QC strategy for US FDA approval of biopharmaceutics

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Biopharmaceutics as an industry is now in transit. By 2006, more than $10 billion in annual sales of biotech product will lose their patent protection. Unlike the small molecules, these biogeneric recombinant proteins have to face a different situation. These so called "follow on biologics" or bio-similar product, does not have a clear path for registration. There are triple hurdles: legal, technical, and clinical hurdles to overcome and in comparison to original product. U.S. FDA is facing pressures from the Congress and had pushed the original time line to "some time next year" for publishing a guideline for registration path for "follow on biologics". The hesitancy comes from Novatis' problem in registration of human growth hormone in Europe. The hurdle is mostly from showing equivalence in clinics, and the use of "originator's" proprietory information.

The characterization of protein product are both time and resource intensive. The proper application and knowledge of analytical methods will ensure a smooth and less traumatic (or heavily criticized) registration process. The "Trio-Equivalence": analytical equivalence, bioequivalence, and clinical equivalence are the best assurance to a successful registration.