

(Part 1/2) Malcolm: I do not think, my post or view posted here should be that “hurtful”, or is it so good and sweet that it hurts.

I started a separate thread, as I thought you usually feel uncomfortable, and complain, in discussing dissolution under different topic and discussion, but it appears that you like to monopolize the LinkedIn, so that only those topics be discussed which make sense to you or in line with your views. I respect you however, such an attitude is not representative of such a senior scientist. So, please either ignore my topics/posts or be reasonable and scientific in discussions.

The topic of the thread is “All it will take is the development of a relevant dissolution method!” which is of general in nature, however, I did highlight my suggestion. If you think there are better alternatives available, which should be fine too. Please note that I provided two links with my post, one for the newly suggested spindle and other for the method for the prediction of blood levels from dissolution data. The later one (Erik, please note that it is continuation of a publication) is even more popular than the spindle one itself. Just a few minutes ago, along with many before, I received the following comments “ ... after all you are my "GURU" for Teaching me IVIVC, I cannot forget your help ever.”

On the other hand, if you like to bad mouth my work or suggestion, it would be much better if you please show some evidence that this is what I suggest and this what, with your results/data, is so bad or wrong about my suggestion. Otherwise, it may hurt your own credibility.

With regard to science part, your comment “but none of them solve the food effect issue and none of them include drug absorption in the mechanism”. Please note that a dissolution test is not about food effect or even absorption. We conduct dissolution test and use absorption/food effect (impact on stomach emptying time) to predict blood levels.

(Part 2/2) I should emphasize that, contrary to present views and literature, drug dissolution does NOT PREDICT absorption, WE use absorption to predict/estimate blood levels from dissolution. So, please correct yourself on this scientific confusion in the literature.

Concerning your comment that “you would still need QbD so lets get back to looking at the concepts of QbD” all I can say, if one likes to develop a flying object (let us say a plane) and ignore “gravity” or its impact on flying what are the chances of success of such a thing. QbD without dissolution falls somewhat in the same category. So, please be objective in your thoughts and writings.

Erik: with regard to your comment “To get a change there is a need for not one but a number of publications in a scientific (peer reviewed) journals. Without a thorough scientific background nobody will feel confident to change from the current method.” I think I have more than one publication on the topic. However, I would like to ask that are you interested in good ideas and approaches, or anything with some supporters like BCS/IVIVC and now QbD without defining “quality”?

Concerning, posting and publishing on LinkedIn, I believe this is the future. Look how frank comments (e.g., Malcolm, Emil, yours and others) and fast, one gets on a topic. I do not think such a critical evaluation, and quick, evaluation is possible with old fashion publications concept. I certainly do not, by

any means, discard that approach and will publish, if I have relevant material not just publishing for the sake of publishing.

So, in short, please discuss and provide ideas and critique, do not be concerned that it is on LinkedIn or more formal “classical” medium, your thoughts/views are of equal value.

Thanks both of you for providing valuable critique on my suggestion and post.