

Overview

Project lifecycle stages:

Design – Planning – Execution – Completion

Key Considerations for each

Areas for Special Focus

Actionable Information

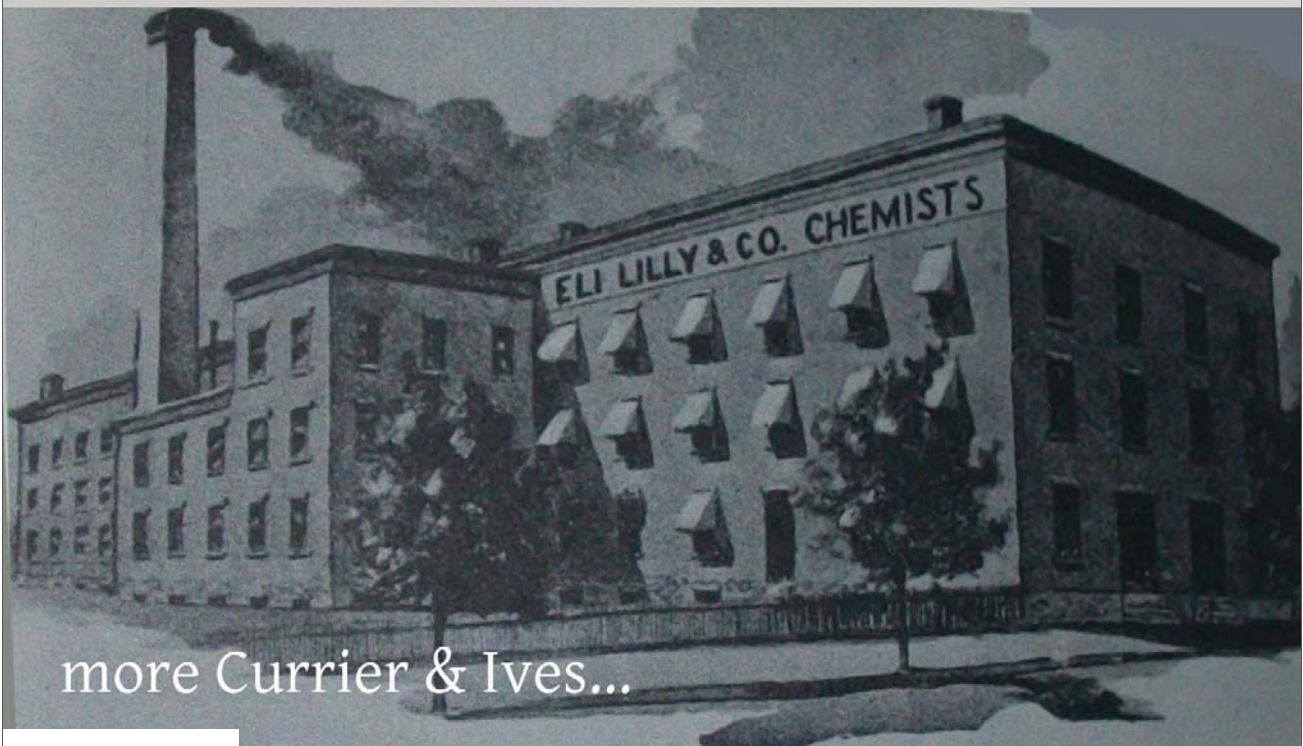
'War Stories'

Q & A

'Retrofit' Project?

Any project executed
post-licensure

whether the Plant is....



more Currier & Ives...

....or Jetsons



Retrofit Projects are executed:

- During Plant-wide Shutdowns
- Concurrently with manufacturing

Presentation focus: Concurrent with Operations



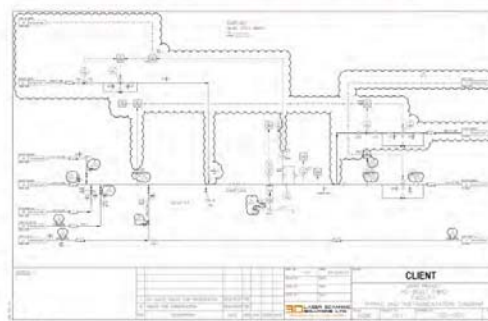
So what?

Project Management
is a Mature Science



A hand-drawn technical diagram of a mechanical assembly, likely a pump or motor component. The diagram shows a cross-section of a housing with internal parts. Key features and labels include:

- Dimensions:**
 - Overall width: 100
 - Overall height: 100
 - Internal width: 60
 - Internal height: 60
 - Flange thickness: 10
 - Internal diameter: 40
 - Internal diameter: 30
 - Internal diameter: 20
 - Internal diameter: 10
 - Internal diameter: 5
 - Internal diameter: 2
 - Internal diameter: 1
 - Internal diameter: 0.5
 - Internal diameter: 0.2
 - Internal diameter: 0.1
 - Internal diameter: 0.05
 - Internal diameter: 0.02
 - Internal diameter: 0.01
- Labels:**
 - "Pump Body" (circled in red)
 - "Pump Head" (circled in red)
 - "Pump Shaft" (circled in red)
 - "Pump Impeller" (circled in red)
 - "Pump Housing" (circled in red)
 - "Pump Cover" (circled in red)
 - "Pump Base" (circled in red)
 - "Pump Mounting" (circled in red)
 - "Pump Flange" (circled in red)
 - "Pump Gasket" (circled in red)
 - "Pump Seal" (circled in red)
 - "Pump O-ring" (circled in red)
 - "Pump Bolt" (circled in red)
 - "Pump Nut" (circled in red)
 - "Pump Washer" (circled in red)
 - "Pump Pin" (circled in red)
 - "Pump Rivet" (circled in red)
 - "Pump Solder" (circled in red)
 - "Pump Weld" (circled in red)
 - "Pump Glue" (circled in red)
 - "Pump Tape" (circled in red)
 - "Pump Paint" (circled in red)
 - "Pump Grease" (circled in red)
 - "Pump Oil" (circled in red)
 - "Pump Lubricant" (circled in red)
 - "Pump Filter" (circled in red)
 - "Pump Valve" (circled in red)
 - "Pump Switch" (circled in red)
 - "Pump Motor" (circled in red)
 - "Pump Controller" (circled in red)
 - "Pump Sensor" (circled in red)
 - "Pump Actuator" (circled in red)
 - "Pump Transducer" (circled in red)
 - "Pump Amplifier" (circled in red)
 - "Pump Inverter" (circled in red)
 - "Pump Converter" (circled in red)
 - "Pump Regulator" (circled in red)
 - "Pump Stabilizer" (circled in red)
 - "Pump Protector" (circled in red)
 - "Pump Isolator" (circled in red)
 - "Pump Separator" (circled in red)
 - "Pump Divider" (circled in red)
 - "Pump Combiner" (circled in red)
 - "Pump Mixer" (circled in red)
 - "Pump Blender" (circled in red)
 - "Pump Grinder" (circled in red)
 - "Pump Mill" (circled in red)
 - "Pump Crusher" (circled in red)
 - "Pump Sizer" (circled in red)
 - "Pump Sorter" (circled in red)
 - "Pump Classifier" (circled in red)
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Procure Services and Equipment...



Install, Qualify...





...resume Production



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



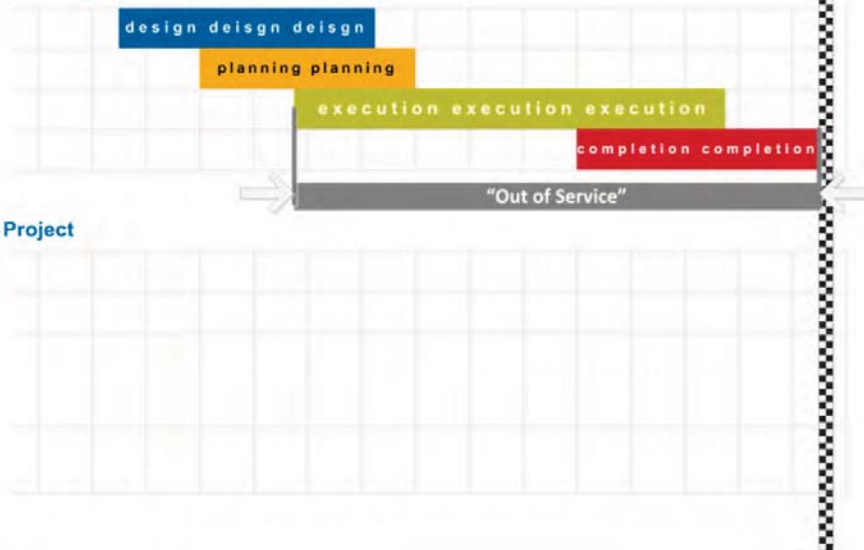
...this is what keeps owners up at night



Consider the view from 30,000 feet....

Comparative Schedules

"Greenfield" Project



Retrofit Project



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Comparative Schedules

"Greenfield" Project



Retrofit Project



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Retrofit Concerns

Design

- Design Basis Accuracy
- Utility Supplies
- Custom Designs

Execution

Planning

Completion

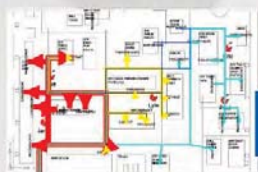
Design Approach

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?



Check for in-progress redlines!

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.)





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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



Connecting

Pharmaceutical

Knowledge

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Retrofit Concerns

Design

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- Utility Supplies
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Execution

- Communication
- C&Q / Training Overlap
- Decommissioning

Planning

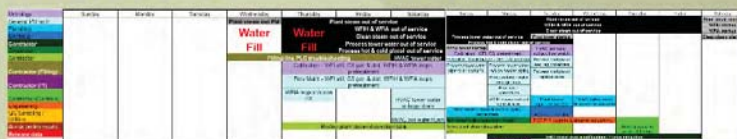
- Mitigating Additional Risk
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- Vendor Management
- Return to service

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

...things just don't go according to plan



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



CAUTION OUT OF SERVICE



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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Execution

- Communication
- C&Q / Training Overlap
- Decommissioning

Planning

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Completion

- **Qualification**
- **Doc Revision**
- **Training (non-Mfg)**
- **Regulatory Filings**

Defining 'Done'

Completion Requirements

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

Retrofit Project

Greenfield Project

Mechanical Work TOPs As-Built Drawings Validation Reports

SOP Revisions
Work Orders
Training / OJTs
Regulatory Filings
Action Notices
Change Controls
Validation Reports
As-Built Drawings
TOPs
Mechanical Work

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



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