings?"
retrofit projects multiply the opportunity for collision

...this is what keeps owners up at night

Consider the view from 30,000 feet....
Successful Retrofit Projects

- On Time Return to Service
- No Unplanned Impact to Production
- On Budget

Comparative Schedules

"Greenfield" Project

note: this is

scope

for

Retrofit Project

scope
Comparative Schedules

"Greenfield" Project

- Design
- Design
- Planning
- Execution
- Execution
- Execution
- Completion
- Completion
- "Out of Service"

Retrofit Project

- Design
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- Design
- Planning
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- Planning
- Planning
- Execution
- Execution
- Execution
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- Execution
- Execution
- Completion
- Completion
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- Completion
- Completion
- "Out of Service"

Planning issues:
- Deferral
- Scope Creep
- Investigative Projects

365 MM$/yr product: 1 day lost revenue = 5,000 man-hr

Reduce Total Cost

Reduce Risk+Lost Revenue
Retrofit Concerns

Design
- Design Basis Accuracy
- Utility Supplies
- Custom Designs

Execution

Planning

Completion

Design Approach

Involve key stakeholders from concept phase
- the usual departments
- Manufacturing, Supply Chain
- QA, QC, Validation, Regulatory, HSE
- Find the schedule constraints
  - KNOW THE DEAL BREAKERS

Identify likely impact areas
- Maintain adequate operational accessibility
- THINK CLEAN
Design Issues

Design basis accuracy
- Don’t assume record set is current
- Walk it down – even the “as-builts”
- Verify performance data
- Investigation work needed?

Risk from all-contract project teams
- Owner lacks true sense of data accuracy
- Limited access to data and ‘where bodies buried’
- No ‘tribal knowledge’ retained
- Reliance on non-engineering resources (e.g. piping specialists) for detail design: less Cost, more Risk

Inaccurate source data is #1 cause of quality incidents

Design Issues

Custom Designs
Troubleshoot before installation

Utilities: Look beyond Generation and Storage
Could new Operating loads or Test loads ‘crash’ a system?

Require that vendor FAT conditions match site conditions
Plan supplemental vendor capabilities or consider alternate FAT site
Start familiarization during FAT (mfg, QC, maint, etc.)
Retrofit Concerns

Design
- Design Basis Accuracy
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- Custom Designs

Execution

Planning
- Mitigating Additional Risk
- Resource Loading
- Vendor Management
- Return to service

Completion

Risks to Manufacturing Environments

- How to prove environments unaffected by retrofit work?
  - build, then clean v. clean while building

- Cleaning roles: Contractor / Mfg / Routine

- Gowning requirements for project space
  - mfg. requirements trump construction

- How to traverse active spaces?

- HVAC impact during retrofit
  - Airflow profiles
  - Sampling requirements
  - Mark a clearance zone around Low Returns to avoid blockage by construction equipment or materials
  - Consider proactively change HEPAs
Process Control / Data Risks

Plan sequences for systems shutdown & startup
• Inter-system communication affected by startup order
• Avoid interlock knots and error message avalanches
• Identify effects on systems remaining in service

Record/confirm version numbers pre-/post shutdown

Make 'as-left' backups of code and parameters
• Especially systems remaining unmodified

Ensure all PLC/DCS backup batteries are refreshed
• Avoid loss of parameters, restoration of obsolete code

Risk of data loss, manufacturing deviations

Resource Planning 1

Internal departmental support
• QC: sampling & testing
• Facilities / Metrology / Cleaning Staff
• Manufacturing: SOP revisions
• Training: for trades, contingent staff, Mfg
• QA and Validation: commissioning and qualification

External Contractor/Trades support:
• Key consideration: Lead Times
  • Vendor Qualification / Audits
  • Requests For Quotations
  • PO Approval and other commercial processes
  • Training: Safety, Quality, Permitting & Reporting
Resource Planning 2

Project Spaces
- Desks, conference rooms, office trailers
- Owner Network IDs / access for key contractors
- Connectivity - 'guest' network or hotspots
- Parking, lockers, non-disposable gowning
- Lay-down areas, special warehousing requirements

Supplies
- Gowning materials
- Cleaning supplies and Production Consumables
- Waste Removal / Recycling

More Planning Tips

Pre-plan the Quality Processes
- for planned activities and contingencies
- Do not use EQMS (e.g. TrackWise) as a PM tool

Harmonize Safety Management
- Agree Project Safety Plan which works with both the Owner's and Construction Manager's procedures

Incentive / Penalty Clauses
- For performance or key personnel

Most Important:
Informed, empowered Decision Makers
Returning to Service

• Installation Complete! We’re done! Umm, No
• Proactively plan:
  • Preparation of TOPs concurrent with construction
  • Handoffs, for each system:
    • Construction -> Commissioning -> Validation -> Manufacturing
    • Handoff procedures/criteria developed by independent Owner resource in cooperation with the CM
  • Release of utilities to support CQV schedule
  • Ramp up Commissioning while Construction ramps down
  • Keep Trades available through commissioning: things break, flaws discovered, adjustments are required

Retrofit Concerns

Design
• Design Basis Accuracy
• Utility Supplies
• Custom Designs

Execution
• Communication
• C&Q / Training Overlap
• Decommissioning

Planning
• Mitigating Additional Risk
• Resource Loading
• Vendor Management
• Return to service

Completion
Keep A Manufacturing Focus

Develop a project-specific Communication Tool
- Mfg needs access to (and approval of) the up-to-date, detailed schedule of activities - avoid surprises!

Orient thinking toward impact avoidance
- Absolutely critical to have 24/7 coverage of 'crisis team' - empowered decisionmakers from Mfg., Quality and Regulatory

Develop a consensus method for communicating changes to the project plan - BOTH WAYS

Some Not-So-Obvious Concerns

- **Startup & C/Q/V**
  - Use to train Mfg / Facilities / QC on new equipment
  - Consider training dependencies
  - Contract Lab Services? Utility Capacity?

- **Decommissioning**
  - Open Investigations, CAPAs, Change Controls?

- **Vibration / Noise**
  - Construction (trenching, etc.) / equipment movement

- **Utility Isolation**
  - Hot Taps, Hot Work, Label Outlets for Contractor Use
Murphy's Law

What if...

- Manufacturing doesn't finish on time

- Equipment is not available or found in an unexpected condition

- State or local inspection issues

- Surprises in the walls
Murphy's not done...

- Non-routine use of systems cause upsets
  - excessive flow, increased velocities, spikes
  - biofilms flaking from drying out
- Opportunities for visual inspection may have unintended consequences
  - what if you find rouge?
- Idle systems can freeze during Winter Shutdowns
- Project Activities create damage
- Repairs interfere with Manufacturing operations

Retrofit Concerns

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Defining 'Done'

Completion Requirements

- SOPs: don’t forget PM, QC, Cleaning, etc.
- Resources for timely closeouts
- Approach: Guilty Until Proven Innocent

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Returning to Service

Quality Requirements (waters, CS, EM, HEPA...)

- Sampling / testing / release
- Consider dependencies (can WFI sampling begin if RO/DI is provisionally or fully released?)
- Contingency Plans for failed samples

Plan the Activation of New Documentation

- SOPs - Manufacturing, Cleaning, EM, Maintenance...
- Training - new curricula, OJTs, other prerequisites - ex: QC training for sampling on new equipment
- Consider dependencies to be ready to operate (can we train on approved drafts?)
Key Takeaways:

Key Takeaway 1

Informed and Accessible Decision Makers

- An informed team can make good decisions fast
Key Takeaway 2

**Resourcing**

'An ounce of prevention...'

- Planning and Investigation
- CQV Support: Mfg + Eng + Validation
- Document Revision / Training
  - Monitoring / Sampling
    - PM / Metrology
    - Cleaning

Key Takeaway 3

**Detailed Plan for Return to Service**

- Agree Dependencies in Advance
- Agree Contingencies in Advance
  - Perform Dry Runs with the Decision Makers