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PFIZER

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MANAGER

Pfizer, being the world's largest research-based biomedical and pharmaceutical company, has to meet the demands of a large number of regulatory authorities, and do so quickly, accurately, and to exacting submission timelines.

My role in the company in Worldwide Regulatory Policy and Intelligence (which is an integral part of Worldwide Regulatory Affairs) is within an Intelligence team that needs to ensure that our global strategy teams are kept fully informed on the latest regulatory news and intelligence - the moment it is available and for every market we're involved in. We do this by compiling an internal regulatory newsletter that is distributed to colleagues throughout the world every day, as well as maintaining a website with daily regional news updates.

The Weekly News Alert from *IDRAC* provides a succinct regional overview of newly added content in the database, and all subscribers can have this alert delivered directly by email.

I depend on *IDRAC* AdComm Bulletins for meeting summaries, voting results, analysis, and regulatory histories of FDA advisory committee meetings.

Some unique *IDRAC* features of particular value to us include individual voting histories as well as profiles of advisory committee panel members, and comprehensive records of voting histories of entire committees. This is important intelligence for project teams preparing for an advisory committee review. Other *IDRAC* features that stand out as unmatched by other regulatory databases are the Guidance Bulletins and Product Approval Bulletins.

Another aspect of my job is answering complex regulatory queries from my colleagues around the world. *IDRAC*'s reference and explanatory content are invaluable to me to ensure I send the right response to each query, quickly and easily.

The contacts I have made over the years with *IDRAC* editors and customer service staff have been mutually rewarding, and the Users' Meetings are helpful venues to meet new staff and exchange ideas, experiences, needs and wants.

One thing that has always impressed me with the *IDRAC* staff is their responsiveness to specific requirements. A number of features we use evolved from 'wish lists' or difficult queries we consulted with the editors about.

The training modules available on the *IDRAC* site are user friendly and always up to date, and individual or group training sessions are offered continually as well.

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