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## Polymeric micellar paclitaxel: Approval challenges and lessons learned

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**C**ynviloq™ (Genexol-PM®), a non-biologic micellar formulation of paclitaxel, utilizes biodegradable di-block copolymers composed of methoxy poly (ethylene glycol)-poly (lactide) to form micellar nanoparticles with paclitaxel containing a hydrophobic core and a hydrophilic shell and is being developed as the next generation nanoparticle paclitaxel. Its target indications are solid tumors such as metastatic breast cancer, lung, ovarian, bladder, pancreatic and melanoma. Herein, we discuss challenges faced and lessons learned from a PK bioequivalence trial of Cynviloq vs. the FDA approved nanoparticle albumin-bound (nab)-paclitaxel (Abraxane®).

### Speaker Biography

Kouros Motamed has been the Director of Drug Development at NantBioScience, Inc. since April 2016. Prior to that, he has served as VP of Strategic Alliances and Clinical Communications and VP of Clinical Development and Nanomedicine at Sorrento Therapeutics from 2013 to 2016. He has also served as a Co-Founder and CSO/CTO of Igdrasol, Inc. and Biomiga Diagnostics start-up companies from 2011-2013. Prior to that, he has served as the MOA and Molecular Biology Group Head at Celgene Corp. and Abraxis BioScience Inc. from 2007-2011. He has held an Assistant Professorship position in the Department of Pathology and Vascular Biology Center at Georgia Health Sciences University from 2002-2007. He has over 30 original publications in peer-reviewed journals, over 50 conference presentations and has 5 issued patents. He has served on the Editorial Board of *Journal of Nanomaterials and Molecular Nanotechnology* since 2013. He has received his BS degree in Biology from University of San Francisco and a PhD degree from the University of California, Davis in Microbiology.

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