

Raw Material Variability
Raw Material CQAs
Global Supply Chain

A thick, horizontal blue brushstroke graphic that tapers to a point on the right side, positioned below the main title text.

PPAR 2011

Raw material variability is a hot topic

IBC's Inaugural
**Biopharmaceutical Raw Materials
throughout the Product Lifecycle**

Strategies to Identify, Test, Control and Mitigate Risk of Raw Material Variability

February 27 - 28, 2012 · Hilton San Diego Bayfront Hotel · San Diego, CA

Event Overview

As the biopharma industry has become more adept at characterizing and understanding variability in its processes, it has become apparent that biopharmaceutical raw materials are a major source of variability throughout the product lifecycle. Raw materials are one of the process parameters outside the control of many companies, and the supply chain for raw materials is becoming more global and increasingly complex.

IBC's inaugural **Biopharmaceutical Product Lifecycle** conference material variability as a potential you find solutions for controlling variability in process development about emerging strategies for the house and vendors) throughout GMP setting. And you'll find new material suppliers to ensure raw standards, and to mitigate risk.

If your company currently has a approaching launch, the safety of your top priorities, and this is everything you need to prepare companies, this is a must-attend and learn from the experiences experiencing the challenges of

Agenda-at-a-Glance Released!



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Which one is preferred in pharmaceutical industry for raw material identification and quantitative analysis? FTNIR from BRUKER OR ABB OR NIR from FOSS. Please provide your comments.

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Staying Within the Lines? Interpolation vs. Extrapolation in the Design Space

Posted on 26 January 2011. Tags: [Carl Anderson](#), [Christine Moore](#), [design space](#), [Duquesne University](#), [Evdokia Korakianiti](#), [IFPAC](#), [Theodora Kourti](#)

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By Agnes Shanley

A presentation at IFPAC last Thursday brought on some heated debate about the Design Space, and just how dynamic it can, or should, be. Should any changes due to unanticipated "real world" situations necessarily trigger the development of a new design space, and post-approval change filings and more testing?

Duquesne University professor Carl Anderson discussed the concept of the "dynamic design space," and tests that he and his colleagues Benoit Igne, Zhenqi Shi, Sameer Talwar and James Drennan had done, to incorporate raw material changes into a design space and test process robustness.

Evaluating an over-the-counter tablet, their goal was to see how, using a QbD framework, operating conditions might be changed to guarantee on-spec products, despite variable raw material quality.



Framework for Discussion

- Remember to focus on process analytics and related topics (e.g. regulatory considerations)
- Process analytics can be at-line, in-line, on-line, or higher level data analyses
- Consider both analyzing RMs before they enter the process, and monitoring/controlling the process to mitigate RM variability

A few examples to get you thinking...

- NIR, Raman, other methods for raw material identification
- Multi-variate analysis to link raw material characteristics to process performance
- Raw material variability & impact on QbD
- Monitoring of surrogate parameters to mitigate raw material risks
- Process control schemes that react to raw material changes

Questions for Discussion: Raw Material Variability & CQAs

- What do you think is the biggest advance in the last few years?
- What do you see as the biggest problem yet-to-be-solved?
- What are the hurdles to solving these problems?