

A specialized forum for  
in-house counsel working on  
pharmacovigilance issues in  
the Life Sciences sector

## what is pvlegal?

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pvlegal is a membership-based forum for in-house counsel working on drug and device safety issues in the Life Sciences sector.

## what sets pvlegal apart?

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- pvlegal is a truly industry-led group; the members determine and customize the agenda for each meeting.
- pvlegal members elect a chairman from amongst the membership who directs the substance of pvlegal meetings and communications, with input from the membership.

## objectives

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- Share and benchmark best practices in the area of pharmacovigilance.
- Facilitate the exchange of knowledge and ideas relating to current challenges, and develop relationships among member companies' in-house counsel.
- Facilitate direct interactions with industry leaders, self-regulatory bodies, and key government regulators/enforcement agencies.
- Keep members updated regarding the latest legal and regulatory developments and enforcement trends in the area of drug and device safety around the world.

## membership benefits

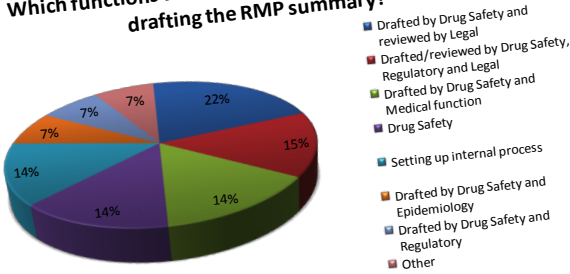
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- Biannual in-person meetings
- Semi-annual conference calls to discuss recent relevant developments on pharmacovigilance, as well as enforcement developments and trends
- Benchmarking reports, prepared based on questionnaires tailored to the interests of the members
- Updates and alerts on relevant legal and regulatory developments
- Access to a members-only, password-protected website with pharmacovigilance background resources and pvlegal work product
- Unique networking opportunities
- Antitrust supervision
- Resources of Sidley Austin LLP's outside counsel on non-company specific questions and the proposal of possible legal solutions to generic problems and issues encountered collectively by member companies

# Examples of graphs and text from benchmarking reports



## Which functions within your company are involved in drafting the RMP summary?



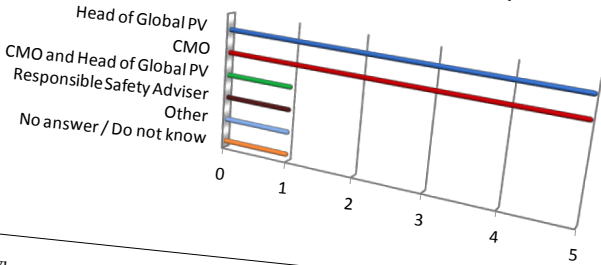
Is your Legal department involved? If yes, how?

Members stated that Legal is or will be involved in drafting or reviewing

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## Who serves as the Chairperson of your company's Global Benefit-Risk Committee?



- What stages of product development are covered by your Global Benefit-Risk Committee (e.g. products in development, approved products, line-extensions etc)?
  - Thirteen members stated that all stages of product development are covered by their Global Benefit-Risk Committee.

Comments:

- "All stages of product development are covered by our Global Benefit-Risk Committee, but we have a separate committee dealing with pre-clinical aspects".
- "The Committee covers the entire life-cycle of our products, from inception to post-market".
- "Our Committee covers investigational products at all stages and also post-marketing data".
- "Within our company the team is formed during Phase I and continues throughout marketing."

- One member did not respond or did not consider the question pertinent.

## pvlegal contacts



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## pvlegal Extranet: Members-only access to reports, meeting materials, pharmacovigilance resources and member contact directory

The screenshot displays the 'Files' tab of the pvlegal Extranet. The interface includes a navigation bar with 'Home', 'Activity', 'Files', 'Contacts', and 'Admin'. Below the navigation bar, there are tabs for 'Attachments', 'Add', 'Delete', 'Move', and 'Copy'. The main content area shows a file tree on the left and a list of files on the right. The file tree includes folders for 'Deleted Items (8)', 'pvlegal', 'pvlegal General Documents (1)', 'Meeting Documents', and various meeting folders from 2016 back to 2007. The file list on the right shows a folder 'July 20, 2016 - Colgate, Piscataway, NJ' and several PDF files, including 'Product Liability Litigation presentation - PV Group Case Packet', 'Case study - Risk Management at CP - H Kukura', 'Impact on PV of Major Changes to Privacy and Data Security Law - C Brown\_S Achenbach', 'Overview of Benchmarking Results and Roundtable Discussion', 'Social Listening and Social Media Challenges in Pharmacovigilance - H Seifert\_G Phillips', 'The Critical Role of Global PV in US Product Liability Litigation - H Levine\_K McDonnell', 'Update on Pharmacovigilance - M Lugard', 'US Drug and Device Safety Developments - T Cope', and '201607 pvlegal agenda'.

## Other Life Sciences Legal Forums

