

America's Got Regulatory Science Talent Competition: Our Experiences



James E. Polli

jpolli@rx.umaryland.edu

Motivation

- To promote student interest in regulatory science – the science of developing new tools, standards and approaches to assess the safety, efficacy, quality and performance of FDA-regulated products
- Co-curricular learning and interprofessional (i.e. optional and fun event)
 - Open to all students at the Baltimore and College Park campuses of the University of Maryland

What has happened?

- “America’s Got Regulatory Science Talent” Competition (first held Jan 2012)
- Each team presents a proposed solution to a current problem in regulatory science
 - Students are referred to the September 2014 “FDA Strategic Priorities” document and other references
 - Can have UM and/or FDA mentor
- See material provided to students
 - <http://www.pharmacy.umaryland.edu/admissions/regulatoryscience/talent.html>
- Food and prizes !

Timing at U of Maryland

- Start to promote around mid-Nov
- Mid-Dec deadline to request a UM or FDA mentor (if have not self-identified a mentor)
- Application deadline is 1 week before the event
- Hold event in late Jan or early Feb (i.e. 2-3 weeks into semester)
- Present at FDA in April or May

Past winning teams

- Online MEDWATCH interface to increase adverse event reporting by consumers
- Liquid barcoding pharmaceuticals for counterfeit pharmaceutical drug detection
- Mobile application conveying safety information to communicate drug hazards
- Leverage search engines to increase participation and signal detection in pharmacovigilance
- A high visibility universal labelling system to communicate risks of hazardous drugs

Interprofessional and co-curricular learning

- Professional students
 - Pharmacy, medicine, law
- Graduate students
 - Life sciences, health services research, public health, pharmaceutical sciences
- Undergraduate students
 - Only one student, but ...

Logistics/Rules

- A team can be either an individual or any number of students, although each team member has to contribute to the proposed solution or the presentation.
- The presentation must be five minutes in duration or less.
- Each presentation is followed by two minutes of Q&A.

Evaluation

- Panel of judges from Maryland and FDA in terms of proposed solution and presentation quality.
 - Proposed solution: novelty and potential significance. Short-term feasibility is a plus, but not a requirement.
 - Presentation quality: verbal communication, visual communication, impact of any AV materials or demonstrations, and Q&A responses

Impact of America's Got Regulatory Science Talent Competition

- Promote student interest in regulatory science
- Students relay how their involvement was a major discussion point during fellowship/job interviews