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The fine balancing act of drug formulation R&D in academia

Statement of the Problem: In universities, pharmaceutical scientists are encouraged to dream of building marvelous creations, such as self-propelled drug delivery systems, self-assembling nanoscale devices and stimulus-responsive drug targeting mechanisms. While immense efforts are spent on accomplishing these transformative feats in chemistry, engineering and biomedicine research labs, the resulting advances are often not practical to translate into the clinical arena.

Methodology & Theoretical Orientation: In order to realign academic, drug formulation research with the more practical considerations inherent to drug product development, many challenges that precede clinical translation must be taken into account and dealt with, at the earliest, inception phase of formulation design. In this regard, my research group has grounded itself in reality, by carefully studying the nanoscale transport and distribution properties of existing drugs, prior to launching itself into a new, formulation design project.

Conclusion & Significance: By pioneering the formulation and development of biomimetic drug complexes, we have been able to balance fundamental discovery-driven research and technological innovation, with the more mundane necessities and regulatory requirements underlying successful clinical translation (from scale-up to manufacturing; and, from sterilization to commercialization).

Biography

Gus R Rosania as Principal Investigator of the Subcellular Drug Transport Lab, is transforming the development of new drug formulations, by elucidating the micro pharmacokinetic properties of drugs in their biological, tissue microenvironments. His research group has pioneered new cheminformatic (mathematical modeling and simulation-based) approaches to the design of small molecule drugs with optimal permeability and intracellular accumulation properties, as well as application of hyperspectral Raman imaging approaches to discover new transport and disposition mechanisms acting at cellular and subcellular levels. His major contributions to pharmaceutical sciences is that his research group has discovered the most potent small molecule drug targeting mechanisms that has ever been identified to date, by studying the mechanisms of intracellular drug crystal formation. This knowledge is now being applied to the invention of new pharmaceutical formulation approaches that are poised to transform the manner in which drugs and formulations are designed, developed and regulated.

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