

## Session Three

# THE GLOBAL REGULATORY VILLAGE – HELPFUL OR HARMFUL TO PATIENTS AND PHYSICIANS

Gavin Corcoran

9:00 am – 9:20 am  
Saturday, Oct 28

The global regulatory environment is changing rapidly for a number of reasons. The cost of drug discovery and development, increased focus by health authorities on adequate pre-market safety assessments and the overall focus on providing efficacious cost-effective therapy on a global basis. This has a number of effects for the drug development process as well as for the practice of medicine and specifically dermatology.

Globalization of regulatory requirements would be a nice concept, but is unlikely to happen. The institution of the ICH guidelines have helped to push this global standard forward, but not every health authority has bought into these concepts.

The talk will focus on outlining the following:

- How global regulatory guidelines for drug approval impact the practice of medicine
- How can decisions be made about clinical trial designs to serve all of these disparate guidelines at once
- How practicing and academic physicians can work together with industry to ensure that patients are served while regulations are met