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IVT's 2nd Annual QbD

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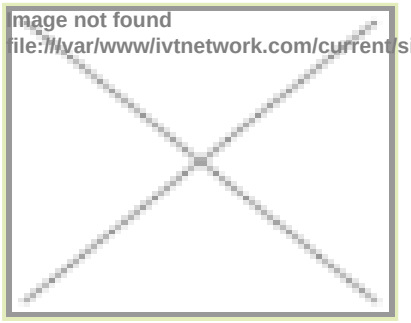

While bio/pharmaceutical companies have embraced the principals of QbD, many have experienced challenges with the complexities of design and implementation of a QbD system. A successful QbD system requires an effective integration of quality standards, business processes for product commercialization and a common vision across all organizational components involved with QbD.

QbD is becoming increasingly used across the industry as a framework for developing process and articulating process understanding to the regulatory community. This generation of a wealth of data in manufacturing associated with a process could be leveraged to improve the development process. Yet, it often is not, for a variety of reasons, despite the manifest opportunities for improving the efficiency of process design.

Employing QbD methodology in product development or applying the methodology retrospectively to already commercialized products is a business decision like any other; management needs to understand the cost, the return on investment and the risks.

Making the Case For QbD in Your Organization
James P. Catania, Managing Consultant, **Tunnell Consulting**

Designing an Effective QbD System
Gary Denney, Director, Product R&D Quality and Supply Chain Management, **Eli Lilly and Company**

Science-Based Pharmaceutical Product DevelopmentThe Quality by Design Approach
Robert J. Serra, Co-founder/Principal Consultant, **QbD Auditing, Inc.**

Opportunities for Quality by Design and the Advancement of Pharmaceutical Manufacturing
John Lepore, Ph.D., Senior Director, Chemical Process Development, **Merck & Co., Inc.**

Implementing a QbD System Company-Wide
Eda Ross Montgomery, Ph.D., Senior Director, Quality: CMC and QbD, **Vertex Pharmaceuticals**

Implementing a QbD Program To Make Process Validation A Lifestyle Rather than an Event
Justin Neway, Ph.D., Chief Science Officer, **Aegis Analytical Corp.**

A QbD Approach to Process Qualification of Post-approval Changes for Biotech Products
Tamas Blandl, Ph.D., Principal Scientist, Process Development, **Amgen Inc.**

Process Predictive Distributions and QbD
John J. Peterson, Ph.D. , Director, Research Statistics Unit, **GlaxoSmithKline**

Bridging from R & D to Ops with Quality by Design (QbD)
Shailesh K. Singh, **Former Wyeth Pharmaceuticals**

Experimental Strategies for Implementing Quality by Design
Ronald D. Snee, Ph.D., President, **Snee Associates, LLC**

Managing a Global Regulatory Submission: The Saxagliptin QbD Regulatory Experience
Gerald DiDonato, Associate Director, Global Regulatory Sciences CMC, **Bristol-Myers Squibb**

Applying QbD Principles to Process Validation
Kevin J. Bittorf, Ph.D., Chemical Engineering, MBA, Process Engineer, Associate Director, Formulation Development, **Vertex Pharmaceuticals**

Implementation of Quality-by-Design (QbD) via a Comprehensive Quality System (ICH Q8, Q9 and Q10)
Bob Mehta, MSQA, MBA, B.S. (Chem), ASQ – CQA, CBA, CRE, CQE, CSSBB, CSQE, Senior Regulatory Compliance Manager, **Edwards Lifesciences**

Developing a Roadmap to Implement Quality by Design
Barry (Bir) Gujral, Ph.D., MBA, Associate Director, Quality Engineering, **Noven Pharmaceuticals, Inc.** and Peter Amanatides, Vice President, QA and QC, **Noven Pharmaceuticals, Inc.**

Building Data-Based Knowledge and Skills Needed to Implement Quality by Design
Ronald D. Snee, Ph.D., President, **Snee Associates, LLC**

Quality Risk Management and Risk-Based Decision Making
Socrates Kyritsis, Director, Oral Product Development Pharmaceutical Sciences, **Merck** and Suliman Chawdry, Principal Scientist, Oral Product Development Pharmaceutical Sciences, **Merck**
