Regulatory Science Training Coordination
An Academician’s Perspective

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• Interest in Regulatory Science is increasing at many universities
  – Some are new programs, some retooling of regulatory affairs
  – While many are certificate programs, others are building towards becoming full fledged Masters w or w/o PhD programs

• Informal Networks exist (e.g., Univ. of Rochester and its Reg. Sci interest group)
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• Formal meeting convened by PhRMA board with organization by Academic Centers in August 2014
  – There are rich and diverse capabilities across the nascent programs (expertise in devices vs. drugs, translational science vs. pharmacology/pharmaceutics, etc)
  – By end of the day, there was still discussion as to what constitutes “Regulatory Science”
  – Discussion made clear that views of focus for training varied from drug development/clinical research to more traditional regulatory affairs
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• Fair agreement on higher level pillars of curriculum and core competencies, definitive output is a work in progress

• FDA has not actively driven that conversation, should they?
  – FDA is in need of a robust, interested talent pipeline
  – FDA alone can know what areas of regulatory science would benefit them most as a focus of specific research and training to advance their mission
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• Academia is not well set up to coordinate and collaborate BUT...
  – With divergent internal resources for pedagogy and science, it would make sense to look to leverage efforts rather than redundant and sometimes inferior efforts in silos
  – Right now, it is relatively few for whom driving a common curriculum development, collaborative mechanisms and coordinating scientific projects to larger outcomes across institutions is a “day job.”
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- So, from my perspective in academia, and taking into account my background with FDA and Industry, an undirected organic growth in regulatory science training and investigations will:
  - Risk training programs that don’t meet expectations of future employers (including FDA)
  - Make it difficult to have diverse, effective interexchange amongst and between academia and FDA
  - Miss leveraging across institutions to have a “whole” that exceeds the capabilities of any one institution in providing the full gamut of regulatory science training.