



LEADERSHIP IN MEDICAL AFFAIRS COURSE ENROLLING NOW

Are you a Medical Affairs professional who aspires to raise the profile of your role in the industry? An existing leader looking to hone your skills or someone looking to move into a leadership role in your organization? The IFAPP Academy, in partnership with Tufts University's Center for the Study of Drug Development, is pleased to announce enrollment for our Leadership in Medical Affairs course.

[Click here for more information.](#)

TABLE OF CONTENTS

Should the Scientific Community Pay for Peer Reviews? • P. 2

Nitrosamine Contamination at a Glance • P. 2

FDA Approves Record Number of New Drugs • P. 3

Covid-19 & Cooler Temps • P. 3

Social Media and Medical Affairs • P. 4

News from the Literature • P. 4

SHOULD THE SCIENTIFIC COMMUNITY PAY FOR PEER REVIEWS?

BY DOMENICO CRISCUOLO

Around the globe, over 100 million hours were devoted to peer reviews of scientific articles in 2020! That's an incredible amount of time, and it's often set forth without proper attention and irrespective of timelines. If you've ever thought it might be nice to be compensated for your efforts, check out [this article](#) from the Lancet, which considers the idea of providing modest payment for peer reviews in scientific journals.¹

Should further consideration be given to compensation for peer reviews? What would that change about your role as a medical affairs professional?



NITROSAMINE CONTAMINATION AT A GLANCE

As [this article](#) in PharmaVoice points out, pharmaceutical development and manufacturing is a complicated world in which more than a few mysteries remain. Nitrosamine contamination in drugs is one of those mysteries, which industry and regulatory agencies are working hard to solve. As we know, simple does not always mean easy, and sometimes the best solution (avoiding the presence of these chemical compounds) is not readily available.²

Check out the EMA's response to nitrosamine contamination [mitigation strategies](#).

Read FDA industry guidance on the issue [here](#).

FDA APPROVES RECORD NUMBER OF NEW DRUGS

BY DOMENICO CRISCUOLO

It was only a few years ago that patients and healthcare professionals were concerned that the FDA approvals of new drugs reached a nadir of fewer than 20 NCEs (new chemical entities). Thankfully, this situation saw a dramatic change in the last decade, and we in the pharmaceutical world are happy to point out that, in 2021, the FDA approved a record number of 50 NCEs!

[Read more here.](#)



COVID-19 AND COOLER TEMPS: WHAT'S IN THE FORECAST?



People living in the northern hemisphere of the globe are getting more relaxed! As we know from the last two years, a mild climate attenuates the infectivity and morbidity of the SARS-CoV-2 virus and its variants. The mild climate arrives timely, as third-vaccination antibodies are now vanishing. Most countries are now wondering what cooler temperatures mean for the virus. For some, as [this article](#) from the New England Journal of Medicine suggests, the answer may be a fourth dose of the vaccine.

“With large waves of infection driven by the B.1.1.529 (omicron) variant of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), alongside evidence of waning immunity after the booster dose of coronavirus disease 2019 (Covid-19) vaccine, several countries have begun giving at-risk persons a fourth vaccine dose.”³

SOCIAL MEDIA AND MEDICAL AFFAIRS: LOOKING AT LIMITATIONS

BY DOMENICO CRISCUOLO

Social media has a significant, two-fold impact on the world as we know it: It is both helpful in disseminating relevant information and can be a hotbed for the distribution of fake news.

Check out [this thoughtful analysis](#) from the Lancet regarding the limitations and benefits of professional social media use in the oncology sector.

We'd love to hear from you. Has social media helped or hindered the way you navigate your role as a Medical Affairs professional? How?



NEWS FROM THE LITERATURE:

Medicines Development Education in Emerging Countries



Whenever we discuss education in pharmaceutical medicine, we often refer to the three most well-known regions: Europe (where the first University courses were established back in the '70s), the USA (where many Universities offer courses in Medicines Development) and Japan (where a few courses were established years ago). But over the last few decades, there has been globalization in Medicines Development which offers many opportunities for “emerging countries” to take a closer look at the education, training, and regulation within their borders.

This manuscript by Prof. Sandor Kerpel-Fronius et. al provides discussion and conclusions about this very topic.

[Click here to read the complete article.](#)

CONTACT US

420 Lexington Ave. Ste. 300
New York, NY 10170

(332) 333-2438



REFERENCES

1. Cheah, P. Y., & Piasecki, J. (2022). Should peer reviewers be paid to review academic papers? *The Lancet*, 399(10335), 1601. [https://doi.org/10.1016/s0140-6736\(21\)02804-x](https://doi.org/10.1016/s0140-6736(21)02804-x)
2. Gibney, M. (2022, April 19). A pharma mystery: Cancer-causing impurities drive joint search for answers. *PharmaVoice*.
https://www.pharmavoiced.com/news/pharmaceutical-impurities-nitrosamines/622244/?utm_source=Sailthru&utm_medium=email&utm_campaign=Issue:%202022-04-19%20PharmaVoice%20%5Bissue:41150%5D&utm_term=PharmaVoice
3. Magen, O., Waxman, J. G., Makov-Assif, M., Vered, R., Dicker, D., Hernán, M. A., Lipsitch, M., Reis, B. Y., Balicer, R. D., & Dagan, N. (2022). Fourth Dose of BNT162b2 mRNA Covid-19 Vaccine in a Nationwide Setting. *New England Journal of Medicine*, 386(17), 1603–1614. <https://doi.org/10.1056/nejmoa2201688>