

## Why Move Design Of Experiments (DOE) Upstream



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10/28/2013

## Agenda

- R&D risk impacts
- Value and challenges of using DOE
- Innovize's experience with Perry's Solutions, Inc.
- Keys to gaining value for key Research & Development (R&D) and Operational Qualification (OQ) activities

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## R&D Risk Impacts

- **Schedule delays**
  - In development
  - For production launch
- **Yield issues**
- **Recalls**

These are each indications of inadequate understanding

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## Value of Using DOE

- **Cost effective final solution**
- **Efficient testing**
  - Speeds time to market
- **Create clear cut understanding**
  - Streamlines and speeds submission
- **Improves innovation and creativity**
- **Well accepted by FDA**

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## DOE Challenges

- **How to use the tools**
  - We created a DOE process to address this issue (Pareto, 2001)
- **Understanding the statistics\***
  - The key tools are easy to understand
- **Misunderstanding about effective sample size impact\***
- **Appropriate scoping\***
  - Smaller tends to be better

**\*Perry's Solutions has Youtube videos on several of these key topics**

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## DOE Challenges (cont.)

- **Using every combination can be overkill**
- **Potential for aliasing important process contributors\***
- **While some tools make a "linear model" assumption, proper analysis and set up can determine non-linear effects**

**\*Perry's Solutions has Youtube videos on several of these key topics**

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## Innovize History

- **Innovize was founded in 1958 as a printing specialist. The company built on this core expertise by adding die cutting and laminating capabilities. Innovize has continually added capabilities to provide superior support and service to the medical and diagnostic market.**



- **Innovize Inc. is privately held, and owner-operated.**

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## Innovize Capabilities and Services

**Innovize is a complete contract manufacturer specializing in;**

- **Converting**
- **Custom die cutting**
- **Laser cutting**
- **Multi-layer laminating**
- **Printing**
- **Packaging**
- **Clean Room / Dry Room**

**Providing;**

- **Product Development**
- **Manufacturing**
- **Supply Chain Management**
- **Inventory Management**
- **Custom Business Solutions**

**Innovize is ISO 9001:2008 and ISO 13485 certified, and FDA registered**

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## Innovize Locations



**Headquarters and Manufacturing Location:**

**St. Paul, Minnesota**

**Sales Offices:**

**Alabama, California and Minnesota**



**Innovize is ISO 9001:2008 and ISO 13485 certified, and FDA registered**

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## Innovize Experience

- **Benefits of DOE:**
- **First project, gain confidence in Root Cause Analysis findings**
- **Quickly resume production after vendor lot rejection**
- **Regained customer confidence**

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## Innovize Upstream Experience

- More benefits by moving DOE upstream:
- Determine process capability of new product design.
  - And capability to achieve capability
- Explore process parameters while meeting through put needs.
- Evaluate design alternatives quickly
- When process window has been explored, opening up other changes is quicker

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## Dreaming About...



Upstream DOE

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## Key R&D Activities

- Create tolerance limits for acceptable performance
- Understand environmental sensitivities
- Determine use conditions
- Understand material options
- Determine critical components

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## Key Operational Qualification (OQ) Activities

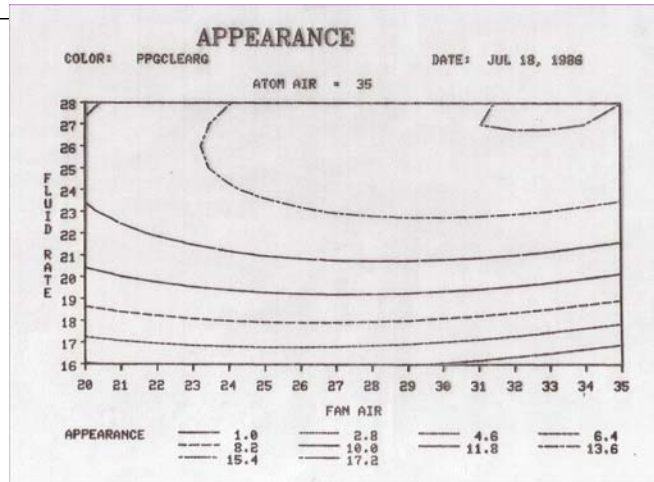
- Process control limits (time, temperature, pressure, line speed, setup conditions, etc.)
- Software parameters and validation
- Process operating procedures
- Material handling requirements
- Short term stability and capability of the process
- Potential failure modes, action levels and worst-case conditions

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## GM Chart



Root Cause Analysis

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## Upstream DOE Keys to Success

- **Keep the DOE small**
- **Consider phased testing – don't solve all of the worlds problems in one test**
- **Start simple – often two levels is appropriate for early evaluation**
- **Consider more variables – do not narrow too quickly**
- **Focus on incremental learning**
- **Don't depend on mimicking past test methods**
  - As products mature, expectations can be raised

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## More DOE Upstream Keys to Success

- Don't wait to design the perfect DOE. If you could, then it is not needed!
- There is still time for "playing around" – it is during PQ that we are "testing for the record." OQ is not passing or failing. It is about learning.
- Test early and often
  - Double your failure rate to accelerate learning
- Use DOE for test method development if there is risk or questions related to measurements. Gage R&R may not be enough.
- Perform good statistical analysis including residuals

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## Conclusion

- The benefits of upstream DOE are well established
- While not a direct FDA expectation, our experience shows a clear acceptance of DOE information in R&D and OQ activities
- If you want to see the reference materials – visit our website
  - [www.PerrysSolutions.com](http://www.PerrysSolutions.com)
  - If interested, email us to be on our quarterly newsletter where we share recent trends and learning points
    - Newsletters are all archived on our publications page

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