# A network for Heads of Safety of Indian Life Science companies & multi-nationals with a presence in the Indian market

pvindia

**Following the successful launch of pvindia in 2016, with participation from: Akums, Alkem, Allergan, Amgen, Bayer, Boehringer Ingelheim, Cipla, Colgate Palmolive, Concordia, Ferring, Glenmark, GSK, Hetero Drugs, IPCA Laboratories, J&J, Macleods Pharma, Merck and Co, Merck Group, Mylan, Novartis, Novo Nordisk, Piramal, Roche, and Sanofi. We are delighted to be hosting our fourth event.**

**pvindia leverages the approach, format, and experience gained from successfully running pvnetworks over the past 15 years in Europe and the USA. This is a unique opportunity to be part of the industry leading global network for Pharmacovigilance professionals.**

**Whilst we believe that drug safety can be a source of competitive advantage, we see a greater mutual benefit in sharing experience and common challenges. Through our pharmacovigilance networks; pvnet, pvconnect, pvtech, and pvindia, our vision is to shape the future of pharmacovigilance by providing PV leaders with an environment to meet and discuss alternative solutions with other industry thought leaders and enable ongoing improvements.**

## What is pvindia?

Launched in March, 2016 **pvindia** provides a neutral platform for pharmacovigilance leaders facing similar challenges to network, debate, compare performance, and share ideas on how to tackle the latest hot issues.

**Date:** Wednesday 07 March, 2018 | **Time:** 09:30 - 16:30 | **Location:** TBD

## Who should participate in the pvindia forum?

- Global or Regional Heads of Safety/Pharmacovigilance
- PV Senior leadership teams at Life Science companies with Pharma, Consumer, Generics, or Mixed Portfolios, responsible for deploying the PV Strategy and System within their organisation

## Why come to the pvindia meeting?

- Be part of the only global PV network
- Over 50 global member companies
- Hear the very latest Global Regulatory and industry insights with representation from Health Authorities
- Compare your PV performance with Industry-wide benchmark data
- Unique networking opportunities with Global PV peers
- Hear case studies from Global Industry Leaders
- Discuss and develop strategies and best practices with Indian PV leaders
- Explore and debate how the Indian PV Region brings value to the Global PV system
- 300+ global industry professionals participate in our meetings each year

## Who to contact

For further information or to register your interest in participating, please contact a member of our networks team at: pvindia@navitaslifesciences.com

## What topics will the pvindia Forum cover?

**Navigating PV change – discuss, learn, implement**

- International regulatory context: FDA, EMA, E2B (R3)
- The future automated PV process landscape
- PVGI – the route to implementation

## What our members say

"The event was simply excellent and we could learn a lot and gain insight on the subject from other companies. We certainly look forward to attending the next pvindia forum"

**- Chief Manager - Head of Global PV, Top 10 Pharma Company**

"*The forum meetings and the gathering of peers is always a fantastic opportunity to network and gain insight, excellent leadership through the sessions - thank you*"

**- Global Head of Pharmacovigilance, Top 10 Global Pharma Company**

"*Our experience with Navitas Networks confirms the membership provides a unique opportunity to uncover strategic and operational insights, which we then apply across our Global PV business, it is highly valuable in shaping our future PV direction*"

**- Head of PV operations - Top 5 Global Pharma Company**

# A summary of the key topics discussed at **pvindia** to date

| | | |
|---|---|---|
| **October 25th 2017 - Themes** | **Navigating Change - Discuss, Learn & Implement**<br>- PvGI guidelines & ROW Regulations<br>- E2B R2 to R3 Migration Preparations<br>- PV Technology Automation using AI | **Speakers from PvGI, Piramal, Glenmark & Oracle** |
| **March 16th 2017 - themes** | **The latest PV Regulatory context**<br>- Crunch time for EudraVigilance: latest framework/timelines<br>- Experience sharing of cross country regulations<br>- Deep dive and industry discussion on PvGI guidelines | **Speakers from: PvPI** |
| **October 25th 2016 – themes** | **PV 360 - regulations, process, technology**<br>- Global regulatory update - crunch time for Eudravigilance<br>- Current tech landscape, future outlook and the possibilities for automation<br>- Getting clarity on PvGI and the impact on the PV system globally and locally | **Speakers from: PvPI**<br>**Case studies: Glenmark Macleods Pharma** |
| **March 3rd 2016 - themes** | **PV in emerging markets**<br>- Global Regulatory insights<br>- How to ensure inspection readiness<br>- Moving beyond compliance | **Inaugural meeting** |

## Key "take outs" from previous pvindia meetings

### PvPi Debrief, R2 to R3 Migration and RoW Guidelines (Oct 2017)

| Observations | Challenges | Opportunities |
|---|---|---|
| - PvPi regulations appreciated but more clarity sought<br>- E2B R2 to R3 migrations, challenging but surmountable with preparations. Many strategies can be applied to handle migration | - Timeline is very short to implement PvGI guidelines<br>- RoW regulations are getting stricter<br>- Unpredictable case volume increase post Nov 22nd 2017 | - Several activities across PV value chain can be automated towards improving efficiency |

### Update and discussion on PvGI (Mar 2017)

| Observations | Challenges | Opportunities |
|---|---|---|
| - Ongoing dialogue between pvindia and PvPI since October 2016<br>- Positive sentiment about the spirit of the new regulations<br>- Aspiration to add global value and enhance patient safety | - Complexity in the detail of the PvGI that requires further dialogue and agreement<br>- Implementation timeline not yet clear<br>- Interface and influence between global and local needed for implementation<br>- New skills, processes and technology may be needed | - Required resource qualifications<br>- Data needed for AE reporting purposes<br>- Alignment with global reporting timelines<br>- Requirements for having an RMP |

### PV technology – latest tools and possibilities for automation (Oct 2016)

| Observations | Challenges | Opportunities |
|---|---|---|
| - Technology is key to managing rising workload today and at the heart of the transformation needed for tomorrow<br>- Major disruption is on the way via automation and cognitive computing | - Case volumes and other demands will continue to rise, technology key to handling<br>- SDB upgrade cycle<br>- New skills required, e.g. manage the robot rather than the process<br>- Still learning the art of the possible | - Learn from today's automation pilots and build the roadmap for the next 5 years<br>- Transformation to increase productivity and re-focus resources on tasks that truly add value for patient safety |

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