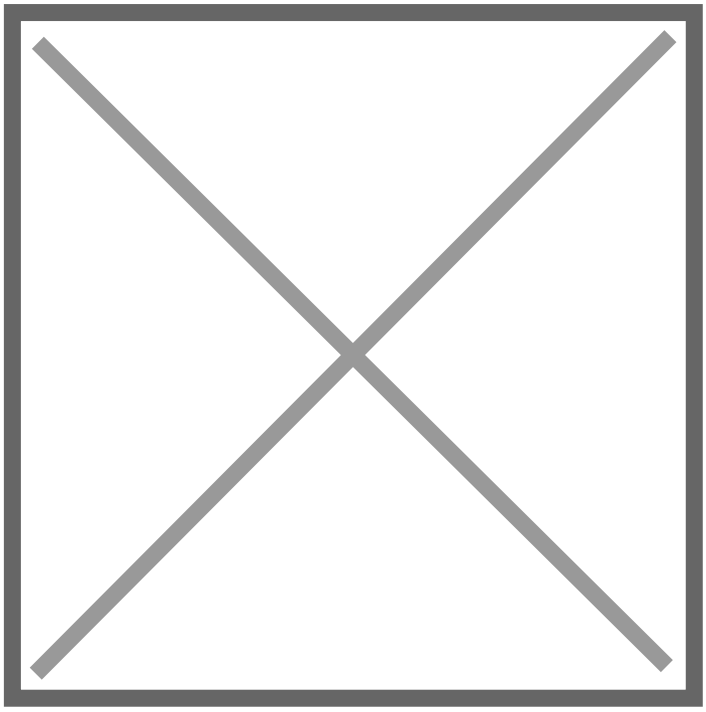
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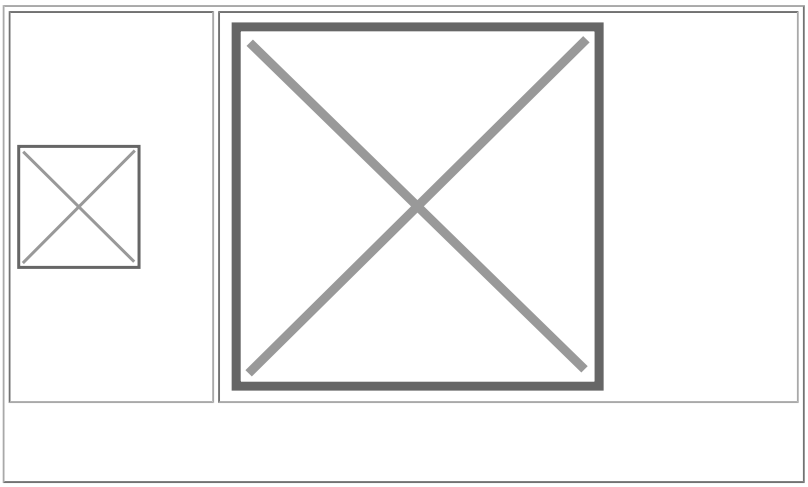
NDDS has a Bright Future

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The future of research will be focused on developing the ability to deliver drugs to targeted regions of the body.



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Amajority of the development work on NDDS has been on small molecules. You will have to go back to the mid-seventies where the earliest NDDS programs that were commercially successful came out of Alza (now Johnson & Johnson) in California. They developed a technology called Oros, a laser-drilled, osmotic controlled released capsule. In many ways, that was the culmination of many years of research and development in NDDS. There were many other programs that were in development, but this was the first time when a technology came to fruition, wherein a product was manufactured commercially and taken to market. One of the earliest products was Procardia XL using the Oros technology, and it became a billion dollar product for Pfizer. Along with that there were some interesting developments in transdermal technologies and patches wherein there is a passive delivery of drugs through the skin. Product development with both these technologies is continuing, and there is a lot of progress that has been made over the years.
So the 1970s was the start for product development using NDDS, and then we have seen products coming about in the 1980s. One of the first products in transdermals was Transderm Scop; it is a patch that is applied behind your ear for motion sickness. You can have fancy technologies in research, but unless it goes into the commercialization of a product, it's all

academic. So these were some technologies which helped in commercially bringing out some products into the market. These are the two significant advances that have set the tone of NDDS research and development.

The scenario today

There has been a paradigm shift because most pharmaceutical companies today have accepted NDDS as a major aspect of their development program. Fewer NCEs are coming to market, and with NDDS-based products, there is lower risk because most often, you are working with a known molecule and working on improving its delivery, so the probability of success is much higher in this case. Again we should refer to the transdermal patch. It is just that earlier it was passive delivery of products but now you have electrical pulses that help in pushing the drug through the skin (iontophoresis) or ultra sound (sonophoresis), and each of these advances can now hopefully also deliver larger molecules/biotech products. Protein and peptides cannot go through the skin passively. You will need such facilitated technologies for their delivery through the skin.

Also, needle-free injection systems have been greatly worked upon, and there are lot of advances happening in making products almost needle free. From the biotech side, one advance that has made a huge impact is the increase in the duration of activity of a drug. In this case for any drug, the technology is such that you can increase the duration of the efficacy of the drug and decrease the dose – that is a paradigm shift. Now we are looking at the scope for oral and other routes of delivery of these molecules. The final frontier, where now you will not deliver proteins and peptides through injectables but through the mouth / skin. There really isn't a product that orally delivers large molecules

Challenges that projects usually have to face On the biologics front, the challenges are much greater than with small molecules. On the small molecules front we have learnt a lot in the past 3 decades and have developed a sizable knowledge bank about different delivery systems. The challenges have been mainly on the manufacturing side and from the delivery systems perspective - it has been more from about longer duration of activity of the drug.

Today, the advances especially if we see in injectables are that we can take an injectable dose maybe just once in a month or over a longer period (depot therapy).

There may not be any novel technologies that may be invented, but definitely, there is work going on in innovating with and improving these legacy technologies. There will be a transition from NDDS to ADDS – Advanced Drug Delivery Systems. As one of the leaders in pharmaceutical space, Lupin has already moved forward and is developing advanced modules of drug delivery, and products based on ADDS.

NDDS has a bright future. You will get more value for a product based on a novel drug delivery system than the conventional technologies available when there is a therapeutic benefit and also you get better patient and consumer compliance. The future of research will be focused on developing the ability to deliver drugs to targeted regions of the body.

In the future we will see significant work in pain management and chronic diseases using NDDS. Awareness of safety is going to a different level and that is where localization of the target becomes important. Oncology is another area. Here a specific antibody / carrier could potentially be targeted towards the tumor and this antibody / carrier will take the drug along with it. There are humongous challenges, but tremendous progress is being made in this field. There will also be a growing need for hormone replacement therapy products using NDDS as the population ages.

Cost

Technological advances cost money and right now products that have been developed over the recent past haven't really gone mainstream in a big way – as a result of which the pricing has remained quite high. The oral technology is now off-patent and fairly accessible – now there will be a natural transition from an expensive high technology product to a relatively less expensive and easily available product over time.

Wherever there is IP involved, the cost will be higher, but once the product goes off patent and becomes available for several companies to use, the cost automatically will come down. But at the end of the day you will not only have to look at the cost advantages but the larger health benefits of NDDS – greater therapeutic benefits, lesser side effects, better compliance and the like - all these aspects are the bigger gains for the patient.

India in the global market

India from the global perspective has a very bright future in terms of the potential from the R&D and NDDS perspective – the Future is real today - even though we are a very small piece of the Global R&D pie. We are setting up processes and systems which will contribute to innovations in NDDS – innovations which will be very competitive and we would be able to do that in a sustained manner. It will take time, but India will take a major leap in this aspect - It is not about potential anymore, but a question of time. We need more investment from the Government to build and ramp up fundamental research capabilities to develop novel products. There is a need for a clear cut directive / direction and focus with objectives and milestones attached to it.

Future in NDDS

A change will be seen in the next ten years because NDDS programs take time in terms of setting up of platforms, developing and sharpening skill-sets and technologies as well as a need for creating knowledge sharing platforms whereby you network with the best global players for joint development. Moreover, the Indian science community which includes the industry and academia has to mature to a level where failure is acceptable in NDDS as there are likely chances of failure in such initiatives

- but you build on those failures and the learning therein, how you manage innovation is what decides and defines success, so the mindset really has to change, to built sustainable success you will have to build infrastructure.
NDDS are always longer term programs with higher gestation periods attached to them than your average generic program,as also the fact that the rates of success attached to these programs may be a bit lower, but the NDDS-based product development will add greater value to both the patients and the healthcare industry!