“In this era of Information Overload, if it was the sole requirement to progress, we’d all be Hercules. A key instrument essential to every regulatory affairs professional’s success: how do we do, a better job of employing regulatory intelligence?”

* Sharon DeGrove Bishop, April 2016
“The Art & Science of Managing Information Before You Need It”

RAPS ‘15 Regulatory Convergence

................. BEFORE you NEED it.....................

RI = Conscious Process of Information
PROACTIVE VS REACTIVE

INNOVATIVE

APPLICATION

INFORMATION

REG INTEL
AREAS of RI in BUSINESS

Identify various regulatory OPTIONS for Product Development = **Design Protocol**:

- **1x set** of development data will apply to **x no.** of Markets? i.e. WHO Climate Zones

Optimise and speed **“time-to-market”** requires strategic thinking **→** Regulatory Strategies;

determine Business Priorities, Project Plan, Allocate,

**Drive information (data)......submit Critical Data** or?
Respond to lengthy MCC Committee Recommendations =

**Time to Market?**
AREAS of RI in BUSINESS

• Global Regulatory Authorities and Acceptance of Data, i.e. type of studies required for a New Indication;

• Reg expertise throughout Product Life-Cycle Management – **Solve** Challenges, don’t **Create** them 😊;

• Engagement in Manufacturing Optimisation activities;

• Engagement in Critical Business Functions, i.e. **product acquisitions, new market entries**;

• Engagement during Merger, Demerger & Divestment activities
INFORMATION Q4 ‘16

• Regulatory Roundup: TGA Consults on Accelerated Assessments for Devices, by Nick Paul Taylor - Published 22 November 2016;

• Reflections on Mergers and Acquisitions in the Healthcare Industry by Mark Gordon, MS, RAC, FRAPS, Sue James, RAC, FRAPS, Steven Knapp, MS, PharmD, Rosanne Yetemian, PhD, MSRS, RAC, Daniel G. Mannix, PhD - Published 18 August 2016

• Data Integrity: New Draft Guidance, Posted 11 August 2016 by Zachary Brennan: The 44-page PIC/S draft guidance, known as “Good Practices for Data Management and Integrity in Regulated GMP/GLP Environments,” is focused on providing industry with “consolidated, illustrative guidance on risk-based control strategies” for data integrity and reliability
The Evolving Role of the Regulatory Professional
by P Travedi & S Travedi [28 October 2016]

This article discusses the multifaceted role of regulatory professionals who must guide internal company functions from product formulation and analytical development, to manufacturing, supply chain, quality control, clinical and non-clinical science and statistics.

The role includes understanding the changing regulatory environment, interpreting laws and regulations and generating relevant data to support compliance.
PROACTIVE VS REACTIVE

INNOVATIVE
APPLICATION
INFORMATION

REG INTEL
BUSINESS MATTERS

PHARMA INDUSTRY
REGULATORY DIVISIONS
CONSULTANTS
HEALTH SCIENCE PROFESSIONALS
Patients
COST & AVAILABILITY OF MEDICINES
Easiest way to learn and understand Business/Commerce, is Connecting with Different Role Players;
SALES Department is NOT Responsible for your Salary 😞
MARKETING’s Demands are Real/Required NOT annoyance;
NEW BUSINESS DEVELOPMENT ensures Business Sustainability;
LEGAL assists Regulatory, Technical Agreements et al;
FINANCE treat them nicely, they pay your Application Fees
"Intelligence without Ambition is a bird without wings."
-Salvador Dali
STYLE PARISI ON CODE

- Coordination is Crime – Mix it Up
- Steer Clear of Bling
- Creative & Affordable
- Never Worship Fashion Idols
- U love Orange Dresses/Pants with Yellow Shoes – *Go For It*, some day everyone will want to copy U
- Avoid Works of Art
EMPLOYEE or RAINMAKER

Attitude
Multifactorial – Merge with the Business
Interpersonal Skills – accommodate personalities & pressures

NEGOTIATE YOUR WAY TO SUCCESS
WITHOUT SELLING YOUR SOUL
What is Your MISSION in life merely to SURVIVE, OR to ADD VALUE; IF so do it with some PASSION, some COMPASSION, some HUMOR, and some STYLE

Maya Angelou