LATEST NEWS AND UPDATES FROM THE FACULTY OF PHARMACY

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FROM 'COMPOUND AND DISPENSE' TO 'COMPOUND, PRINT AND DISPENSE' – THE COMING OF THE 3D DRUG PRINTING

A possible scenario in the near future - you have a prescription from the doctor which you receive via your smartphone. You then take it to a pharmacy where you will have your medications compounded, 3D printed and dispensed by the pharmacist, just like a print-on-demand service, currently offered for clothing and housewares. You may choose the colour, shape and size of your tablets, and perhaps to have several medications embedded within one single tablet so that it is convenient for you to swallow just one, instead of the usual handful of tablets. For refills, you simply return to the pharmacy and have them printed. Forget about the queue at the hospital. Even better, if you have enough funds, procure a drug 3D printer and print the medications at home. Then, simply e-consult the pharmacist on the proper use of the medication.

Hitherto, the major part of a pharmacist's task is upon receiving a prescription from the doctor, to compound or prepare, and then dispense the medications to the patient. This practice may be somewhat modified in the coming years.

In This Issue:

With the advent of Industrial Revolution 4.0 (IR4), there is an integration of smart technologies and production systems, and this includes with the pharmaceutical manufacturing practice. One major aspect of IR4 is additive manufacturing (AM). AM is 'the process that aggregates materials to create objects starting from their three-dimensional (3D) mathematical models, usually by overlapping layers and proceeding in the opposite way to what happens in the subtractive manufacturing, a process of chipping away or removing of excess materials' (ISO/ASTM52921-1).

The layering method is akin to the preparation of multilayer tablets long developed in pharmaceutical manufacturing. These tablets consist of an active core supplemented by one or more layers applied during tableting which act as barriers and regulate drug release. Multilayer tablets play a major role in the oral sustained drug delivery system.

In view of this, pharmaceutical compounding should be able to adopt additive manufacturing like a duck takes to water. The 3D printing of pharmaceuticals would be on the horizon sooner than we thought. A company set up in the United Kingdom, FabRx Ltd., states on its website as having produced the world's first pharmaceutical 3D printer for personalised medicines. "Using our propriety PrintletsTM technology, we can create a range of personalised medicines, composed of specific dosages, API (Active Pharmaceutical Ingredients) combinations, shapes, sizes and release profiles", it says.

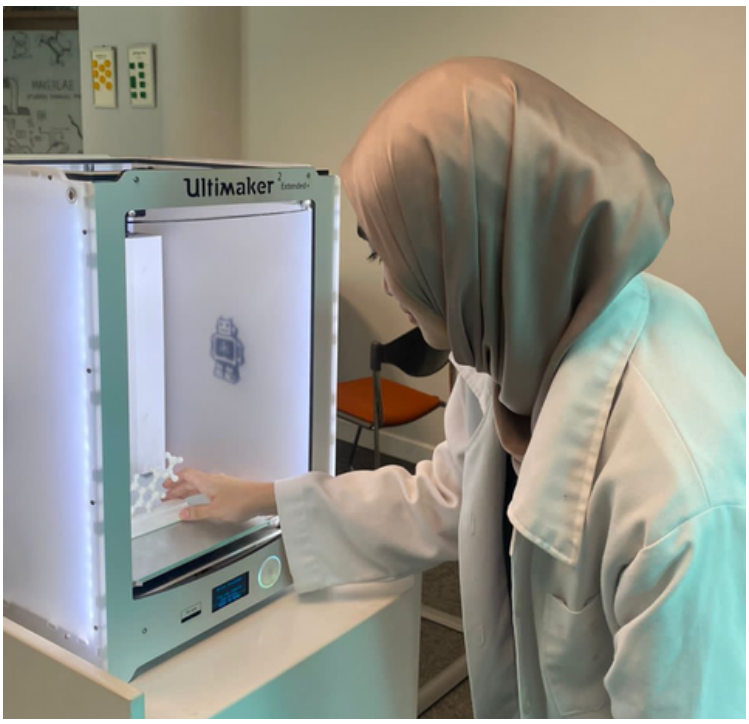
From the above claim, it seems that the phrase 'personalised medicines' is now being coined in another realm. With the plural 'medicines' it connotes medications meant for an individual, not necessarily based on his or her genomic profiles, but rather, any medicine prepared for the use of that specific individual as, when and where required. For this purpose, in the not too distant future, one can even print one's own paracetamol at home or in a neighbourhood pharmacy, provided the appropriate 3D printer, actives and raw materials required to compound the medicine are available. You only need to consult the pharmacist on the proper way of using the medicine.

Indeed FabRx boasts of 'M3DIMAKER, the world's first pharmaceutical 3D printer for personalised medicines'. Imagine, if this bioprinter became ubiquitous like the current 2-D printer, you might print your own medication without having to visit the pharmacy or clinic, especially for refills.

Overall, 3-D drug printing is expected to provide several benefits. For example, an option to select the shape and size of a tablet based on the patient's preference, the ability to replace a cocktail of drugs into a single tablet thus enhancing compliance, the flexibility of controlling drug release by either slowing it down or accelerating to achieve the optimum effect of the drug, and the possibility of printing drugs in small quantity for an orphan disease, i.e. a rare disease that affects a very small number of the population. The last point is crucial as the big pharma may find it unprofitable to produce drugs in small quantities to serve this sector.

In the big picture, 3-D drug printing may save cost in the production and testing of drugs, compared to the huge and complex pharmaceutical manufacturing facility required at the moment. In terms of the impact on the environment, the 3-D drug printing is considered eco-friendly production, although this point is debatable.

The challenges facing this additive manufacturing method for drug production are plenty, for instance the high cost, due to the lack of economies of scale. Inaccurate designs can also lead to misprinting of drugs.



Another hurdle is the regulatory quagmire. However, this is not unsurmountable. In 2015, Aprecia Pharmaceuticals successfully obtained the approval of the Food and Drug Administration, United States of America for its 3D-printed anti-epileptic, Spritam (levetiracetam). The drug which simply evaporates in the mouth with a sip, is very useful for children and older people who have trouble swallowing.

Hence, if one can prove that the drug, whether produced through subtractive or additive manufacturing, fulfils these conditions, namely quality, safety, efficacy, then it can meet the regulatory requirement. The successful registration of Spritam with FDA signals the completion of the proof of concept of 3D printed drugs.

As far as Universiti Teknologi MARA (UiTM) is concerned, 3D printing has been adopted in teaching and research activities for many years. According to Dr Siti Azma Jusoh, Senior Lecturer at the Faculty of Pharmacy, and Coordinator of MakerLab at UiTM Selangor, it would be better to start with 3D printing of nutraceuticals or supplements to test the water, before embarking on pharmaceuticals.

She added that bioprinting is the next challenge. Bioprinting is the printing of bioengineered structures using biochemicals, biological materials, and living cells based on computer-aided design. Hence, printing of body spare parts to replace defective organs, tissues and cells is becoming a reality, despite the tough challenges faced by 3D bio-prospectors.

The Faculty of Pharmacy UiTM is working with a couple of international partners to venture into 3D drug printing research and development. In the meantime, the curriculum content on pharmaceutical industry process is being updated to include this aspect of additive manufacturing to sensitise students of the realities of this aspect of IR4.0. They will also be alerted to the future role of a pharmacist as an expert in 3D drug printing. Thus from the current practice of ‘compound and dispense’, they will have to move to ‘compound, print and dispense’.

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