

AAPS Connection

American Association of Pharmaceutical Scientists

August 2012

AAPS Biotechnology 101

Fundamentals of Biotherapeutics Development eLearning Series

The online AAPS Biotechnology 101 is a comprehensive, multi-module course developed for those interested in learning more about the field of biologic development, to fill training gaps, and to address new employee orientation. Since launching in November 2011, over 750 people have viewed lectures, and AAPS has received a great deal of positive response.

The training course was developed for

- professionals seeking to expand their knowledge to include biopharmaceuticals.
- college students and faculty members seeking to augment their training in biotechnology.

This series offers

- Lectures by leading experts from industry and academia,
- Convenience of self-paced learning,
- Coverage of the current state of biotherapeutics, and
- Practical perspectives from practicing scientists.

With cutting-edge, applied science highlighted, the course provides

- Introduction and Overview—5 hours of programming
- CMC—6 hours of programming
- Preclinical—5 hours of programming
- Early Clinical—4 hours of programming
- Late Clinical and Post-approval—6 hours of programming

The four AAPS Biotechnology 101: Fundamentals of Biotherapeutics eLearning program sponsors—Amgen, Bristol—Myers Squibb, Genentech and SGS—have each agreed to help support educational opportunities in the pharmaceutical sciences. Their generous grant provides funding for 100 graduate and postdoctoral students toward one complimentary

AAPS Biotechnology 101 eLearning lecture and a one-year AAPS membership. Apply today online!

Preview

Previews each of the 25 lectures available now! All previews can be viewed on the AAPS Biotechnology 101 website. Bulk pricing discounts are available.

For more information visit www.aaps.org/BT101.

2012 AAPS Annual Meeting and Exposition Travelships

APPLICATION DEADLINE: JULY 27, 2012

The American Association of Pharmaceutical Scientists (AAPS) will be offering a number of travelships to the AAPS Annual Meeting and Exposition, October 14–18 in McCormick Place, Chicago. Travelships will be awarded to those who submit and have an abstract accepted to the 2012 AAPS Annual Meeting and Exposition.

To submit a contributed paper, please visit www.aaps.org/2012submit.

For more information and eligibility requirements, please visit www.aaps.org/Awards-and-fellows.

AAPS Online Career Center

AAPS membership has its benefits!



As a member of the American Association of Pharmaceutical Scientists (AAPS), you have access to a myriad of valuable benefits, including the AAPS Online Career Center!

AAPS's Online Career Center is available to AAPS members and non-members. However, your professional affiliation with AAPS helps align you with an elite group of highly qualified individuals, illustrating a commitment to the increased visibility and recognition of the pharm sci industry, ongoing professional development, and educational opportunities.

Posting your resume or CV with AAPS's Online Career Center is the perfect way to join with many of your colleagues in making your job board the premier resource tool for top industry employers!

Visit careers.aaps.org and create your profile today!

AAPS-FDA Upcoming Meeting

Stay tuned!

The American Association of Pharmaceutical Scientists (AAPS) and the Food and Drug Administration (FDA) are joining together to host the fifth bioanalytical workshop *Quantitative Bioanalytical Method Validation and Implementation: The 2012 Revised FDA Guidance*.

The workshop will provide a forum for open discussion between industry and FDA on FDA's 2012 revisions to the bioanalytical method validation guidance. Stay tuned to the AAPS website (www.aaps.org) and the *AAPS Newsmagazine* for more information, including the workshop dates and registration.

This is one workshop you do not want to miss!

2012 AAPS Workshop on Predicting and Monitoring Impurities in API and Drug Products: Analytical and Regulatory Issues

October 13–14, 2012
McCormick Place, Chicago

Goals and Objectives

Stability has long been recognized as critically important in the drug development process, affecting both the safety and efficacy of drugs. The ability to rapidly predict and assess the potential for stability and safety concerns is an important part of speeding the development of innovative drug therapies. This workshop will discuss the foundational aspects of building stability into the development process to enable predictability and assurance of safety and efficacy. Innovative methodologies for development of effective stability control strategies will be presented. The workshop will provide participants a forum to discuss a comprehensive array of topics such as stress testing, chemical stability, predictive tools, excipient issues, physical stability concerns, genotoxic degradation products, in-use stability, analytical methodologies, and lean stability options. Issues related to global filing of new API and drug products, especially those in emerging markets, will also be explored.

For more information visit www.aaps.org/Impurities.

2012 AAPS Workshop on Patient-Centric Drug Delivery, Product Design and Development: Meeting Requirements in Future Healthcare

October 13–14, 2012
McCormick Place, Chicago

Goals and Objectives

With the increasing focus on the overall therapeutic outcomes of a drug therapy, including patient quality of life and patient populations with different needs, patient-centricity in drug product development, design, and manufacturing is becoming of prime importance. This accounts for specific age groups, like pediatric and geriatrics, as well as patient populations in specific disease areas, like

rheumatoid arthritis or Parkinson's disease, and the emerging concept of personalized medicine, due in part to the increase of diagnostics. With the increasing complexity of drug therapy, patient-centric drug delivery will play a key role in medication adherence and contribute substantially to the therapeutic outcome. Patient-centric drug product development and design is yet a new and challenging area that might impact the entire product life cycle and future drug development programs. The scientific and technology advancements of the past decade have created a good base for the patient-centric drug product development, design, manufacturing, and distribution that will be discussed in this workshop. Workshop participants should leave the workshop with a clear understanding on the different aspects of patient-centric drug products and gain insight on the latest science and regulations.

For more information visit www.aaps.org/PatientCentric.

2012 AAPS Workshop on 21st Century Oral Bioperformance Prediction and Testing

October 13–14, 2012
McCormick Place, Chicago

Goals and Objectives

Specific goals of this workshop are to present new ideas and approaches to the development of more physiologically relevant tests and approaches that accurately reflect in vivo oral bioperformance, including

- physiological factors influencing oral dosage form performance,
- key physicochemical principles impacting dissolution and bioavailability,
- dosage form design considerations,
- non-compendial and novel dissolution testing methodologies, and
- predictive tools of oral bioperformance.

For more information visit www.aaps.org/Bioperformance.

Upcoming AAPS Meetings

Log onto www.aaps.org/meetings for details

- October 13-14, 2012
2012 AAPS Workshop on Predicting and Monitoring Impurities in API and Drug Products: Analytical and Regulatory Issues
McCormick Place, Chicago
- October 13-14, 2012
2012 AAPS Workshop on PatientCentric Drug Delivery, Product Design and Development: Meeting Requirements in Future Healthcare
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- October 14-18, 2012
2012 AAPS Annual Meeting and Exposition
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