Science In Medical And Pharmaceutical Institutions, Including Regulatory = Nonsense!

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During the past week, I have received email invitations to attend an upcoming webinar titled "Challenges in Development and Testing of Complex Drug Products." It is a fancy title for selling a test, and its development approaches, known as a drug dissolution test. The webinar is organized by: The Society For Pharmaceutical Dissolution Science, US Chapter (https://spds.us/).

It is a test used to develop and assess the pharmaceuticals such as tablets and capsules. It is a standard requirement to obtain marketing approval for any solid oral product by all regulatory authorities, including FDA, Health Canada, EMS, NHS, etc., practically without exceptions.

The test has been in use for at least four decades, so what challenges does one face in its use that people have to organize webinars and other scientific conferences on the topic?

The test is extremely simple, as I have done this for 25+ years as a scientist while working at Health Canada. It is based on stirring a tablet or capsule in water (or buffer solution) to monitor drug release from the tablet or capsule. I believe there possibly cannot be any simpler test in any analytical/testing laboratory. In short, the test is to establish drug dissolution/release from the products.

However, the problem is that if one is given a product and asked to determine the drug release characteristic of the product using the test – no one can do it. Why – because THE test cannot test the characteristic (drug release) it is supposed to do or promoted for – **it is a fact**!

In the medical and pharmaceutical areas, their way of doing the test ("science") is first to assume the characteristics and then adjust the experimental conditions to make the assumption sellable. No joking; this is how this test is conducted and is considered science or scientific. One must first tell whether it is a fast-release product or a slower or even slower one.

In non-technical terms, you are given a ball to determine its weight, but in pharmaceutical science, you are given the presumed weight and asked to develop a scale to show the ball weighs exactly the presumed weight. The fancy name of this exercise is developing a product-specific dissolution test. Therefore, practically every product comes with its scale (test conditions).

The FDA is a champion in this regard for developing scales (dissolution tests, link, link), and this is what they sell as challenges. Moreover, the tests often fail in actual practice, so the FDA or regulatory experts are there to "guide" how to change or modify the test to get the "dissolution/release" one wants.

In theory, these (in vitro) drug dissolution tests reflect drug release in vivo, i.e., in the GI tract, and such are known as in vitro-in vivo correlation (IVIVC). However, it would be important to note these IVIVC studies have never been successful in showing this relationship – **never**! However, products having results outside their specifications for dissolution tests are rejected, with a claim that they would not provide expected in vivo release –

how? When in vitro and in vivo relationship does not exist. Therefore, often the response is that the medical/pharmaceutical experts have done all the (clinical) research supporting their claims.

In reality, no valid scientific test is available, including clinical. There are no scientifically valid in vitro (dissolution test) and in vivo (bioavailability/bioequivalence) tests. It is all fake and bogus science and evaluation of pharmaceutical products (link).

The main reason is that for any test to be considered valid, it requires validation using a reference standard, having independently established the characteristic one is after, in this case, drug dissolution or release. However, there is no such reference standard available – **none**!

Therefore, all testing in vitro or in vivo is conducted using non-validated tests; otherwise, a crime punishable by law.

Anyone claiming otherwise is ignorant of the relevant science and/or lying. However, unfortunately, regulatory authorities are precisely making such claims and forcing these illogical and not scientific practices on the industry-leading to fake science, by extension, harming true science, industry, and public health and well-being.

A more disturbing aspect is that scientific-sounding webinars/conferences are sold by experts, with blessings from regulatory institutions, particularly the FDA, to authenticate or sell false science.

All this claimed research and science, promoted in webinars, conferences, publications, and guidance/guidelines, add zero value to product development and assessment but deception about the quality of the products.

The recent version of the fake science/test disaster is the COVID-19 pandemic based again on testing (i.e., PCR) developed by regulatory experts or their subcontractors ("scientists"). I have explained the fakeness and weakness of this test from different angles on my blog (link) and recently published book (link).

Briefly, it is based on the same principle as drug dissolution testing. First, it is to be assumed that there is a virus that has presumed RNA. Some chemicals are mixed, and then, following a narrative, some pictures are drawn to declare that the "presumed" virus has been found.

So far, the world has not seen any direct or indirect evidence of the virus or its RNA. They are all made up or imaginary claims – certainly, science is absent. The only reason this scenario exist is that the authorities enforce it. Otherwise, there is no truth to the claim that there is a virus and/or any related illness.

In conclusion, science is absent in regulatory practices. However, authorities promote and impose some beliefs and opinions by calling them science. It creates enormous issues for applying and implementing appropriate and valid science for assessing pharmaceuticals and therapeutics. This deficiency at the regulatory level requires immediate attention for correction.