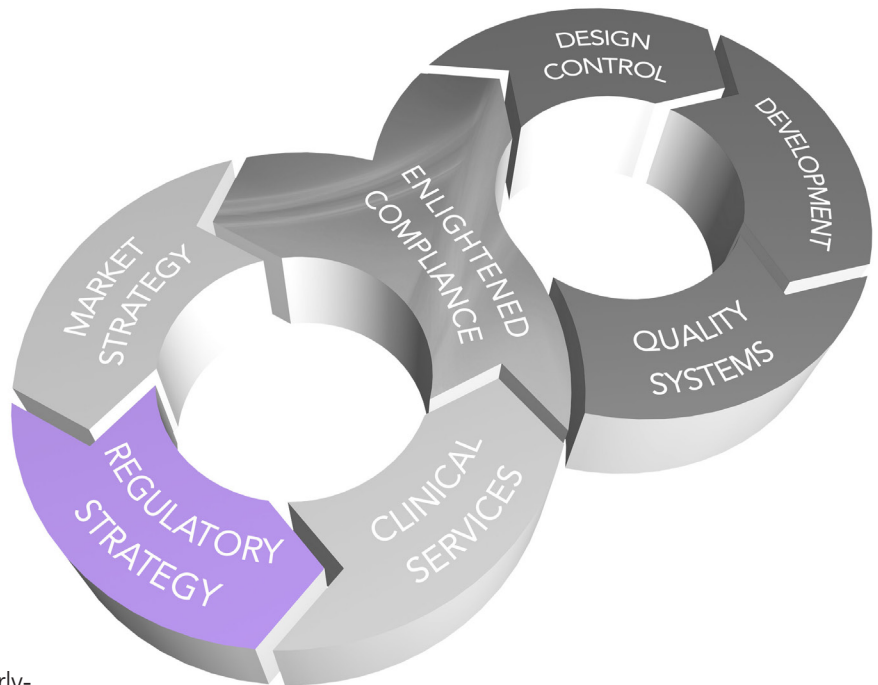


# REGULATORY STRATEGY

## Strategic Advantage

Regulation imposes a heavy burden, but it can also be a source of significant market advantage. The higher you set the bar for yourself, the tougher you make it for competitors to duplicate your success.

Regulatory strategy presents your best opportunity to unite compliance efforts with broader business goals. Developing a regulatory strategy is a key step in developing overall business strategy for *any* life sciences company.



## Early Partnerships

There is no single regulatory pathway for IVDs. Early-stage choices made about intended use, product claims and partnerships can have a profound effect on both the regulatory process and the success of the product itself.

Determining the best pathway for a particular product will include addressing a number of questions, such as:

- Is it sufficient to have a “me too” intended use statement or do we need something that will set us apart from the competition?
- Is our product used in diagnosis of a disease or is it simply one piece of information that the physician uses in conjunction with others?
- Is there a way to get a basic claim now and then work to get an expanded claim once we’re already on the market?
- Have I considered how my regulatory choices may affect my prospects for reimbursement?

## Enlightened Compliance

The journey from lab bench to the regulated market is challenging enough in the best of circumstances. It can be made vastly more difficult when IVD development is approached as a series of isolated one-off projects, each requiring a different set of expert inputs.

Enlightened Compliance is an integrated perspective that unites different project phases and types of expertise around a common strategic outcome. Integration allows us to go beyond saying what *should* work to show what *does* work.

Most companies already possess some of this expertise, but few can deploy the full range. That’s where Myraqa comes in. We don’t just fill the gaps, we provide as much or as little structure as it takes for all the pieces to fit together.



## About Myraqa

Myraqa is the leading IVD consulting firm. Founded in 1998 as a solo practice, Myraqa has grown to include leading experts in Regulatory, Quality, Clinical, Biostatistics, Development and Marketing.

[www.myraqa.com](http://www.myraqa.com)