

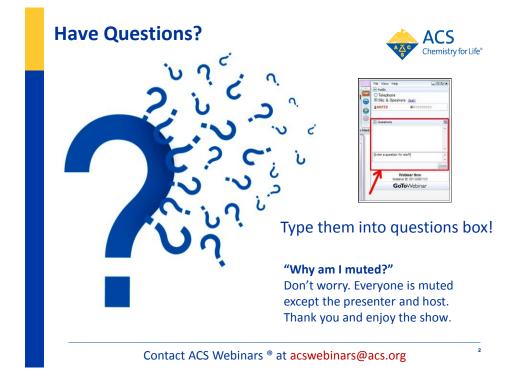


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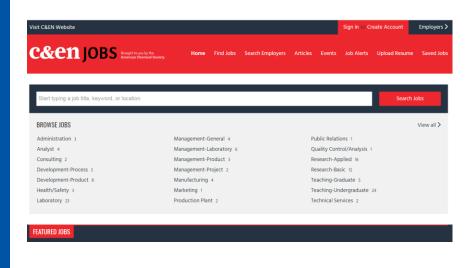






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Thursday, March 23, 2017

Fighting Cancer: Allostery and Targeting Cancer Cell Metabolism

Session 3 of the 2017 Drug Design and Delivery Symposium

Stefan Gross, Director of Enzymology, Agios Pharmaceuticals Scott Edmondson, Director of Chemistry, AstraZeneca

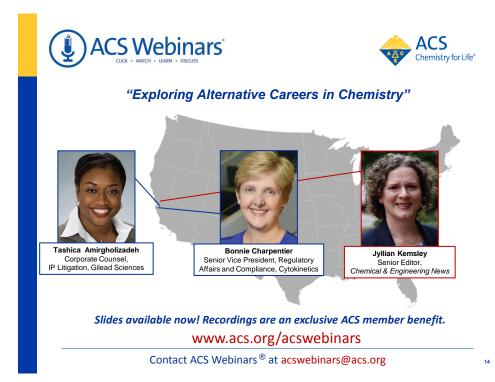
Thursday, March 30, 2017



Sustainability Challenges of the Textiles, Dyeing and Finishing Industries: Opportunities for Innovation

Co-produced with the ACS Green Chemistry Institute

Richard Blackburn, Associate Professor, University of Leeds Joseph Fortunak, Professor of Chemistry, Howard University



c&en



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Jyllian Kemsley, Senior Editor, Chemical & Engineering News j_kemsley@acs.org, @jkemsley

https://cen.acs.org









Which of the following best describes why you are tuning in today?

- I am not in the workforce yet but am interested in alternative careers in chemistry.
- I would like to transition from a traditional to more alternative chemistry career.
- I am curious to find out more about alternative chemistry careers.
- It's Thursday and I always tune into ACS Webinars!

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Background



- Interest in chemistry began in middle school
- Baylor University (Waco, TX)
 - B.S. (A.C.S. certified) in Chemistry and Minor in Mathematics
 - Studied Electrochemistry with Dr. Thomas Franklin
 - Performed medicinal chemistry research at Merck
- Attended the California Institute of Technology (Caltech) (Pasadena, CA)
 - Ph.D. Chemistry
 - **Thesis**: Fundamental Aspects of DNA-mediated Charge Transport
- Law School at the University of California, Berkeley (Berkeley, CA)
 - Focused on intellectual property
- Patent litigation associate at Sidley Austin LLP (Los Angeles, CA)





- Biopharmaceutical company (Foster City, CA)
 - Portfolio and pipeline includes treatments for HIV/AIDS, liver disease, cancer, inflammatory and respiratory diseases and cardiovascular conditions
- Responsible for contested matters in the U.S. and ex-U.S.





Are you planning to transition jobs in the near future?

- Yes, I would like to transition now.
- Yes, I plan to make a transition in a few years.
- Not sure for now but I have pondered it.
- No, I am content with my current position.



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Bonnie Charpentier, PhD

Education and Career Highlights

- Bachelor degree in Anthropology
- PhD in Plant Physiology
 - Dissertation required lots of analytical chemistry (pine trees in space)
- First job post-PhD:
 - Analytical Chemist at Procter and Gamble 10 years · Analytical and flavor chemistry; became interested in approval of new molecules in foods
- Moved to California First job in Regulatory Affairs
 - Syntex, later bought by Roche (total ~10 years)
 - Small biotechs
 - Cytokinetics

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Current Position: Senior VP Regulatory and Compliance

Responsible for three departments

- Regulatory Affairs
- Regulatory strategy
- Regulatory operations
- Technical Writing
 - Clinical
 - · Chemistry, Manufacturing and Controls (CMC)
- Quality Assurance
 - QA for Good Manufacturing Practices (GMP)
 - Clinical Quality Assurance
- Drug Safety and Pharmacovigilance













C

Cytokinetics



Regulatory Affairs

Selected responsibilities

- Strategy and planning for benefit/risk assessment of potential new drugs
- Collaborate with clinical, nonclinical and CMC groups to ensure appropriate studies are done.
- Communication and liaison with regulatory authorities (e.g., FDA, EMA); prepare for and manage meetings
- Regulatory intelligence and currency with rules and guidances
- Preparation of regulatory documents and dossiers
- · Managing collaborations with partners

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Regulatory Affairs

Skills useful for the job

- Technical background
- Ability to interpret data and collaborate with technical teams
- Analytical thinking skills
- · Ability to communicate clearly across different disciplines
- Ability to transition quickly from detail to big picture (and back)
- Negotiating skills
- Crisis management
- Influencing others
- Patience

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Regulatory Affairs



Sources of Information

- U.S. Food and Drug Administration (FDA)
 - www.fda.gov
- International Conference on Harmonisation (ICH)
 - www.ich.org



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Fan of the Week

Hongnan Cao, Ph.D. Senior Researcher Department of Pharmacology Baylor College of Medicine ACS member for 4 years strong!

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