

CHEMICAL & BIOMOLECULAR ENGINEERING
Center for Biomanufacturing Science & Technology

CBST SEMINAR

Thursday, December 5, 2019
366 Colburn Lab
1:30 p.m.



“Accelerated Stability Assessment Program (ASAP): Using Science to Drug Expiration Dates”

Setting the expiration date for products (especially drugs), can take more than a year and limit how quickly valuable drugs can get to patients. Developing physical chemistry to help with this problem has had a dramatic effect on the process. ASAP employs isoconversion (time to hit the specification limit at each condition) with designed temperature/RH (and oxygen) conditions (based on a humidity-corrected Arrhenius equation) to build a model for degradant formation for drug products. Once the model is built, the shelf-life inside packaging can be determined based on the calculated RH inside the packaging. These methodologies provide for far better predictions of shelf-life (expiry) than previously possible at a significantly reduced time frame (2-3-weeks). ASAPprime® employs this science in combination with statistical tools to enable accurate estimations of shelf-life with many factors determined computationally (e.g., packaging, storage conditions, storage excursions).

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Dr. Ken Waterman received his B.S. degree with honors in Chemistry from UCLA, his Ph.D. in Physical Organic Chemistry from UC Berkeley and conducted post-doctoral studies in physical and photo-chemistry as an NIH research fellow at Columbia University. Dr. Waterman worked 12 years at Polaroid (as a distinguished scientist) developing imaging products, then 13 years at Pfizer (as a Research Fellow) working on drug stability, drug delivery, biopharmaceuticals and prodrugs. He is the author of over 70 publications and was made an AAPS Fellow in 2011. In 2011, he started FreeThink Technologies which both produces and licenses the accelerated stability software package ASAPprime® and is a CRO that has Connecticut-based laboratories specializing in stability for pharmaceuticals, generics, OTCs, nutraceuticals and consumer products.



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