# About OMICS Group

OMICS Group is an amalgamation of Open Access Publications and worldwide international science conferences and events. Established in the year 2007 with the sole aim of making the information on Sciences and technology 'Open Access', OMICS Group publishes 500 online open access scholarly journals in all aspects of Science, Engineering, Management and Technology journals. OMICS Group has been instrumental in taking the knowledge on Science & technology to the doorsteps of ordinary men and women. Research Scholars, Students, Libraries, Educational Institutions, Research centers and the industry are main stakeholders that benefitted greatly from this knowledge dissemination. OMICS Group also organizes 500 International conferences annually across the globe, where knowledge transfer takes place through debates, round table discussions, poster presentations, workshops, symposia and exhibitions.

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# OMICS International Conferences

OMICS International is a pioneer and leading science event organizer, which publishes around 500 open access journals and conducts over 500 Medical, Clinical, Engineering, Life Sciences, Pharma scientific conferences all over the globe annually with the support of more than 1000 scientific associations and 30,000 editorial board members and 3.5 million followers to its credit.

OMICS Group has organized 500 conferences, workshops and national symposiums across the major cities including San Francisco, Las Vegas, San Antonio, Omaha, Orlando, Raleigh, Santa Clara, Chicago, Philadelphia, Baltimore, United Kingdom, Valencia, Dubai, Beijing, Hyderabad, Bengaluru and Mumbai.

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## Role of pharma industries in the improvement of the PV system

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# In spite of enhanced legislation and scrutiny, withdrawals & fines continue

2014 Takeda fined $6 billion and Eli Lilly $3 billion for **concealing risk** of possible pioglitazone & bladder Ca link

2013 J&J fined $2.2 billion for **promoting unapproved use** of Risperdal

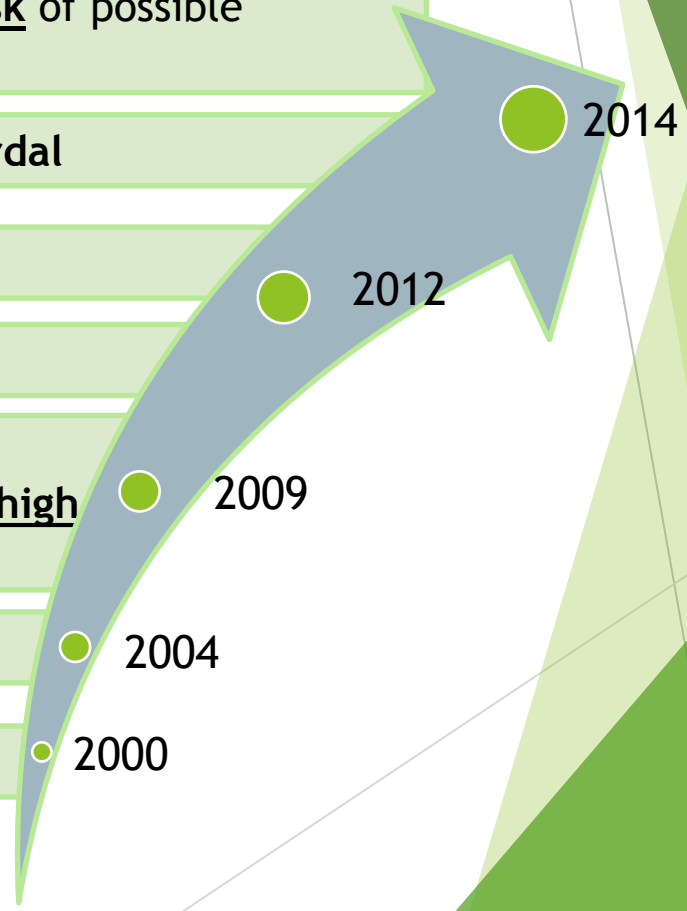
2012 Avandia **safety data not reported**, GSK fined $3billion

2010 GSK's Avandia **suspended** due to cardiovascular events

2005 Pfizer' Bextra withdrawn due to safety concerns
2009 Pfizer fined $2.3 billion in 2009 for **promotion of dangerously high doses**

2004 Vioxx **withdrawn** due to thrombotic events

2000 Cisapride **withdrawn** due to cardiac arrhythmias

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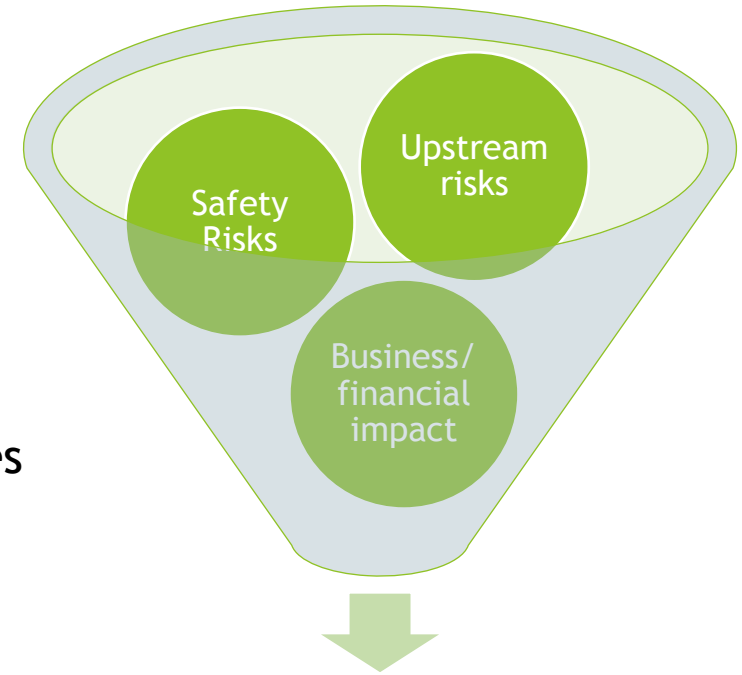
# … sadly pharma has a history of being rather reactive in nature

[1]Can lead to

- Regulatory fines
- Litigation costs
- Reduced stock value
- Damaged reputation

Impact can limit future confidence & ability to finance safety initiatives and as a result compromise the management of safety-related operational issues[2].




Safety-related & operational issues

[3]Significant failings can result in +ive change:

Thalidomide

- Heavily regulated use in a comprehensive risk management system
- Effective & approved treatment in myeloma and leprosy

Tegenero TGN1412 incident

- Review by expert scientific group, the MHRA investigation, and updated FIM CT legislation

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# The challenge- how many drugs are launched and then prescribed and/or used as authorised?

Answer- not many….

- So how can the PV system be structured to enable/ensure safe use?
- Can pharma companies even collect enough data[1], especially in the post-marketing environment to:
  - Determine that presciber and patient behaviours support safe use of the product?
  - Make the right conclusions based on the available data?
  - Allow them to act quickly to address safety signals that emerge after a drug has been approved?

  - Yes, although difficult this can be achieved through proactive risk management planning
  - Yes, with an appropriate PV system[2] and analytics and dashboards[3] in place
  - Yes, through coordination and collaboration with the authorities and other stakeholders[4]

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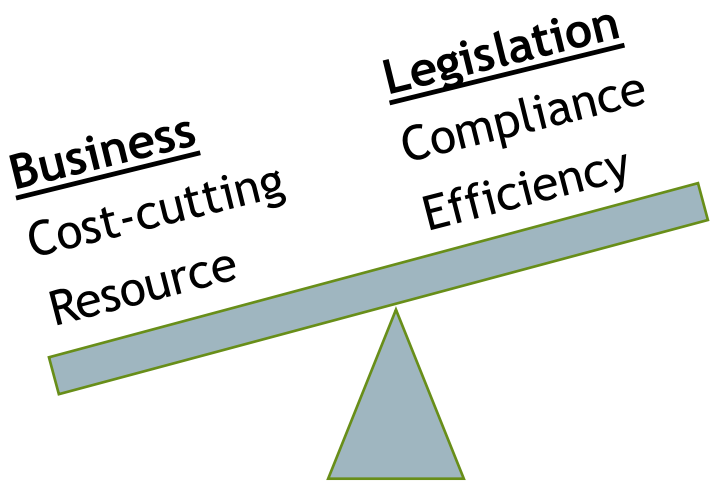
# Compliance with recent legislative changes undoubtedly helps… But is compliance enough?

- Compliance is the minimum standard, not the gold standard
- What should be done and what can be done by pharma to improve PV to balance the needs of the business and that of legislation?
- Compliance and design of robust PV systems can be a major challenge to pharmaceutical companies
- Balance can be achieved through cost-of quality[1]:
  - Adoption of a right first time approach- i.e. cost-of quality
  - Design and management of effective PV Quality Systems and business-process management[2]

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# Industry is being challenged by the expectation for self-regulation*

## Exceeding compliance

- Smarter PV system design
  - Integrated with partner functions
- Process control methodology
  - Focuses on efficiency and process effectiveness
  - Compliance as an outcome, not a goal per se
  - Identifies real process/ quality objectives

## Investing in proactive PV

- Increased data collection for new drugs & new/potential risks
  - Risk-based approaches to data collection, follow-up and medical review**
  - Targeted questionnaires, additional interventions
  - Effective use of social media
- Preparation of Development RMPs
- Proactive portfolio review***

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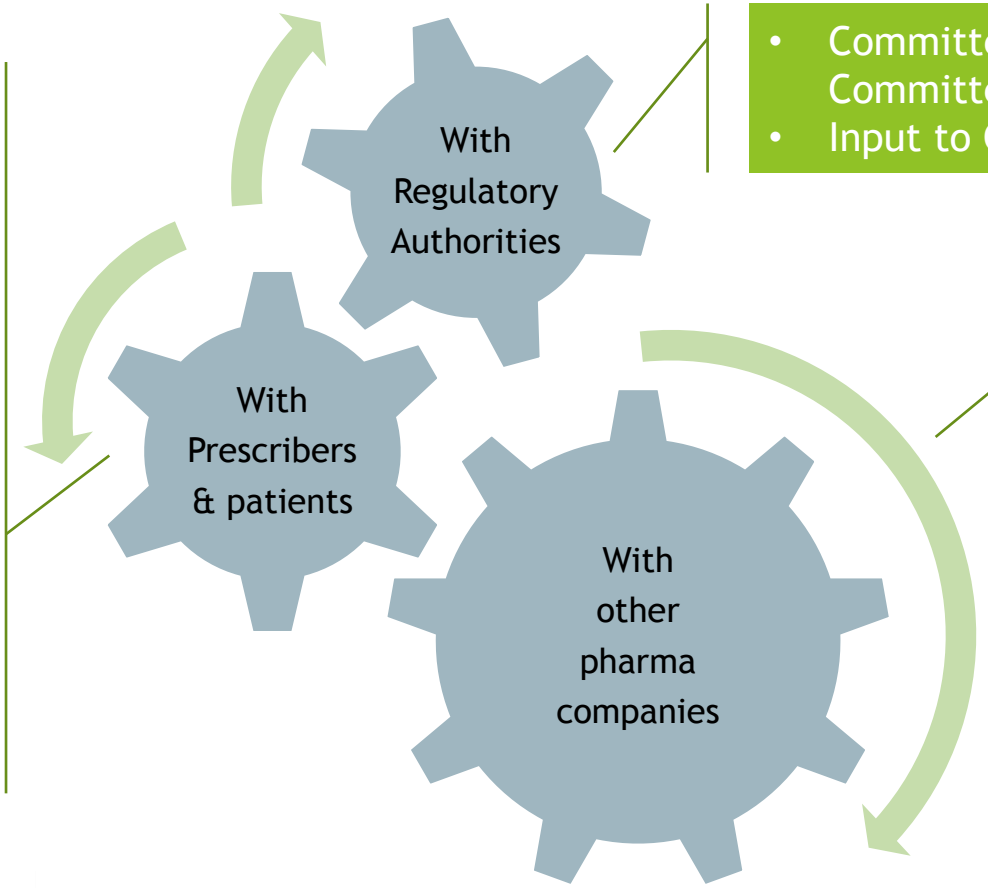
# Beyond a robust PV QMS, industry is beginning to collaborate more

- Involvement with prescriber & patient groups[1]
- High quality patient information
- Focus on transparency & trust
- [2] Useful products- as perceived by patients
- Use of patient-centric technology[3]




- Committees e.g. MHRA Consultative Committee
- Input to GVP legislation[4]

- Creating partnerships to optimise innovation[5]
  - Reducing risk, increasing transparency and access to results
- Industry working groups e.g. EFPIA, ISOP, PIPA, RQA
- Creating partnerships to make products available to new territories

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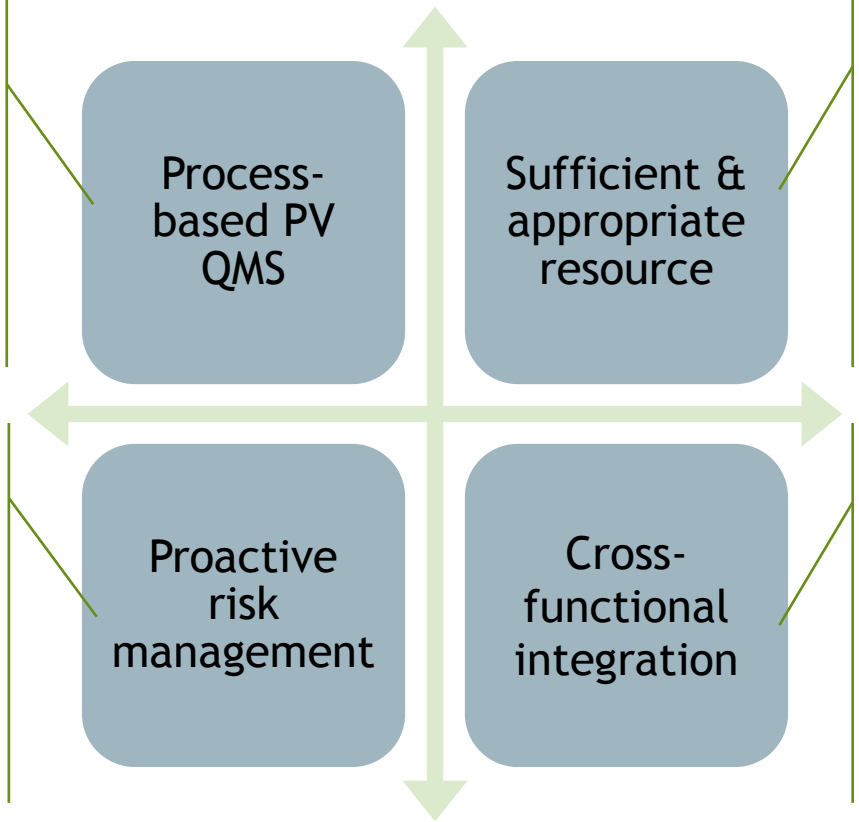
# 4 major opportunities for pharma companies to improve PV system…

Embed process and systems into day-to-day operations. Focusing on the desired outcome of quality will increase efficiency & compliance




A robust PV system will help capacity management.

Linking competence to roles & responsibilities within each process will help keep valuable staff

With the right team in place with access to the right data will enable appropriate decisions to be made- increasing ownership, collaboration, and continuous improvement.

Cross-functional data-driven teams with access to appropriate analytics are best-placed to monitor and assess risk

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# TMC PV services

- Provision of EEA & Local QPPV services
- PV system review & PV auditing
- Signal Detection & Management
- Generation of PV System Master File
- Benefit-Risk assessment, and (d)RMP generation
- Generation and management of DSURs, PADERs and PBRERs
- EudraVigilance & XEVMPD registration
- Literature searches
- Provision of global safety database
- AE & SAE case handling
- Provision of RP for EudraVigilance services
- Global ICSR & SUSAR ICH E2B-compliant submissions

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# Let us meet again..

We welcome you all to our future conferences of OMICS International

**5th International Conference & Exhibition on Pharmacovigilance & Clinical Trials**

On

**September 19 - 21, 2016** at Vienna, **Austria**

http://pharmacovigilance.pharmaceuticalconferences.com/

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