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2-day In-person Seminar:

FDA's Regulation of Regenerative Medicine including Stem Cell Treatments, Tissue Engineering and Gene Therapies

By: **Gwen Wise-Blackman, Ph.D**, Principal Consultant, Gwen Wise-Blackman Consulting, LLC

Location: San Francisco, CA | February 1-2, 2018

SPEAKERS

Gwen Wise-Blackman, Principal Consultant, Gwen Wise-Blackman Consulting, LLC

Gwen Wise-Blackman, Ph.D., has 20 years of combined experience in Cell-Based Assays and Quality Systems. She has worked at DuPont Pharmaceuticals, Catalent Pharma Solutions (formerly Magellan Laboratories and Cardinal Health), and Salix Pharmaceuticals. She is currently Principal Consultant at Gwen Wise-Blackman Consulting. Her career focus has been in High-Throughput Screening, Cell-Based Assay Method Development and Validation, and Quality Assurance. Gwen has a Bachelor of Science degree in biology from M.I.T and a PhD in Pharmacology from UVa. She is a member of ASQ and AAPS.

COURSE DESCRIPTION

Stem cells harness the power to differentiate into numerous cells upon stimulation. This has led to their wide exploration across all of medicine, including high risk diseases. Of course, significant scientific breakthroughs in the use of stem cells to prevent, diagnose, and treat numerous diseases has caused numerous start-up companies to form. Despite, such promise, the FDA has yet to approve stem cell therapies for a wide range of diseases, except cord blood-derived hematopoietic progenitor cells for certain indications.

This tutorial will provide an historical context for the use of stem cells in medicine, where the field has been and where it is going.

It will also provide the few examples of FDA approved use of stem cells in medicine and what is needed for the field to progress. For example, in 2006, the U.S. FDA implemented regulations governing the use of human cells, tissues, and cellular and tissue-based products in humans including bone, ligament, skin, dura mater, stem cells, cartilage cells, and various other cellular and tissue-based products. Currently, there is an ongoing debate in industry on how such therapies should be regulated, in particular by the FDA or under the practice of medicine, under federal law or state law, and as drugs or simply biologics.

LEARNING OBJECTIVES

Upon completing this course participants should have an understanding of:

- Fundamentals of stem cells
  - What is all the excitement about
  - How to control stem cell differentiation
  - Sources of stem cells
  - Incorporating stem cells into biomaterials
  - Avoiding immune system clearance of stem cells
- FDA regulatory approvals for the use of stem cells in medicine
  - Currently approved use of stem cells in medicine
  - FDA guidance documents for stem cell technologies
  - Global approval of stem cell technologies
  - How the FDA regulates regenerative treatments and therapies
  - The use of human cells, tissues, and cellular and tissue-based product criteria and "Minimal Manipulation Standard"
  - The drug and biological approval process
  - Regenerative products as medical devices
  - How to design appropriate clinical trials
  - Applicable good manufacturing and good laboratory practices
  - Product labeling, marketing and advertising
  - FDA and other federal agency enforcement action
- Future thoughts on approaches for regulatory approval of stem cell technologies
  - Remaining hurdles
  - Outlook for new technologies

AGENDA

Day One (8:30 AM – 4:30 PM)

Registration Process: 8:30 AM – 9:00 AM

Session Start Time: 9:00 AM

- **Fundamentals of stem cells**
  - Definitions
  - What is all the excitement about
  - How to control stem cell differentiation
  - Sources of stem cells
  - Incorporating stem cells into biomaterials
  - Avoiding immune system clearance of stem cells
  - Research examples pre-clinical approval
  - Research examples post-clinical approval
- **FDA regulatory approvals for the use of stem cells in medicine**
  - Currently approved use of stem cells in medicine
  - FDA guidance documents for stem cell technologies
  - Global approval of stem cell technologies

Day Two (8:30 AM – 4:30 PM)

- **FDA regulatory approvals for the use of stem cells in medicine (continued)**
  - How the FDA regulates regenerative treatments and therapies
  - The use of human cells, tissues, and cellular and tissue-based product criteria and "Minimal Manipulation Standard"
  - The drug and biological approval process
  - Regenerative products as medical devices
  - How to design appropriate clinical trials
  - Applicable good manufacturing and good laboratory practices
  - Product labeling, marketing and advertising
  - FDA and other federal agency enforcement action
- **Future thoughts on approaches for regulatory approval of stem cell technologies**
  - Remaining hurdles
  - Outlook for new technologies
  - Strategies for commercializing stem cell technologies
- **Questions**

WHO WILL BENEFIT

This course is designed for professionals in stem cell, biotech, pharmaceutical and animal drug companies, veterinary hospitals and clinics. The following personnel will find this session valuable:

- Senior quality managers
- Quality professionals
- Regulatory professionals
- Compliance professionals
- Production supervisors
- Manufacturing engineers
- Production engineers
- Design engineers
- Labelers and private labelers
- Contract manufacturers
- Importers and custom agents
- U.S. agents of foreign corporations
- Process owners
- Quality engineers
- Quality auditors
- Document control specialists
- Record retention specialists
- Medical affairs
- Legal professionals
- Financial advisors and institutional investors
- Patent lawyers
- Graduate students
- Academic faculty and professors
- Clinicians
- Entrepreneurs

Registration Form

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Seminar Topic: FDA's Regulation of Regenerative Medicine including Stem Cell Treatments, Tissue Engineering and Gene Therapies

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