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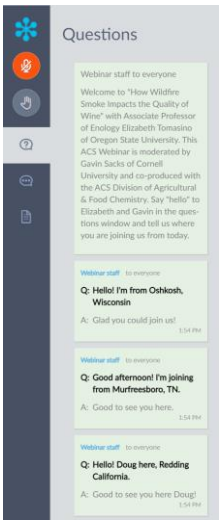

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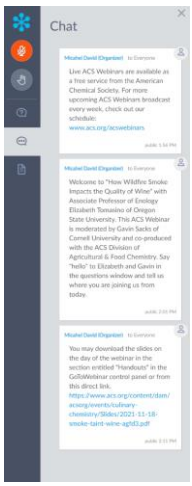

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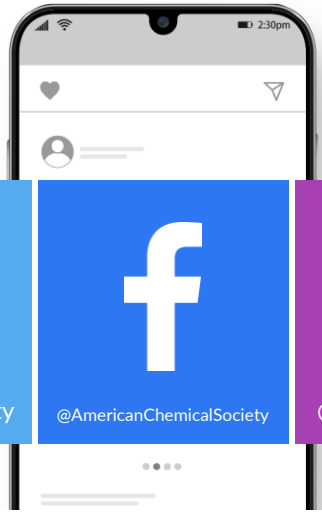

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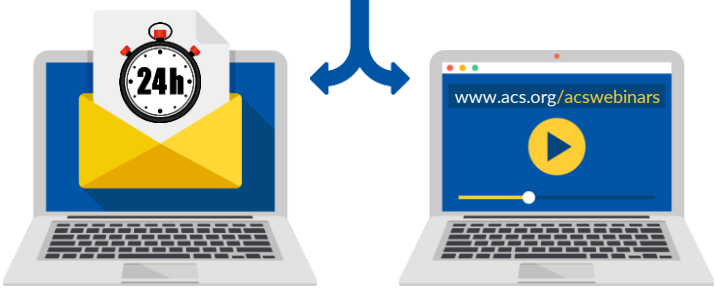

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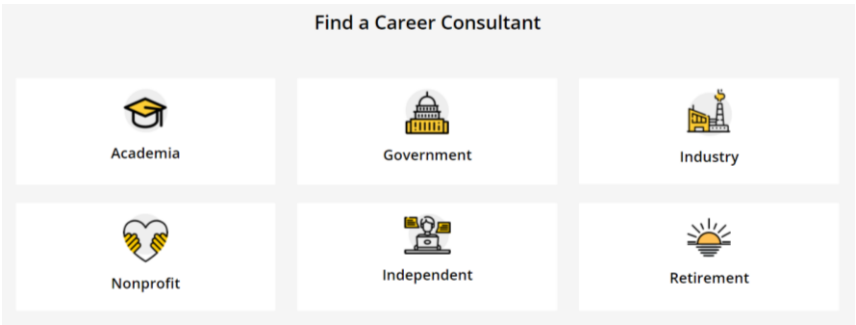

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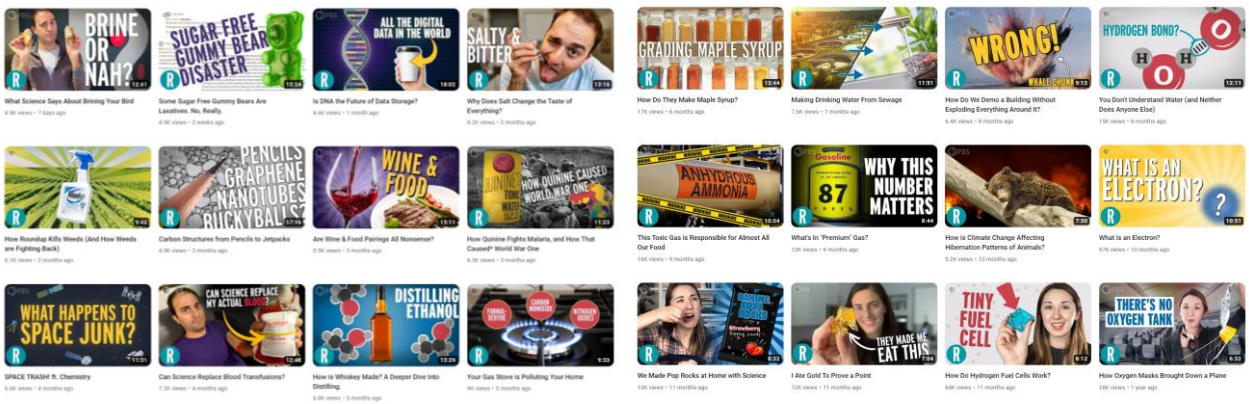

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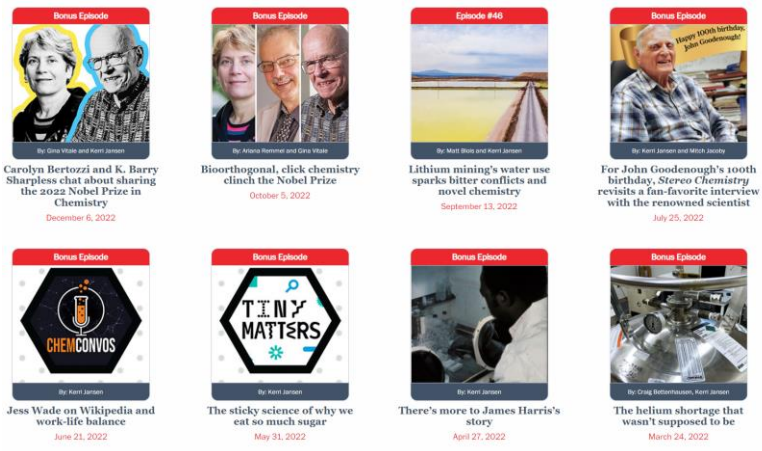

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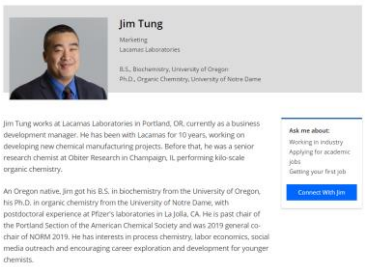

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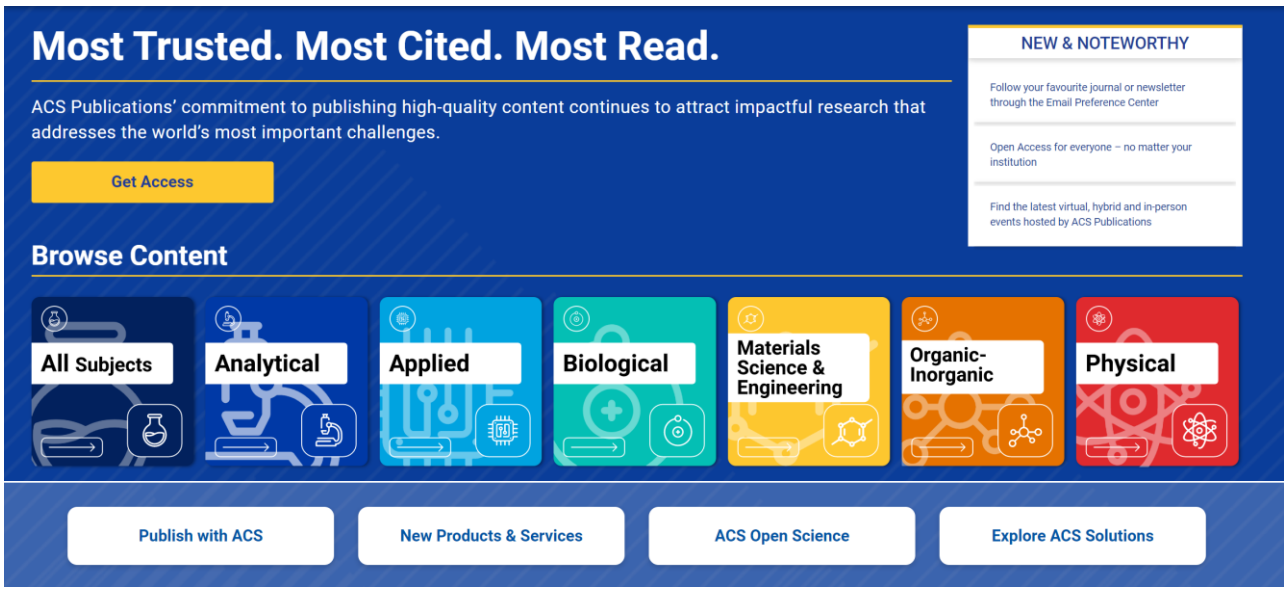

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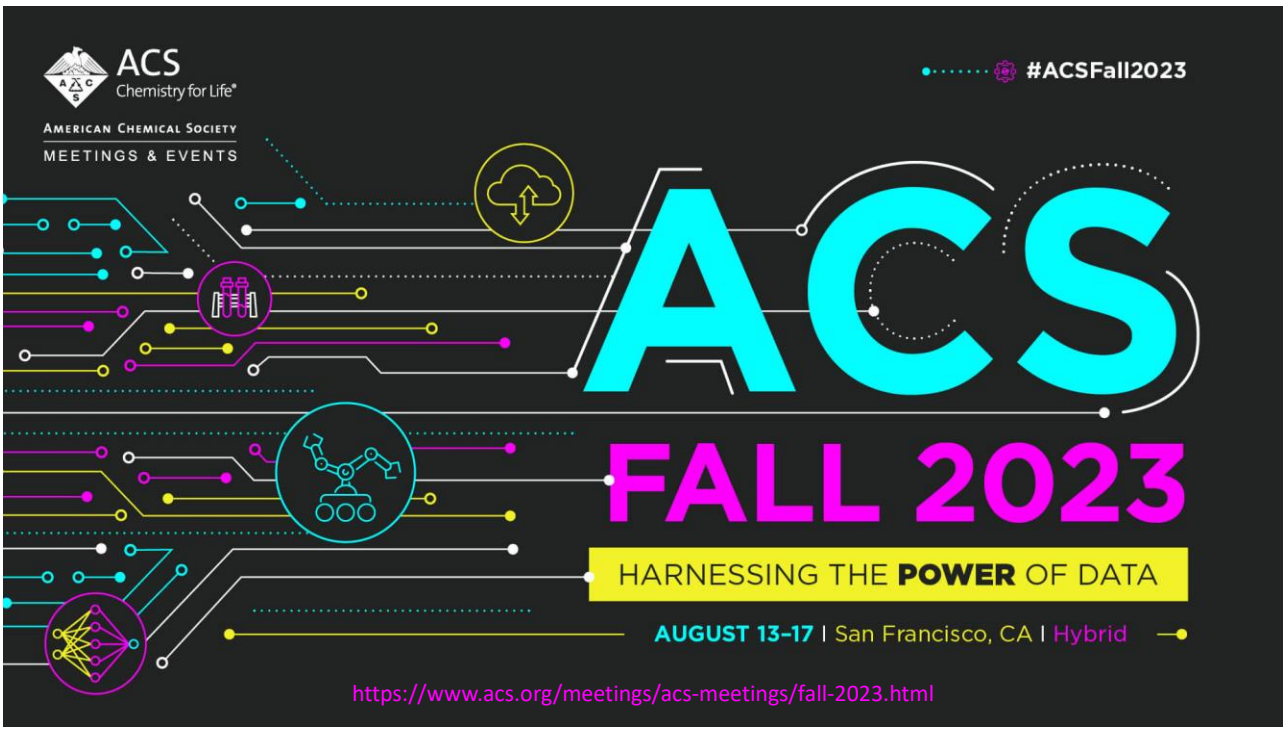
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Process Chemistry: What Is It and How It's Done

August 12th | Grand Hyatt San Francisco

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This course is an overview of process chemistry, which is a support branch of synthetic chemistry. A survey of what process chemistry is and how a process chemist performs their work is covered. Important topics covered include:

Key Topics Include:

- The SELECT paradigm.
- A comparison of batch versus continuous flow chemistry.
- Retrosynthetic analysis.
- Process case studies from pharmaceuticals and chemical manufacturing
- An overview of Design of Experiments (DoE).

Facilitated by

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Process Chemistry: A Day in the Life

JOSEPH A. MARTINO III, MS

Adjunct Professor of Chemistry, Immaculata University and ACS Institute Instructor

BRYAN TWEEDY, BS

Assistant Director, ACS Education, Office of Career and Professional Education, American Chemical Society

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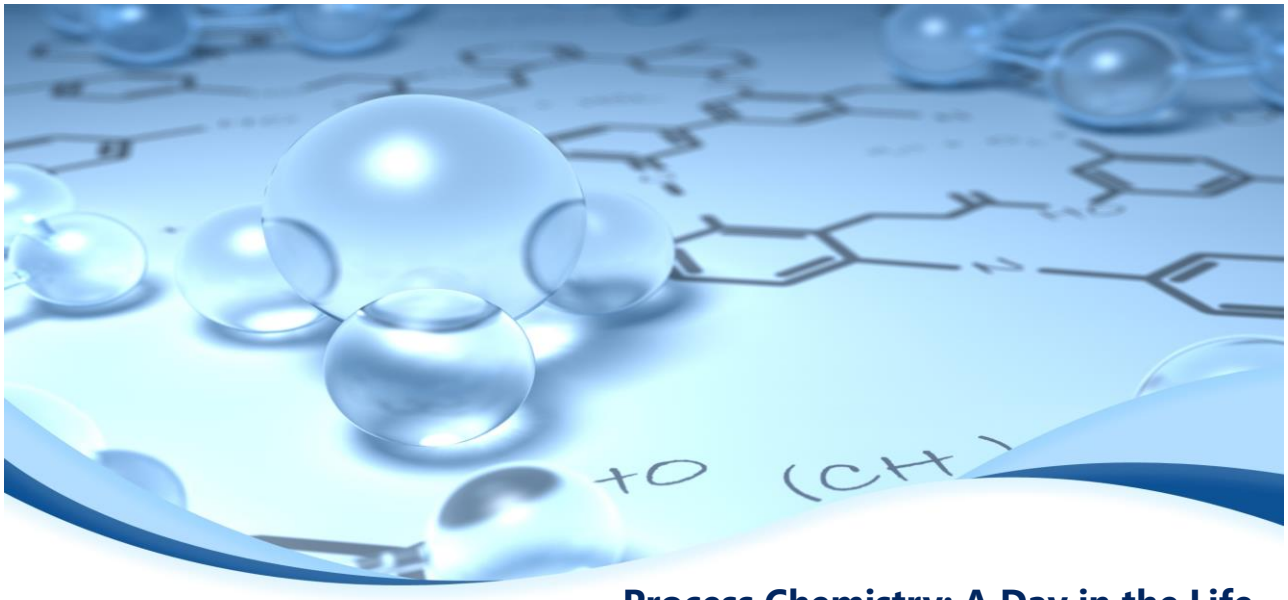

Process Chemistry: A Day in the Life

Presentation for ACS Webinars
June 8, 2023

Joseph A. Martino III

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A little about me

- MS, Chemistry, Villanova University (go Wildcats!)
- Senior Chemist, Arkema, King of Prussia, PA
- Scientist, GlaxoSmithKline, King of Prussia, PA

Currently

- Wearer of multiple hats for ACS
- Adjunct Professor of Chemistry, Immaculata University

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Audience Survey Question

ANSWER THE QUESTION ON BLUE SCREEN IN ONE MOMENT

What experience do you have in process chemistry right now?

- None
- Just starting
- 1-2 years
- More than 2 years
- 10+ years

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What is Process Chemistry?

- **A subset of synthetic chemistry – can be organic, organometallic, or inorganic.**
- **A service function to synthetic chemistry – this is not basic R&D, but an application of it!**
- **Main goal of process chemistry is to answer the following questions?**
  - Can a small-scale synthesis be scaled up at all?
  - If it is scaled up, what are the differences between the small-scale experiment and the large-scale experiment?
  - Can the large-scale experiment be transferred to plant equipment?

The ultimate goal is to manufacture commercial quantities.

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Types of Process Chemistry

- **Chemical Development:** A dedicated department which takes the original synthesis of a compound, re-works it to make it more efficient, and runs preliminary large-scale experiments up to the kilogram scale on kilo-lab equipment.

- **Process Development:** A dedicated department which takes current, large-scale synthesis and either updates the synthetic sequence or qualifies starting materials of a current plant synthesis to ensure final produce specifications.

Chemical and Process Development frequently interact with chemical engineers.

Do not confuse Process Chemistry with Large-Scale Preparations Chemistry!

Large-Scale Preparation Chemistry: In-house functionality where large quantities of compounds are made for internal company customers.

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Interaction with Chemical Engineers

- **The chemical engineer is ultimately responsible for manufacturing the synthesis on a large, commercial scale.**

- **The process chemists work with the chemical engineer:**
  - Work with the engineer to construct lab equipment that mimics plant equipment.
  - Modify the execution of the reaction to simulate as closely as possible what happens in the plant.
  - Monitor the plant reaction on transfer to ensure reproducibility from lab equipment to plant equipment.

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Pros and Cons

PROS

- You get to wear multiple hats.
- You interact with multiple groups.
- You get exposed to cool chemistry on a very large scale.

CONS

- You will not get to develop a new chemical reaction.
- You will most likely not get published for this work.
- You are dealing with more hazardous situations than on a small scale.

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Audience Survey Question

ANSWER THE QUESTION ON BLUE SCREEN IN ONE MOMENT

What's the largest scale reaction that you ran?

- No reaction – just curious about process chemistry
- 0 – 100 mg reactions
- Gram-scale reactions
- Kilogram-scale reactions
- Pilot plant and up

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A Walkthrough…

You are given a compound that medicinal chemists have found to have efficacy in a therapeutic area.

Your task: Devise a synthesis to transfer to manufacturing.

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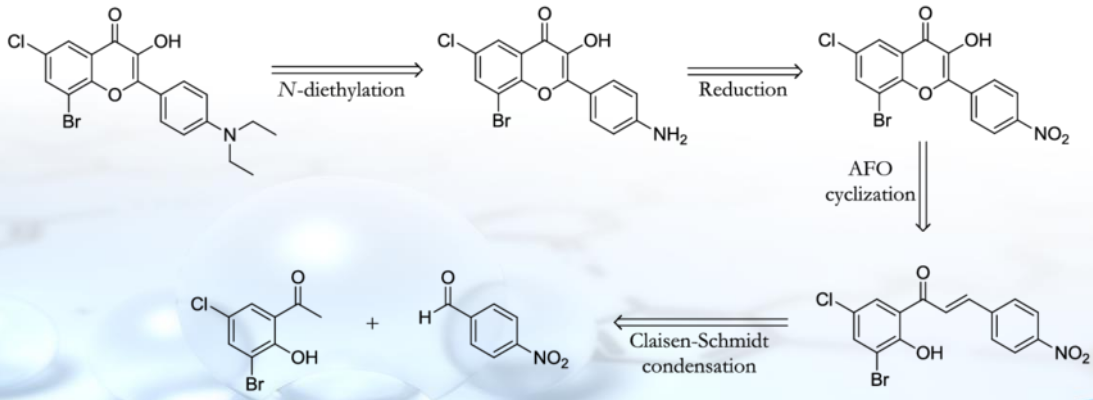
Remember Retrosynthesis?



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Retrosynthesis

- **For organic synthesis, thought process is this:**
  - You devise a compound never made before
  - You break down the novel compound to its starting materials.
- **For process chemistry, thought process is this:**
  - The compound is made and already in the bottle. It is no longer novel (though may be IP).
  - The synthesis for the compound is already made.
  - Can you devise a synthesis with a smaller number of steps?

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Next, the library

- **Did someone do this on a large scale before?**

(Why reinvent the wheel?)

- **Most important: If it was done on a large scale before, is it in a patent?**

Your company might need to license it if it is – this can cost some $$$$$$$.

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Next, RUN THE EXPERIMENT!

- **The compound has been made – you're not reinventing the wheel . . . unless you devised a synthesis with fewer steps from retrosynthesis. Then you run on small (mg) scale to prove concept.**
- **Once concept is proven (or if it's proven and you're happy with the current synthesis), you scale it up to look for scale-up effects**
  - Exotherms (launch hazard, temperature control)
  - Agglomerations (no "bowling balls" in a reactor!)
  - Viscosity issues (do you get a slurry and can you move it?)
- **Scale up further (1L scale, 2L scale, 5L scale, kilo-lab scale)**

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End Game . . . Or Is It?

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This Might Be Your End Game!

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Batch Chemistry? Or Continuous Flow Chemistry?

Batch Chemistry

- Synthesis performed in a reaction vessel or vessels with the goal of making one quantity of a given compound.
- Mathematically modeled using Continuous Stir-Tank Reactor system (CSTR)

Continuous-Flow Chemistry

- Synthesis performed in tubing or piping, where reagents are mixed *in situ* at a defined flow rate, forming product which is dispensed in a collection vessel.
- Mathematically modeled using Plug-Flow Reactor system.

There are some plant operations that use batch/continuous flow hybrids.

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We made it! Now we must optimize it!

Design of Experiments (DoE)

- Use of statistical analysis to determine the most optimal parameters to run a chemical process
- This process is based upon Analysis of Variance (ANOVA)
- The purpose of this statistical work is to determine a mathematical model that is statistically valid in order to determine optimal parameters for specific, maximized responses (i.e.: enantiomeric excess, percent yield, etc.)
- Goal is to find a "sweet spot" of parameters to reproducibly obtain a maximized end result.

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The SELECT Paradigm

Butters, *et al*, *Chem. Rev.* 2006, ***106 3002-3027.***

A system designed by process chemists at Pfizer

- **Acronym which stands for Safety, Environmental, Legal, Economics, Control and Throughput**
- **Emphasizes that process chemistry is inherently interdisciplinary**
  - Frequent interactions with HES personnel.
  - Must design processes in accordance with FDA/EPA/TSCA/EINECS rules.
  - Must be certain that you are legally authorized to practice the chemistry (Is it yours? Or do you need to license it?)
  - Can you afford to practice the chemistry? Do you need an infrastructure investment to do it?
  - Obviously, you need to control the chemistry and maximize the product produced.

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Pharmaceuticals vs. Chemical Manufacturing

Process chemistry is not limited to pharmaceuticals!

- **Process chemistry can also be found in chemical manufacturing.**
- **This can take the same format as pharmaceuticals (i.e.: scale up and optimization of an existing small molecule process).**
- **This can also utilize DoE (think polymer chemistry)**
- **In the chemical manufacturing context, process chemistry can also re-explore existing processes**
  - Qualifying raw materials for existing processes
  - Qualifying proposed modifications to existing plant infrastructure

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Thank you for your attention!

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