



YOUR PHARMACEUTICAL  
REGULATORY,  
CLINICAL DEVELOPMENT &  
MANAGEMENT SOLUTION

# RELY ON CONSULTANTS WITH VARYING EXPERIENCE AND BACKGROUNDS.



Allows us to customize our services  
to meet your needs

# OUR STRENGTHS

## Regulatory Strategy

ANDA, and NDA regulatory pathway strategy (including 505(b)(2)) for branded and generic products; post-marketing responsibilities including pharmacovigilance; experience with orphan drug products.

## Clinical Trial Management

A service targeted towards companies who do not have the staff or the bandwidth for a current project. We help in the selection of the CRO, bid defense, protocol development, study oversight, GCP auditing, etc. We can become the face of the sponsor to the CRO. We have clinical project managers, GCP auditors, statisticians, and more available to work on your project.

## Medical Device Development

Experienced in the preparation of 510K's, we can take you from conception through filing of your medical device.

## Bioequivalence Trial Strategy

Assistance with scientific and regulatory challenges associated with atypical BE studies.

# EXPERIENCE

Regulatory strategy  
expertise in IND's ANDA's  
and NDA's

Set up and managed  
six successful  
vasoconstrictor studies  
with U.S., Indian and  
South African CRO's

Medical Device  
Business Development  
of five 510(k)'s

Company has access to  
CMO's and a "proven"  
82 person sales force.

# REG TEC CLIENT ADVANTAGES

- ▶ Reg Tec has over 100 years of combined regulatory experience in the pharmaceutical industry.
- ▶ A varied and experienced group of technical and regulatory associates to support our clients.
- ▶ Freeing you to work on your next project—Reg Tec is the bridge between the sponsor and the CRO helping to assure that your trial runs smoothly



Acella Pharma	Glenmark
Torrent	Watson
Solaris	G&W Labs
Belcher Pharma	Sovereign
Breckenridge	Tedor
Mayne	Impax
Metrics Pharma	Effcon Labs

OUR SKILL SET'S  
HAVE HELPED THESE  
COMPANIES

# LOCATION

## Main Office

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## Our Website

[www.Reg-Tec.com](http://www.Reg-Tec.com)

