Chemical Hazard and Engineering Laboratory

CHEL

- Bachelor’s degree in chemical engineering , University of Illinois, PhD from the National University of Singapore.
- Postdoctoral fellowship at the University of California, Berkeley
- Leading thermal hazard lab, manufacturing facility, and handled tech transfer responsibilities across the globe.
- Developing control strategies and ensuring their successful execution at partner facilities.

INTERNATIONAL CONSORTIUM *for* INNOVATION & QUALITY *in* PHARMACEUTICAL DEVELOPMENT

Dust Hazards with Emphasis on Pharmaceutical Operations

Ayman Allian- Senior Director, Engineering Technology and Process Safety

Agenda

- Who are we?
- Dust explosivity hazards in the chemical Industry
- Dust explosivity hazards in the pharmaceutical industry
- Survey format and objectives
- Survey format and highlights
- What’s in the pipeline?

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Who are we?

- Pre-competitive group under the- **International Consortium for Innovation and Quality in Pharmaceutical Development-** IQ Consortium is a not-for-profit organization of pharmaceutical and biotechnology companies
- IQ Thermal Hazard Group: Founded 5 years ago to share best practices

https://iqconsortium.org/

INTERNATIONAL CONSORTIUM for INNOVATION & QUALITY in PHARMACEUTICAL DEVELOPMENT

Current IQ Consortium members include:

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Agios
Alnylam
Amgen, Inc.
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Bayer HealthCare
BeiGene
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Bristol Myers Squibb
CSL Behring
Daiichi Sankyo
Eisai, Inc.
Eli Lilly and Company
EMD Serono
Erasca, Inc.
F. Hoffmann-La Roche
Genentech
Gilead Sciences
GSK PLC
Idorsia
Incyte Corporation
Janssen
Merck & Co., Inc.
Mitsubishi Tanabe
Moderna Therapeutics
Novartis
Novo Nordisk
Organon
Otsuka
Pfizer
Regeneron
Relay Therapeutics
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Sarepta
Seagen
Servier
Sunovion
Takeda
Teva
UCB Pharma
Vertex, Inc.
Xencor

IQ Acknowledgement

- This presentation was developed with the support of the International Consortium for Innovation and Quality in Pharmaceutical Development (IQ, www.iqconsortium.org). IQ is a not-for-profit organization of pharmaceutical and biotechnology companies with a mission of advancing science and technology to augment the capability of member companies to develop transformational solutions that benefit patients, regulators and the broader research and development community.
- Information discussed in this presentation were generated from the IQ Thermal Hazards WG.

Who are we?

- Initial focus was on thermal hazards
- Dust explosivity in the pharmaceutical industry
- Driving force
  - Dust explosivity hazard is real
  - Safety is first, but across the pharmaceutical industry
    - Development timelines are shrinking
    - Low material availability for testing in early phases of development

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

- Won ACS Editor award, due to its impact was granted free access around the globe even for non ACS members

Article is on the "most read" with >40,000 downloads

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[∇]

Article

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

Ayman D. Allian*, Onkar Manjrekar, Nisha P. Shah, Michael J. Toth, and Han Xia

Organic Process Research & Development, Articles ASAP (Article) Subscribed
Publication Date (Web): October 27, 2025
DOI: 10.1021/acs.oprd.5c00198

Abstract | Full text | PDF

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Dust explosivity in the chemical industry

- Metal dust can be a fire and explosion hazard, titanium, copper, and brass particles.

- In the chemical industry 2019, 87% of the global fatalities recorded occurred because of dust explosions
  - Out of these accidents, up to 65% were due to organic dusts.

- In the chemical industry Q1 2020, 26 dust explosions occurred worldwide, and 80% of them were caused by organic dusts.

Cloney, C. 2019, Dust Safety Science−Combustible Dust Incident Report, 2019.
Cloney, C. 2020, Dust Safety Science−Mid Year Combustible Dust Incident Report, 2020.

Dust explosivity in the chemical industry

Image adopted from: U.S. CHEMICAL SAFETY AND HAZARD INVESTIGATION BOARD, Report No. 2008-05-I-GA, September 2009, SUGAR DUST EXPLOSION and FIRE

February 2008, Imperial Sugar manufacturing facility in Port Wentworth, Georgia, USA.

- 14 workers were killed and 36 injured.

Vorderbrueggen, J. Imperial sugar refinery combustible dust explosion investigation. Process Saf. Prog. 2011, 30 (1), 66−81.
** U.S. CHEMICAL SAFETY AND HAZARD INVESTIGATION BOARD, Report No. 2008-05-I-GA, September 2009, SUGAR DUST EXPLOSION and FIRE
https://www.csb.gov/videos/inferno-dust-explosion-at-imperial-sugar/

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Solid Handling in the pharmaceutical industry

1. Milling in Pharmaceutical industry
   - Control the particle size of APIs
2. Charging operations
3. Formulation, excipients and blending operations
   - Optimize a drug's delivery and performance
4. Packaging

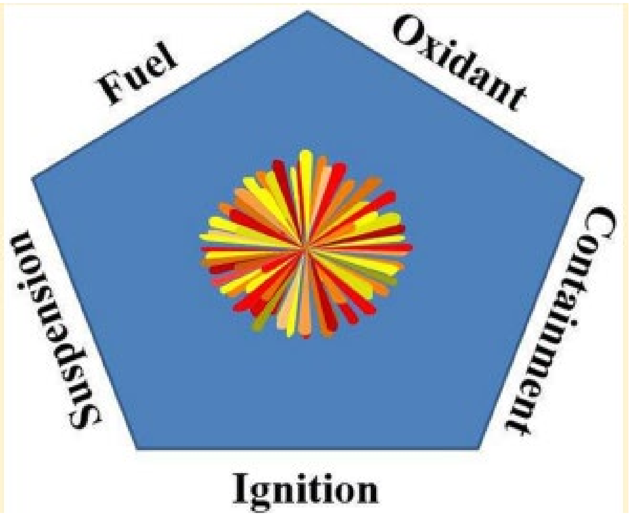


Image adopted from: Nicholas S. Reding and Mark B. Shiflett, *Industrial & Engineering Chemistry Research* **2018** *57* (34), 11473-11482

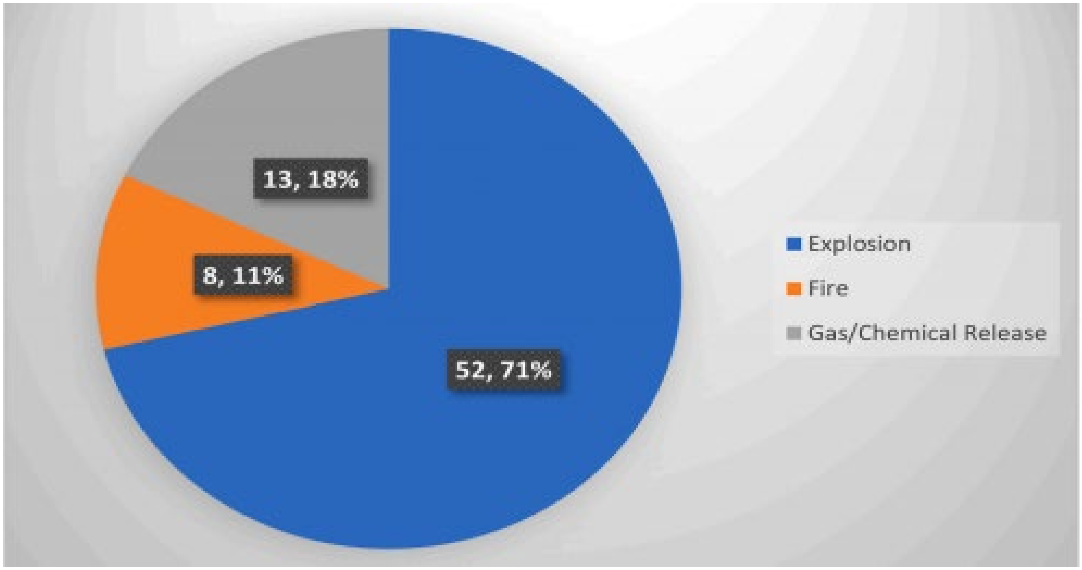
Ralph Zhao, Theodore R. Furman, and Megan Roth, Organic Process Research & Development 2021 25 (11), 2566-2577

Explosions in the pharmaceutical industry

On January 29, 2003, an explosion and fire destroyed the West Pharmaceutical Services plant in Kinston, North Carolina, causing six deaths, dozens of injuries, and hundreds of job losses.

https://www.csb.gov/west-pharmaceutical-services-dust-explosion-and-fire/

Process safety incidents in the pharmaceutical industry



- 73 process safety incidents leading to 108 fatalities found between 1985 and 2019
- >70% of the incidents were explosions.

Maaz S. Maniar, Apoorv Kumar, Ray A. Mentzer, Global process safety incidents in the pharmaceutical industry, Journal of Loss Prevention in the Process Industries, Volume 68, 2020.

Agenda

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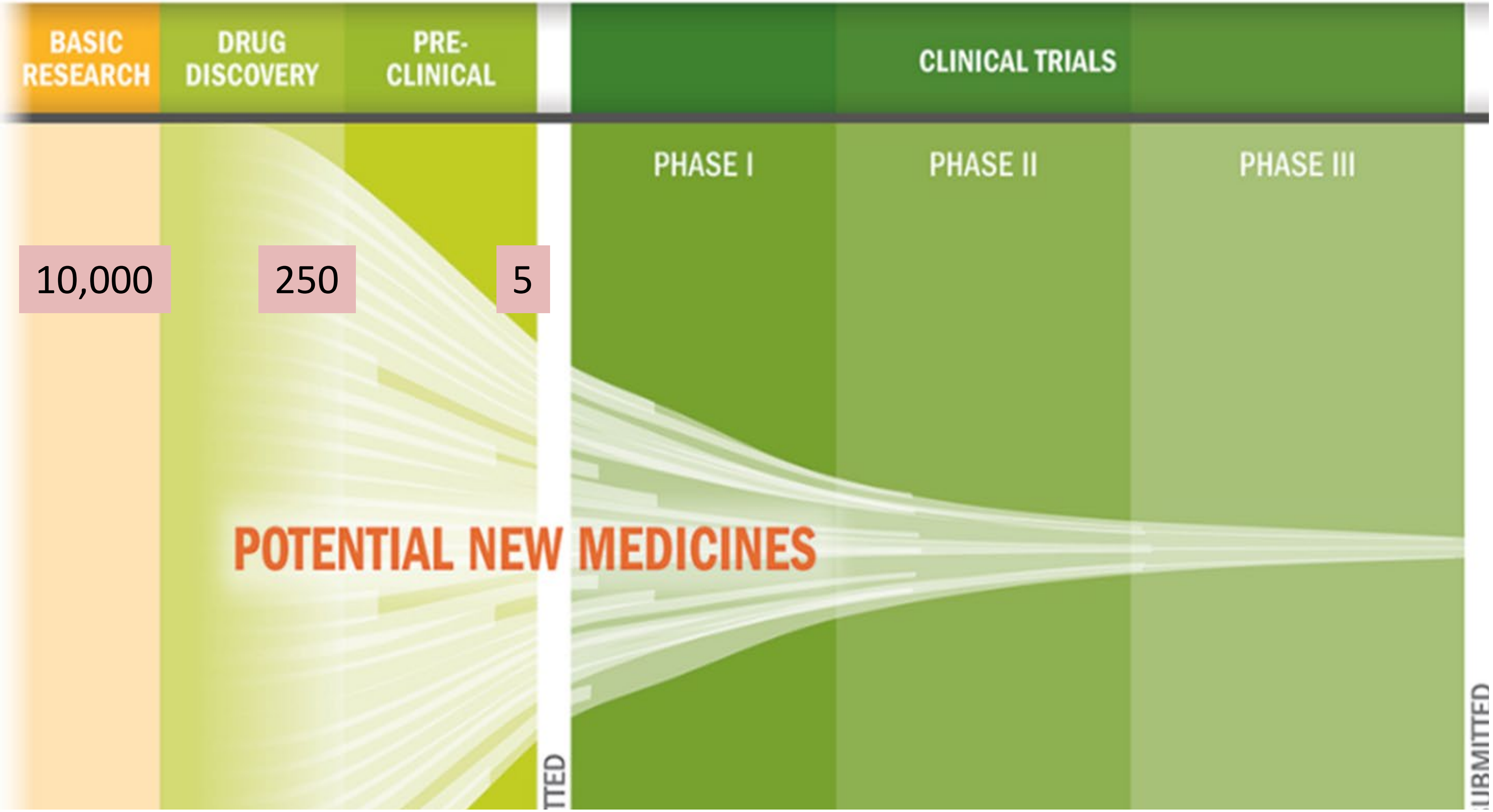
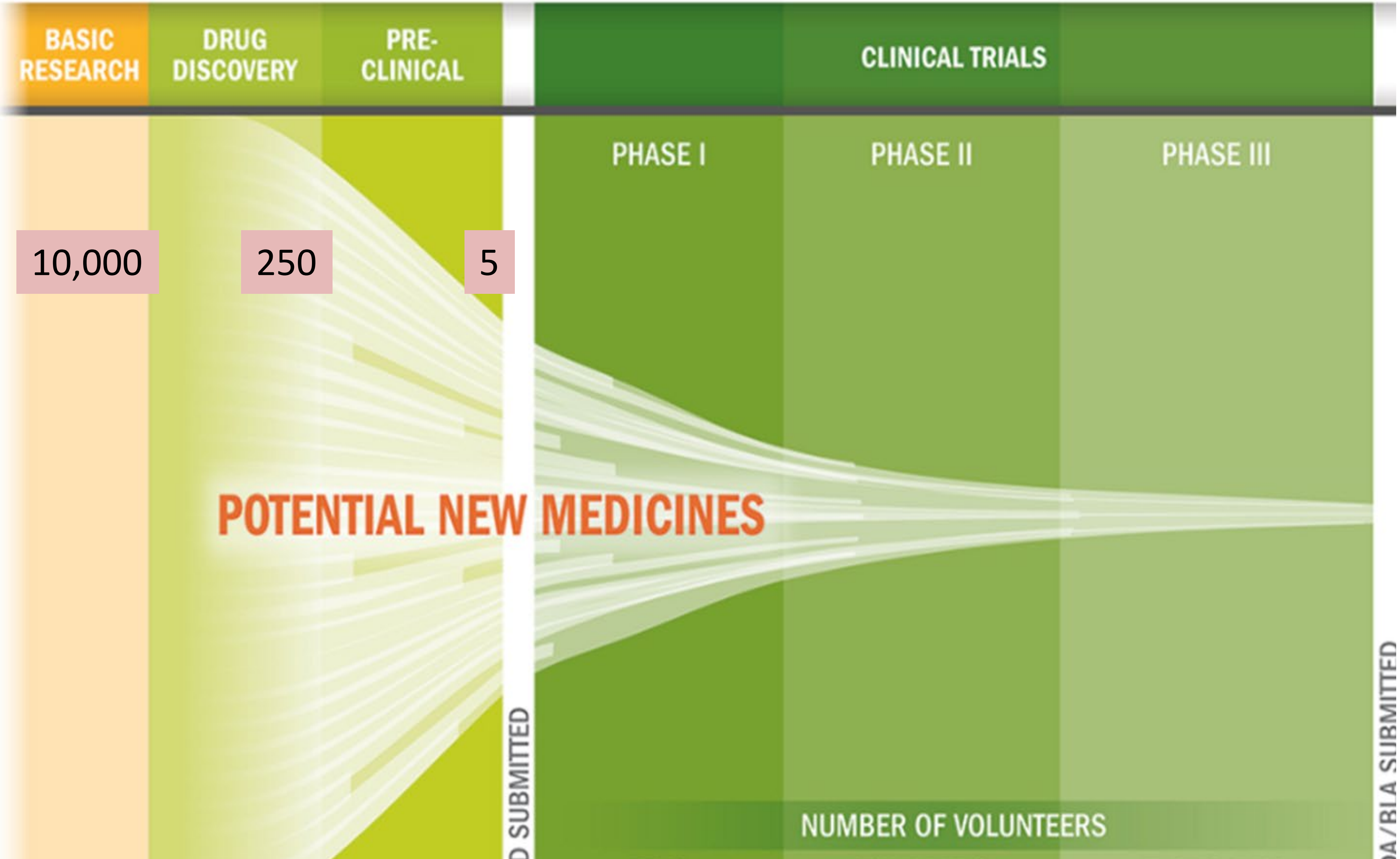
Stages of the drug development process



Reproduced from the PhRMA website with permission

Stages of the drug development process



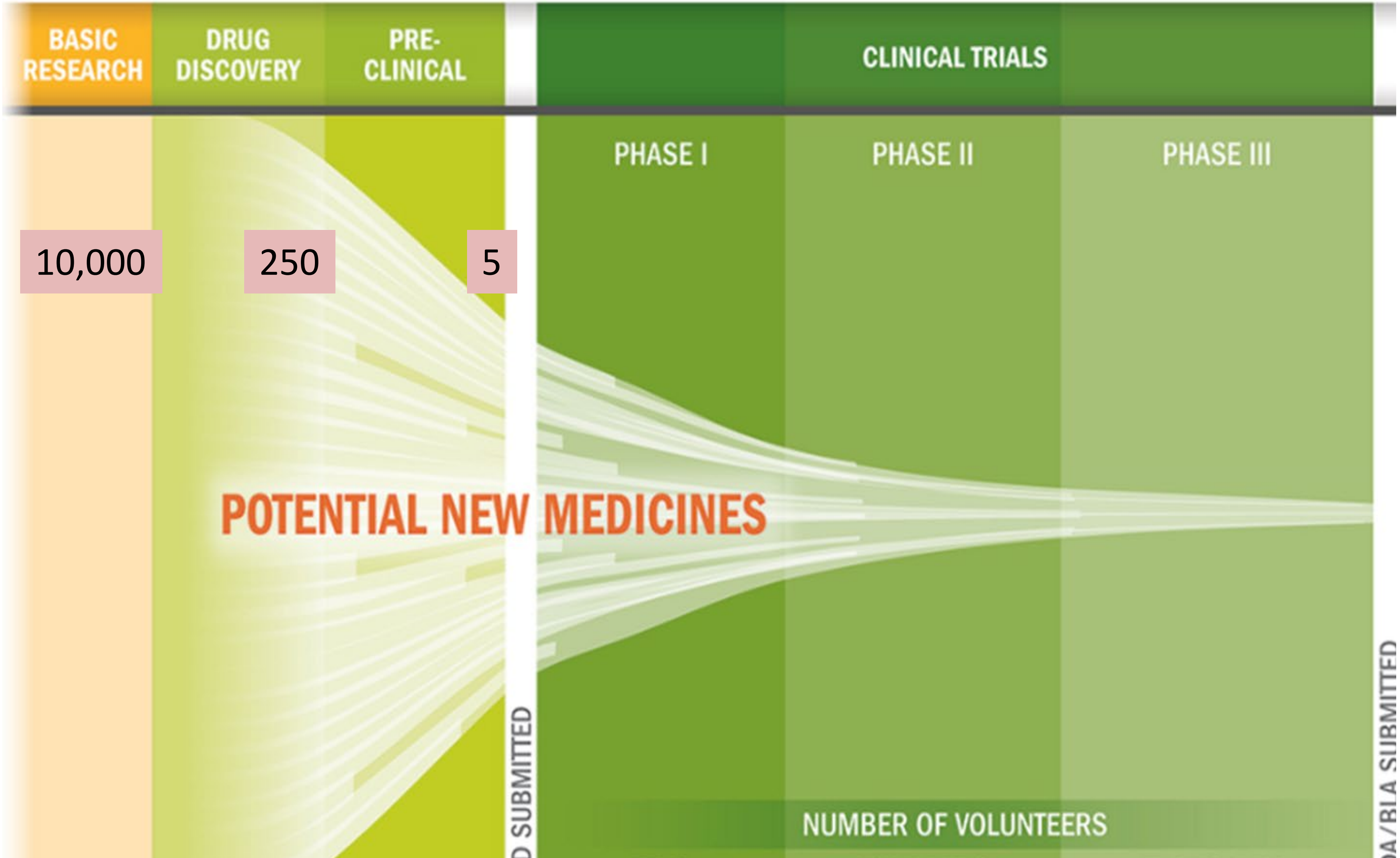
Consensus on definitions

- Early Stage: Programs conducted in a lab environment, at discovery/MedChem scale.

- Mid-Stage: Progressed from discovery to process research and development, (First In Human) and/or are in process characterization in the development lab, kilo lab and/or pilot plant.

- Late Stage: Progressed from Mid-stage to tech transfer to production facility internally or at a CMO, engineering runs, validation and commercial delivery.

Stages of the drug development process – how this has to do with dust explosivity testing in Pharma?



Objectives

- Understanding how pharmaceutical companies address dust explosion hazard and understand if approaches and testing are impacted by the phase of development and/or scale of operations.
- There are plethora of tests (MIE, MIT, LIT, Kst, Pmax, volume resistivity, charge decay):
  - When are these tests are deployed during phase development?
  - Implication on operation, inertion is required, grounding personnel and equipment
  - The apparatus used and method deployed ASTM, EU and UN.
  - What tests are done internally and what tests are outsourced?
- Sharing best practices and bringing the learning to our own companies.
- Not just helping our own companies, but also the industry at large as we did with the first paper.

The Survey

- Survey questions were discussed and formulated in the working group
- We have good participation, 11 companies participated. Answers were blinded before analysis
- Team members from Lilly and Abbvie (Ayman and Zhe) lead the writing, analysis of the data - Zhe retired
  - Team members (Han, Mike, Onkar and Nisha) started to craft a paper

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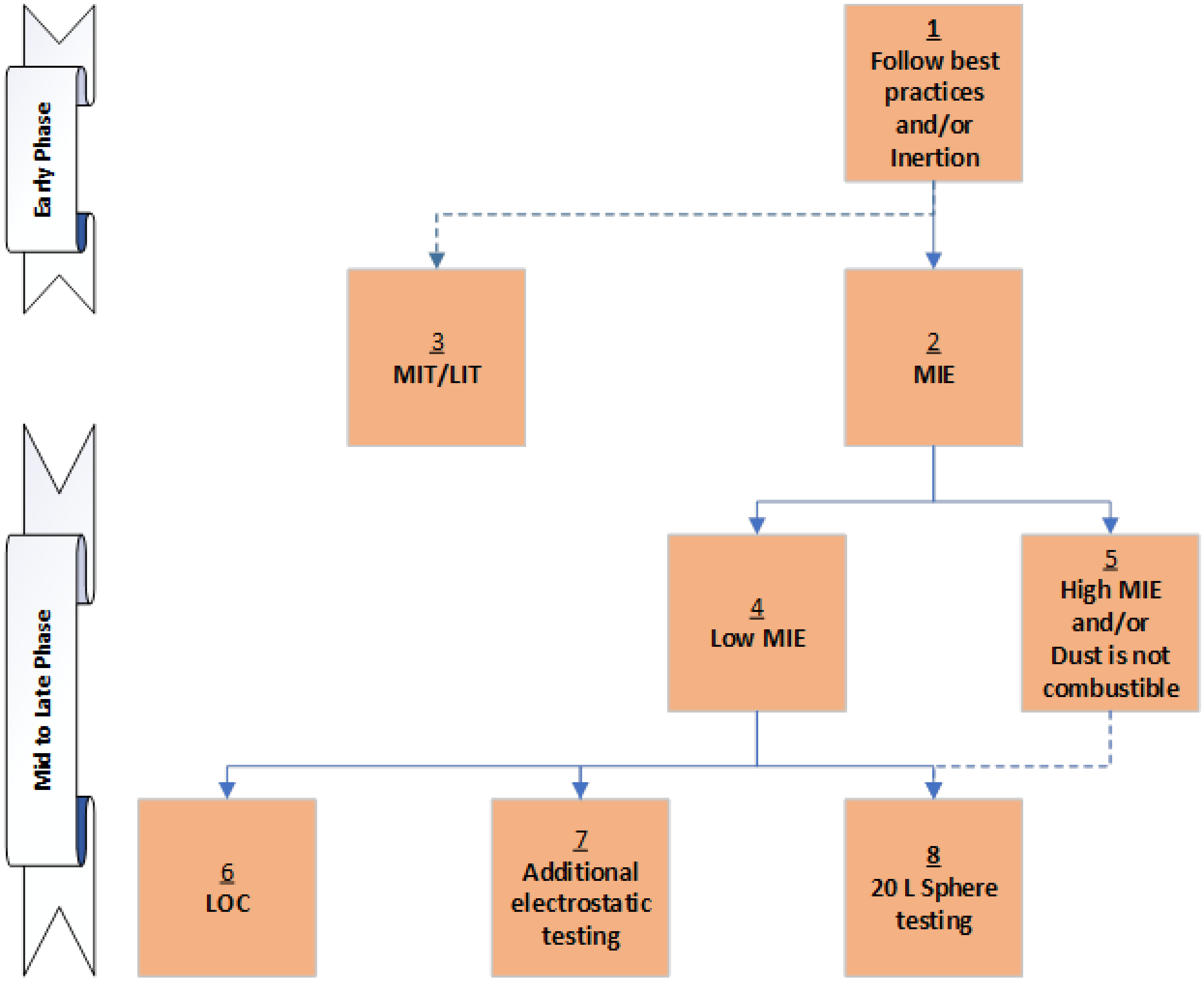
Summary of from the survey

- Approaches discussed might not be the best practices and are subject to change
- They represent the current state of how surveyed companies conduct their hazard evaluation.



Pharmaceutical Unit operation that drives dust explosivity testing

	MIE	MIT	Screening	LIT	20 L Sphere testing	MEC	LOC	Electrostatic Testing
Total Number of companies that perform the test	11	11	4	8	10	4	8	7
De-agglomeration	5	2	1	2	2	0	1	2
Milling	7	5	2	2	4	2	3	4
Loss-in-weight feeding	3	1	0	1	2	0	0	3
Auger feeding	4	3	0	2	2	1	0	4
Roller compaction	5	3	1	2	1	0	1	1
Dry Granulation	7	3	1	2	5	1	3	5
Wet Granulation	1	1	0	1	2	0	0	1
Compression	5	2	0	1	2	0	0	2
Encapsulation	2	1	0	1	2	0	0	1
Tray Drying	2	4	0	4	2	1	1	1
Fluid Bed Drying	6	7	1	4	5	1	3	3
Spray Drying	6	4	1	3	4	1	2	3
Pneumatic Conveying	4	3	0	2	2	0	0	5
Dust Filters	4	2	0	1	4	1	2	3
Cone Blenders	7	3	1	2	5	1	5	4
Cone Mills	7	6	0	2	4	2	3	4

Pharmaceutical Unit operation that drives dust explosivity testing

- Most widely tests deployed
  - MIE, MIT, LOC
  - 20 L Sphere tests

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Pharmaceutical Unit operation that drives dust explosivity testing

- Most widely tests deployed
  - MIE, MIT, LOC
  - 20 L Sphere tests
- Unit operation that drives dust hazard testing
  - Milling
  - Dry granulation
  - Fluid bed drying
  - Cone blenders
  - Cone mills

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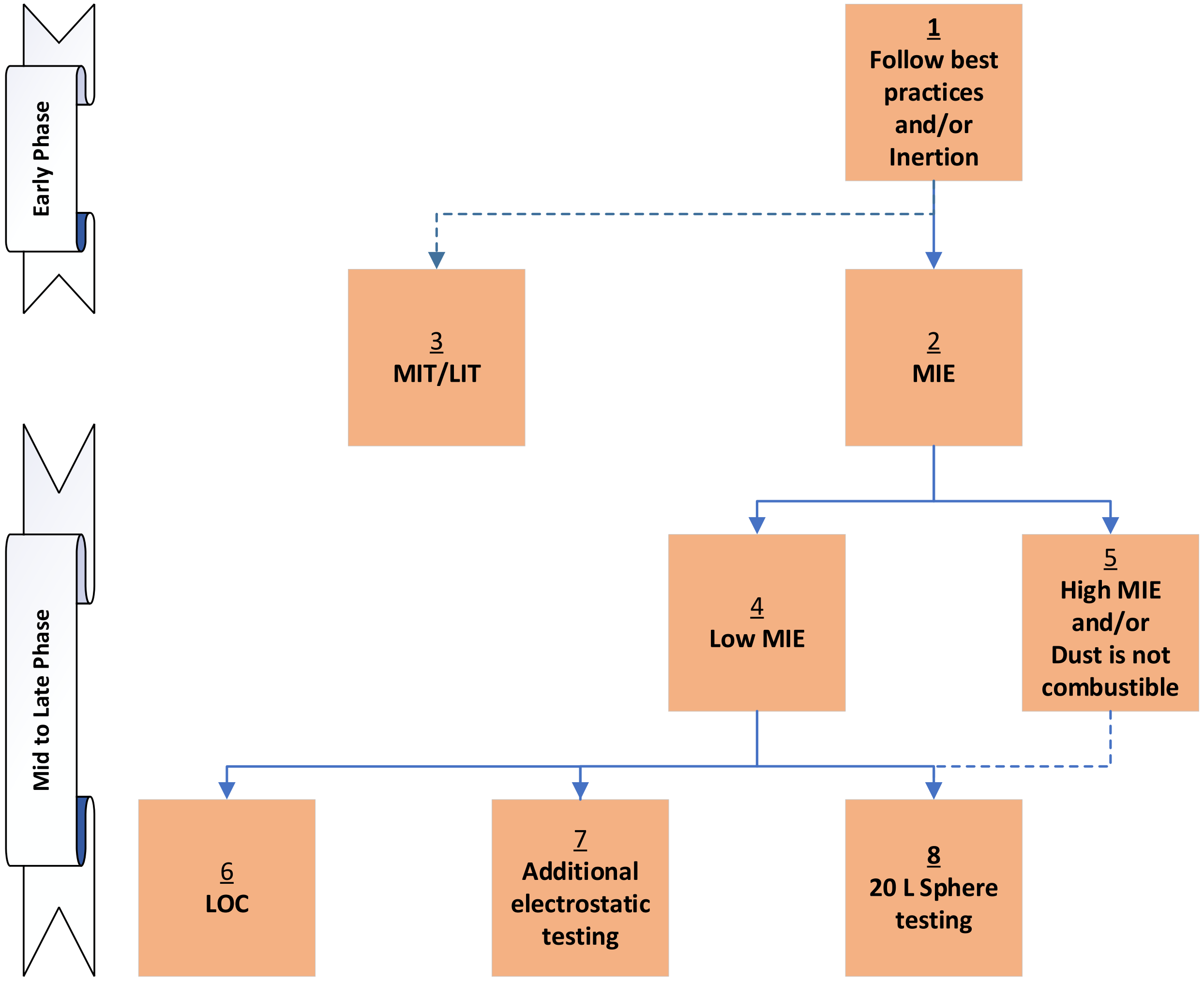
Cone Mills	7	6	0	2	4	2	3	4

Pharmaceutical Unit operation that drives dust explosivity testing

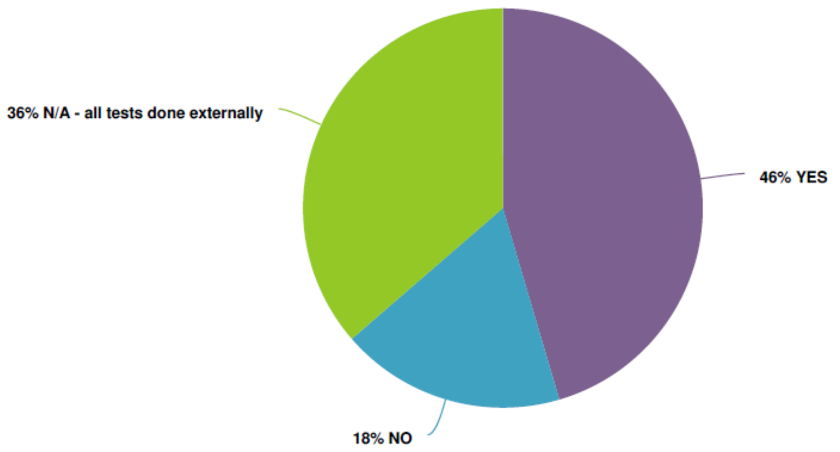
- Early phase
  - Material are very scarce
  - Dust hazard data is not available
  - Engineering controls
- Mid to Late Phase
  - Start with MIE testing
  - Low MIE can drive addition dust hazard testing



If you do testing internally, can your company handle potent compounds? What is a potent compound?

- 5 companies said yes.
- Occupational exposure limits (OELs) are regulatory values which indicate levels of exposure that are considered to be safe (health-based) for a chemical substance in the air of a workplace
- What is considered potent?
  - OEL<10 $\mu g/m^3$
  - OEL<5 $\mu g/m^3$
  - Two companies indicated that if OEL>1 $\mu g/m^3$ testing can be handled

3. If you do testing internally, can your company handle potent compound?

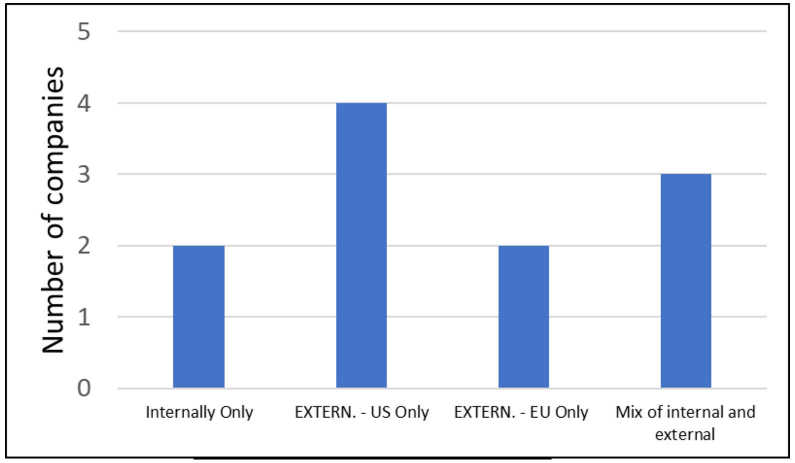


Value	Percent	Responses
YES	45.5%	5
NO	18.2%	2
N/A - all tests done externally	36.4%	4
		Totals: 11

Minimum Ignition Energy

Extremely important test: Minimum ignition energy (MIE) can be interpreted as the probability of the occurrence of a combustible dust explosion

- All survey respondents indicate they routinely use the results of the MIE test
- Where they do it
  - Two companies do it internally only
  - Four companies outsource these tests but within the US
  - Two companies outsource it to firms in the EU
  - Remaining pharma companies utilize a host of these options



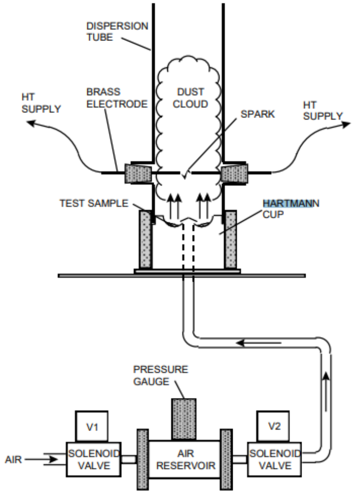
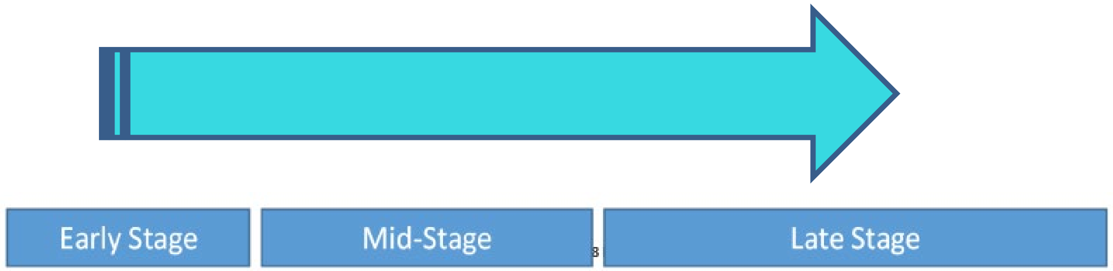


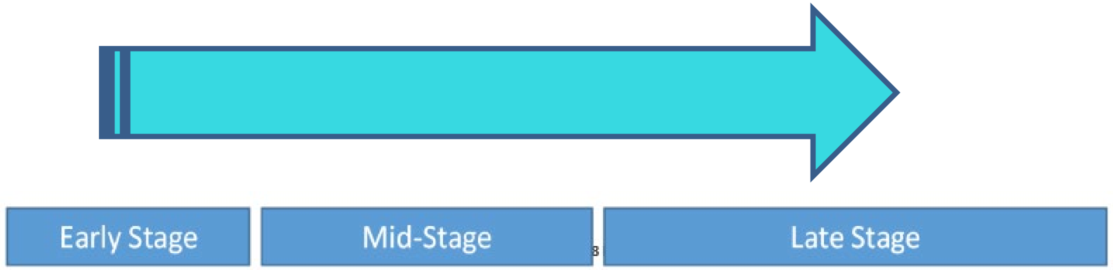
Image adapted from Dust explosion hazards, The United Nations Economic Commission for Europe

Minimum Ignition Energy- Double Click on it



- Does the stage of development impact when this testing is triggered?
  - Two companies said No
  - No companies do it in the early phase of development
  - 3 in the Mid-Stage
- Is there a mass threshold that your company uses to trigger this test?
  - Eight companies said No
  - Two said yes - >5 Kg, 100 Kg

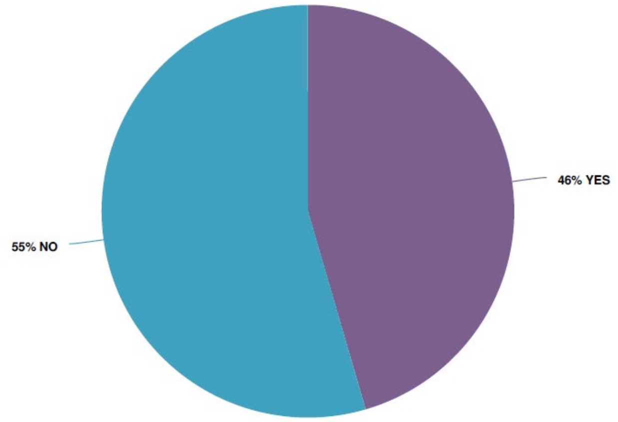
Minimum Ignition Energy- Double Click on it



- Test apparatus and Standard used
  - 1.2 L Vertical tube (Hartman tube)
  - ASTME2019
  - EN ISO/IEC 80079-20-2:2016 (Clause 8)
- What are the red flags and/or impact of this study?
  - >10 mJ (grounding personnel)
  - >30 mJ would require inertion and grounding

Combustible Dust Determination (Initial Screening)

- Combustible Dust Determination (Initial Screening) – Similar to MIE but powerful ignition source is used
  - Not widely utilized.
  - More than half don't carry out these tests.
  - Done in the Mid-Stage.
- Type of apparatus and method
  - 1.2 L Vertical tube (Hartman tube)
  - ASTME2019
  - EN ISO/IEC 80079-20-2:2016 (Clause 8)
- Red flags: If initial screening test is positive:
  - Consider running full test with more sample.
  - Default to precautions needed for highly ignition sensitive powders.



Value	Percent	Responses
YES	45.5%	5
NO	54.5%	6

Totals: 11

Dust Explosivity Testing

Dust Explosibility Characteristics (Kst, Pmax) of Organic Chemical Dusts

Pmax

- Maximum explosion overpressure (Pmax)
  - Difference between pressure at the time of ignition (normal pressure) and pressure at the highest point from a dust explosion in the testing chamber
- Provide understanding of the damaging pressures that may be generated during a dust explosion
- Tests conducted typically in 20 L sphere

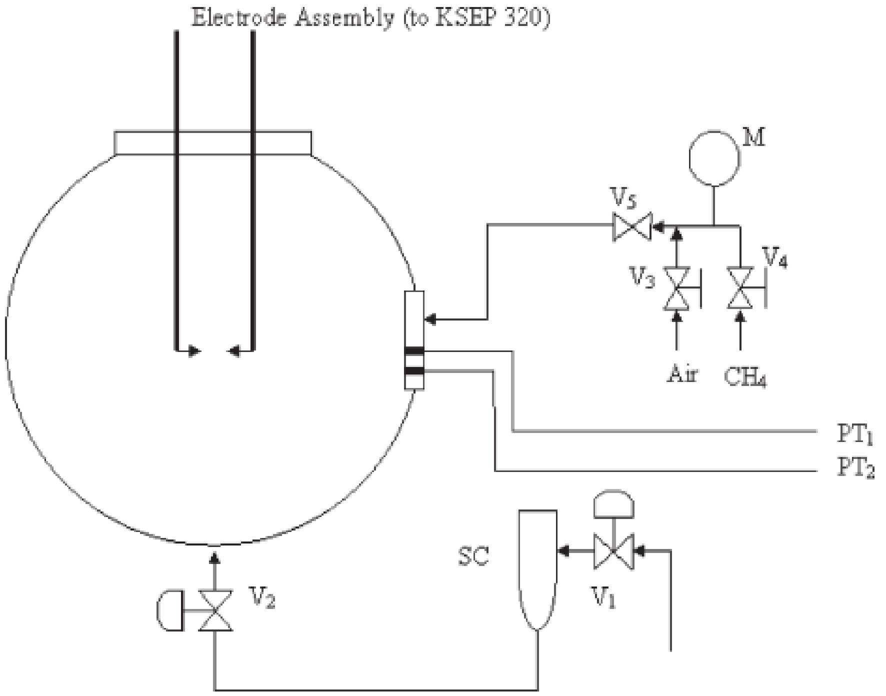


Figure 1. Schematic view of the Siwek 20-L spherical vessels for the determination of dust explosion parameters.

Image adopted from -Combined Effect of Ignition Energy and Initial Turbulence on the Explosion Behavior of Lean Gas/Dust-Air Mixtures Almerinda Di Benedetto, Anita Garcia-Agreda, Paola Russo, and Roberto Sanchirico Industrial & Engineering Chemistry Research 2012 51 (22), 7663-7670

Dust Explosibility Characteristics (Kst, Pmax) of Organic Chemical Dusts

Kst

- The dust deflagration index, Kst, is a rates of pressure rise normalized in 1 m^3 vessel
  - St-0, no explosion
  - St-1, 0 < Kst < 200, weak explosion (dust explosion class 1)
  - St-2, 200 < Kst < 300, strong explosion (dust explosion class 2)
  - 300 < Kst, very strong explosion (dust explosion class 3)
- Used to design containment, isolation, explosion protection (e.g., explosion relief venting, explosion suppression .

Olga J. Reyes, Suhani J. Patel, and M. Sam Mannan, *Industrial & Engineering Chemistry Research* **2011** *50* (4), 2373-2379

Dust Explosion Severity (Kst, Pmax)

- Dust Explosion Severity (Kst, Pmax)
  - 10 Companies conduct this test
  - 3 companies have the capability
  - 2 companies do internal testing only

  Available sites for outsourcing
  - 6 US sites are available
  - 4 EU available sites for testing
  - 1 testing center in Asia
- Does the stage of development impact when this testing is triggered?
  - 1 Mid-Stage
  - 9 Late Stage
- Is the test triggered by Mass?
  - 8 No
  - 2 Yes, (>1 Kg, 5 Kg, 10 Kg)
- Type of apparatus and method
  - 20 L sphere
  - EN ISO/IEC 80079-20-2:2016 & EN 14034-2, 14034-1
  - ASTM E1226
- Red flags: Kst = 3 or Pmax > 10 bar: Milling not allowed in our plants without technical modifications.

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Minimum Explosivity Concentration (MEC) and Limiting Oxygen Concentration (LOC) of Combustible Dust Clouds

MEC

- Only half of companies carry out this test
- Two companies have this internal capabilities
- Availability in US (4 companies are utilizing them)

LOC

- More than 80% of companies conduct this test
- Only one company has this capabilities internally
- Where are these tests are done
  - 6 firms in the US
  - 3 in EU
  - 1 in Asia

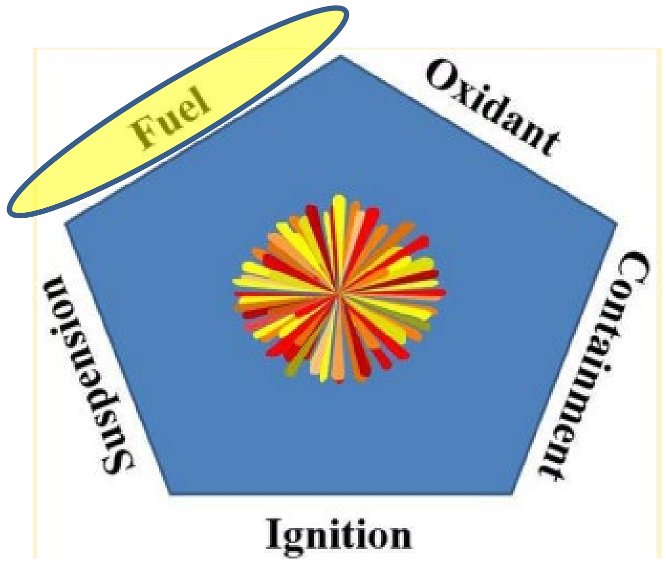

Image adopted from: Nicholas S. Reding and Mark B. Shiflett, *Industrial & Engineering Chemistry Research* **2018** *57* (34), 11473-11482

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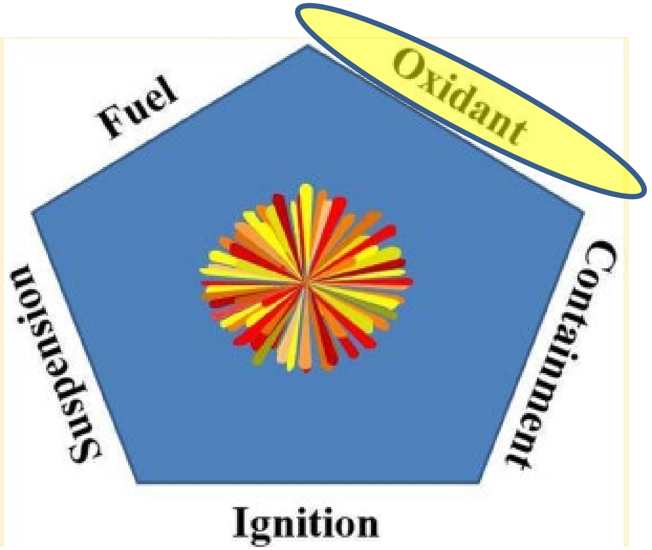

Image adopted from: Nicholas S. Reding and Mark B. Shiflett, *Industrial & Engineering Chemistry Research* **2018** *57* (34), 11473-11482

Minimum Explosivity Concentration (MEC), Limiting Oxygen Concentration (LOC)

MEC

- Test triggered by mass
  - No
  - Rarely done unless specifically using as basis of safety. We normally assume a worst case MEC of 20g/m3. In most cases we are well below the worst case MEC
- Type of tests and standard used
  - 20 L Sphere
  - EN 14034-3, ASTM E1515
- Red flags: operation close or above MEC require further action.

LOC

- Stage triggered, When it is used
  - 0 early stage
  - 0 mid-stage
  - 6 late stage
- Test triggered by mass
  - 8 No
  - Test is triggered when we are required to use inertion based on MIE or other factors.
- Type of tests
  - 20 L Sphere
  - EN 14034-4
- Red flags: If a particularly low LOC was observed (< or = to 5% v/v)

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LOC

- Stage triggered, When it is used
  - 0 early stage
  - 0 mid-stage
  - 6 late stage
- Test triggered by mass
  - 8 No
  - Test is triggered when we are required to use inertion based on MIE or other factors.
- Type of tests
  - 20 L Sphere
  - EN 14034-4
- Red flags: If a particularly low LOC was observed (< or = to 5% v/v)

Minimum Ignition Temperature (MIT) of a Dust Cloud and Layer, Hot Surface, Ignition Temperature of Dust Layer (LIT)

MIT

- Widely used, 10 companies, execute these tests
- 4 companies have this internal capability, and two companies rely exclusively on their internal capabilities.
- 6 companies use US based safety labs, 4 Europe and 1 in Asia

LIT

- Seven companies conduct this test
- 3 companies have this internal capability and those companies don’t outsource these tests.
- Available sites for outsourcing
  - 3 firms in the US
  - 3 in EU
  - 1 in Asia

Minimum Ignition Temperature (MIT) of a Dust Cloud, Layer, Surface Ignition Temperature (LIT)

MIT

- Stage triggered, When it is used
  - 0 Early Stage, 3 mid-stage, 6 late stage
- Test triggered by mass
  - 8 No, 2 yeses
    - 5 Kg, **Milling >1 kg**
    - When MIE is triggered, MIT is done (does not take a lot of material)
- Type of tests
  - BAM Oven, Godbert-Greenwald Furnace
  - EN 50281-2-1 & EN ISO/IEC 80079-20-2:2016 (Clause 8.1), ASTM E1491
- Red flags: (1) MIT less than 340°C (2) Less than 300°C "Must be inerted"

LIT

- Stage triggered, When it is used
  - 0 early stage, 2 mid-stage, 5 late stage
- Test triggered by mass
  - 6 No, 1 Yes
  - Equipment required.
- Type of tests
  - Hot plate
  - EN 50281-2-1 & EN ISO/IEC 80079-20-2:2016 (Clause 8.2) and ASTM E2021
- Red flags: LIT is above maximum temp. of equipment in the plant (with safety margin) then it would raise obvious concerns. Less than 300°C must be inerted

Minimum Ignition Temperature (MIT) of a Dust Cloud, Layer, Surface Ignition Temperature (LIT)

MIT

- Stage triggered, When it is used
  - 0 Early Stage, 3 mid-stage, 6 late stage
- Test triggered by mass
  - 8 No, 2 yeses
    - 5 Kg, Milling >1 kg
    - When MIE is triggered, MIT is done (does not take a lot of material)
- Type of tests
  - BAM Oven, Godbert-Greenwald Furnace
  - EN 50281-2-1 & EN ISO/IEC 80079-20-2:2016 (Clause 8.1), ASTM E1491
- Red flags: (1) MIT less than 340°C (2) Less than 300°C "Must be inerted"

LIT

- Stage triggered, When it is used
  - 0 early stage, 2 mid-stage, 5 late stage
- Test triggered by mass
  - 6 No, 1 Yes
  - Equipment required.
- Type of tests
  - Hot plate
  - EN 50281-2-1 & EN ISO/IEC 80079-20-2:2016 (Clause 8.2) and ASTM E2021
- Red flags: LIT is above maximum temp. of equipment in the plant (with safety margin) then it would raise obvious concerns. Less than 300°C must be inerted

Static Electricity

- Walking on the carpet, touching a doorknob (30 mJ)
    - Metal Scope
- Materials rub against each other; they may become electrically charged.
- Flowing of non-conductive fluid

Lab Scale Model of AFD

Lab AFD: Charles D. Papageorgiou, Christopher Mitchell, Justin L. Quon, Marianne Langston, Suzanna Borg, Frederick Hicks, David am Ende, and Mark Breault, Organic Process Research & Development 2020 24 (2), 242-254

Volume Resistivity and Charge Relaxation

Volume Resistivity

- Measures the conductivity of a dust/powder sample.
- 9 companies conduct this tests (Internally and/or externally) with 4 companies having this important capability internally.
- 5 companies use US based safety labs, 2 Europe.

Charge Relaxation

- Identifies the electrostatic charge decay time of a dust sample.
- 6 companies conduct this test with 3 companies having this internal capability.
- Companies outsource these tests to 4 US based safety labs.

Minimum Explosivity Concentration (MEC), Limiting Oxygen Concentration (LOC)

Volume Resistivity

- Stage triggered
  - 0 Early Stage
  - 1 mid-stage
  - 5 late stage
- Test triggered by mass
  - No
  - Yes, 5 Kg or If MIE < 10 mJ
- Type of tests and standard used
  - High Resistance (Teraohm)
  - EN IEC 60079-32-2 & also EN ISO/IEC 80079-20-2:2016 (Clause 8.4)
- Red flags: The grounding requirements will be stressed for Products with high resistivity.

Charge Relaxation

- Stage triggered, When it is used
  - 0 early stage
  - 1 mid-stage
  - 3 late stage
- Type of tests
  - Charge Decay Apparatus
  - BS7506 Part 2
- Red flags: After having gone through final processing (filtration, drying and isolation) charged powder must be allowed to relax its charge before further handling.

Agenda

- Who are we?
- Dust explosivity hazard in the chemical Industry
- Dust explosivity in the pharmaceutical industry
- Survey format and objectives
- Survey highlights
- What’s in the pipeline?

  Transportation and Shipment

Conclusion

- Pharmaceutical industry is very conscious of the dust hazard
- Conduct battery of tests internally or at an external sites
- Several tests are not conduct at the early phase

- Engineering control
- Computational and risk assessment tools

Thermal Hazard IQ Forum

GILEAD
Takeda
Shire
VERTEX
abbvie
AMGEN
Lilly
MERCK
Johnson & Johnson
gsk
Pfizer
Bristol Myers Squibb
Boehringer Ingelheim
TEVA
TEVA PHARMACEUTICALS LTD
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