

pharma QbD

Better Science. Better Business.

MISSION

PharmaQbD.com advances a smarter approach to drug development—a more scientific, efficient and less “hit-and-miss” approach. It does this via peer-to-peer exchange of best practices, as well as solutions-oriented, actionable information and ideas to improve the drug development process.

There is an urgent need for “best practices” for implementing Quality by Design (QbD) programs and thinking within the drug industry. Currently, as the pace of new drug introductions slows and some established “blockbusters” are found to have serious safety issues, it can take 10-12 years and \$1 billion to develop a new drug. Drug makers need to optimize quality and safety, as well as “manufacturability” from the earliest stages of any drug’s development and to improve speed to market.

This critical industry movement is being advanced by FDA, EMEA and other global regulatory agencies, and is a key part of the ICH’s (International Council for Harmonization) Q8, 9 and 10.



QbD DEFINED

A strategic approach to drug development, Quality by Design requires getting the product, process, packaging and manufacturing “right the first time.”

QbD requires that drug development teams develop a deep understanding of critical process and product attributes, that they design controls and testing based on that understanding and use the knowledge that they gain during the product’s life cycle to continuously improve it.

The concept of QbD requires breaking down boundaries between functions such as development, QA, process development and manufacturing to promote better science and facilitate more economical product development.

Two core concepts are the “design space” and “design for manufacturing”— developing processes and a product, at the front end, that will optimize product quality and manufacturing efficiencies.

CLEARING THE CONFUSION

Recent polling of PharmaManufacturing.com's (PharmaQbD.com's sister property) audience has found that most industry members ranked internal company QbD programs as "extremely important" or "important."

However, many are confused about the terminology and concepts behind QbD.

Some may wonder, "Is QbD just another "TLA" (three-letter acronym) from FDA?"

Many view senior and middle management as the main obstacles to implementing QbD, which requires investment in the right tools (among them, the analytical systems required for Process Analytical Technologies) early in the product development cycle.

Offering both high-level and tactical content, PharmaQbD.com serves both practitioners and management, at all levels. The web site offers best practices and technical articles for engineers and scientists, QA and QC professionals, IT and regulatory affairs professionals. In addition, PharmaQbD features economic and business case discussions of interest to senior and C-level management.

What are the top three goals within your organization this year?	
	Response
Improve internal quality management	59%
Improve manufacturing agility	48%
Improve capacity utilization	47%
Improve alignment of internal goals with those of business partners (contract research, manufacturing and other suppliers)	41%

What are the biggest hindrances to improving organizational efficiencies and quality within your organization?	
	Response
Top management	36%
Middle management	34%
Regulators' expectations	16%
Other	16%
Line operators	14%



PharmaQbD CONTENT FOCUS

PharmaQbD's content includes feature articles, news, white papers, audio and video content focused on Design (Design of Experiment, Design Space, Design for Manufacturing), Control, Compliance and Continuous Improvement.

It also stimulates the exchange of best practices and the latest thinking among members of the pharmaceutical development community. In short, its goal is to help drug industry professionals develop pharmaceuticals with better science and better business in mind.





PharmaQbD AUDIENCE

Scientists

- Chief Scientist
- Members of the Technical Staff

Director, Manager, VP, SVP of:

- Process development
- Product development
- Technology transfer
- Research and Development
- Business development
- Clinical R&D
- Clinical safety and pharmacovigilance
- Clinical manufacturing
- Clinical supply operations
- Clinical trial and project management
- Chemical Manufacturing Control (CMC)
- Compliance
- Quality Assurance and Control
- Outsourcing
- Regulatory affairs
- Risk management
- Strategic planning and alliance development
- Manufacturing and Operations
- Engineers

"C" Level Executives

- CEO
- President
- CFO
- COO

AUTHORITY

Launched by the publishers of *Pharmaceutical Manufacturing*, *The Drug Industry's Voice for Manufacturing and Operational Excellence*, PharmaQbD is directed by a highly skilled editorial team as well as a panel of expert advisors and contributors from within the industry. Advisors represent R&D, manufacturing, mid-level and senior management, as well as FDA, EMEA and ICH committee members.

COMMUNITY-FOCUSED

- Blogs
- Expert Advice
- Virtual Events

PharmaQbD.com Marketing Opportunities



Industry Research Survey Sponsorship

PharmaQbD.com surveys the industry on major issues facing the pharmaceutical and biopharmaceutical industries. Your company can sponsor the research. Sponsorship enables you to ask customized questions and receive the names of all respondents.

Webcasts

Authoritative, professional webcasts can bring your message to the industry's professionals, either as archived or as live, interactive events.

Podcast Sponsorship Program

Podcasts have exploded onto the scene as a quick, convenient, portable means to convey complex information on niche topics. This is a turnkey sponsorship program that is a superior lead generator. We'll find the topic and speaker. All you have to do is follow up on the leads.

Custom E-Newsletters

We'll create an exclusive, co-branded e-newsletter for you utilizing our content co-mingled with your content on a topic that fits with your overall marketing message. You'll get 100% share of voice, plus content that advances your corporate message.

White Paper Sponsorship

This enormously successful program delivers your white paper to thousands of interested and pre-qualified readers, generating highly qualified leads.

In-Article Text Box Ad

Here you'll have the ability to embed a 400-character text box ad in PharmaQbD.com's articles. These can be placed contextually or across multiple articles.

Blog Sponsorship

PharmaQbD.com's blogs reaches thousands of professionals in the industry. It features multimedia content, including videotaped interviews with industry leaders, offering you an opportunity to showcase your company and its message.

Knowledge and Solution Centers

These are company- or product/technology-specific landing pages on our site that contain all your relevant product content combined with a company or product overview. We also "gate" you high-value content like white papers or webcasts behind registration, so you'll generate high-quality sales leads. A "Contact Us" form is included as well.

E-newsletter sponsorship opportunities

PharmaQbD's E-News can help you reach thousands of buyers and get a high return on your investment. Containing original, topical features, the latest industry news and technical insights, our e-newsletters give you high response rates from your key prospects. PharmaQbD.com E-News covers all aspects of drug development and regulation via in-depth feature articles, technical analysis and the latest word on the people, companies and agencies making headlines in the global pharmaceutical arena. It also introduces new products and services, and spotlights key industry events and courses.

Industry-leading digital media offerings from PharmaQbD.com

Carefully built to meet our users' needs for deep, searchable and actionable content, it combines news, original topical articles, white papers, webcasts, podcasts, expert advice, and carefully chosen product and vendor information to provide comprehensive industry insight.

Our integrated marketing programs create top-of-the-line awareness and generate targeted sales leads from qualified buyers.



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