

INTEGRATING PROCESS SAFETY AND INNOVATION

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WHO AM I?

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- Work experience includes:
 - Diamond Shamrock – specialty chemicals
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 - Olin Hunt – microelectronics chemicals
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 - BOC Gases – industrial gases
 - Schering-Plough - pharmaceuticals
 - ALZO International, Inc. – specialty chemicals

ATTRIBUTION



Information presented on these slides was obtained (with permission) from:

- **Integrating Process Safety and Innovation** – Peter N. Lodal, P.E. and Jennifer F. Mize, P.E., CEP Magazine, October 2016
- *...as well as 35 years of experience in the chemical process industry!*

Introduction

“This is a GREAT idea...what could possibly go wrong?”

- Innovators are an optimistic
- Process safety professionals are pessimistic
- What is needed is to meld the two productively, so that innovations can be brought to market safely.



The “SMEA”

- Hence, the need for a “*Success Modes and Effects Analysis*” (SMEA) at a very early stage in the development process.
- SMEA is the logical converse to the *Failure Modes and Effects Analysis* (FMEA) technique.
- At its most basic level, the SMEA asks the question:

“What if your proposal *succeeds*,
just as you anticipate?”

The SMEA Process: A Phased Gate Approach for Development / Innovation Projects



- **Invention or Discovery**
 - *Something new has been found!*
- **Business Case**
 - *What unmet customer or market needs will this product fulfill?*
- **Technical Feasibility**
 - *By what route / mechanism / process can this product be made?*
- **Commercial Feasibility**
 - *Can this product be made profitably?*
 - *Will people actually buy it for a price that makes it commercially attractive?*
- **Product Launch / Commercialization**
 - *Where will this product be made, and in what quantities?*

Stage 1

Invention / Discovery



- The innovation process begins with the discovery or development of something novel or unique, which appears to meet a commercial or technical gap in the market.
- SMEA can help guide laboratory work to arrive at decisions on:
 - *solvents,*
 - *raw materials,*
 - *synthesis pathways,*
 - *other technical issues that can impact commercial and technical viability.*
- Information even at this stage can facilitate an Inherently Safer analysis

Stage 2 The Business Case

- Do we understand the inherent risks of the process as proposed (solvents, raw materials etc.)?
 - *If so, are we willing to accept those risks?*
 - *If not, what information will need to be generated to make such a determination?*
- Is this a brand new product line for us, or is it an extension of existing products?
 - *Who else makes this product?*
 - *Is there information about this product already in the literature?*
- Such information, even if only qualitative, uncovered at this stage will be critical to a successful SMEA

An Example

- A process, where Stage 1 developmental efforts had been funded and staffed for some time, was presented to site management for full funding and implementation in an existing commercial scale facility.
- In the process of obtaining approvals to move forward, site management was only then made aware of the use of several raw materials and solvents which the site was unwilling or incapable of handling consistent with the corporation's risk management policy.
- This stopped the implementation dead in its tracks, and required substantial rework before acceptable alternatives were identified and vetted.

Lesson learned

- **Identification and review of the overall process chemistry is crucial before exiting the laboratory.**
- **Such requirements are particularly germane when using existing facilities which have not been specifically designed for the proposed chemistry, versus “green field” construction.**
- **Even for green-field construction, the cost of accommodation for risk mitigation may cause the project to be economically unattractive.**

Stage 3 Technical Feasibility

- At this stage, laboratory work is directed at finalizing the synthesis routes and process conditions to produce the desired material at the specifications and purity required.
- This sets the basis for the piloting efforts to follow in Stage 4.
- The fundamental question to be asked is:

“With the basic process developed in Stage 1, and the Business Requirements set forth in Stage 2, are we willing to proceed to Stage 3?”

Stage 3 Technical Feasibility

- You can often convince yourself that a process can be safely run at pilot scale due to limited quantities of materials.
- The effectiveness of the SMEA depends upon extending this analysis to the proposed commercial stage.
- SMEA questions at Stage 3 must focus on five issues for the commercial facility (not simply the pilot or demonstration facility).

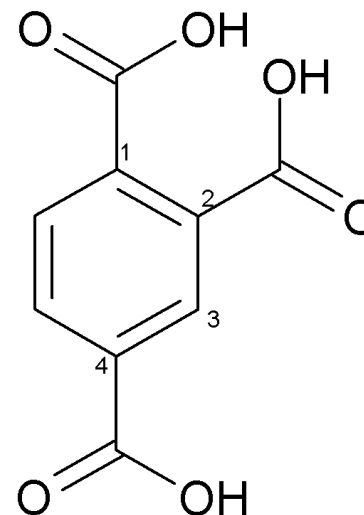
Stage 3 **Technical Feasibility**

These five categories are:

- 1. Raw Materials**
- 2. Processing Conditions and Hazards**
- 3. Products, By-products, Waste Streams**
- 4. Storage and Warehousing Issues**
- 5. Transportation Issues**

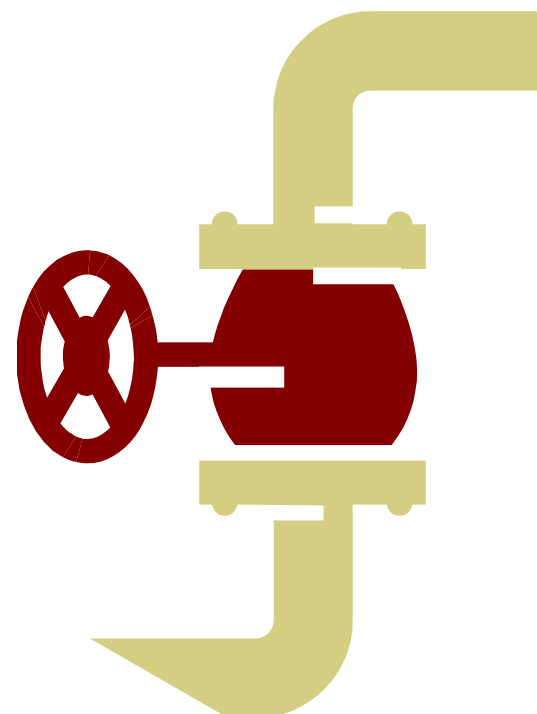
RAW MATERIALS

- **What raw materials will be needed?**
 - » *Available domestically?*
 - » *If imported, subject to tariffs?*
 - » *Available form (liquid, solid, gas)?*
 - » *Subject to environmental restrictions?*
 - » *Limited shelf-life?*
 - » *Minimum order volumes?*
 - » *Long lead-times?*
 - » *Standard / specialty product?*
 - » *Subject to specific manufacturing requirements, (e.g. USP, Kosher)?*



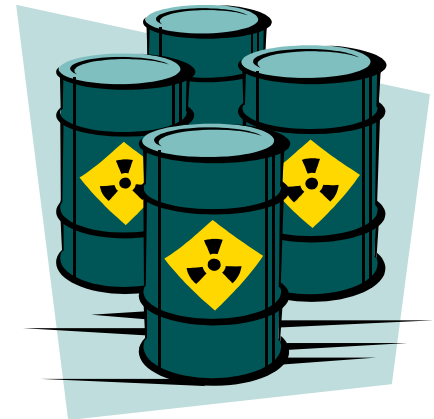
PROCESSING CONDITIONS

- **How do we make this stuff?**
 - » *Is existing equipment sufficient?*
 - » *Viscosities?*
 - » *Melting / boiling points?*
 - » *Phase changes?*
 - » *Exotherms / endotherms?*
 - » *Temperature / pressure / vacuum?*
 - » *Catalyst systems used?*
 - » *Packaging requirements?*
 - » *Equipment clean-up issues?*
 - » *Potential for cross-contamination?*
 - » *Minimum batch sizes?*



HAZARDS

- Will safety training be required?
- Will new MSDS's be required?
- Will new safety equipment be required?
- Are raw materials on the air permit list?
 - » *Permit modification required?*
- Are any new hazards being introduced into the plant?
 - » *Annual batch reporting issues?*
- Will equipment clean-up generate waste material?
 - » *Disposal issues?*
 - » *Wastewater system upset potential?*



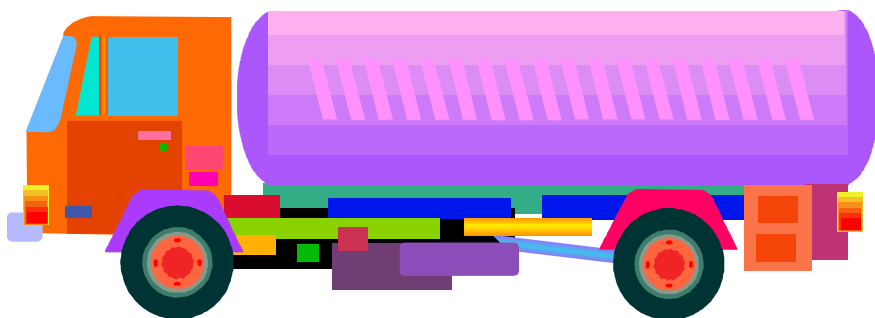
BY-PRODUCTS / WASTE STREAMS

- What are they?
- Quantities?
- Can they be re-used?
- Will customer take them back?
- Will they need to be disposed of?
 - » *Hazardous or non-hazardous waste?*



STORAGE / TRANSPORTATION ISSUES

- **Special storage requirements?**
 - » *Heated / refrigerated storage req'd?*
- **Special shipping requirements?**
 - » *Heated / refrigerated shipment req'd?*
- **Shelf-life issues?**
 - » *Does it “go bad”?*
- **Can it be reworked if necessary?**



Stage 3 **Technical Feasibility**

- **In the extreme, certain answers at Stage 3 may constitute a “showstopper”, including (but not limited to):**
 - **Waste that cannot be economically handled**
 - **Lack of reliable raw material supply**
 - **Utility requirements beyond the site’s capabilities**
 - **Products, intermediates or wastes that fall outside the company risk tolerance guidelines**

An Example

- **An innovation process with a strong business case based on laboratory data was moving towards piloting efforts. The overall mass balance for the proposed process showed that the volume and concentration of the waste streams could not be easily handled by the site's existing treatment facilities (incineration, wastewater treatment).**
- **Shipping the waste off-site involved a significant increase in costs, as well as additional environmental issues associated with over-the-road transport of this material.**
- **The commercial feasibility was greatly impacted by consideration of this additional cost.**

Lesson Learned

- **Evaluation of manufacturing support capabilities (including permitting issues) need to be initiated very early in the process to ensure that they do not become either critical path items (delaying commercialization) or complete barriers to commercialization.**

- The technical veracity of the process should be well developed:
 - *Processing conditions and overall composition ranges are established*
 - *Processing equipment selected and (if necessary) designed to determine commercial feasibility.*
- Yields, space-time ratios, recycle and purge streams are determined and optimized through piloting efforts.
- *Chemistry variations should be minimal at this stage.*

Stage 4 Commercial Feasibility



- The piloting efforts must include identification of potential safety concerns during upset conditions.
- A working knowledge of the **intended** chemistry is not sufficient to ensure reactive hazards are adequately addressed.
- The **unintended** chemistry, such as side reactions, decompositions, and unidentified intermediates, can lead to unsafe conditions.
 - *Physical property and VLE accuracy are critical at this stage*
 - *Consider information specific to relief design*

Stage 4

Commercial Feasibility



- **The results of the SMEA performed in Stage 3 can now be rolled into the hazard assessment done for the pilot or demonstration facility.**
- **Each of the five Stage 3 categories can be incorporated into the appropriate process node.**
- **The information can be used to address the potential hazard directly, or propose a resolution plan which will generate the required information for a full assessment.**

- **Extrinsic factor issues:**
 - *Facility siting issues,*
 - *Design of processing and storage equipment,*
 - *Specific transportation options will need to be assessed and addressed.*
- **The hazard assessment should include solutions for both the pilot and full-scale facilities**

- Particular attention should be paid to areas where solutions greatly differ between pilot and full-scale operations:
 - *Ventilation (running in a hood at 100 ft/min face velocity)*
 - *Relief Scale-up*
 - *Heat Transfer (especially for exothermic reactivity issues)*
 - *Control and Automation issues (no longer in glass)*
 - *Dynamic issues (heat up, cool down, other transitions)*
 - *Shrapnel / overpressure protection (piloting in a high pressure cubicle) where distance may be the only practical full scale solution.*

An Example

- A process which had been fully vetted from a safety and regulatory standpoint was ready for commercialization. However, basic design information (pure component physical properties, VLE, etc.) had been estimated, rather than measured, at the pilot stage in order to facilitate the engineering design process. Ideal properties were assumed and used for equipment sizing.
- On start-up, the plant did not perform up to expectations, and required additional investment to correct design issues uncovered in the initial product runs, delaying product delivery at the projected sales volume.

Lesson Learned

- **Identify raw materials / intermediates / products which do not have basic design data available, and begin a parallel laboratory or literature search effort to generate or discover the needed information.**

Stage 5

Launch / Commercialization



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WHERE
TECHNOLOGY
CONNECTS

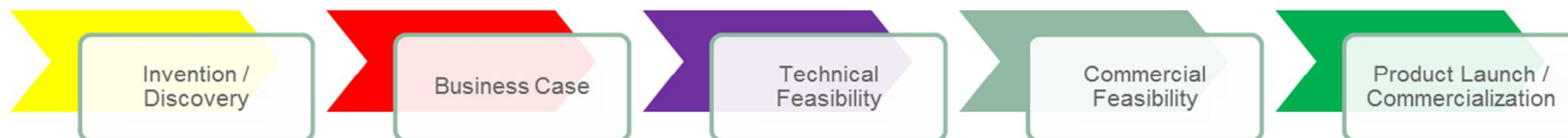
- If Stages 1-4 are successful, Stage 5 is a straightforward matter of using the technical outputs from Stages 1-3, along with the commercial and regulatory inputs of Stage 4, to determine whether the product can be commercialized successfully.





- All successful launches must meet the same basic criteria:
 1. **Commercially viable** - *There are customers willing to pay for what you are making*
 2. **Profitable** - *Customers are willing to pay enough to provide a reasonable rate of return*
 3. **Legal** - *All regulatory and statutory requirements are being met*
 4. **Socially Acceptable** - *The community in which the product is being made is willing to accept its presence*
 5. **Safe** - *The safety risks (personnel and process) have been identified and addressed adequately*

Conclusion



- **Successful application and implementation of the SMEA concept will insure that all of relevant criteria for moving from invention to product launch are met in a satisfactory and timely manner.**

"There is no expedient to which a man will not resort to avoid the real labor of thinking."

Sir Joshua Reynolds



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