



International Perspective: How does the US FDA involve medical experts?

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Questions



- 1. How the FDA recruits and trains medical experts – as reviewers, and as members of advisory panels
- 2. How medical experts identify questions for which special guidance should be prepared
- 3. How regulatory science is developing as an academic or clinical subspecialty for all medical fields in the USA
- 4. Any other US insights that are important for engaging with health care professionals (e.g. reporting incidents, and contributing to registries)

How the FDA recruits and trains medical experts – as reviewers, and as members of advisory panels:



- **FDA getting expert feedback:**
- Part time or full time employment of experts in the field
- Advisory Committee meetings – comprised of experts in the fields directly applicable to the feedback being sought – members are Special Government Employees. **Need to be cleared of COI**
- Get feedback on a specific regulatory application (homework)
- Get feedback on a general topic
- Individual feedback from Special Government Employees

Medical Experts



- Network of Experts: Recommendations from Medical Societies, e.g., ACC, AHA, HFSA
- Mechanism to quickly get advice from external experts from a number of Societies
- Can include medical societies and non-medical societies (e.g. engineering societies)



Internal Education The Staff College



- The 'staff college' is a division called "Division of Employee Training and Development."
- Continuous conversations with individual supervisors about employee development to try to tailor training to individual needs.

Other areas of training



- Experiential Learning Program – local and non-local training opportunities directly related to review areas.
- Individual manufacturer visits, learning about manufacturing, R&D labs, e.g. Abbott Laboratories
- Individual labs – such as ones used by industry to perform some of the testing and services FDA reviews and sees – biocompatibility, sterilization, mechanical testing
- Training on clinical trial design and practical clinical trial considerations including statistics

Internal Education Opportunities



- Scientific meeting attendance – hear about research and trial results and up and coming devices
- Internal 'Rounds' or scientific discussions applicable to devices areas
 - VAD rounds
 - HF rounds
- Application for internal grants to ask questions
 - publications
- Recent review of PRO's



FDA Partner Training Events



- CME Events through Georgetown University Center of Excellence in Regulatory Science and Innovation
- Continuing Education by Partners
- On-Line CME Event: NIH Clinical Center Grand Rounds
- Employee Education System- VHA Train
- CDC Train



Thank You!