OQSIE

Quality by Design

Q&A eBook with OQSIE

GENERIS

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About OQSIE

Our clients leverage our breadth of operations and quality assurance capabilities to rapidly deploy specialized expertise for their unique needs, where those resources are needed anywhere in the world. Consultants are deployed in the mode and cadence most appropriate for our client's organization and situation.

This Q&A eBook with OQSIE will delve into:

- three batch validation;
- regulatory compliance in product development and quality systems; and
- how to lead an integrated QbD implementation strategy.

OQSIE will also be discussing these topics at a Lunch & Learn at Generis' American Biomanufacturing Summit taking place May 23-24th in San Diego, CA.

With three batch validation being phased out by the FDA, how will this affect the pharmaceutical and biotech industries?

Three batch validation is a shorthand way of describing the upshot of FDA's guidance in 1987 in which manufacturing process validation is achieved by documenting that the process is reproducible. i.e., three batches, typically produced in phase III, run with the exact same parameters yielded product within specifications.

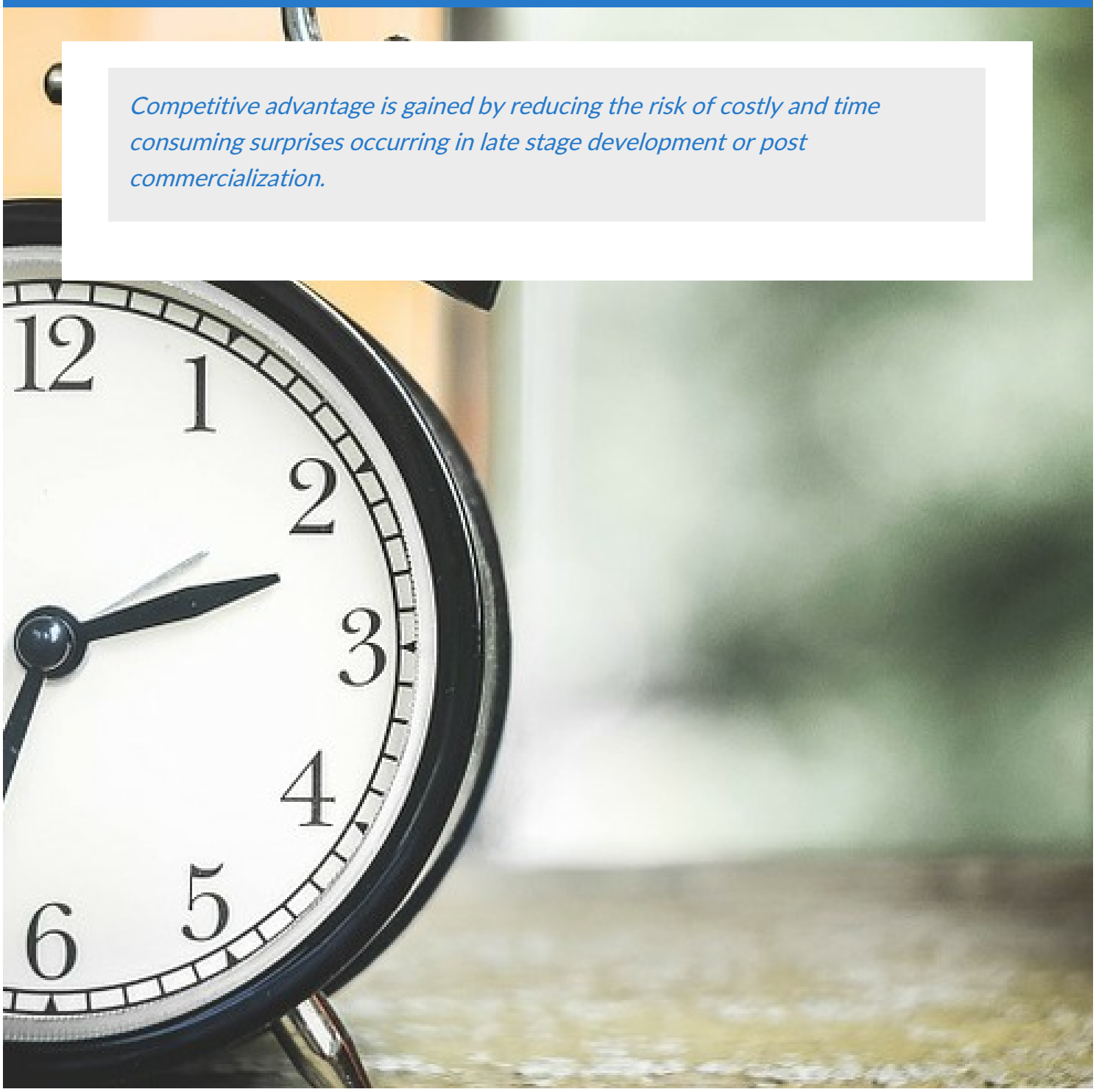
In contrast, FDAs 2011 guidance stresses scientific evaluation beyond reproducibility to include how robust the process is to potential changes in parameters or raw materials and to build this process knowledge throughout the product lifecycle.

EMA's guidance of November of last year actually seems to allow less rigor than suggested by FDA in 2011; citing economic and speed to market concerns.

The short answer is that these are guidance, not law. The industry's movement from documentation of reproducibility to scientific evaluation of process robustness as a means of mitigating risk throughout the product lifecycle appears to be driven more by competitive self-interest than concerns about NDA submissions. In fact, savvy, risk averse organizations often focus on products in post commercialization which were developed without an evaluation of robustness.

How can organizations capitalize on this change and gain a competitive advantage?

Competitive advantage is gained by reducing the risk of costly and time consuming surprises occurring in late stage development or post commercialization.



QbD is also emerging as an integral factor in regulatory compliance in product development and quality systems, but how can you use QbD to reduce risk and cost?

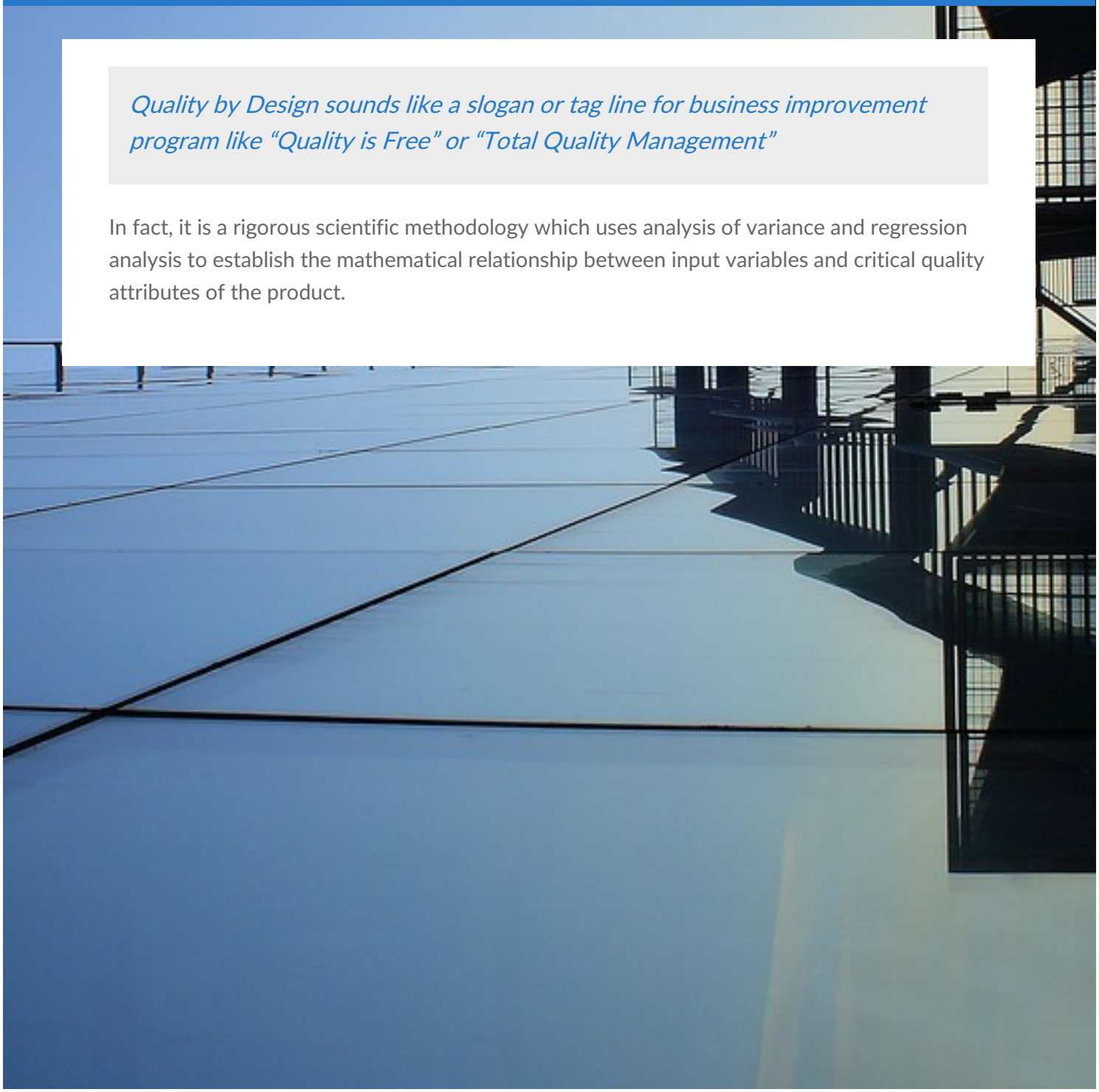
Going to market absent an understanding of the relationship between input variables and critical quality attributes, CQA, is inherently risky and, therefore, potentially very costly.

The cost of a delayed launch, for example, can have far reaching cost implications. However, beyond avoiding costly surprises, organizations employing QbD will not only identify parameters and raw material characteristics which have a strong effect on CQA, they will also be able to identify those that do not, allowing them to avoid setting and trying to meet unnecessarily tight specifications for those characteristics and giving them greater latitude in supplier selection.

What are some of the most common misconceptions about QbD?

Quality by Design sounds like a slogan or tag line for business improvement program like "Quality is Free" or "Total Quality Management"

In fact, it is a rigorous scientific methodology which uses analysis of variance and regression analysis to establish the mathematical relationship between input variables and critical quality attributes of the product.



How can organizations proactively develop and lead an integrated QbD implementation strategy?

Top management's recognition that risk management through process knowledge is a product lifecycle issue as opposed to a once and done aspect of development is a good first step.

That recognition should catalyze organizational development whose ultimate goal is a broad organizational understanding and competence in QbD concepts and tools beyond Product Development to include Operations, Engineering, QA, Regulatory Affairs and even Finance.

In your experience, what has the outcome been like when an organization has led and successfully integrated a QbD implementation strategy?

Well, for one thing, they don't need to bring in expensive consulting talent in a crisis mode because their process is drifting and they don't know why.

Organizations that have developed broad competency in the concepts and tools of QbD which allows them to avoid these costly surprises. One often overlooked advantage of broad organizational development QbD is that coordination between Regulatory, Development, Engineering and Operations as Regulatory puts together the CMC section of an NDA. This alone can yield significant competitive advantage because a coherent, integrated description of the process and it's capability demonstrates the understanding FDA describes in the guidance of 2011.

Operations & Quality Systems Improvement Experts (OQSIE)

OQSIE

OQSIE will be hosting a Lunch & Learn at Generis' American Biomanufacturing Summit May 23-24th in San Diego focusing on "**QbD, A Risk Management Strategy for Competitive Advantage.**"

Fine out more about OQSIE's serivces below!

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