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)**
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!