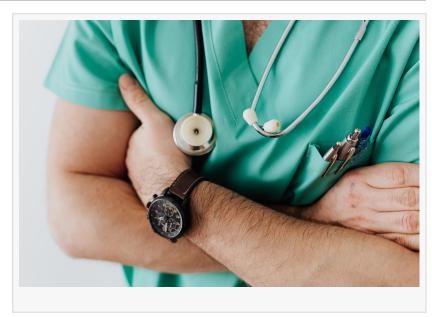


## The Center for Professional Innovation & Education Launches New Cell & Gene Therapy Product Lifecycle Course

CfPIE launches its latest life sciences course, Cell and Gene Therapy Product Lifecycle, Course

MALVERN, PENNSYLVANIA, UNITED STATES, January 16, 2023 /EINPresswire.com/ -- The Center for Professional Innovation & Education (CfPIE), the leader in life sciences training, recently launched its latest life sciences course, Cell and Gene Therapy Product Lifecycle, to support the ongoing development of innovative technologies in the cell and gene therapy segments of the



pharmaceutical market. This virtual introductory course will run on March 1, 2, & 3, 2023, from 9:00 to 5:00 CST.

The design of this comprehensive course is to offer valuable cell and gene therapy insights for employees directly involved in the product life cycle processes. These include product design emphasizing technological advances in genome editing such as CRISPR/Cas, ZFNs and TALEN, EMA classification (ATMPs subclasses), and product development and commercialization of European, Japanese, and US markets.

"We believe this course will heavily benefit business decision-makers in the cell and gene therapy fields of Clinical Design & Development, R&D, Product Development, Regulatory, Strategy, Operations, and Market Access Management because it covers clinical trial design aspects and 'up-to-date' regulatory landscapes highlighting successful marketing authorization and reimbursement strategies," says Mark Mazzie, CfPIE founder and CEO.

The course directive is to teach how to effectively navigate cell and gene therapy product development and create long-term value by obtaining sufficient information on the specific clinical, technological, and commercial issues through the implementation of novel clinical

solutions relying on Real World Evidence, patients' biomarkers, and the appropriate regulatory approval paths from early product approval to marketing authorization and post-approval.

The instructor is <u>Natalia Haraszkiewicz-Birkemeier</u>, Ph.D. and her specialties are biopharma and cell and gene therapy. She is the founder and current Strategy & Business Consultancy CEO of BioPharma First (BPF). With over 15 years of expertise in biopharmaceutical product development, she is a GCP, Strategy & Prince2 certified expert focusing on strategy and operations. In addition, Natalia provides consultations on novel therapies in the context of biologicals, cell and gene therapies, precision medicines and marketing approval strategies.

"Clinical trials play a pivotal role in the understanding & development of novel, innovative health(care) solutions for patients, HCPs, and stakeholders. By working together, advancing science and leveraging various technologies, we are capable of preventing and diagnosing health problems." says course instructor Natalia Haraszkiewicz-Birkemeier.

Dr. Haraszkiewicz-Birkemeier received her Master's in (Bio)chemistry and Immunology from Wroclaw University and her Ph.D. from the University of Amsterdam. She pursued her post-doc fellowship in Medicinal Chemistry and accomplished two post-graduate degrees in Clinical Trials and an MBA specializing in corporate finance and strategy.

During the three-day course, participants will engage in topics which on day one include harnessing the potential of cell and gene therapies such as autologous therapies vs allogeneic cell therapy, somatic therapy vs germline therapies, in vivo vs ex vivo therapies, what the current global landscape looks like, genome editing and the technological and clinical limitations of product development, applications of biomarkers for rare disease patients, and creative solutions for clinical development including de-risking clinical trials.

To learn more about the Cell and Gene Therapy Product Lifecycle course, please visit the <u>CfPIE</u> <u>website</u> or call 1-610-648-7550.

About the Centre for Professional Innovation and Education CfPIE is an industry leader in providing technical training for the pharmaceutical, biotech, skin and cosmetics, and medical device disciplines. CfPIE delivers over 300 courses worldwide annually, brought to you virtually, in class, or customized on-site. CfPIE continues to bring excellence and relevance to the courses they deliver.

Mark Mazzie
The Center for Professional Innovation & Education, Inc
+1 610-648-7550
email us here
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