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Monitoring and Quality

by Design (QbD) in

Clinical Trials Avoiding

errors, collecting data

that is fit-for-purpose,

and reducing patient

burden are just a few

of the many benefits of

applying Quality by

Design (QbD)—an

approach that focuses

resources on the errors

that matter to decision

making during a trial,

such as primary

endpoints and patient

safety.

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**Quality by Design |  
Clinical Trials  
Transformation  
Initiative**

Vatché Bartekian  
President, Vantage  
BioTrials, Inc. Abstract:  
Quality by design for  
clinical trials comprises  
an independent entity  
responsible for quality  
standards and an  
integrated system  
where each person is  
accountable for quality.  
This article explores

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myths about quality and provides a general overview of the principles and philosophy of quality by design.

**Quality by Design  
for Clinical Trials -  
SoCRA**

1 Clinical Quality By Design: FDA Point of View Jean Mulinde, M.D. Senior Policy Advisor . Division of Clinical Compliance Evaluation , Office of



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**Clinical Quality By  
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View**

The concept of Quality-by-Design (QbD) has been the gold standard for defining quality expectations in manufacturing operations but similar standards lack for the conduct of clinical trials. It is generally accepted that the quality of clinical trial

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operations varies based on the sponsor, the clinical sites involved in trials, and the resources available with the sponsor.

**FDA's Quality by Design (QBD) Guidance for Clinical Trials ...**

Quality-by Design (QbD) emphasizes building quality into a process from the beginning, and has been successfully

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utilized in the manufacturing arena. Applied in clinical development, this approach examines the design and objectives of a trial protocol to identify “Critical to Quality (CTQ)” factors (e.g. key data and trial processes).

## **Quality by Design (QbD) in Clinical Trials - Build Bullet**

...

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**How the  
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...

Quality must be part of the design of a clinical trial. Consequently, the latest ICH E8(R1) draft guidance now clearly focuses on critical to quality factors to protect subjects and generate reliable and meaningful data. What is Critical to Quality? E8(R1) also states that the quality of clinical

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research relies on good  
design and good  
design ...

## **Quality by Design | ICH E8(R1) General Considerations for ...**

As a result, QbD  
provides a robust  
framework for the  
design and  
implementation of  
processes that achieve  
a consistent level of  
quality and meet the  
pre-defined standards.  
Although

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pharmaceutical development has historically focused on a “quality by QC” approach, whereby emphasis is placed only on the final control and release of a product, the QbD approach builds quality into the product ...

**The advantages of a  
‘Quality by Design’  
approach in pharma  
...**

Quality by Design

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reflects the research and applied training conducted at Dartmouth Medical School under the leadership of Gene Nelson, Paul Batalden, and Marjorie Godfrey. The book includes the research results of high-performing clinical microsystems, illustrative case studies that highlight individual clinical programs, guiding principles that are



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**Quality By Design: A  
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Quality by design is an approach that aims to ensure the quality of medicines by employing statistical, analytical and risk-management methodology in the design, development

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and manufacturing of medicines. One of the goals of quality by design is to ensure that all sources of variability affecting a process are identified, explained and managed ...

### **Quality by design | European Medicines Agency**

“Hence Quality by design relate to Product Performance”.

Definition The

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pharmaceutical Quality by Design (QbD) is a systematic approach to development that begins with predefined objectives and emphasizes product and process understanding and process control, based on sound science and quality risk management.

**Pharmaceutical  
“Quality by Design”  
(QbD): An**

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**Introduction ...**

It is generally more efficient to build quality into a clinical study than to find and fix quality problems after the fact. This QA philosophy is called “Quality by Design” (QbD). The “Design” in QbD has two meanings: First QbD is a way to design high-quality processes. Second, QbD designs (intends) to improve quality.

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## **Quality by Design in Clinical Research - Vantage BioTrials**

Quality & compliance. With more than 250 quality experts, the QbD group is your partner for advice and support when controlling quality risks throughout your product's life cycle. In the clinical research field we consult and support you in: Audit services (sites,

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sponsors, systems and technology) Inspection preparation

## **Clinical Solutions - Quality by Design**

Quality-by-Design

(QbD) has been applied recently for a dynamic pharmaceutical co-precipitation process (Huiquan et al., 2009, Huiquan et al., 2011).

7.1.10.

Nanosuspension

preparation. Sudhir et al. (2009) worked on

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quality by design approach to understand the process of nanosuspension preparation.

**Quality by design approach:  
Regulatory need - ScienceDirect**

In order to ensure the quality of a clinical trial, it is therefore important to conduct quality planning in parallel with the process to design and

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prior to the conduct of the trial. Quality planning consists of prospectively establishing quality goals and developing the products and processes required to deliver a quality trial.

## **Quality by Design in Clinical Trials: A Collaborative ...**

Building Systematically building quality into a clinical trial design to ensure that processes



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are focused on what is critical, and are performed in a way that mitigates errors that would have the greatest impact on subject safety and data quality. Quality by Design (QbD) into trials Early and ongoing The process by which potential risks that could affect subject safety, data quality or ...

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**Model Approach -  
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