ABSTRACT

Application of Dynamic Modeling to a Solvent Recovery Area
at a Pharmaceutical Manufacturing Plant

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As with any complex system, the day to day decisions required to run a manufacturing operations system involves the need to understand and manage the dynamic behavior associated with such systems. Without a thorough understanding of these dynamics, it is very difficult to design appropriate control systems to decide when it is necessary to intervene and what the optimum intervention policies should be. The natural dynamics of the system play a crucial part in deciding how the management control systems should be set up. A dynamic model can be used to gain the understanding that is required to better manage operational systems.

In particular, a dynamic model was created for a solvent recovery system at a bulk pharmaceutical manufacturing plant, using the ithink/Stella software package. This is a closed loop system in that the customers and suppliers of the system are one and the same. The model accounts for all sources of common cause variability, time lags, as well as information and material flow in the system. It can also model the resource utilization (people, equipment, utilities, etc.) of the system.

The model has been used to optimize solvent inventory levels, reduce cycle times and to create a dynamic staffing model. It has also been interfaced with some of the support systems, most notably the purchasing system for new solvent, the maintenance system and the analytical system. This can lead to increased levels of efficiency from these support systems. It has also led to an increased rate of learning and has improved knowledge retention in the solvent recovery operations team. Operational targets have also been set which better reflect the system's dynamics. This had led to reduced tampering with the system and better system management practices. At a personal level with the operations team, the model has helped change the attitude from being that of a victim of the system to being that of a controller of the system.

In the future, the intention is to interface the model output with other support areas such as utilities. Additionally, this approach of dynamic modeling will be applied to other operational areas such as waste treatment, maintenance and batch processing.

What is the goal?.....

Deliver the customer *correct amount* of *usable product* at the *required time* for the *lowest possible cost*.

Approach

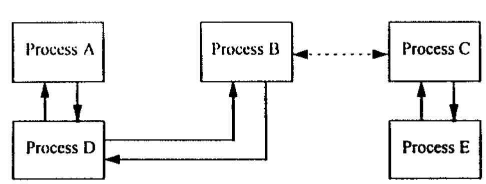
Develop a single integrated and synchonized schedule to manage resource capacity against resource demand.

Initial Situation - Culture

- Process knowledge not encoded into manufacturing instructions.
- Common cause variability of system not understood.
- Costs of manufacturing not understood.
- Reactive (victim-like) work environment.
- Customer *valid* requirements not understood nor negotiated.

Initial Situation - Structure

- Processes managed independently.
- Customer and supplier one and the same (closed loop).
- System boundaries not defined.
- Some equipment campaigned between products.



Why Model? -- Desired Outcomes

Create control system which predicts system outcomes, when to intervene, and what the optimum intervention policies should be enhancing our ability to:

- solve complex decision problems;
- understand limitations of system structure;
- understand natural system variability (dynamic);
- synchronize and improve efficiency of system;
- retain system knowledge;
- drive organizational learning faster.

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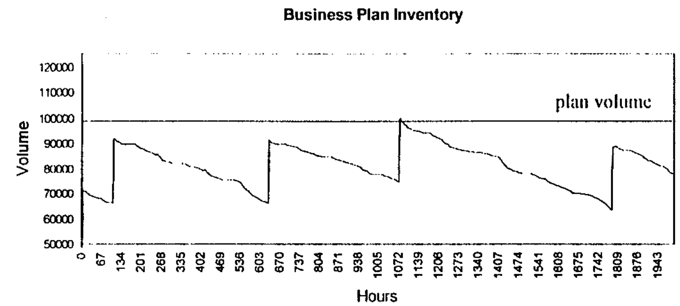
Model Development

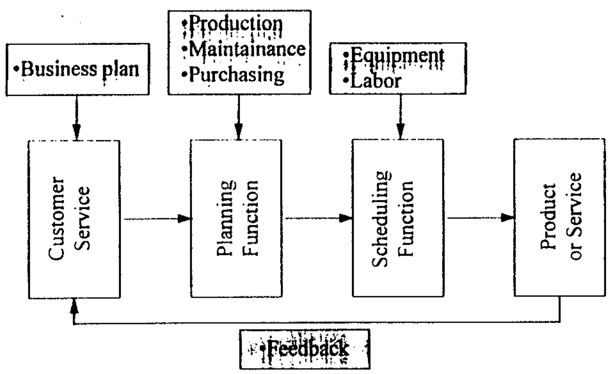
- Define system boundaries and accountabilities
- Create manufacturing instructions (sequence and method)
- Generate material balance of entire system
- Encode system structure
  "Plumbing":
    - material flow
    - operational interdependencies
  "Decisions":
    - decision making policies
    - unwritten practices
- Test/validate results against actual system outcomes

Customer Service

Business Plan:
Meet and/or exceed customer requirements maintaining inventory less than plan.

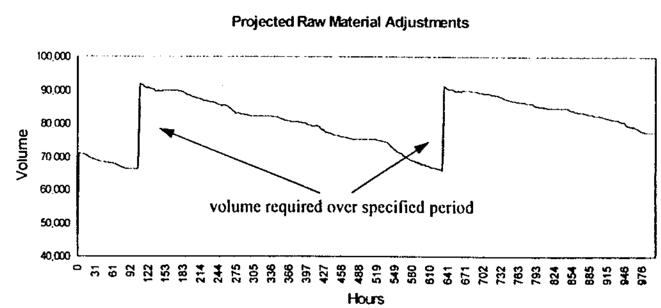


Example



Planning Function

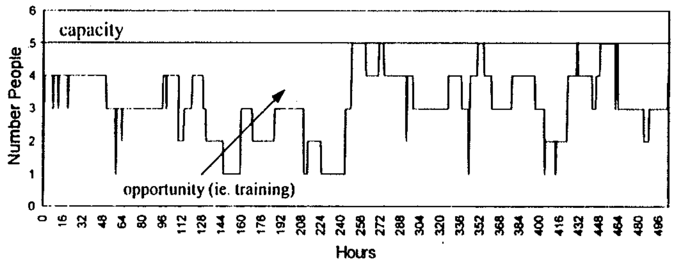
Raw Material Requirements:
Purchase adequate raws to compensate for natural losses of system.



Scheduling Function

Labor Requirements:
Effectively schedule resource demand and not exceed resource capacity.

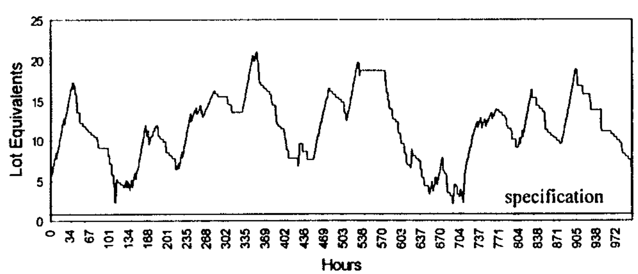
Projected Staffing Requirements



Product or Service

Customer Requirement:
Maintain usable material inventory above one (1) lot equivalent.

Projected Usable Inventory Level



Overall Results

- Cycle time mean reduced 40%
- Cycle time variability (3-sigma) reduced 55%
- Inventory volume reduced (optimized) 33%
- Manufacturing instructions/intervention policies developed
- Control limits/targets established which reflect system dynamics
- Dynamic staffing model developed
- Predictable production schedule implemented
- Production schedule extended to functional partners
  (est. interface with Maint., Utilities, Analytical, Purchasing)
- System tampering reduced

Cultural Observations

- New view of control system definition & application has emerged
- Activities are shifting from reactive to proactive
- Able to manage manufacturing operations with skill in months rather than years
- Work environment: Fear of Unknown to Exploring Possibilities
- Value and implication of change easily tested to assist in prioritization