Chemical Product Design

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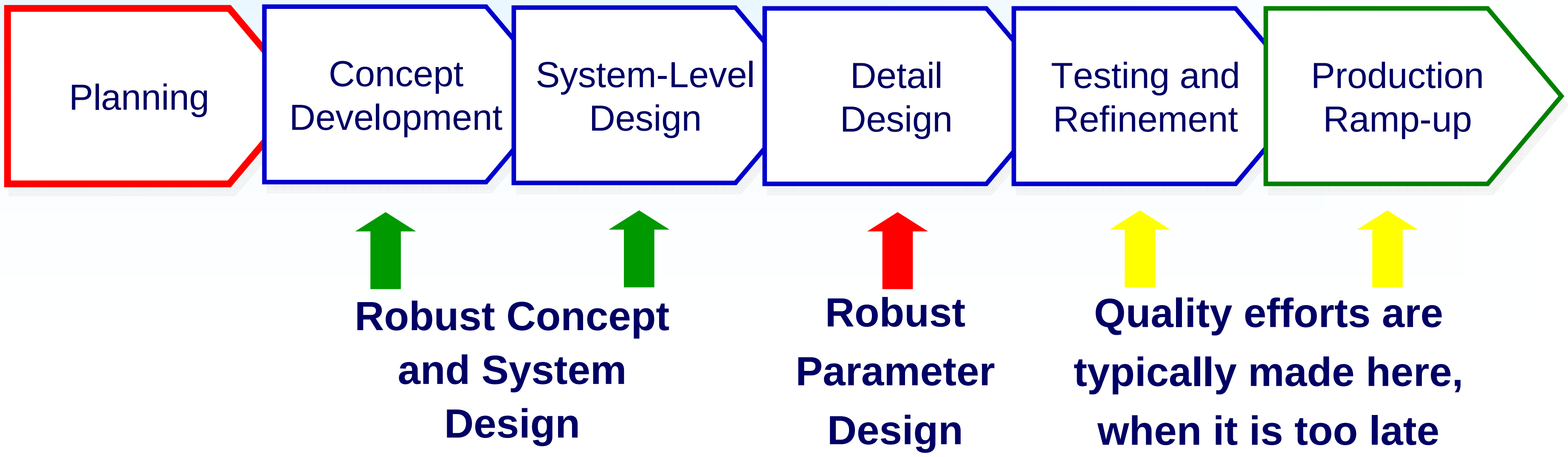
PART XII. Risk Assessment
Risk Management

- Risk Assessment
- Risk Management

Robust Design and Quality in the Product Development Process



Risk Assessment & Risk Management

- **Product Selection**

  - Object criteria (heat transfer, kinetics)

  - Subjective criteria (comfort, ease of use)

  - Engineers typically aren't comfortable with the subjective criteria, but we need to use them anyway.

- **Unknowns – What if we aren't sure if various aspects of a new product will work? Missing synthetic steps? Transport situations outside of the realm of typical correlations?**

- **This is risk:**

  - *Risk assessment: how serious is our lack of knowledge vis-à-vis our product design? This will be about money eventually.*

  - *Risk management: how can we reduce the risk?*

Risk Assessment & Risk Management

Properties of Risk

- Future
- Probability
- Possible Impact or Loss
- Time Dependent
- May Provide Opportunities

Types of Risk

- Technical
- Performance
- Schedule
- Cost
- Field Supportability
- Security

Basic Sources of Risk

Unrealistic constraints

Budget

Schedule

Performance

Incorrect Inputs

Requirements

Instructions

Expectations

Resources

People

Funding

Training

Program Risk

Poor Results

Technically non-compliant

Late Delivery

Too Expensive

Poor Quality

Unsafe

Risk Assessment Process

◆ **Identify & catalog the risks**

- Discuss the risks with our core team and with others in our organizations, especially those in manufacturing, who up to now may have been less involved with product design than other groups.

- Contact customers, especially the lead users of our product

- Consultants who looking for problems outside our organization's experience

◆ **Can we estimate the degree of risk with our current technical tool set ?**

- Choose a probability and a consequence of each risk

(a) Probability < 0.3 : Risk is *Negligible* Consequences of a risk is small < 0.3

(b) Probability around 0.5 : Risk is *Significant* Consequence is significant around 0.5

(c) Probability > 0.9 : Risk is *Very Likely* Consequence is severe enough to kill the project > 0.9

◆ **How do our current product design choices compare in terms of risk ?**

[Risk Level] = [Risk Probability] * [Risk Consequence]

Risk Assessment Process

- **Reduce the Risk before Proceeding with Product Development**
  - Traditional method of risk management in product development
  - This method works well, bur it is slow and can be expensive
- **Accept the Risk and Proceed**

Note that time to market is a key consideration in product development today – hence delay = risk; while doing more research to reduce risk always seems to be the best policy, delay in product development can kill a project, and hence be the more risky course.

When balancing delay versus more research / development, some issues are considered too important to society allow for their neglect:

- Health
- Environment
- Safety

Risk versus Stage of Development: New Drugs

Status	Chemical Status	Quality Status	Risk
Preclinical efforts	**Major process work needed**	**Few methods available**	**High**
Phase I clinical trials	**Laboratory procedures available**	**Analytical development necessary**	**High**
Phase II to Phase III clinical trials	**Pilot plant production**	**Analytical methods in place**	**Moderate**
Late-stage clinical trials	**Production process fixed**	**Methods validated**	**Low**
Mature product	**Plant process available**	**Quality control key**	**Low**
Generic drug	**Patents available**	**Methods sometimes available**	**Moderate**

Source: **Charles M. Boland, Cedarburg Laboratories, quoted in** ***Chemical Engineering News,*** **Feb. 14,2000.**

Wind Power vs. Fuel Cells for Home Energy Production

In many European companies, electricity companies are required to provide power to homes at a fixed connection fee and standard cost per unit consumed, regardless of the homes' remoteness. Laying many kilometers of cabling to connect a single house to the national grid is clearly uneconomic. **Investigate alternative sources of electric power for isolated homes.**

- **Needs** – We will not attempt to provide electric heating, but will aim to fulfill all other normal domestic requirements, such as cooking, lighting, cooling, and so on. A little research indicates typical power require-ments to average 3kW with a peak loading of 15kW (mainly a result of cooking). This provides our specs.

- **Ideas** – There are a very large number of ways of generating electricity, some obvious (such as hydro-electric power), others more bizarre (natural gas from manure). Idea generation and initial screening might lead one to consider four leading contenders: a diesel generator, wind power, solar power, and a fuel cell

- **Selection** – For us, as the electricity provider, the primary selection criterion is going to be cost, both in terms of capital and the running cost providing the specified power. (Remember we can only charge the standard, national rate.) Clearly our solution must also be acceptable to the customer.

Wind Power vs. Fuel Cells for Home Energy Production

Risk Assessment for Wind Power

Risk	Probability	Consequence	Risk Level
Customer Acceptability	**0.5**	**0.5**	**0.25**
Regulatory Acceptability	**0.5**	**0.7**	**0.35**
Maturity of Technology	**0.1**	**0.3**	**0.03**
Reliability	**0.7**	**0.3**	**0.35**

***Note*: The most serious risks are regulatory and reliability**

Risk Assessment for the Fuel Cell

Risk	Probability	Consequence	Risk Level
Customer Acceptability	**0.3**	**0.5**	**0.15**
Regulatory Acceptability	**0.1**	**0.3**	**0.03**
Maturity of Technology	**0.5**	**0.7**	**0.35**
Reliability	**0.5**	**0.5**	**0.25**

***Note*: The risks assume hydrogen can be handled dsfely**

Example: Taking Water Out of Milk at The Farm

◆ **Transportation of milk from remote dairies expensive; mostly transport of water**

◆ **Typical dairy could reduce 4,000 kg/day to 1,000 kg/day of concentrate**

◆ **Four unit operations considered**

- Evaporation
- Absorption
- Spray drying
- Reverse osmosis

Example: Taking Water Out of Milk at The Farm

The Initial Screening…

- Evaporation most established technology; Be careful energy integration
- Absorption into inorganic gels cannot be achieved selectively without large energy use requirements during regeneration
- Absorption into organic gels – not selective!
- Spray drying – useful only at 50% solids and above, not useful for milk
- Reverse osmosis – membrane will foul easily in presence of heterogeneous substance such as milk.

Hence, evaporation makes the cut….but we have to carefully design for most efficient use of energy.

Example: Taking Water Out of Milk at The Farm

Evaporation Choices

- Extensive energy analysis suggests use of 64℃ steam to vaporize 60℃water, heat pump to provide energy to 60℃ residual water
- Three possible forms of evaporators

- Falling Film

- Centrifugal Evaporator

- Membrane Evaporator

Example: Taking Water Out of Milk at The Farm

General Specifications

- Physical Properties of Milk
  - Like that of water
  - Density: 1000 kg/m^3
  - Thermal Conductivity: 0.6 W/m-°K
  - Viscosity goes from 0.9 cP (milk) to 10 cP (milk concentrate)
- Total Heat Transfer

$$Q = UA\Delta T = \Delta\hat{H}_{vap} N_1$$

where U is the overall heat transfer coefficient

A is the evaporator area, N_1 is 3000 kg/day or 0.035 kg/sec

ΔT **is the temperature difference, in this case 4 °C**

$\Delta\hat{H}_{vap}$ **is the specific heat of vaporization at 60 °C, here about 2430 kJ/kg**

Example: Taking Water Out of Milk at The Farm

What do we need to determine to make a decision ?

- UA = 21 kW / °K
- $$\frac{1}{U} = 1 / h_{steam} + 1 / h_{wall} + 1 / h_{milk}$$

where h_{steam} is the individual heat transfer coefficient of the condensing steam

around 5000 W/mK

h_{wall} is that of the evaporatior surface, typically 20,000 W/mK

h_{milk} (penetration theory) ~k_T / δ, where δ is the thickness of the layer

(of milk) and k_T is the thermal conductivity

- Thus, $h_{milk} \sim 0.60 / \delta$

Example: Taking Water Out of Milk at The Farm

Falling Film Evaporator

- Calculation of Film Thickness

- A smooth film requires a Weber number (We) greater than a critical value of 2

$$We = (\rho v^2 \delta / \sigma) \geq 2$$

where, ρ is the milk's density; v is the its velocity; σ is its surface tension

- For a film falling due to gravity:

$$v = \rho g \delta^2 / 3\mu$$

where, g is the acceleration due to gravity and μ is the viscosity

- Combining the equations

$$\delta = \left(\frac{18\mu^2\sigma}{\sigma^2 g^2} \right)^{1/5} = \left[\frac{18(0.1\, g / cm\ sec)^2\ 30\, g / sec^2}{(1\, g / cm^3)^2\ (980\ cm / sec^2)^2} \right]^{1/5} = 0.14\ cm$$

Thus, h_{milk} ~ [(0.60 W/mK) / 0.003 m]; A is hence 100 m^2

Example: Taking Water Out of Milk at The Farm

The Other Options

- Centrifugal Evaporator
  - **Average film thickness:** $\delta = 25\,\mu m$
  - **U is about 5000 W/m²°C**
  - **Evaporator area A is 5 m^2**
  - **Unfortunately, centrifugal evaporators are very expensive – over $50,000**
- Membrane Evaporator
  - **Membrane spacer:** $\delta = 600\,\mu m$
  - **U is about 900 W/m^2°C**
  - **Evaporator area A is 23 m^2**
  - **Membrane modules: $10/ m^2…… but membrane evaporators represent a new tech.**

Example: Taking Water Out of Milk at The Farm

Risk Associated with Membrane Evaporator

Risk	Probability	Consequence	Risk Level	Mitigation
1. Difficult to make heat transfer membrane	**0.1**	**0.5**	**0.05**	**Use parallel heat exchange technology**
2. Difficult to make evaporation membrane	**0.3**	**0.5**	**0.15**	**Existing data suggest, at most, required membrane area doubles**
3. Cannot easily manifold the module	**0.5**	**0.2**	**0.10**	**Can mitigate with larger steam channel**
4. Evaporation flow is slow	**0.5**	**0.2**	**0.10**	**Use larger membrane spacer in steam channel**
5. Cannot satirize effectively	**0.3**	**0.9**	**0.27**	**Chemical cleaning pre-ferred, but requires no dead spots**