Laying the Foundation: How to Build a Process Safety Team in the Pharmaceutical Industry

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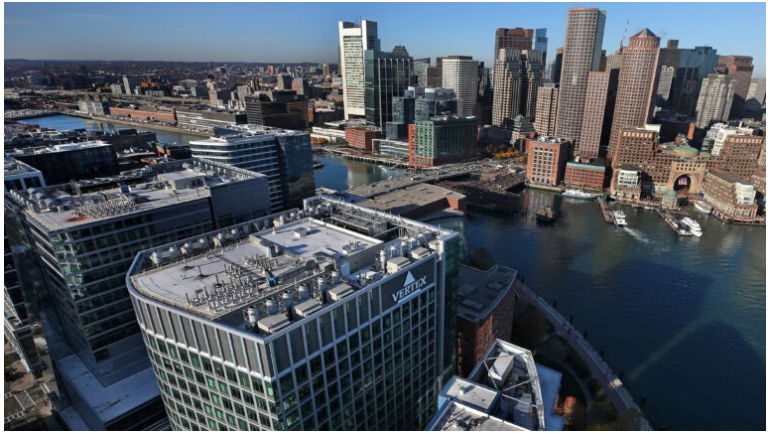
(Spring 2026)

May 7, 2026

An Amazing Opportunity Was Presented…

The offer:

- **Lead development of assets coming out of Boston Medicinal Chemistry Department**
- **Design and build your own process safety team**
  - **Equipment**
  - **Workflows**
  - **Across three sites (Boston, San Diego, and Oxford)**



Boston, MA

Non-GMP and GMP equipment trains from 10 L up to 250 L

San Diego, CA

Oxford, U.K.

Non-GMP equipment trains from 1 L up to 50 L

Process Safety Testing Requires a Tiered Approach

Important Publications

Organic Process Research & Development

Safety/Environmental Report

pubs.acs.org/OPRD

Merck's Reaction Review Policy: An Exercise in Process Safety

Ephraim Bassan,[*,†] Rebecca T. Ruck,[*,‡] Erik Dienemann,[†] Khateeta M. Emerson,[†] Guy R. Humphrey,[§] Izzat T. Raheem,[∥] David M. Tschaen,[§] Thomas P. Vickery,[†] Harold B. Wood,[⊥] and Nobuyoshi Yasuda[§]

https://pubs.acs.org/doi/10.1021/op4002033

ORGANIC PROCESS RESEARCH & DEVELOPMENT

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Article

Process Safety in the Pharmaceutical Industry—Part I: Thermal and Reaction Hazard Evaluation Processes and Techniques

Ayman D. Allian,* Nisha P. Shah, Antonio C. Ferretti, Derek B. Brown, Stanley P. Kolis, and Jeffrey B. Sperry

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Process Safety in the Pharmaceutical Industry—Part II: Process Safety Labs and Instruments Used in Process Safety Labs for Thermal Hazards

Lady Mae Alabanza,[▽] Ayman Allian,[▽] Antonio C. Ferretti,[▽] Max Sarvestani,[▽] Jeffrey B. Sperry,[▽] Zhe Wang,[▽] Han Xia,[*,▽] and Shasha Zhang[▽]

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Process Safety in the Pharmaceutical Industry—Part III: Dust Hazard Evaluation

Published as part of Organic Process Research & Development special issue "Celebrating Lilly: 150 Years of Being a Medicine Company".

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***Key Takeaway:* As the scale increases the risk increases, the number and complexity of process safety tests also increases**

The Tiered Approach to Process Safety Testing

Tier	Research Lab	Scale-up Lab	Kilo-Lab	Pilot Plant	Commercial Manufacturing
1	✓				
2	✓	✓			
3	✓	✓	✓		
4	✓	✓	✓	✓	
5	✓	✓	✓	✓	✓
Typical scale	Up to 10 g	10 g to 500 g	100 g to 5 kg	10 kg to 50 kg	100s of kg to MT

Process Safety Testing Tiers

Tier 1 – Research Lab

Up to 10 g

In-House Process Safety Testing

Desk Screening

- Safety data sheets
- HEFG/ExFG lists
- Rule of 5
- Bretherick's Handbook of Reactive Chemicals
- CAMEO compatibility matrices
- Oxygen balance calculation

Instrumentation

- None (may have access to DSC or TGA)

Outsourced Testing

- DSC

Process Safety Workflows

- General Laboratory Safety
  - Desk screening
  - Proper PPE selection
  - General waste management
  - Proper storage of chemicals

Process Safety Testing Tiers

Tier 2 – Scale-up Lab

Up to 500 g

In-House Process Safety Testing

Desk Screening

- Safety data sheets
- HEFG/ExFG lists
- Rule of 5
- Bretherick's Handbook of Reactive Chemicals
- CAMEO compatibility matrices
- Oxygen balance calculation

Instrumentation

- **DSC**

Outsourced Testing

- **Calorimetry**
- **Off-Gas measurements**

Process Safety Workflows

- General Laboratory Safety
  - Desk screening
  - Proper PPE selection
  - General waste management
  - Proper storage of chemicals
- **DSC Workflow**

Process Safety Testing Tiers

Tier 3 – Kilo-lab

Up to 5 kg

In-House Process Safety Testing

Desk Screening

- Safety data sheets
- HEFG/ExFG lists
- Rule of 5
- Bretherick's Handbook of Reactive Chemicals
- CAMEO compatibility matrices
- Oxygen balance calculation

Instrumentation

- DSC
- **TSu (or equivalent)**
- **Calorimetry (with off-gas measurements)**

Outsourced Testing

- **ARC**
- **Impact Testing**
- **Explosivity Screening**
- **Autocatalysis screening**

Process Safety Workflows

- General Laboratory Safety
- DSC Workflow
- **Tech-transfer guidance for kilo-lab**
  - **When to perform TSu testing**
  - **When is calorimetry required**
  - **Identifying autocatalytic decompositions**
- **Mitigating static hazards workflow**

Process Safety Testing Tiers

Tier 4 – Pilot Plant

Up to 50 kg

In-House Process Safety Testing

Desk Screening

- Safety data sheets
- HEFG/ExFG lists
- Rule of 5
- Bretherick's Handbook of Reactive Chemicals
- CAMEO compatibility matrices
- Oxygen balance calculation

Instrumentation

- DSC
- TSu (or equivalent)
- Calorimetry (with off-gas measurements)
- **ARC**
- **Impact Testing**
- **Explosivity Screening**
- **Autocatalysis screening**

Outsourced Testing

- **Friction testing**
- **Dust testing**
- **U.N. testing**
- **Vent sizing**

Process Safety Workflows

- General Laboratory Safety
- DSC Workflow
- Tech-transfer guidance for kilo-lab
- Mitigating static hazards workflow
- **Tech-transfer guidance for pilot plant**
- **Explosivity testing workflow**
- **Dust testing workflow**

Process Safety Testing Tiers

Tier 5 – Commercial Manufacturing

Up to MTs

In-House Process Safety Testing

Desk Screening

- Safety data sheets
- HEFG/ExFG lists
- Rule of 5
- Bretherick's Handbook of Reactive Chemicals
- CAMEO compatibility matrices
- Oxygen balance calculation

Instrumentation

- DSC
- TSu (or equivalent)
- Calorimetry (with off-gas measurements)
- ARC **and vent sizing**
- Impact Testing
- Explosivity Screening
- Autocatalysis screening
- **Dust testing**
- **Friction testing**

Outsourced Testing

- **U.N. testing**

Process Safety Workflows

- General Laboratory Safety
- DSC Workflow
- Tech-transfer guidance for kilo-lab
- Mitigating static hazards workflow
- Tech-transfer guidance for pilot plant
- Explosivity testing workflow
- Dust testing workflow
- **Tech-transfer guidance for commercial manufacturing**

Process Safety Testing at Vertex

Process Safety Testing Tiers

Tier 3 – Kilo-lab

Up to 5 kg

In-House Process Safety Testing

Desk Screening

- Safety data sheets
- HEFG/ExFG lists
- Rule of 5
- Bretherick's Handbook of Reactive Chemicals
- CAMEO compatibility matrices
- Oxygen balance calculation

Instrumentation

- DSC
- **TSu (or equivalent)**
- **Calorimetry (with off-gas measurements)**

Outsourced Testing

- **ARC**
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- General Laboratory Safety
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Process Safety Testing Tiers

Tier 3 – Kilo-lab

Up to 5 kg

In-House Process Safety Testing

Desk Screening

- Safety data sheets
- HEFG/ExFG lists
- Rule of 5
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Instrumentation

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Process Safety Workflows

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All the tools, techniques and technology in the world are nothing without the head, heart and hands to use them wisely, kindly and mindfully.

-Rasheed Ogunlaru

Selecting the Right Process Safety Professionals is More Crucial Than Any Instrument

An **effective** and **high-performing** process safety team has:

- A mix of chemical engineers and chemists
- Strong interpersonal communication skills
- Scientific curiosity
- Attention to detail
- Clear and concise communication abilities
- The desire to find solutions to problems but not afraid to say no
- A passion for continuous improvement

Thank you!