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EXPRESS PHARMA

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+ Leadership

Dr Ian Hudson
CEO, MHRA

Policy
Gap analysis of some key stakeholders of Indian pharmacovigilance

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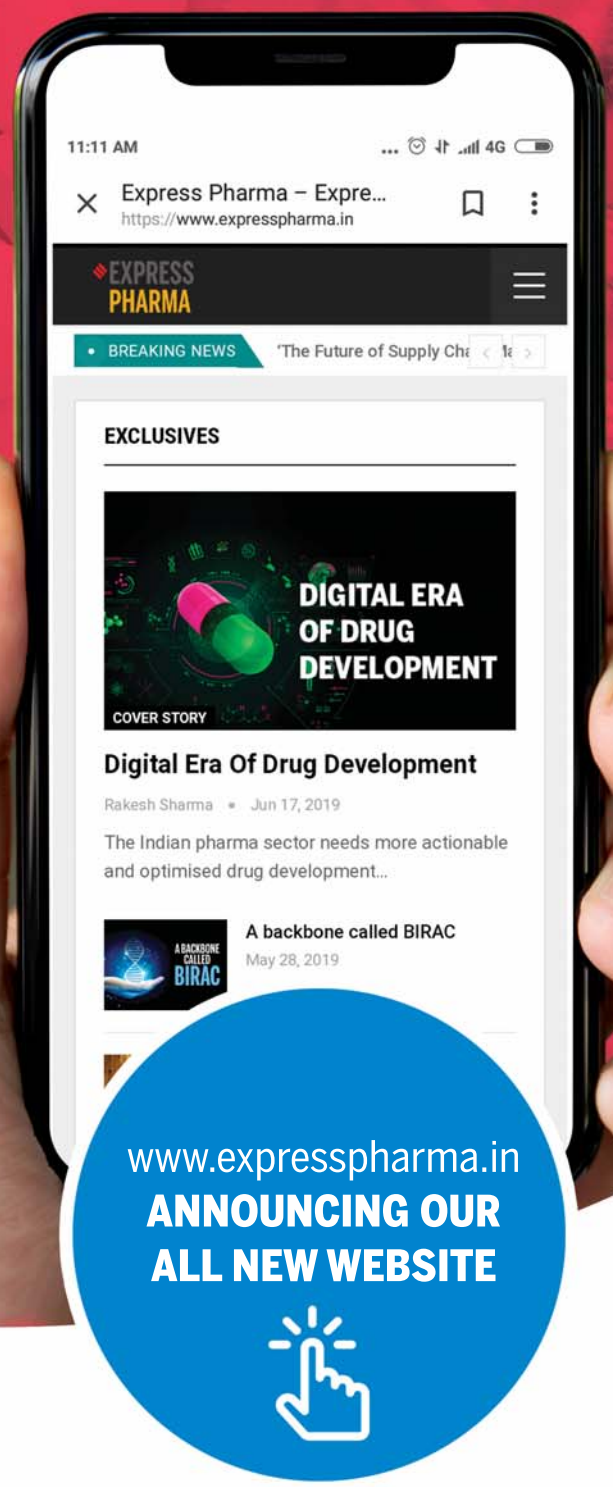

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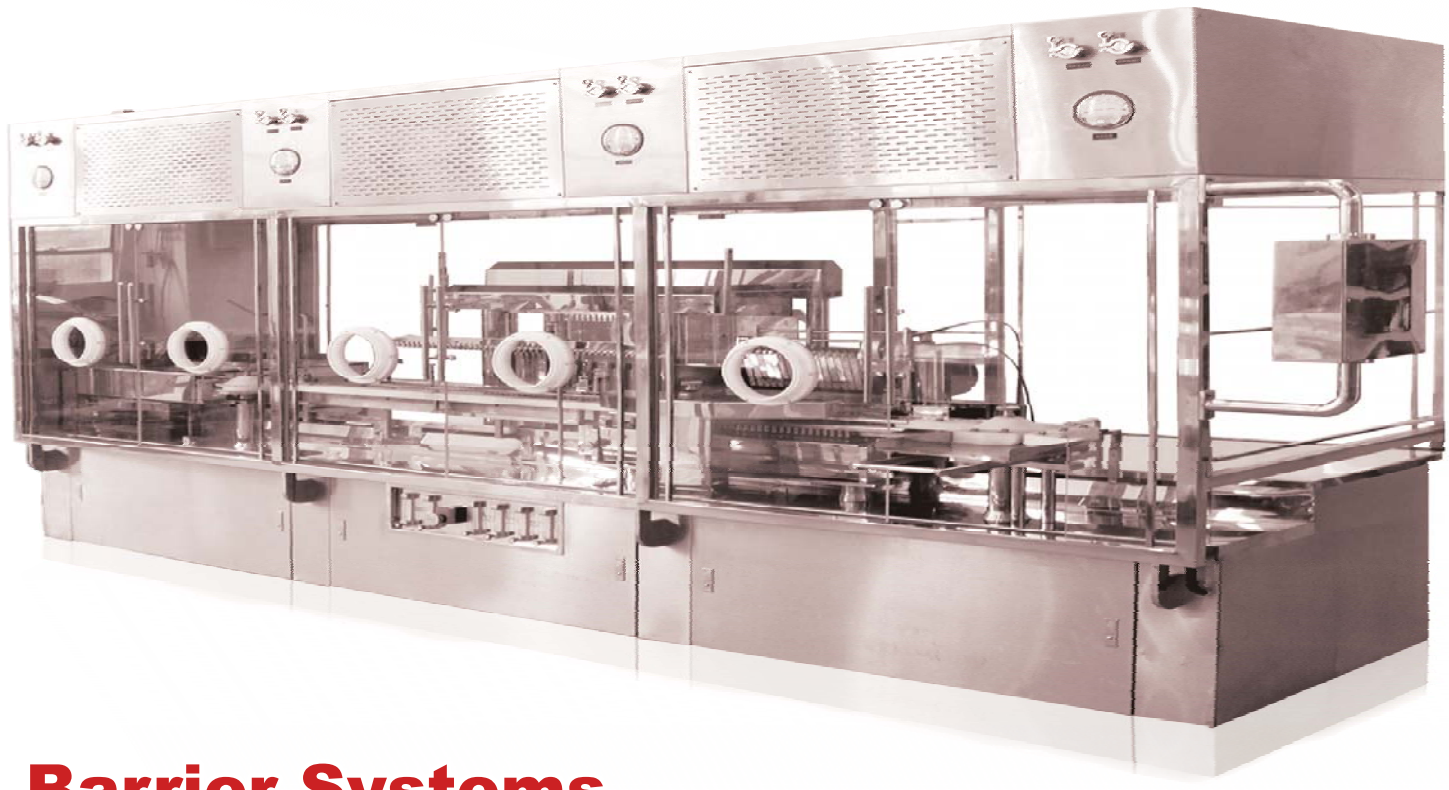

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Time for a policy push for pharma

The recent Union Budget was, once again, a huge disappointment for the pharma sector. With such a huge repeat mandate, this is the honeymoon year for the NDA-2, when they could have taken bold steps.

Yet, Finance Minister Nirmala Sitharaman chose the safe incremental way.

And though the pharma sector will benefit indirectly from the increased allocation to health schemes, there was no firm push or incentives.

The pharma sector has had several long standing demands, like the one for weighted deduction for R&D. But this and others were ignored once again.

Such a step would have decreased the burden of investments in R&D, especially when the return on investments (RoI) on R&D is taking longer than expected.

The stats prove that focus on pharma R&D is faltering. According to ICRA, aggregate R&D spends of top few domestic companies which had increased from 5.9 per cent of sales in FY2011 to close to 9 per cent in FY2017, moderated to 8.8 per cent during FY2018 and dropped further to 7.8 per cent in FY2019. ICRA expects R&D budgets to remain at 7.5 per cent-8 per cent. This optimisation of R&D, due to decreasing R&D profitability, will result in slimmer R&D portfolios over the next few years. This is not a good long-term trend.

Satish Reddy, Chairman, DRL, regrets that there was nothing in the Union Budget to fuel growth in the healthcare and pharma sectors, which is disappointing. He was particularly keen on seeing a change in the weighted deduction for R&D which did not happen. A positive policy move of this kind would have spurred R&D and innovation in pharma and other sectors according to him.

DRL has been one of the earliest among pharma companies in India to invest in R&D. But the longer than expected gestation period seems to be straining the company's resources. DRL has already started selling some brand assets to finance current research projects.

Delayed policies and faulty implementation have endangered the fundamentals of India Pharma Inc. For instance, the delayed implementation of the API policy, to incentivise Indian companies to manufacture key intermediates and APIs, has resulted in India's dependence on China. Around 67 per cent of India's bulk drug imports in FY19 were from China. And with little of no new investments in API facilities in India, the situation will only get worse.

Delayed implementation of the API policy has resulted in India's dependence on China

This dependence for APIs is proving costly on two fronts. We cannot control either input cost or more important, quality. While the first erodes our profit margins, the second is a grave reputational risk. The risk can be mitigated with regulatory compliance, but this adds to the capex and further erodes profit margins.

A report from India Ratings and Research (Fitch Group), believes that US-focussed Indian pharma players would be required to step up regulatory compliance in FY20-FY30 as they invest in a complex generics/specialised/innovative play. Input quality risk stemming from high dependence on Chinese players has been an emerging concern in 2018-2019, leading to product recalls initiated by major players. The Fitch agency believes that securing the supply chain is likely to emerge as top priority as several complex generics and innovative pipeline will hit the markets in the next decade.

We will soon be in a similar situation on the R&D front as well. More companies will reduce research budgets. Will policy makers arrest this slide before it is too late?

India has strong laws, but weak implementation. This has been the long standing criticism in India.

But what about protecting those who implement these laws? On June 21, Ravindra Mohan, a drug inspector in Bihar was assaulted while carrying out his duties.

This follows the tragic death of Neha Shoree, drugs inspector and zonal licensing authority in Punjab, on March 29 this year. She was shot dead, in her office no less, by a chemist whose license she had cancelled for selling habit forming drugs.

The All India Drug Control Officers' Confederation (AIDCOC) has been urging the states to provide security cover for its officers so that they are able to conduct their duties without fear of reprisal. More than 30 per cent of AIDCOC staff are women officers and this lends an particular urgency to the situation.

It is ironic that on one hand we talk of identifying and penalising counterfeiters. But on the other hand, we do not seem to appreciate the guardians of our medicines. How many Neha Shorees will it take for us to protect our protectors?

VIVEKA ROYCHOWDHURY *Editor*
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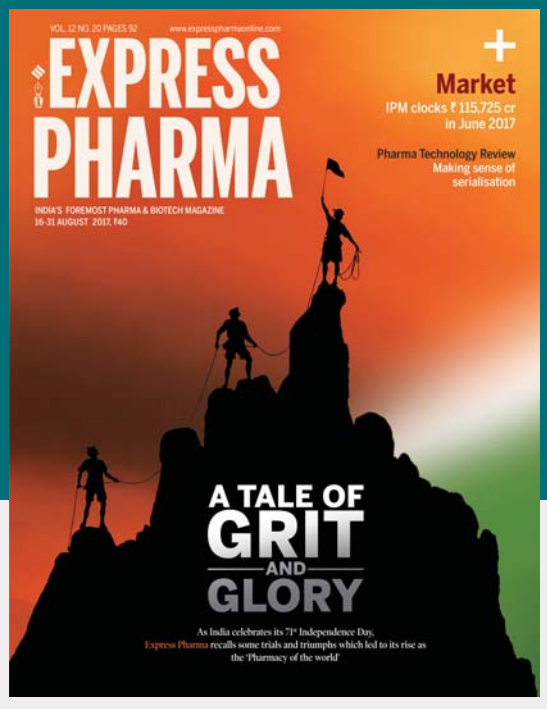
Express Pharma has been the backbone of this sector since 20 years. It is what the experts look to when the entire industry looks to them. That is because the magazine contains a potent mix of innovative ideas, cutting-edge analyses and expert insights. It's no wonder then that the finest in the field trust the foremost in the field.



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INTERVIEW

We must protect public health

On a recent visit to Mumbai, **Dr Ian Hudson**, CEO, Medicines and Healthcare products Regulatory Agency (MHRA) spoke with **Viveka Roychowdhury** on how the Agency is working with pharmaceutical companies to increase compliance with Good Manufacturing Practices (GMP) as well as preparing for Brexit and beyond

I think it is important that if any data integrity issues are raised, that the company fundamentally addresses what had gone wrong in their process to make sure it's addressed

We have seen quite a few lapses in pharma Good Manufacturing Practices (GMP) in terms of inspection outcomes. What are MHRA's insights on this issue, with respect to inspections conducted by the Agency's staff at pharma manufacturing sites in India? What is the progress made? What are the suggestions for the way forward?

We've been inspecting a number of manufacturing sites here in India. These include both manufacturing as well as clinical trial sites. From time to time, yes, there are problems with manufacturing sites here (in India), just as there are with other sites all over the world in other places that we inspect.

What is important is that we work with the company to address any findings there are, to make sure the company gets back in compliance as soon as possible, that the impact on any medicines is assessed as quickly as possible and appropriate action is taken. We always focus on a public health point of view, in terms of what are the impact of any findings on public health.

So yes, from time to time there are manufacturing issues, whether it's here in India, or in the UK, Europe or the US or where ever they (the sites) are. But most of the time, things are fine.

Are there any specific repeat observations that keep coming up, recurrent challenges that the MHRA observes? For instance, the US FDA has found recurrent data integrity issues and pharma companies in India are addressing those issues. What are the trends in observations from MHRA inspections?

I think it is important that if any data integrity issues are raised, that the company fundamentally addresses what had gone wrong in their process to make sure it's addressed. I do not want to talk about individual companies but it is absolutely critical that companies look at what has gone wrong and if there is an issue, to address it.

Clearly, India has a critical role in the production of (medicinal) products across the world. Something like 28 per cent of medicines in the UK market are made in India, either the active ingredient or the final product. It is absolutely important that wherever medicines are manufactured, they are manufactured appropriately standards, that there are no data integrity issues, and the data and results are reliable. Fortunately, the results are fine most of the time but on occasion there are issues. Then the challenge is (to find out) why, what when wrong, and making sure that the company addresses it at the highest level in the company and action is taken accordingly.

What are the other issues besides data integrity that come up when there is GMP non-compliance?

From time to time, issues do arise in the manufacturing process but that is the same where ever the manufacturing occurs. Manufacturing is a complicated business. Sites are fine most of the time but occasionally there are problems and things need to be addressed.

As I mentioned, we would take a risk-based approach to decide if there are risks to the public as a consequence of this, and the company must get into compliance but in the meanwhile, (we ask) do we need to take any action on the product or on the manufacturer to ensure that they get back into compliance.

And on the clinical research and trials sites?

Most clinical trial sites around the world are fine but issues do arise sometimes. Some are relatively minor and of little consequence. Occasionally, we find issues which are of more significance, in which case we need to work through what's going on. Is it simply a mistake or is it something more serious than that? At the end of the day, fundamentally, is the data reliable and are those subjects appropriately protected in the clinical research? That's what we aim for in our inspections.

Major violations on the manufacturing or clinical research side need be taken very seriously and addressed at the highest level of the companies. There cannot be a tolerance of anything else other than compliance with

the regulations. They must absolutely weed out any problems with data integrity, etc. That is a message I would like to send out loud and clear.

But what I would not like to say is that the rest of the world is fine and India isn't. That is not what I am saying at all. We can sometimes see problems wherever the trial is conducted or manufacture takes place, whether India or elsewhere.

It is particularly critical for India given that it is a source country for manufacturing for much of the world's pharma products as India is described as the pharmacy of the world.

How can companies prepare before interactions with the MHRA?

In a recent presentation in Mumbai, I described some of what's happening in the MHRA, in the supporting innovation, pharmacovigilance, and some ways companies could prepare before interactions with MHRA. My advice is that they should be transparent and upfront, and discuss problems with us rather than hiding them. We are going to find about about them sooner or later. We may have seen them before and can suggest ways to help out. We both have the same goal to provide safe medicines to patients.

What have been the changes in the MHRA to deal with Brexit and beyond?

A lot of the work at MHRA is independent of Brexit. We see that we have a clear responsibility to support innovation. We have all sorts of mechanisms to do that. Innovation has a very broad definition. It can mean new ways of manufacturing, new ways of doing things. We have an innovation office, who would be happy to talk to companies to advise them. We've got help lines and scientific advice provisions as well. Basically, we want to have an open door policy.

We want to see products developed safely for the benefit of public health. To ensure that at the end of the day, the public can derive the benefit from well-made medicines. We put a lot of effort into the innovation space.

We also have a pharmacovigilance programme, with the Yellow Card Scheme, which is the scheme for reporting adverse drug reactions or medical device alerts. In the yellow card system, we are looking at a number of things to increase reporting by promoting the scheme to healthcare professionals. We expanded the scheme to not only include adverse drug reations but medical device adverse incidents, defective medicines, potential counterfeit medicines,. All of these can be reported through the yellow card scheme.

We are also looking to get the yellow card integrated into the healthcare systems to ensure that healthcare professionals have easy access to it as well. We are also looking to see how we can evaluate signals from the yellow card scheme rapidly by using large data sets. For example, we've got the clinical practice research data link covering a large anonymised healthcare records data bank

of 35 million patients, so we can very quickly take a potential signalling issue through the yellow card scheme to then look to see if it is a genuine issue, if so at the size of the issue, so that we can very quickly refute or confirm the issue from the signal and do the linkage that way. We are also looking to see how we can collaborate with others in the outside world in terms of best use of this data from a safety point of view.

We've also developed a Yellow Card app, which can be downloaded from the Apple App Store or the Google Play Store. This is useful for healthcare professionals or anyone to report safety issues to us.

We also feed safety information down the Yellow Card app, so you can follow a particular drug to see if there were any safety alerts or what's been reported about it. This technology has been made available for others to potentially use. Other countries are potentially using that for their safety reporting. Companies can potentially use it, for example, for their sales rep to report to the database etc.

On the inspection side, we are looking at other models. For example, how far can we go in terms of desktop inspections for sites that have a good history of compliance, taking into account results from other regulators. This helps us prioritise our work by considering if we can do a desktop inspection to assure ourselves that things are fine. They will never fully replace site inspections but they might help us decide that we do not need to go this year to a particular site. We would ask the manufacturer for information on the site, whether there were issues, any out-of-specifications, etc. So if they've got a good track record of compliance, and there is nothing to report, then we may put our resources to another site where there has been more problems.

We are also looking to see how much we can rely on other regulators' inspections in our own decision making. For instance, we can consider if there is a need for us to go and inspect if other stringent regulators, for instance, like the US FDA or Health Canada or Australian Therapeutic Goods Administration (TGA) has been to a site. If the site was good, can we rely on this and factor it into our own decision making. We are moving in this direction.

> We work with the company to address any findings there are, to make sure the company gets back in compliance as soon as possible, that the impact on any medicines is assessed as quickly as possible and appropriate action is taken

Another thing that the inspectorate is looking at is having compliance teams to assist companies where there are problems to help get back into compliance as soon as possible, to be producing compliant products as soon as possible.

We are also looking at what we can do to be fully prepared for new approaches in the future. Whether it's bedside manufacture or the use of artificial intelligence in manufacturing, we're making sure we're gearing up for that side of things. We also work very closely with inspectorates around the world.

The UK government also supports innovation in the life sciences sector, including the generics part of the sector. This is an important priority for the UK government. We have things like the accelerated access review, which looks at not just how products are brought to patients, not just the regulatory piece but also the HTA, etc.

The responsibilities of the MHRA are actually quite broad. We have the regulatory centre within the agency, which is responsible for medicines, medical devices, blood components, herbals, homeopathic medicines. We have an enforcement as well policy function. British Pharmacopoeia is part of the agency as well.

But we have two other centres within the agency. One is the the Clinical Practice Research Datalink (CPRD), with anonymised healthcare records with over 35 million patient lives in the database for research purposes.

This is a fantastic tool for observational-type research like on safety of statins in the market place, safety of pertussis vaccine in pregnancy, refuting the link between MMR and autism, etc. These studies can be done on a large size population database. We are also using this database to see how this can support clinical trials going forward. The MHRA approves in the order of 1000 clinical trials a year. 25 per cent of all European clinical trials are done in the UK or involve the UK. We've got a very progressive environment for clinical trials in the UK, with a lot of investments in the clinical research networks. We are very keen to support new ways of doing clinical trials like adaptive trials, etc. We are very supportive of these new ways.

In addition, we are looking at using the electronic health records (EHRS) through CPRD to support clinical trials, so you can screen for the inclusion and exclusion criteria of a clinical trial to see if it is viable or not. We can come up with a list of patient records and doctors can approach these patients who might be eligible for a particular trial, to ask them if they'd like to participate in the trial or not or when a patient visits a doctor, a message flashes on the doctor's screen that this patient is eligible for this trial, do you want to enroll them or consent them? The EHR can then be used to randomise patients as well as follow patients.

The third centre is the agency is the National Institute for Biological Standards and Control (NIBSC). Here, we produce biological standards, these are physical standards in a vial. We produce 90 per cent of the world's biological standards.

October 30 is a milestone for the Brexit process. What is the MHRA doing to assure pharma companies and investors that the UK is open for business given the Brexit context, in both scenarios of a 'soft' and 'hard/no deal' Brexit?

UK will remain a member of the EU until the end of October, unless an implementation period is ratified through Parliament earlier. If it is agreed, then we enter the implementation period, where we will be subjected to the same regulation. We will be doing the same in terms of regulation of medicines and medical devices at least until October. After October, we are either in the implementation period or we are a standalone regulator, so the agency is currently planning for both, either an implementation period or we would leave (the EU) without a deal.

Over the longer term, the UK government's preferred position is to negotiate continued participation in the European medicines and medical devices systems. We would still be working with the medicines and medical devices network across Europe. But that requires negotiation and it may or may not come to be. We then prepared extensively, for the end of March and now it carries over to the end of October, for the possibility of no deal, wanting an implementation period and wanting a future relationship with Europe. We've issued extensive guidance to industry to help them prepare for a no deal Brexit. We've prepared draft legislation, as well as extensive guidance to let companies know what they would need to do. If we ended up in a no-deal situation as a standalone regulator, we also looked as some additional options like rolling reviews, accelerated assessment of new applications or targetted review based on existing European review, etc.

Our approach in all of this has been to be as pragmatic and helpful as possible, to be as open and supportive to industry as possible. But commensurate with our role of protecting public health. We must make sure, first and foremost, that we do that. We did not want to introduce any unnecessary burdens. For example, we said we'd take the same dossiers as the European authority; we would not ask for anything more. The feedback has generally been that companies have appreciated our open, flexible and helpful approach.

We see we have an important role to play internationally. We are very keen to help and support and collaborate with other regulators internationally and that is not going to change post-Brexit. We will still interact with our counterparts in Delhi and in other places across the world as well as through the International Coalition of Medicines Regulatory Authorities, which we currently chair. We are also doing work to help to support developing regulators. We will still be part of the international regulatory community wanting to help because its for the benefit of public health for all.

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INTERVIEW

Netmed.com's expansion will ensure faster delivery and efficient order management

Less than five-year-old, e-pharmacy Netmed.co has already established its presence in almost every household and is continuously striving to grow bigger. The company is looking forward to operating within a conducive legal framework and having an organic as well an inorganic growth. **Pradeep Dadha**, Founder and CEO, Netmeds.com talks about the company's business strategies and expansion plans with **Usha Sharma**

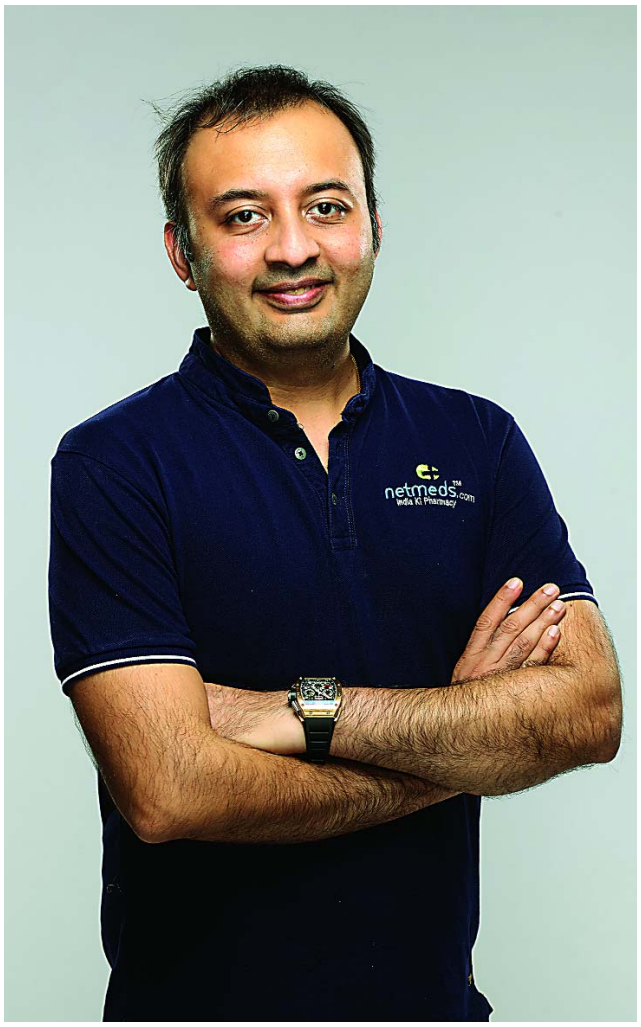
Netmed.com has planned to open 26 Fulfillment Centres (FCs) across Indian metros and tier II cities by the year 2020. Where will those warehouses be?

We plan to set up 26 Fulfillment Centres (FCs) across metros and tier II cities by the year 2020 in an effort to reach rural as well as urban areas and facilitate quick and efficient last-mile delivery of medicines. Currently, Netmeds has 14 Fulfilment Centres across the country spanning over 3 lakh sq. ft, with three centres in Chennai and the rest in Bengaluru, Hyderabad, Delhi, Mumbai, Kolkata, Ahmedabad, Pune, Noida, Lucknow, Raipur and Guwahati. The largest FCs are currently situated in Hyderabad and Kolkata — both spanning 25,000 sq ft. Each of these cities process over 100,000 orders every month. We recently established new master warehousing facilities in Delhi NCR and Mumbai followed by four more support centres in tier II cities namely, Indore, Jaipur, Patna and Chandigarh. Netmed will set up six more FCs in tier II cities after assessment of demand in different zones. These FCs will span over 2 lac sq ft. covering top metros and tier II cities of the country.

How will the company's new warehouses scale-up the delivery process efficiently? And how is it different from your other competitors?
The new facilities will improve the customer experience by enabling faster delivery, higher fill rates and improve the overall efficiency of logistics and supply chain management at Netmeds.com. These state-of-the-art facilities will ensure speedy order processing and efficient inventory management. The newest addition to our warehousing and operations facility will not only ensure faster delivery and efficient order management but also make medicines accessible to previously non-serviceable parts of the country.

What is the market size of Netmed.com in India and post the setup of the 26 FCs how much do you expect it to increase?
Our growth will be market-driven. Our healthcare niche is still nascent, to the extent that the industry as a whole is yet to scratch even a single percentage point of the overall retail pharmacy spend. According to Frost & Sullivan, the e-pharmacy market in India is estimated to grow at a CAGR of 63 per cent by 2022. As the industry settles into a comfortable position, new regulations are put in place and the public continues to embrace the concept, we expect exponential growth in the sector. Netmeds serves about 3.7 million customers, as a result of 20 per cent month-on-month growth, doing about 10,000 orders a day and shipping them to more than 600 cities, including metros, as well as tier II, III and IV towns and rural villages.

The latter half of the last year has seen some tough times for online pharmacies. Though the sector is yet to get framed guidelines, how do you see the future of online pharmacies?



> Our goal is to make medicines affordable and accessible to every Indian and to reach even the most outlying corners of the country

We support the government's initiative towards providing quality healthcare and affordable medicines to the masses. And we believe that the draft on e-pharmacies will further bring clarity on the legal as well as the social responsibilities that entail the e-pharma industry. As directed by the Delhi High Court, the Centre has released a draft for further consultation and due diligence. We believe that the government will enforce regulations on the conduct of e-pharmacies after careful consideration. As a fully licensed pharmacy, Netmeds.com is committed to adhering to all the guidelines and standards as prescribed under the Drugs and Cosmetic Act, Personal Data Protection Bill as well the Pharmacy Act.

Regulations for online pharmacies are likely to be among the Modi government's priorities in the first 100 days of its second term in office. We look forward to operating within a conducive legal framework that would give a much-needed push to the e-pharma and related health-tech businesses. According to an EY report, the e-pharma industry is expected to reach a combined market size of $2.7 billion by 2023. Market sentiments, overall improvement in the legal and the regulatory environment and enthusiastic adoption of e-pharma and other health-tech companies by consumers in itself is an indicator of the growth in this sector.

In the recent past, online pharmacies have chosen to grow inorganically. How will this trend shape the industry? And what are the challenges and the opportunities associated with it?
Inorganic growth avenues such as acquisitions/mergers are merely a way to strengthen the product suite and offerings at Netmeds.com. Netmeds.com acquired online video consultation app JustDoc in September 2018 venturing into healthcare services, diagnostics and consultation. In March 2019, Netmeds also acquired health tech start-up KiViHealth, a clinic management platform providing cloud-based, Artificial Intelligence (AI) powered tools for effective doctor-patient interaction. With these acquisitions, Netmeds.com continues the transformation into a complete healthcare product and service company.

How is Netmed.com impacting the patients' lives?
Netmeds.com has become the online pharmacy market leader, by realising the need for intelligent, far-reaching and quick healthcare solutions in urban and rural areas. Our goal is to make medicines affordable and accessible to every Indian and to reach even the most outlying corners of the country. Setting up FC in tier II cities helps us achieve that objective. Through these centres, medicines are readily available, allowing us to process and deliver orders quickly and efficiently, thereby reducing the overall turnaround time even in the most under-served areas. The newer and bigger warehouses will give us more control and scalability. This is an important step towards Netmeds' goal of becoming a pan India patient-centric, complete healthcare product and services company.

What are the company's strategies for the domestic market and are there any plans to expand its footprint in the global market?
Netmeds will focus on the domestic market for now. Our plans include what one might describe as a sort of a contrarian approach. Although we are fully aware of and on board with tech advances and their importance in the healthcare scenario, we are moving to expand our 'non-tech' presence by opening physical 'brick-and-mortar' with franchisees. We think the local, traditional walk-in pharmacy can continue to play an important role in the local neighbourhoods, and even these 'good old-fashioned' stores can be completely up-to-date, aided by new tech inventory management and even may offer online video consultations.

Likewise, with the rising trend toward implementation of AI, we are taking great care to be sure that our customer service and patient outreach touchpoints continue to maintain the empathetic quality necessary to provide holistically effective healthcare. The future plans of the company include creating partnerships with other pharma/nutritional companies and using data analytics to enable the targeting of specific patient groups.

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INTERVIEW

‘Our goal is to attain leadership in Indian veterinary vaccine segment’

Veterinary vaccine manufacturer Biovet plans to invest Rs 200 crore for further expansion and aims to capture 50 per cent market share in the next two years. **Dr Panduranga Rao Pavuluri**, Vice President-Production, Biovet, talks about the company’s strategy to acheive this goal and its areas of focus in an exclusive interaction with **Usha Sharma**

Tell us about the initiatives that Biovet has taken up. What is the objective behind making an investment of Rs 200 crores for building a new facility?
Biovet is a technology-driven company with several new products in the pipeline. Presently, we are producing veterinary vaccines. Recently, we have made an announcement of Rs 200 crores for expanding our Foot & Mouth, Brucellosis Vaccine manufacturing facilities in Malur. Out of the total, Rs 150 crore is for the construction of two production lines for foot and mouth disease vaccine. And Rs 50 crores will be invested in the construction of Brucella vaccine manufacturing facility. With the currently available line, there will be three lines dedicated to three different strains of foot-and-mouth disease (FMD) vaccine.

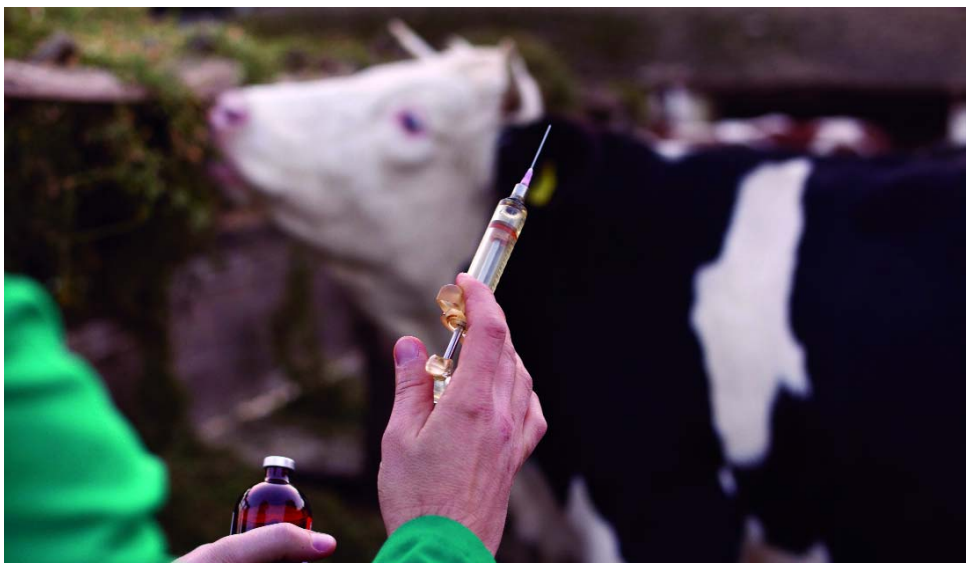
How are you arranging for the funds?
We are arranging the required funds from internal accruals and the partial amount will be borrowed. The Fermentation technology for Brucella vaccine is developed in house, which will enable us to produce the vaccine in large scale. The technology is designed for high dense cell cultures for better production of viral vaccines.

Which vaccines will be manufactured in the new facility and by when the commercial production will begin?
From the new facility, we will be manufacturing the Brucella vaccine and veterinary vaccines for FMD. Brucella vaccine will be ready for a commercial license in the next three months. The facility is already ready and undergoing the validation process. The

commercial production of the foot and mouth disease vaccine from the new facility will begin by April 2020. Under its research and development initiative, the company is developing vaccines for Infectious Bovine Rhinotracheitis (IBR) and Classical Swine fever vaccine. And to improve the production processes, it has also initiated high dense cell cultures for bacterial and mammalian cells and Vaccine- based platform for recombinant DNA technology to develop new generation vaccines.

Why is the company focussing on developing veterinary vaccines? Are there any encouragements or initiatives made by the state or central government? Tell us more about that!
For the next five years, our emphasis is on foot and mouth disease and Brucella control. We are happy that the Central government has already taken initiatives to control animal diseases. And under this initiative, Government of India is providing 100 per cent assistance for procurement of vaccine and vaccination. Our focus is on developing veterinary vaccines.

The FMD virus is similar to Polio virus and Bharat Biotech has been playing an instrumental role in polio eradication in India. How severe is the FMD problem in India and will it hit the country's economy?
FMD and polio viruses belong to the same family but they are not similar. Let us not mingle each other. FMD vaccine is highly contagious and in unvaccinated animals, it may affect virtually 100 per cent. It causes disease in cattle-buffaloes, sheep, goat, pigs- and wild animals. The total estimated losses due to FMD in India are estimated at about Rs 25000 crores per year. Vaccination is the only control approach available. The disease has a devastating effect on the rural economy.



What are your plans to work closely with the government and how you initiate it?
We diligently work with central and state governments, animal husbandry departments and acquire vaccine strains from them. Biovet supports seminars, workshops and training camps to help veterinarians and farmers to understand the importance of vaccination.

Besides India, which other markets have FMD vaccines requirements and will you be tapping those markets as well? And how are you planning to execute them?
There is demand in the Middle East, Central Asia, South Asia and South East Asia. We are in the process of engaging with the respective nation's regulatory authorities and registering with several countries. At present, we are exporting to Iran and Bangladesh.

Why is vaccination better for big production animals than feed additives?
Vaccination is a preventive measure taken to make the animal resistant to infectious diseases. Well-fed animals are also susceptible to diseases if not vaccinated. Whatever the feeding status, vaccination is essential in animals.

How will vaccination for veterinary segment reduce antibiotic abuse?
Antibiotics are used to control bacterial diseases. However, antibiotics are also used indiscriminately in animals during viral infections. During the outbreaks of foot and mouth disease, huge quantities of antibiotics are being used to prevent animals from contacting other diseases. Vaccination does help reduce this type of antibiotic usage.

Bio-waste is a big issue in the industry, how are you handling environmental safety issues?
Unlike the pharma industry, vaccine manufacturing is considered to be a green industry. All the wastewater is treated in our ETP plant and used for gardening and fodder development. We are not releasing any effluents. A small amount of (1-2 kg per day) biomedical waste which is produced is through Polychlorinated Biphenyl (PCB) approved service providers. Around 95 per cent of our biomedical waste is biodegradable. We deject the use of plastics or other one time use consumables. Most of our filters are cellulose-based which is biodegradable.

What percentage of the market share has been captured by Biovest in India and what are your plans to further increase it?
Presently, we have a 25 per cent share in the large animal vaccine segment; we are targeting to touch 50 per cent in the next two years. We continue to invest in the latest technologies to improve the production and we are collaborating with national and international institutions for the development of new products.

Do you think that other pharma companies will also join this space?
The veterinary vaccine industry is a high volume and low-profit industry, and due to this, we do not expect many pharma players venturing into this market.

In India, whom do you consider as competitors?
Our motto is 'the diseases are our competitors and we need to defeat them.' Further, all three companies in the field i.e, Biovet, Indian immunological, Hyderabad and Brilliant Biopharma Hyderabad are unable to meet the demand in India. We are investing to create new facilities to meet this demand. Once we meet the domestic demands, we will increase our focus on export markets.

Tell us about the company future plans.
Our goal is to attain leadership in Indian veterinary vaccine segment and to expand our global footprints. We are continuously investing in introducing new technologies like high dense cultures perfusion systems to increase production. Biovet is introducing these technologies first time in the veterinary vaccine field.

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UPCOMING EVENTS

INDIAN PHARMACOVIGILANCE DAY 2019

Date: July 26, 2019
Venue: Mumbai
Summary: The Indian Pharmacovigilance Day 2019 conference will see expert speakers from the industry, health authorities, research bodies, academia and healthcare delivery centres, share their perspectives on the multi-faceted outlook of the discipline of pharmacovigilance in India and deliberate on the challenges they expect to face in 2019. Dr J Vijay Venkatraman, Managing Director and CEO, Oviya MedSafe, will give the welcome address.

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ACE HYDERABAD 2019

Date: August 7, 2019
Venue: Hotel Millennium Grand, Hyderabad
Summary: Gangwal Chemicals will organise ACE Hyderabad 2019, a technical seminar to discuss opportunities in product-specific requirements, upcoming trends and requirements of the pharma industry. The event will witness participation from different departments like R&D head, purchase and decision makers, and will also allow them to interact with their industrial peers. The company launched ACE platform in Ahmedabad with an objective to create a forum for its prospective and existing clientele. It is an endeavour to strengthen the relationship with customers based in South Zone – Hyderabad.

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Curtain raiser of 71st IPC concludes in Chennai

AIDCOC is hosting the congress, institutes Dr Neha Shoree award for Best women Drugs Control Officer at national level

Usha Sharma

The President of 71st Indian Pharmaceutical Congress (IPC), Ravi Uday Bhaskar released the brochure of 71st IPC at a recently held ceremony in Chennai. The theme for this year's Congress is 'Healthcare System-Responsibilities of Regulators and Pharma Industry,' which will be held at Sri Ramachandra Institute of Higher Education and Research, Chennai from December 20-22, 2019.

Dhilip Kumar M, Secretary-Local Organising Committee (LOC), 71st IPC, welcomed the delegates and Dr Jayanta Choudhury, President, AIDCOC felicitated Ravi Uday Bhaskar, President, IPCA. Besides felicitating the Chairman of the LOC, Dr Vijayaraghavan, he also extended his gratitude to other key dignitaries with floral greetings.

This year, the All India Drugs Control Officers' Confederation (AIDCOC) is hosting the Congress.

The day also witnessed second Indian Pharmaceutical Congress Association's (IPCA) meeting of 71st Indian Pharmaceutical Congress (IPC). Members of LOC, along with the Indian Pharmaceutical Congress Association (IPCA), congregated to discuss the functional strategies of the 71st IPC.

Procedures of the meeting began with a welcome address by Dr TV Narayana, General Secretary, IPCA, who thanked all the participants of the meeting. In his address, he updated the attendees about the first IPCA meeting, which was held in Mumbai at Sun Pharma House.

Narayana also informed that Ravi Uday Bhaskar, Director General, Pharmexcil and Secretary General, AIDCOC has been elected as a President of IPCA 2019, and he has taken over from Dilip Shanghvi, MD, Sun Pharma.

Addressing the meeting, Bhaskar expressed his concerns over the format of existing IPC. His talk deliberated on various topics associated with the monotonous format of IPC. Recalling the IPC legacy before the local and international trade exhibitions ventured into the Indian market, he mentioned that earlier IPC had maintained the merits and its respect in the industry, academia and all other areas of pharmacy were well appreciated. He also pointed out IPC's contribution for the development of the pharmacy profession in India. Commenting on the present scenario, he mentioned that the focus is on generating more number of participants than the value offered.

Members of LOC, along with the Indian Pharmaceutical Congress Association (IPCA), congregated to discuss the functional strategies of the 71st IPC

Further, he stressed on the need to change the format of the existing congress and also expressed his opinion that if it is required, the council should not continue with exhibition model, as it is a burden to IPC rather than value addition. He requested all the members to introspect and suggest value addition to the congress.

In his summing up, he also suggested that the council should consider taking external expert's assistance who will help them in brainstorming sessions and support the council in designing the new model of conduct of IPC.

During the brainstorming session, participants unanimously agreed to have an external experts intervention and few members also suggested not to have IPC every year. The discussion also emphasised on keeping the student community in consideration while initiating a change in the existing IPC model. Experts, who were part of the meeting, also suggested that committee members can also present white papers of their focussed research areas.

The meeting witnessed members' concerns over resolutions which were made during the past IPCs and implications on its implementations. To this, the council members also stressed 'to a point that the responsible committee should have a mechanism or form a sub-committee to discuss about the progress of resolutions with the respective government bodies.

In the course of meeting, the council decided to have memorial lectures in the name of Diptish Chakravorty who was the Secretary of IPCA for more than three decades and Dr BD Miglani, who was the Founder Secretary of Indian Hospital Pharmacists' Association (IHPA)

In the remembrance of women drug inspector, Dr Neha Shoree who was shot dead at the Drug and Chemical Testing Laboratory, Kharar near Chandigarh in April this year, the Council in principle agreed to instituted an award which will be honoured to women regulators.

Lastly, Dr Arun Garg, Joint Secretary, IPCA presented the vote of thanks.

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Lifesciences industry posts 49 deals worth $107.4 bn in June 2019

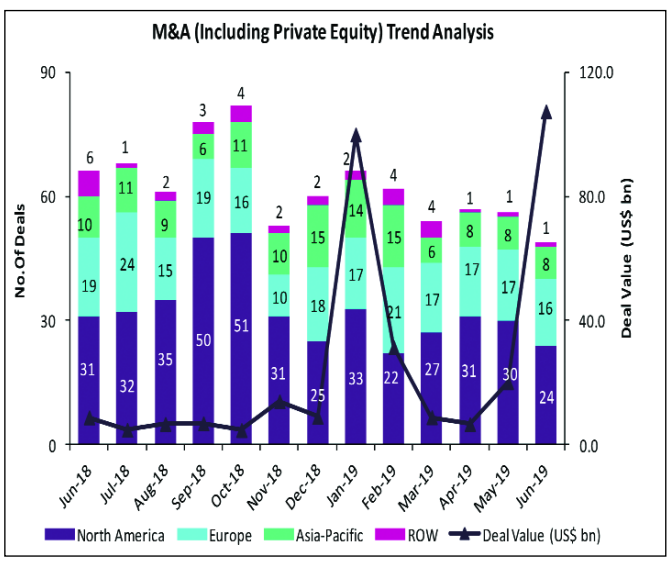
The healthcare industry reported 77 VC deals worth $1.2 billion in June 2019

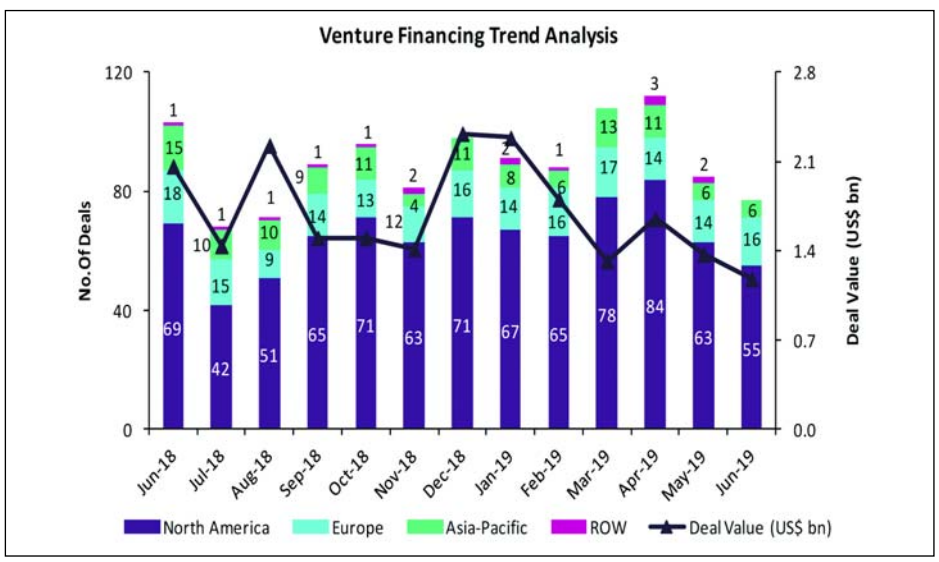
In June 2019, the healthcare industry reported 49 deals worth $107.4 billion as compared to the last 12-month average (June 2018 to May 2019) of 64 deals worth $18.5 billion, according to GlobalData. AbbVie's proposed acquisition of Allergan, a pharmaceutical company for $85.7 billion has contributed 80 per cent to the total deal value in June 2019. This acquisition enables AbbVie to expand and diversify its revenue base with new therapeutic areas. Pfizer acquiring Array BioPharma for $11.4 billion; Dassault Systemès' proposed acquisition of Medidata Solutions for $5.8 billion, and Vertex Pharma acquiring Exonics Therapeutics for $1 billion are other notable deals announced in June 2019.

The healthcare industry reported 77 venture capital (VC) deals worth $1.2 billion in June 2019, compared to the last 12-month average (June 2018 to May 2019) of 91 deals worth $1.7 billion. Encoded Therapeutics Inc. raising US$104 million in Series C financing round; Oncologie raising $80 million in Series B financing round; ADC Therapeutics raising $76 million in extended Series E financing round; and BlackThorn Therapeutics raising $76 million in Series B financing round are some of the major VC deals reported in June 2019.

Deal Date	Acquirer (s)	Target	Deal Value (US$ m)
25-Jun-19	AbbVie Inc (US)	Allergan Plc (Ireland)	85,737.4
14-Jun-19	Pfizer Inc (US)	Array BioPharma Inc (US)	11,400.0
12-Jun-19	Dassault Systemès (France)	Medidata Solutions Inc. (US)	5,800.0
6-Jun-19	Vertex Pharmaceuticals Inc (US)	Exonics Therapeutics Inc. (US)	1,000.0
4-Jun-19	Cordlife Group Ltd (Singapore)	Global Cord Blood Corporation (Hong Kong)	912.0

Deal Date	Acquirer (s)	Target	Deal Value (US$ m)
26-Jun-19	Matrix Capital Management Company, LLC; Altitude Life Science Ventures; Alexandria Venture Investments; ARCH Venture Partners LP; RTW Investments LP; Menlo Ventures; Venrock Inc; Boxer Capital LLC; Illumina Ventures	Encoded Therapeutics Inc (US)	104.0
10-Jun-19	Korea Investment Partners Co Ltd; Pivotal bioVenture Partners LLC; Nan Fung Life Sciences; Panacea Venture Healthcare Fund I, L.P; Undisclosed Investor(s)	Oncologie Inc (US)	80.0
12-Jun-19	Undisclosed Investor(s)	ADC Therapeutics SA (Switzerland)	76.0
13-Jun-19	Altitude Life Science Ventures; Johnson & Johnson Innovation – JJDC Inc; Mercury Fund; Alexandria Venture Investments; The Scripps Research Institute; Polaris Partners LLC; ARCH Venture Partners LP; Vertex Ventures HC; Biomatics Capital Partners LP; GV Management Co LLC; Premier Partners LLC	Blackthorn Therapeutics Inc (US)	76.0
17-Jun-19	Temasek Holdings (Private) Ltd; Viking Global Investors LP; Cormorant Asset Management LLC; HBM Healthcare Investments AG; Goldman Sachs & Co LLC; Barer & Son Capital; Terra Magnum Capital Partners	Viela Bio (US)	75.0





PHARMA PACKAGING

AN EVOLVING SPHERE

Pharma companies are looking at newer methods and approaches to minimise packaging costs while addressing important goals like enhancing patient compliance

By Usha Sharma

The Indian pharma market is expected to grow at a Compound Annual Growth Rate (CAGR) of 18 per cent by 2020, driven by an ageing and growing population, rising income levels, emerging medical conditions and new diseases, etc., as per Market Research Report. And, as packaging plays a crucial role in this industry and is a connector between the industry and the end consumer, it will have a bigger role to play in times to come. Global pharma packaging market is expected to reach $104,882 million by 2022 from $68,749 million in 2015, growing at a CAGR of 6.27 per cent from 2016 to 2022, according to the report.

So, what are the major disruptors in this arena and what are their impact? Let's examine

Growing therapeutic areas

Well, as per the information available in the public domain, oncology, central nervous system (CNS) disorders and infectious diseases are the top three therapeutic areas. According to GBI research, almost 7,000 new cancer products are in the pipeline, nearly double the respective totals of CNS and infectious disease products currently lined up.

Chandiprasad Ravipati, Head-Packaging, Aurobindo Pharma shares, "Highest number of anti-cancer drugs are in pipeline across the developed countries almost twice in recent years, both in innovator (branded) and in the generic sector, accounting about 30 per cent of total R&D on new molecules. Highest R&D expenditure is on this segment with assurance of high returns."

Santanu Chowdhury, Sr GM-Packaging Development, Sun Pharmaceutical Industries too opines similar. He says, "Pharma companies are focussing on oncology and biosimilar products, probably they consider that these areas deserve focus owing to its formulation complexity and potent characteristics. Thus, we are also seeing a lot of progress in the packaging of the drugs in this segment."

Similarly, many experts believe that biologics also get high R&D focus.

As Shivaji Chakraborty, Asst GM, Packaging Development, Fresenius Kabi Oncology remarks, "Biologics are undoubtedly the future of medicine. These complex medicines cannot be mass produced as they are not chemically synthesised. Biologic medicines can only be produced in small batches. As biologics differ so much in structure, we won't see mass production of generic biological packaging, instead tailored products will be the priority."

However, biologics are temperature sensitive and vulnerable to contamination, thereby making packaging design more difficult. Materials like glass, plastics and rubber aren't suitable, due to the ability of metals to be extracted, which could degrade the biologic protein structure. Hence, there is a lot of packaging innovation in this arena to protect the effectiveness of biologics.

Changing regulatory norms

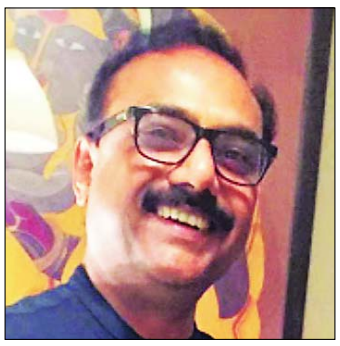
Another aspect that impacts packaging in pharma market is the changing regulatory requirements across the globe. In the last five years, global regulators have tightened their grip on the industry and taken stringent measures to address issues of drug access and quality.

To cite an example from India, Tripti Nakhare, Sr General Manager, Regulatory Affairs & PDD, FDC, reminds us of a statement from Prime Minister Narendra Modi asking doctors to prescribe medicines using their generic or chemical names and not the brand name, which caused a flutter in the industry.

Likewise, across the globe, regulatory reforms are in fast forward mode and India has to

The government can help packaging industry by reducing import costs and taxes on raw materials such as glass, plastics, paper and board

ChandiPrasad Ravipati
Head-Packaging,
Aurobindo Pharma



Government should be cognizant of the effort, resources and investment that requires to be compliant to global quality norms besides promoting innovation for the overall benefit of healthcare system

Santanu Chowdhury
Sr GM-Packaging Development,
Sun Pharmaceutical Industries

If the government wishes to implement the track and trace, some monetary help should be extended to SMEs as implementation of these projects runs in crores of rupees

Tripti Nakhare
Sr General Manager,
Regulatory Affairs & PDD,
FDC

For the printed packaging material, regulatory changes is a curse and once the changes are done, it should continue for four to five years thereby reducing the burden of frequent changes in artwork

Ajay Bapat
Packaging Head,
Emcure Pharmaceuticals

We won't see mass production of generic biological packaging, instead tailored products will be the priority

Shivaji Chakraborty
Asst General Manager,
Packaging Development,
Fresenius Kabi Oncology

catch up with the latest regulatory requirements such as Drug Supply Chain Security Act (DSCSA) for the US market and Serialisation and Tamper-Evidence requirements of EU-FMD. As the US and EU markets are very relevant to India Pharma Inc, these two regulations will have significant impact. But, being compliant with these norms would create a considerable cost-burden on the players.

As Ravipati points out, "These two are major projects for the entire pharma industry depending on these markets. The investment for serialisation and aggregation, serialisation and tamper-evident feature on packing lines and packaging materials is significant to the tune of Rs 5 to 10 crore based on the number of packing lines."

He also informs, "Tamper-evident labels have to be affixed on both the sides of cartons for the European market and this is an additional cost. Font size regulation for labelling of Health Canada resulted in switching over multi-layer labels from conventional single-layer pressure-sensitive labels. This is an added cost by 2 to 2.5 times."

Highlighting the impact of regulatory changes on pharma companies' balance-sheet, Nakhare acknowledges, "In 2018, the following GSRs were released that led to changing all the packaging materials of all pharma companies. Fortunately, sufficient timeline was given to consume the existing stocks for most companies with conservative inventories. GSR 222 (Brand name/generic name proportion), GSR 408 (Schedule G, H, H1 to be placed in a red box), GSR 277 (some steroids included in Schedule H drug). However, the proofing, plate/cylinder costs and implementing the change levied heavy costs on the pharma companies. Inspite of all efforts, some write-off are bound to happen and when the entire domestic market is considered, the write-off also were in crores of rupees."

Ajay Bapat, Packaging Head, Emcure Pharmaceuticals, expresses, "For the printed packaging material, regulatory changes is a curse. Every now and then, there are new requirements and the whole set of artwork, printed components need to be revised. Look at the recent requirements of Track and Trace, regulations for Schedule H warnings, removal of red line for prescription was the focus area when it comes to artwork changes. The printed packing material, affecting the environment and balance sheet, has to be thrown out (of course after trying to consume the maximum)."

However, he also believes, "All the changes are to be done together. Whatever time is required to study the process, it can be taken initially, but once the changes are done, it should continue for four to five years thereby reducing the burden of frequent changes in artwork, PM and internal QMS documents like BOM, batch records, etc. Every change is a cost to the organisation and has to be reduced."

This is possible only if the pharma packaging industry becomes more innovative, flexible and affordable. Thus, regulatory challenges are a major factor driving change in the pharma packaging industry.

Improving patient adherence

Patient adherence is another challenge due to fast pace of life and patients being unaware of the consequences of non-adherence. And, packaging, if used effectively, is a great solution to tackle this problem.

As Chaudhury says, "Patient adherence to dosage regime, as prescribed by physician, is probably the single most important factor to intended cure other than various other aspects such as the nature of disease and specificity of individual state of health. Lack of awareness, indiscipline approach, forgetfulness, old-age syndrome are the biggest contributors to non-adherence in India. Certainly, packaging can play a big role through development of simple packaging, say calendared, pack or bringing out cost-efficient smart packaging."

Ravipati also explains, "With very low per capita purchase of medicines in India and less affordability, patient adherence is a big challenge. In fact, lack of patient adherence in rural areas is very disturbing. While there will be improvement in these rates as a result of growing healthcare insurance by state and central governments in the last few years, packaging of selective therapeutics can be designed as per the prescribed dose and made affordable."

Nakhare further informs, "We all know that the smart and intelligent packaging is fast catching up in India. And why is it happening? With the thrust of Indian FDA on boosting the generic sale, setting up Jan Aushadhi stores, etc., pharma companies have to innovate to convince the doctors and patients and hence they have to come up with solutions to improve the appeal of the packs by offering some additional benefits. Moreover, with the fast pace of life in metros, most people are not able to adhere to the dosage regime and hence companies are providing packs or associated technologies that reminds the patient to take their medicines on time and the dos and don'ts if they miss any doses."

For instance, use of QR codes to give out product information as a sizeable population uses smart phones in India. Elaborating on this point, Nakhare suggests, "The rural population has to be educated about completing doses of antibiotics, going for follow up to doctors. Providing ways to communicate with the rural population vide smart packaging and communicating in their regional languages may help. Use of QR codes that link to the website that may communicate about the product in the language known to them may help." Thus, most of the experts encourage growing adoption of smart packaging design and assert the need for packaging solutions that can communicate effectively with patients and prevent counterfeits.

Can pharma go the FMCG way?

Nevertheless, there is a lot more that can be done to optimise the potential of packaging but it would also require significant investments. Therefore, can the FMCG sector, which has come up with some good solutions in packaging give some new ideas to improve pharma packaging as it strives to strike a balance between cost and innovation? What do the pharma packaging experts feel about it?

Chowdhury feels that it's unlikely that pharma industry

would follow, at least in coming years, on packaging-free products primarily due to basic difference between consumption within human body versus use over human body. However, the pharma industry is now patronising 'less is more' concept and sustainable packaging through various initiative programmes.

"I don't think pharma industry can do away with product packaging," says Ravipati. But he also suggests, "Wherever over packaging is there, it can be reduced. Bulk packages are common in pharma industry for hospital supply. Also, due to the advent of information technology, some packaging, especially prescribing information to medical practitioners and medication guides/patient information sheets, can be made electronic and available to pharmacists to dispense. This will result in saving packaging material, especially paper, which will also have an environmental impact. With increase of e-pharmacies, there can be less packaging by manufacturers supplying medicines in high bulk packs.

Becoming future-ready

However, everyone is in accordance that pharma packaging has to evolve and enhance to meet the future demands of the industry. And, the experts opine that investing in technology and eco-friendly initiatives will also prove crucial.

Ravipati explains, "The cost of pharma packaging is expected to reduce with the advancement in technology and eco-friendly packaging. Growth in demand for reusable and eco-friendly packaging is expected to drive the market. Additional feature which is becoming more significant is patient and administrator convenience."

He also informs, "Technological advancements in pharma packaging result in immense innovative and advanced applications to pharma and biopharma industries to improve their packaging standards. In the ever-growing technological environment, more types of packaging materials are available which offer more. Package designing is focussed on this aspect to create and sustain brand loyalty in the market."

Citing another example, Chakraborty adds, "Digital watermarks will also become more widely used, offering an extra layer of protection by providing invisible, encoded data on packaging that can only be verified by specialised software. It can be captured using webcam, mobile phones and other scanning device but is invisible to the naked eye."

Expectations from the government

At the same time, the industry also feels that government support can be of aid in ushering progress and enabling regulatory compliance.

Chowdhury feels, "The government should be cognizant of the effort, resources and investment that requires to be compliant to global quality norms besides promoting innovation for the overall benefit of healthcare system. Moreover, it must come forward for funding and special concession interms of pricing cap, commonly known as NPPA."

Nakhare adds, "Talks are on to implement track and trace for the domestic market as well. If the government wishes to implement the same, some monetary help should be extended to SMEs as implementation of these projects runs in crores of rupees. Since most companies have implemented the DSCSA requirements for the US markets and FMD for Europe, they are aware of the challenges in implementing the system."

Seeking government support might be an alternate but not the long-lasting solution to the industry. So, the industry needs to evaluate all the possible solutions which can minimise the usage of pharma packaging material following the patient adherence and eco-friendly way. As we know protection and trend in the industry is more in adapting newer technology, pharma companies will continue with it.

Ravipati also shares his views and states, "Overall packaging for a drug product cannot be compromised and cannot be reduced. In fact, better packaging is required for new drug delivery systems. The government can help the packaging industry by reducing import costs and taxes on raw materials such as glass, plastics, paper and board. It can play a major role in encouraging packaging research and development at academic, institutional and industry levels."

The pharma packaging industry in India has become more innovative, flexible and affordable and the country needs to catch up with the latest regulatory requirements. Regulatory challenges can play a major role in driving the change in pharma packaging industry. Though adoption of smart packaging design and the need for packaging solutions is the need of the hour, there is a lot more that can be done to optimise the potential of packaging, which will require significant investments. The packaging industry needs to evaluate possible solutions which can minimise the usage of pharma packaging material following the patient adherence and eco-friendly way.

Thus, the pharma packaging industry is transforming rapidly and while the government can definitely speeden its growth journey, the players themselves should restrategise to become more innovative and responsive to the demands of the life sciences industry. Fortunately, the stakeholders of this industry have already taken note of this fact and they are devising various approaches and investing significantly to become more patient-centric even as they leverage the growth potential in this segment. Thus, it is to be hoped that the pharma packaging industry will become much more value-driven and grow from strength to strength in the days to come

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Gap analysis of some key stakeholders of Indian pharmacovigilance

On World Pharmacovigilance Day, **Dr J Vijay Venkatraman**, Managing Director & CEO, Oviya MedSafe, takes stock of the country's pharmacovigilance programme and suggests ways to plug the gaps

Ever since the Pharmacovigilance Programme of India (PvPI) was launched on July 14, 2010, Indian pharmacovigilance has been making continuous and commendable progress. This strong and sustained growth resulted in the Ghaziabad-based Indian Pharmacopoeia Commission (IPC), the National Coordination Centre (NCC) of PvPI, becoming a WHO Collaborating Centre for Pharmacovigilance in Public Health Programmes and Regulatory Services in 2017, among several other achievements. With the success of India's pharmacovigilance story being now well-accepted in the global arena, this may be the right time for us to exercise prudence and perform a gap analysis to comprehend what more we should do in order for India to be even more productive in pharmacovigilance in the future. It is obvious that such an analysis should focus on the same key stakeholders whose contributions led to the building of the success story in the first place. This article aims to provide a brief overview of the gaps seen in some of the key stakeholders of Indian pharmacovigilance, in the view of the author.

PvPI structure

The basic unit of PvPI is an Adverse Drug Reaction Monitoring Centre (AMC), which refers to medical colleges, hospitals and centres of public health programmes in India, which are authorised to collect suspected ADR reports from healthcare professionals and/or consumers and forward them to the NCC at IPC, Ghaziabad. At the moment, India has more than 250 AMCs directly connected to the NCC. The NCC analyses the received reports and provides recommendations, if any, to the Central Drugs Standard Control Organization (CDSCO) which is India's National Regulatory Authority. All the reports received by the NCC are submitted to the Uppsala Monitoring Centre in Sweden which is the WHO Collaborating Centre for International Drug Monitoring. In addition, the NCC is well-networked with several national health programmes and government institutions which share ADR information with the NCC. Apart from the above, the NCC also receives reports from the industry since 2015. The process flow of PvPI is illustrated in *Figure 1* below.

Healthcare professionals (HCPs) and consumers

HCPs and consumers in India may report suspected ADRs to the PvPI or to the concerned pharmaceutical company. Both the PvPI and the pharma industry have adopted traditional as well as electronic modes for accepting ADR reports. While the report may be processed in a similar manner at both ends, the report sent to the industry would also eventually reach the PvPI via industry reporting. On the other hand, there is no mechanism at present for reports sent to the PvPI directly to be classified and forwarded to the concerned pharma companies.

Although the term HCP may refer to any member of a healthcare delivery team, the reality in India is that most of the healthcare environments are clinician-centric. Therefore, the comfort level a particular clinician has with ADR reporting is the most important determinant of the 'pharmacovigilance activeness' of the respective healthcare facility itself. Clinicians enthusiastic about reporting ADRs would implicitly inspire their entire team of HCPs to be 'pharmacovigilant' and thereby motivate them to bring any ADR information they receive to the knowledge of the clinicians. A clinician validating an ADR report collected by another member of the HCP team also provides the much critically needed 'medically confirmed' status to the case. But, such scenarios are still rare in India which is proven by the fact that the number of ADRs reported in India is still negligible compared to the population of the country. So, why do clinicians not report the ADRs they encounter?

Apart from the usually stated primary reason of lack of time which is obviously a stark reality in India, there are so many other factors that impede doctors from reporting ADRs. First and foremost: a doctor is not able to see the purpose of ADR reporting as they are not made aware of the life cycle an ADR report would go through after it has been received from the doctor. In several one-on-one interactions the author had with renowned clinicians, it transpired that even scientifically inclined doctors were of the opinion that a drug once approved was to be considered always safe and also safe for all patients all the time. The dynamic nature of the benefit-risk profile of a drug is unfortunately not attached due significance in the typical doctor's cabin where the focus is more on the disease rather than the drug. Whenever the safety profile of a particular drug is discussed, doctors tend to refer to results of clinical trials for the data rather than looking for the more relevant safety information reported in the post-authorisation phase. This could partly be because the former is easily made available to doctors by pharma companies through their medical representatives. Hence, unless a doctor understands the benefit the patient community at large could possibly beget from the ADRs they report, it is unreasonable on the part of other stakeholders to expect doctors to report ADRs especially when they are struggling to find time to provide treatment to all their patients in the first place.

The next key factor could be the fear of potential legal implications which may arise following the reporting of an ADR. While this fear may appear irrational to other stakeholders, a closer look at why doctors feel so reveals that many of them have the apprehension that the mere occurrence of an ADR in a patient under their treatment may get tagged as their 'medical negligence' and result in medico-legal suits. It may be too premature and unrealistic to ignore this apprehension in India where consumer courts have penalised doctors in such instances even in the absence of any medication error. Medication errors occur due to medical negligence and may result in adverse outcomes. But, to assume every ADR to be an outcome of a medication error is unscientific. In addition, the risk of physical assault on doctors by the relatives of patients, which has become more pronounced in the recent times, may significantly discourage doctors from opting to report ADRs. Doctors are also wary of being harassed by government authorities if an ADR report they sent in good faith may be turned against them during enquiries in future. More than all these, doctors feel that they may lose their reputation just by being alleged of negligence even if it did not get proved eventually, as it is perceived to increase the risk of inability to continue their practice in the same locality in the long-term. Last but not the least, doctors practising in medical institutions governed by a hierarchical structure may face roadblocks from senior members of their own fraternity and/or from the administrative heads of the concerned institutions that may be averse to reporting ADRs due to a multitude of reasons.

While we still have to go a long way to resolve the above-mentioned issues, it is high time we started addressing them. Promoting healthy interactions between medical societies and the pertinent government authorities would help in quelling the undue fears and apprehensions of the medical community. The distinction between a spontaneously occurring ADR and a medication error should be made clear to all stakeholders. The fact that "even a good drug can do harm" should be

understood by doctors, patients, regulators, media and judiciary alike. In a conversation, the author had with a past National President of the Indian Medical Association (IMA), it transpired that the IMA could insist to the government that a doctor should be considered to have done his/her duty if they have reported a spontaneously occurring ADR to the PvPI and should be protected by the government from harassment by authorities or by relatives of patients. Moreover, the report made by the doctor to PvPI should be considered as a legal evidence of the doctor's proper handling of the situation unless a medication error is proven to have happened. On another note, the inclusion of clinical pharmacists in the healthcare team could drastically improve the reporting rate of ADRs, as they possess the relevant expertise and would have sufficient time to interact with the patients and prepare the reports which could finally be signed off by the doctor.

Coming to consumers, we have two distinct types in India: (i) the patient who consumes medicines prescribed by their doctor and (ii) the self-medicator who consumes medicines at their own discretion. Those patients who properly comply with the prescription usually trust their doctor and therefore we can anticipate that they would also share any suspected adverse drug experience only with their doctor. While such faith in the doctor is good for doctor-patient relationship, this also transitions the responsibility of reporting the ADR to the doctor. Some patients may withhold the suspected ADR information assuming that it may not be related to the doctor's prescription. Only an intuitive proactive question from the doctor may bring out that information. Nevertheless, it must be remembered that only expected ADRs can be specifically sought for by the doctors. It is therefore advisable to ask open-ended questions in order to diagnose unexpected ADRs. Hence, it is quite premature to expect patients to report ADRs directly to PvPI/industry and in fact, it poses the inherent risk of leading to inadequate or inaccurate reporting, especially given the scenario that patients in India may also be taking traditional/alternative medicines with or without the knowledge of their doctor and the same may not get revealed in their directly reported ADRs which are not medically confirmed. Self-medicators have different problems and erroneously think they do not need a doctor's advice. This often leads to a wide range of ADRs, some of which may be life-threatening. This gap is unfortunately rampant in India as enforcement of laws prohibiting sale of prescription drugs over the counter is not always uniform and stringent.

Apart from educating consumers of risks pertaining to intake of medicines and on how to report ADRs, consumer associations and forums must also take upon themselves the mission of discouraging self-medication practices. The consumer society needs to be vigilant of traditional medicines and alternative medicinal products which are incorrectly claimed to be free of adverse effects. It is pertinent to recall that the Ministry of AYUSH introduced a new Central Sector scheme for promoting pharmacovigilance of AYUSH Drugs in 2018. Care must be taken by the governmental authorities as well as the consumer community to actively disregard and rebuff unscientific messages spread on social media about the adverse effects of drugs and instead promote validated health information from authorised sources. All other stakeholders of Indian pharmacovigilance should come together to augment the consumer's understanding of the subject on an ongoing basis.

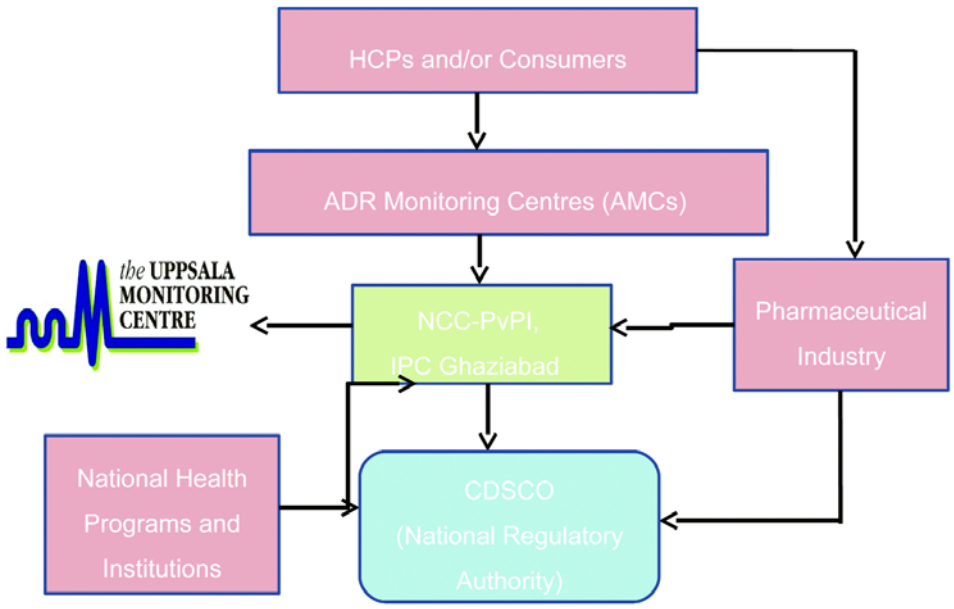


Figure 1: PvPI Process Flow

ADR Monitoring Centres (AMCs) and NCC-PvPI

As explained above, an AMC is the basic unit of PvPI. Typically, an AMC is situated in a medical college and the co-ordinator of the AMC is usually the head of the department of pharmacology in the college. Every AMC has a pharmacovigilance technical associate appointed by the NCC who works in tandem with the co-ordinator. The spectacular performance of some very active AMCs in terms of numbers of ADR reports collected was a key reason for India to achieve the recognition of being the first country to contribute more than 100000 reports to UMC's Vigibase database as early as 2014. Further, the completeness score of the reports from India was 0.94 out of 1, which again points to the diligence exercised by the concerned AMCs.

However, the AMCs have their own share of challenges. While most of these AMCs try to make clinicians in their medical college aware of ADR reporting and also offer their support in paperwork, clinicians do not seem to have warmed up to the idea even in the case of AMCs located within government institutions. The active AMCs have achieved numbers by proactively going for rounds in the hospital wards with requests for ADR reports, thereby jeopardising the spontaneous nature of the ADR report itself. However, until clinicians move into a mindset to report the ADRs they encounter in their practice seeing it as a professional duty rather than a favour they do to the pharmacology department, we are unlikely to get all ADRs occurring even in an institution that has an in-house AMC. Some AMCs have been successful in roping in clinical professors by inviting them as speakers for the pharmacovigilance seminars they organise. On the other hand, it is also true that quite a number of AMCs in different parts of the country are entirely or mostly inactive, due to a variety of reasons. Some private hospitals enrolled themselves as AMCs for fulfilling their accreditation obligations but have since then been found to hesitate to forward the ADRs received. Optimal functioning of all AMCs with the unconditional support of the respective medical college/hospital administration would be the ideal solution for all the above-mentioned challenges. However, the NCC does not seem to have the wherewithal for ensuring this homogeneity across 250+ AMCs across the length and breadth of our country. Hence, the state health authorities throughout India should be formally and actively involved in PvPI activities in order to ensure appropriate checks and balances in the system.

At the NCC, the advantage is that it is centralised and well-connected with each AMC which in turn has access to UMC's Vigiflow software. Therefore, the data received by the NCC is already as validated as possible. The centralised team of pharmacovigilance technical associates at the NCC streamline the flow of information. Nevertheless, the NCC is unable to provide permanent government job positions for the associates and suffers from attrition as no attractive career progression is visible for the associates. Naturally, this gap results in a manpower crunch which at times impacts the turnaround time. Further, the lack of a centralised pharmacovigilance database even after nine years of the new PvPI being implemented is a major pitfall that has to be urgently rectified. Last but not the least, the NCC should devise an objective method for analysing the effectiveness of the AMCs in a periodic manner and subject themselves also to external audits to pursue excellence.

Conclusion

Although Indian pharmacovigilance still has numerous challenges ahead, it must be remembered what PvPI has achieved is extraordinary, considering the fact that all these have become a reality within a short span of nine years and that this has been India's first successful pharmacovigilance programme after a few failed attempts in the last few decades. It obviously means that we have learnt a lot from our past mistakes and have strategised PvPI accordingly. Similarly, there is quite a lot of room to be optimistic about the betterment of Indian pharmacovigilance in the years to come, with each stakeholder complementing the other with mutual strengths.

Microsoft Sharepoint Online: A vaccine for US FDA's 483s, Warning Letter plague?

Ram Balani, CEO, FDASmart, explains how a customised, list-based Sharepoint GxP search can enhance enterprise pharma SOPs with US FDA cGMP regulatory compliance

IT COMES as no surprise to anyone that flawed, incomplete Standard Operation Procedures (SOPs) or SOPs in good order but not adhered to are the number one cause for US FDA 483 deficiency Inspectional Observations or worse, Warning Letters (actual US FDA sourced, compiled statistics below in this article. SOPs are written documents on step by step work performed during the manufacture, processing, packaging, storage and distribution of pharmaceutical drugs that presumably guarantees safe and reliable drugs with consistent quality. Simple enough.

Why then are SOPs still flawed ? Many ways; some obvious, some not.

SOPs can be flawed:

- When SOPs are written by a solitary enterprise personnel without the participation of other stakeholders downstream and upstream the drug manufacturing process.

(NOT written by a TEAM! Those of you who caught on to the term 'team' as a play on words with Sharepoint (e.g. team sites) are ahead of the game with where this article is headed, congratulations!).

- When SOPs ignore or clearly lack written documentation of reference to infer compliance with FDA 21 CFR Part XXX predicate rules including cGMP (Parts 210 and 211), GLP (Part 58) & Quality Systems Regulations (Part 820), etc.

Cite Id	Reference Number	Short Description	Long Description	Frequency
1105	21 CFR 211.22(d)	Procedures not in writing, fully followed	The responsibilities and procedures applicable to the quality control unit are not [in writing] [fully followed]. Specifically, ***	185
3603	21 CFR 211.160(b)	Scientifically sound laboratory controls	Laboratory controls do not include the establishment of scientifically sound and appropriate [specifications] [standards] [sampling plans] [test procedures] designed to assure that [components] [drug product containers] [closures] [in-process materials] [labeling] [drug products] conform to appropriate standards of identity, strength, quality and purity. Specifically, ***	124
2027	21 CFR 211.192	Investigations of discrepancies, failures	There is a failure to thoroughly review [any unexplained discrepancy] [the failure of a batch or any of its components to meet any of its specifications] whether or not the batch has been already distributed. Specifically, ***	100
1361	21 CFR 211.100(a)	Absence of Written Procedures	There are no written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess. Specifically, ***	91
1215	21 CFR 211.67(b)	Written procedures not established/followed	Written procedures are not [established] [followed] for the cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing or holding of a drug product. Specifically, ***	68

FIGURE I. Summary of US FDA 483 Observations with Drugs Oct 2016-Sept 2017 -Top Five (5) Deficiency Observations

This article focusses on (a) when SOPs are written NOT by a TEAM but unilaterally by a single author presumably the subject matter expert or task performer and (b) when SOPs ignore or lack references to infer US FDA GxP regulatory statutes compliance. Microsoft's Sharepoint can assist with ample doses of remedy for both! Sharepoint is FAST emerging as the new 'darling' in the pharma, biotech and medical devices sector.

Deficient SOPs being a dominant source of US FDA 483 adverse inspection observations or worse Warning Letters have not gone unnoticed, i.e. many pharma companies now deploy the use of Sharepoint as its collaborative platform for development of SOPs. SOPs are written, modified, reviewed, approved, stored or archived and transmitted using the workflow collaboration features of a Sharepoint team site, for example, regardless of globally dispersed team members.

Microsoft's Sharepoint Online, as most of you know, is deployed on the cloud and accessible with most browsers, no installations required. Add to that various other features such as its integration with Office 365, workflow enhancements, embedded communication or blog site out of the box without programming and much more makes it easy to see how Sharepoint can advance SOP writing to new heights. Sharepoint seems slated to replace the old school style of the solitary SOP writer(s) with a team driven, cloud-based efficiency and ease of deployment second to none.

SOPs written with a joint team approach using a downstream/upstream group of stakeholders with diverse domain specialties or subject matter qualifications adds a tremendous and critical value to the SOP writing process. It's a game-changer.

Some pharma stakeholders involved with SOPs are listed below as an example but by no means is exclusively complete since situations may vary from one enterprise to another.

- Formulators of drugs and manufacturing processes
- Technical writers
- Safety personnel
- Environmental personnel
- Quality assurance (QA0 or quality control (QC) personnel

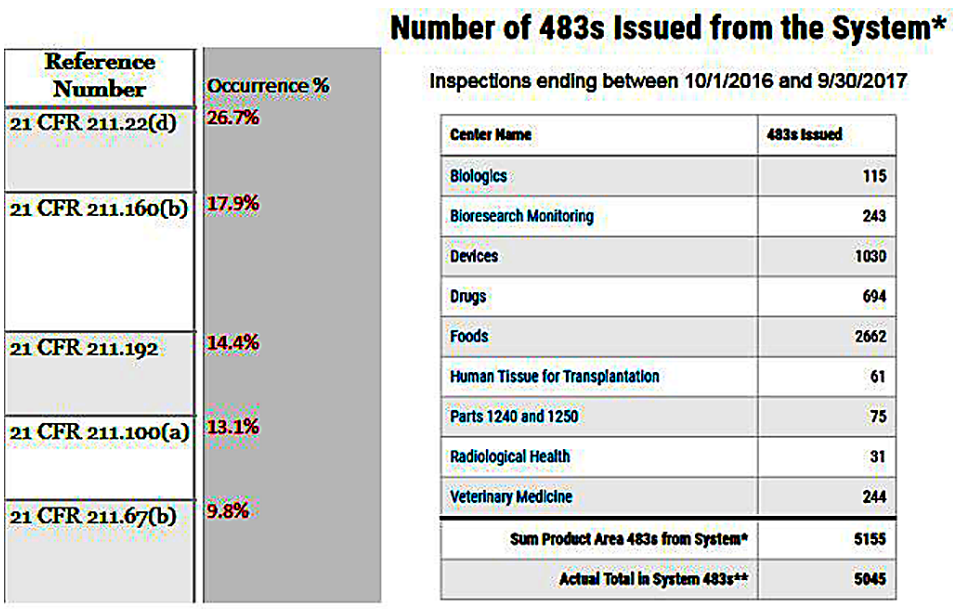


FIGURE II: Frequency Percentage (%) of cGMP 21 CFR Part 211 Statute Deficiencies

FIGURE III: HYPOTHETICAL SCENARIO OF STAKEHOLDER/ROLE/GMP MATRIX (HYPOTHETICAL BUT PLAUSIBLE)

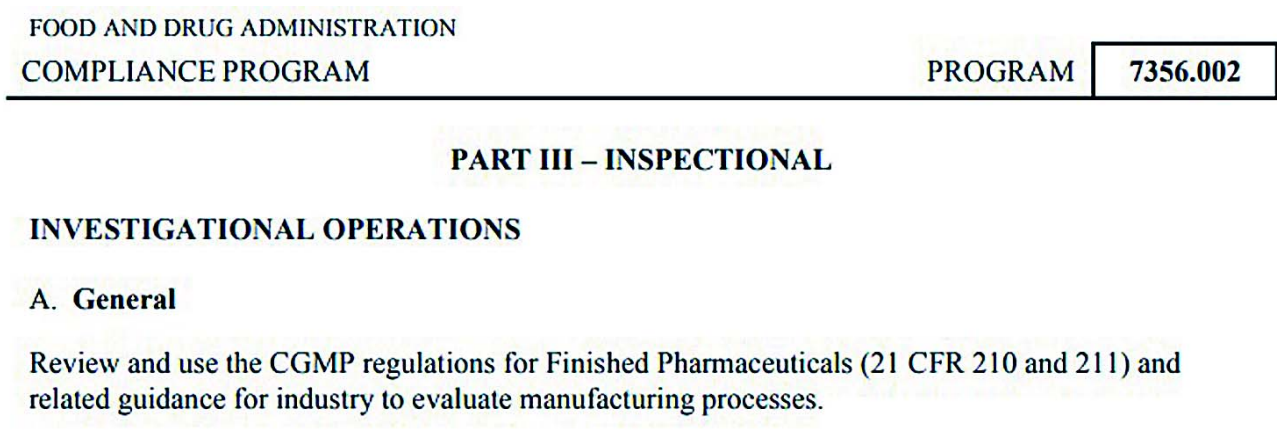
Stakeholder/Role	Function in the Pharma Enterprise - SOP	US FDA GMP Part 211
(1) Warehouse receiving manufacturing plant facility warehouse	Warehouse receiving neglects to inform downstream process personnel or QA Lab of API source or container/ closure change	Possible GxP (GMP) Part 211 statutes violated if recording API source or container/closure change is not specified in SOP at warehouse acceptance/warehouse receipt of API shipment logs
(2) Downstream personnel batch mixing	Receives component specified by SOP from warehouse, routine performance of in-process batch mixing of components; SOP remains unmodified with new container/closure containing API	Not well versed with US FDA GxP predicate rules (Parts 210 & 211), e.g. formulation mixing
(3)-Quality Assurance QC Laboratory	A QA lab personnel would normally perform stability testing on APIs but unaware of API sourcing container/closure change; SOP not modified, no stability study for possible contamination	Well versed with Part211 predicate GMP rules, but API source or container/closure change missed, drugs potentially adulterated since no sample integrity re-testing or stability study performed
(4)-Regulatory compliance Remote HQ Facility	Regulatory staff typically remotely located at HQ site - little to no contact with remote plant site; Not informed with change in API source container/closure	Masters of GMP Part 211 Predicate Rules-API source or container/closure change un-accounted for; fails to catch Part 211 violation

- Regulatory compliance staff or experts
- Calibration or maintenance personnel on any equipment described in the SOP
- Employees who will actually be using the SOPs to perform their jobs.

Using a team approach in the SOP production process just makes good plain sense. A joint team SOP development process offers many benefits.

A key benefit that bears repeating with team SOP development is that SOPs are bound to be more complete and up to date since many personnel from various stakeholder departments are jointly involved in the SOP document production when certain events or milestones occur.

Some examples might include when a manufacturing or packaging process is modified or a new equipment is installed for use or a vendor replaced for API sourcing. When the manufacturing process or environment or some protocol changes, other SOPs outside of the change agent or source will likely be impacted. How and where within the enterprise the ripples effect of the change is felt on existing SOPs and its subsequent impact(s) on US FDA GxP predicate statutes needs to be dealt with to stay in compliance. They are most likely NOT. This is pharma's Achilles' heel! SOPs, whether defective or not adhered to today still remain the main source or leading cause of deficient 483 inspectional observations or Warning Letters from US FDA inspectors. Why?



FOOD AND DRUG ADMINISTRATION

COMPLIANCE PROGRAM PROGRAM 7356.002

PART III – INSPECTIONAL

INVESTIGATIONAL OPERATIONS

A. General

Review and use the CGMP regulations for Finished Pharmaceuticals (21 CFR 210 and 211) and related guidance for industry to evaluate manufacturing processes.

Source: https://www.fda.gov/media/75167/download

US FDA GxP or predicate rules (e.g. cGMP- 21 CFR Part 210 & Part 211) govern safety, effectiveness and quality of drugs that meets GxPs regulatory compliance. They are tightly bound and embedded within the framework of US FDA drugs manufacturing oversight. GxP statutes and US FDA guidance publications are the 'WHAT' FDA expects you to be in compliance with while your enterprise written SOPs purportedly fulfills the enterprise's performance of the 'HOW' to put it succinctly.

Simply put, 483s deficiencies exists because there remains a gap between the 'WHAT' and the 'HOW', the two don't often 'tango'.

For written SOPs to be 'unflawed' and sufficiently meet US FDA GxP regulatory expectations, SOPs need to be written is such a fashion that shows HOW US FDA GxP compliance are fulfilled in the context of SOP written steps and performance. SOPs with only document name, title, version, approver name, scope of the SOP, actual process or task steps therein, etc are not enough!

Apart from cGMP statutes referenced to infer FDA compliance as part of the written SOP record, SOPs must then be followed to a tee and moreover, diligently updated as things change within the enterprise. It's the crucial step in avoiding the dreaded US FDA 'adulterated' drug label.

Need convincing? Read on.

Note the instructions to US FDA Inspectors below straight out of the US FDA's Drug Quality Assurance Compliance Program for Drug Manufacturing Inspections instructs inspectors to:

"Review and use the CGMP regulation of Finished Pharmaceuticals (21 CFR 210 and 211) and related guidance for industry to evaluate manufacturing process." *(Derived from Part III Inspectional below, i.e. US FDA instructions)*

"Furthermore, this inspection approach will provide for fast communication and evaluation of findings. Inspectional observations noting CGMP deficiencies should be related to a requirement."

"Guidance documents are not to be referred to as the justification for an inspectional observation. The justification comes from the statute and the CGMP regulations. Guidance documents do not establish requirements."

See Figure
Part III-Inspectional below

Translated in English, the section on Part III-Inspectional says: cGMP Parts 210 and 211 are legal statutes that can serve as the basis for issuing deficient 483 observations (or Warning Letter if not remediated), while US cGMP FDA Guidances are mere interpretations of those statutes.

(*Spoiler alert: US FDA cGMP Guidances, however, do still reference the same cGMP Parts 210 and 211 statutes for actionable legal proceedings if needed*)

Simply said, the long overdue take-away for the enterprise from all these is: it's time

FIGURE IV: HOW A CUSTOMISED, REPURPOSED MICROSOFT SHAREPOINT ONLINE SEARCH WORKS?

A custom Sharepoint-list based search to simulate a better cGMP 21 CFR Part 211 predicate rules or statutes search system experience requires some heavy-duty, manual 'lifting' or pre-processing is the bad news. However, after a one-time load then exposing the 21 CFR Part 211 content from www.fda.gov harvested and repurposed for Sharepoint use — a rich, powerful advanced search capability second to none is now possible! This article explores a limited number of use case(s) using a test Sharepoint GxP search site with repurposed, harvested content from FDA.GOV cGMP website pages that we continue to collect and compile. As a result, complex Sharepoint list-based search results lets one mine Part 211 cGMP predicate rules with advanced keywords (AND (default), OR, NOT, Wildcard "*" , NEAR operators). See further below for Sharepoint GxP search use cases/samples using the stakeholders API source and Container, Closure change hypothetical scenario matrix for possible contamination

We used this GxP List site and advanced operators to illustrate the context of this article's SOP/GXP gap narrowing goal . Using Sharepoint Online with the repurposed GxP List -one can easily solicit answers to questions such as " What potential Part 211 predicate regulation or statute are impacted when 'container' and/or 'closure' changes as they relate to 'contamination' ' or 'sampling plan' of the Quality Control lab or labeling within the Packaging Department!

Sharepoint customisation beyond out-of-the-box was involved to achieve a dual /cleaner user search results experience either (a) specific to the Part 211 predicate rules list only or (b) site-wise that includes the entire Sharepoint GxP site which for the time being only contains a few 21 CFR Part XXX multiple content types, i.e. CFR Parts 820, 210, 211, etc. The GxP List also includes the US FDA Drug 483 Investigational Observations compilation (Figure I & Figure II both) discussed in this article and for time being, only two US FDA PDF Guidances (interpretations not statutes) as benchmarks for more enterprise fine-tuned searches pre-US FDA inspections post 483 Inspectional Observations (& 15-day replies to US FDA) or one forbids-to respond with CAPA and remediation to a US FDA Warning Letter.

The recent Akorn Pharma US FDA Warning Letter will be addressed as a FOLLOW-UP post-mortem or forensics with the Gxp/Sharepoint List Search i.e. drilling down on past 483 observations regardless of actions intended that led to US FDA Warning Letter to Akorn January 3, 2019 for cGMP statute violations remediation. Akorn Warning Letter accessible here at the US FDA website.

https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/akorn-inc-558914-02042019

to get inside the US FDA inspector's 'head' long BEFORE he conducts his inspections of your premises and its operations. You can be sure your SOPs on the record in writing and their strict performance adherence (or lack thereof) coupled to cGMP statutes compliance on the manufacturing plant floors will be INVESTIGATED to justify any deficiency discoverable with your enterprise inspectional observations.

Evidencing above figures on the top page, one only needs to glance at the char(s) (Figure I, II) reproduced from the US FDA website.

Source: https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/fy-2017-inspectional-observation-summaries#Drug

It's appalling and frankly surprising to see the number one reason for 483 deficiency observations are due to either written procedures (including SOPs!) not existing or being followed at 26.7 per cent occurrence and moreover these 483 deficiencies were attributed to QC as responsible! QC is where the enterprise relies on for quality assurance policing, its mission failed miserably. But why does QC fail? Drug manufacturing is inherently complex, there's no one size fits all. Having SOPs written concisely is one stab to simplify any complex process to ensure consistent, always-on-the spot, routine but consistent performance of repetitive steps by anyone. Add to that the fact that US FDA cGMP statutes are so extraordinarily comprehensive yet so precise that no one person can possibly have a total command of most 21 CFR Part xxx, we have mission impossible or so it seems.

> GxP statutes and US FDA guidance publications are the 'What' FDA expects you to be in compliance with while your enterprise written SOPs purportedly fulfills the enterprise's performance of the 'How' to put it succinctly. Simply put, 483s exists because there remains a gap between the 'What' and the 'How', the two don't often 'tango'

To explain further why enterprise compliance with US FDA cGMP is a 'beast', a hypothetical scenario is helpful *(Figure III)*.

As one can see from Figure III, various enterprise stakeholders command different levels of experiences with upstream/downstream SOP process step-by-step tasks and/or the underlying implied GMP regulatory compliance statues (e.g. Parts 210 and 211). This gap amongst various enterprise stakeholders between the across-the-board SOP step-by-step processes vs. GMP statutes awareness or sophistication continues to be 'big hole' that muddies the SOP team writing process or their adherence.

Relying on QC alone can never be enough. This is undeniably and factually shown in the previous US FDA deficiency compilation, i.e. even QC which is held accountable to the entire enterprise as guardians of the ultimate quality assurance oversight, failed miserably with inspection observation deficiencies in 2016-2017. It is therefore mission critical for SOP development that MORE stakeholders across the enterprise need to step up to the plate to own up or assist with GxP compliance. Each stakeholder role must be preemptively more vigilant as to how changes on their respective turf's SOPs changes impacts the entire process chain.

To paraphrase — what we have now is a classic 'right-arm' does not know what the 'left-arm' is doing scenario. Take note that your enterprise is at a disadvantage and no where close to match a US FDA inspector prowling about your premises who is 'ambidextrous'. US FDA inspector(s) are groomed to evaluate your pharma enterprise written SOP thoroughly in the context of US FDA cGMP statute compliance they expertly know all too well to the point where, if allowed to, he can justifiably and legally declare your drugs adulterated when necessary!

So the question that goes — a-begging then is — how do you narrow or tighten the spread or gap between written SOPs on the enterprise records and their inferences towards US FDA Gxp statute compliance ? (eliminating the gap might be nice!).

Are your SOPs across-the-board processes or tasks sufficiently written and performed to completely factor in Part 211 regulatory statute compliance since that's exactly what a US FDA inspector is gunning for to investigate when he comes visiting your enterprise premises? Can your SOPs withstand the 'domino' effect where a change downstream ripples into upstream operations potentially with serious consequences if unattended?

Each stakeholder needs to look with vigilance beyond his/her immediate enterprise functional 'cubby-hole' given one's subject domain expertise in the context of GMP predicate rules compliance. Easier said than done!

This can better be illustrated

with another hypothetical scenario, i.e. that of a manufacturing plant site, for example, where a container/ closure of an API vendor source or formulated drug stored over time has changed.

Given this scenario, how will various parts of the enterprise and their respective SOPs be impacted? What cGMP Parts 210/211 statutes needs to be incorporated anew or modified? Who is responsible for these additions or changes? When are these changes to be instilled into modified SOPs or new established tasks?

Containers and closures are made from a variety of materials including glass, plastic and metal while formulated drug being stored might be a solid, liquid, or gas or sterile? It is naturally vital to check whether there are any undesired interactions between the formulated drug and the new, replacement container.

For instance, there needs to be testing (QC laboratory needs to do spot-test and then some over an extended time period via stability study testing) carried out to see whether any of the formulation ingredients have become adsorbed on to the plastic replacement container or whether any plasticiser, lubricants, pigments or stabilisers are leaching out to the formulated preparation. Labels and their adhesives might also need to be checked out to ensure no leaking into the formulation contained, i.e. could be an actionable task for other stakeholders (e.g. labeling or packaging department)

How does your enterprise proceed to manage this and more countless changes and modification to the manufacturing life cycle chain that may go unnoticed or unaccounted for by mistake, omission or even deliberately? One logical and prudent inclination would be to search the entire inventory of existing enterprise SOP documents on the record (which Sharepoint team sharing can enhance) or check with a local on-site or central QC for inferences on quality assurance with matters of API source or container/closure change and their ramifications.

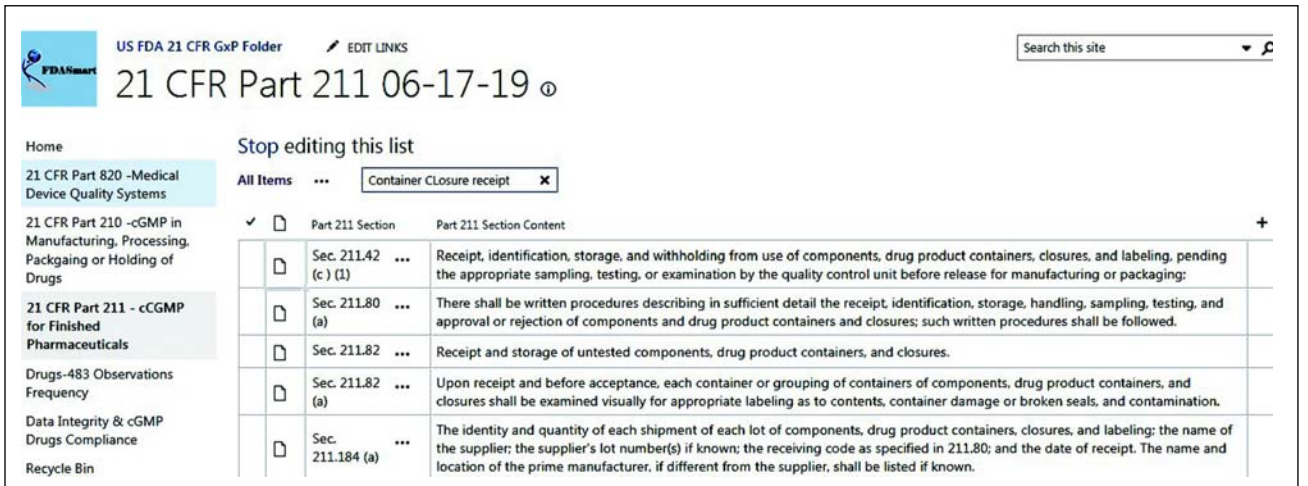


FIGURE V

Moving forward with Sharepoint Online GxP, some use case scenarios are put to the test for the Warehouse Receiving, Downstream Batch Mixer and Quality Control personnel when "container", "closure" changes and given a specific stakeholders search context of interests namely: (1) 'receipt' for Warehouse receiving, (2) "contamination" for Batch operator or (3) 'sampling" for QC.

Sharepoint GxP Search 1:

(a) Stakeholder is Warehouse Receiving Personnel.
(b) Context of Interest is "receipt" "container" "closure"
(c) GxP Sharepoint Result: See Figure V. 211.80(a) is most relevant- but so are 211.42, 211.180,211.184(a) – all mention 'receipt.'

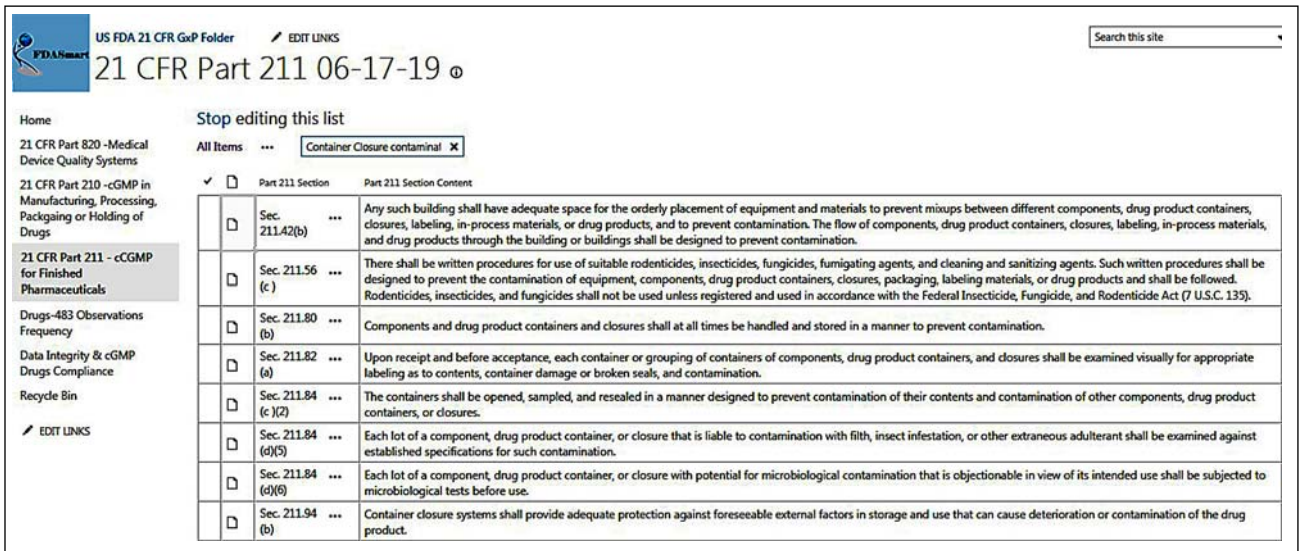


FIGURE VI

Sharepoint GxP Search 2:

(a) Stakeholder is Downstream Batch Mixing Operator
(b) Context of Interest is 'contamination' 'container' 'closure'
(c) GxP Sharepoint Result: 211.184(c) (2) is most relevant – ""The containers shall be opened, sampled and resealed in a manner designed to prevent contamination of their contents and contamination of other components, drug product containers, or closures.

Can you afford to merely rely on the QA group blindsighted ? NOT! Consider QC's record given the 483 deficiency statistics compilation from above showing laboratory control failed onerously in almost one out of every 5 times (17.9 per cent) with its flawed oversight of [components],[drug product containers] [closures] [labeling] from lacking [scientifically sound and appropriate [specifications][standards] [sampling plans] and their potential ripple effects on drug quality integrity.

Notwithstanding QC are not 'masters of their universe', an easy-to-use, independent (of QC) GxP search seems inevitable in order to pre-discover potential GxP deficiencies or gaps from one stakeholder to the next that could possibly arise with the necessary SOP alterations or updates . These days, we feel mostly assured that since we are in the midst of an information/data explosion where just about anything on everything is documented on some website page somewhere, we can seek answers online and in some way begin to muddle through this problem even if just to know what we do not know!

The challenge is not whether the information we need (GxP statues impacted) exist but how to find them given a very specific though hypothetical but plausible use case scenario above starting with the venerable US FDA (www.fda.gov) website.

'Piece of cake' you say — try this challenge then:

(a) "What 21 CFR Part 211 GMP statues (Part 211 and Section(s)) must anyone in-

cluding QC be investigating where 'container' 'closure' 'contamination' are used as search keywords ! "(**want to know what US FDA GMP Part 211 statutes are impacted when container closure are referenced with contamination?**)

The logical place to start would be here — the US FDA.GOV link (content) for 21 CFR Part 211-Current Good Manufacturing Practice for Finished Pharmaceuticals, *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=211&showFR=1*

Any luck with the single-word 'Ctrl-F' to find 'container' 'closure' 'contamination' references in 21 CFR Part 211.XX link pages above ? Not likely, 'Ctrl-F' is limited to single word searching!

(b) An alternative search site might be this link (search page) below provided by no less than the US FDA itself. Again-try searching for the answer to the same question above: 'container' 'closure' 'contamination'.

Site below was created by the US FDA to 'assist' searching GxP so they say. *https://www.accessdata.fda.gov/SCRIPTs/cdrh/cfdocs/cfcfr/CFRSearch.cfm*

And the answer is? Time to despair? All is lost. Not quite.

Microsoft Sharepoint Online Search may provide a solution — though tedious to develop or set-up, it works! *(See Figure IV: How a customised, repurposed Microsoft Sharepoint Online Search works)* .

Microsoft's Sharepoint search has been touted as a new generation search, we tend to agree.

To get some sense or glimpse of how a repurposed, list-based Microsoft Sharepoint GxP search from US FDA website harvested content might look like -please consult the Sharepoint GxP search scenarios screen shots captured in Figures V through VII above. See also screenshot captured as Figure VIII-A and Figure VIII-B.

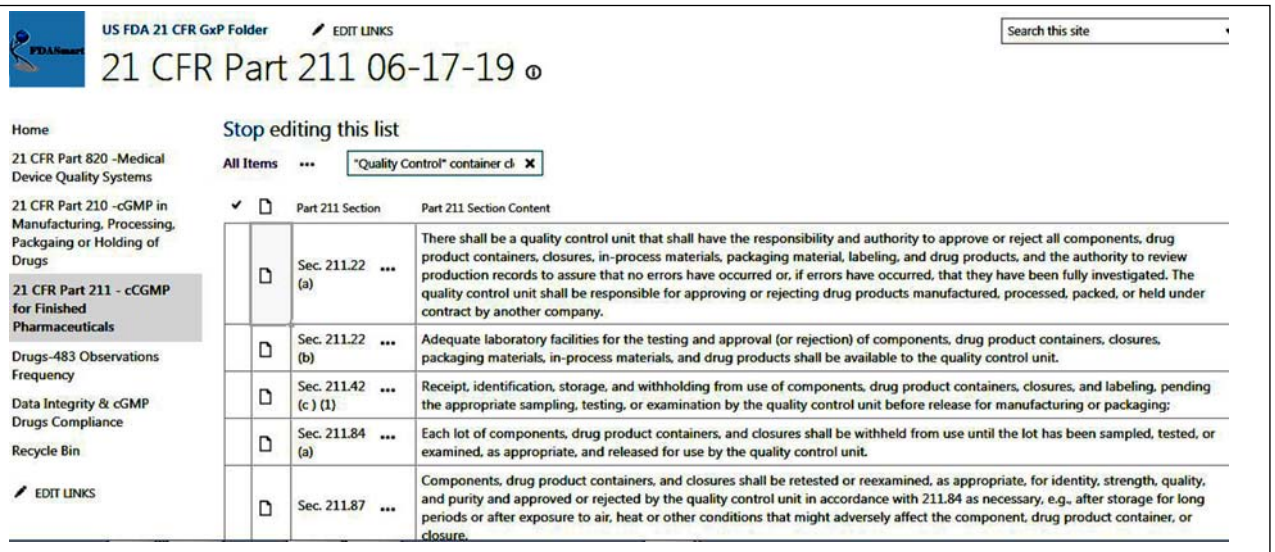


FIGURE VII.

Sharepoint GxP Search 3:

(a) Stakeholder is Quality Control

(b) Search Context of Interest is "Quality Control" "Container" "closure"

(c) GxP Sharepoint Result:Comprehensive list of Quality Control functions including approval or rejection – see Figure VII.

While the above scenario search use cases are based on hypothetical matrix laid out before, there is nothing hypothetical about the search use case scenarios below based on the US FDA 483 deficiency inspection observations compilations:

(a) 26.7 percent deficiency where "The responsibilities and procedures applicable to the quality control unit are not (in writing) (fully followed)." (a Part 211.22(d) violation)

A quick Gxp Sharepoint search of "quality control" writ* (writ* is wildcard for written, writing, write) gives us the Part 211 GMP statutes that QC are responsible for to be in writing! *(See Figure VIII-A)*

Conclusion

The industry can expect more globally dispersed groups working together despite time zone differences, best practices and cultural challenges. SOPs are and will continue to be the lifeblood of day to day pharma manufacturing across the enterprise and with even more complex processing including biologics, one can expect evolving US FDA regulatory compliance and vigilance to go along with it.

On-demand collaboration and their challenges must evolve to new heights with more robust collaborative, integrated and feature-rich platforms like Microsoft Sharepoint Online which is paving the way with team site workflows in SOP development. Context-rich 'search' is the next frontier to facilitate fine-tuned, pervasive GxP compliance so it becomes not just a tribal QC village but embedded across the pharma DNA not with mere words but in action!

The recent Akorn Pharma US FDA Warning Letter (January 2019) will be addressed as a FOLLOW-UP Express Pharma 'post-mortem' article featuring a forensic analysis of the Akorn Warning Letter's cGMP Part 211 violations.The analysis will, however, go beyond the Warning Letter and analyse 'pre-emptively' previous 483s issued to Akorn after past inspections (whether No Action or Voluntary or Official Indication type).

The *Express Pharma* Part II-follow up article will attempt to determine what actions or remediation steps Akorn should/could have discerned as 'clues' or cGMP directives to pursue remedies on its own before the US FDA issued its Warning Letter (last resort!) with a smart(er) search of US FDA cGMP Part 211 statutes or predicate rules using the actual Akorn 483 texts or inspection observation content from the FDA. We will, in this follow-up article, fish out 'keyword(s) or combination thereof similar to what was done in the GxP search case scenarios (hypothetical) in this article. We will of course be using another version of the Gxp/Sharepoint List enhanced this time with more FDA website content including guidance on data integrity and sterile drugs processing still also repurposed as Sharepoint lists for searching. Akorn Warning Letter can be previewed here at the US FDA website - *https://www.fda.gov/ inspections-compliance-enforcement-and-criminal-investigations/ warning-letters/akorn-inc-558914-02042019*

In the Warning Letter, the US FDA recommends hiring a consultant to assist Akorn with their remediation and CAPA measures to rectify the cGMP violations. No offense to pharma consultants, they serve a good purpose but by no means in our opinion should Akorn stop there. It should be a foregone conclusion that in the end, the enterprise itself (Akorn) must on its own, long after the cGMP consultant(s) are gone, get its act together with cGMP! (and not rely on consultants hired to to fix the current deficiencies not necessarily pre-empt new ones!)

The article below, by *Express Pharma's* Editor, Viveka Roychowdhury, "Beyond a Culture of Compliance', is most instructive. In the article she states:

"Many companies, following the remedial actions prescribed by the US FDA inspection reports, have also turned to third-party consultants to get an independent impartial view of their systems and processes as well as train their teams. How effective are such GMP consultants, given that they remain 'outsiders' and insiders might have a better chance of identifying cGMP gaps? More so, since they will move on once the period of their consultancy is completed? How can a company internalise the advice and make more permanent changes?"

(https://www.expresspharma.in/cover-story/building-a-culture-of-compliance/)

Instilling heightened cGMP awareness or even sophistication to those inside the enterprise calls for 'insiders' to do more 'heavy' lifting on their own i.e. realise that seeking out compliance with cGMP statute should be built-in within and across the enterprise into the organisation and not merely shopped into the enterprise from outside (consultants) only when forced to do so!

7/9/2019 21 CFR Part 211 06-17-19 - All Items

Stop editing this list

All Items ... "Quality control" writ*

✓		Part 211 Section	Part 211 Section Content	
		Sec. 211.22(d) ...	The responsibilities and procedures applicable to the quality control unit shall be in writing; such written procedures shall be followed.	
		Sec. 211.100 (a) ...	There shall be written procedures for production and process control designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess. Such procedures shall include all requirements in this subpart. These written procedures, including any changes, shall be drafted, reviewed, and approved by the appropriate organizational units and reviewed and approved by the quality control unit.	
		Sec. 211.160 (a) ...	The establishment of any specifications, standards, sampling plans, test procedures, or other laboratory control mechanisms required by this subpart, including any change in such specifications, standards, sampling plans, test procedures, or other laboratory control mechanisms, shall be drafted by the appropriate organizational unit and reviewed and approved by the quality control unit. The requirements in this subpart shall be followed and shall be documented at the time of performance. Any deviation from the written specifications, standards, sampling plans, test procedures, or other laboratory control mechanisms shall be recorded and justified.	
		Sec. 211.192 ...	All drug product production and control records, including those for packaging and labeling, shall be reviewed and approved by the quality control unit to determine compliance with all established, approved written procedures before a batch is released or distributed. Any unexplained discrepancy (including a percentage of theoretical yield exceeding the maximum or minimum percentages established in master production and control records) or the failure of a batch or any of its components to meet any of its specifications shall be thoroughly investigated, whether or not the batch has already been distributed. The investigation shall extend to other batches of the same drug product and other drug products that may have been associated with the specific failure or discrepancy. A written record of the investigation shall be made and shall include the conclusions and followup.	
		Sec. 211.198(a) ...	Written procedures describing the handling of all written and oral complaints regarding a drug product shall be established and followed. Such procedures shall include provisions for review by the quality control unit, of any complaint involving the possible failure of a drug product to meet any of its specifications and, for such drug products, a determination as to the need for an investigation in accordance with 211.192. Such procedures shall include provisions for review to determine whether the complaint represents a serious and unexpected adverse drug experience which is required to be reported to the Food and Drug Administration in accordance with 310.305 and 514.80 of this chapter.	

Some items might be hidden. Include these in your search

FIGURE VIII (A)

(b)– Moreover, as a bonus, we may also discover clues as to which GMP 211 statutes are implicated for a specific drug-making process stakeholder by searching Sharepoint Gxp with keywords like: "failure" "writ*" (find cGMP Part 211 statutes where failure at has to be acknowledged in writing, or written)

211.92 deals with drug production, control records, packaging and labeling etc while 211.198(a) deals with oral or written complaints – either or both falls in the lap of Quality Control duties! *(See Figure VIII-B)*

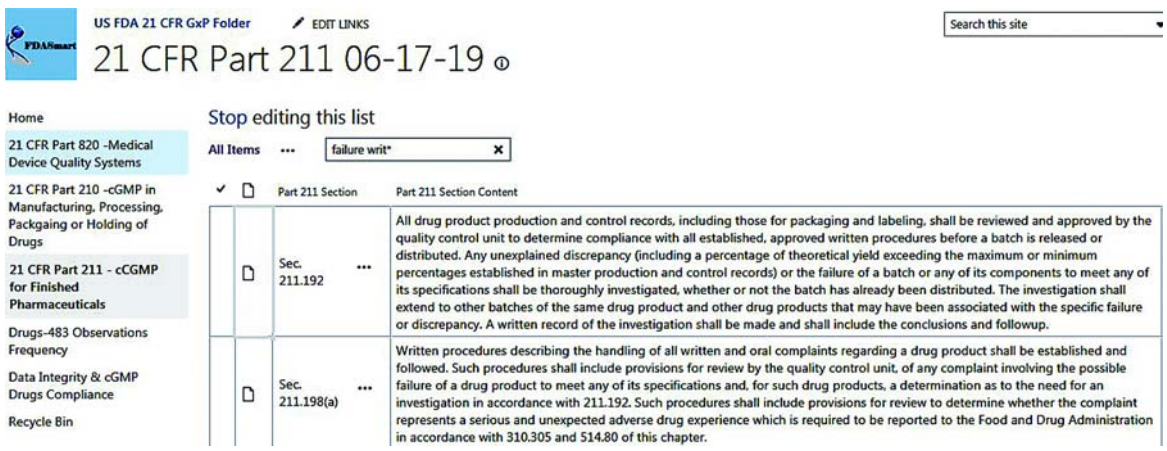


FIGURE VIII (B)

To put this in the right prospective, this FDA cGMP site content harvested and repurposed into GxP Sharepoint list search system is by no means perfect but surpasses current given alternative searching) provided by the US FDA or even brute-forced Advanced Search.

Sharepoint Online allows customisation of Sharepoint search algorithm to crawl external website content with BCS. (Business Connectivity Services and Data Connectors). This may be worth exploring further but would likely require Sharepoint advanced .NET programmingif Sharepoint search crawling of FDA.Gov website is even possible. At the very least, the Sharepoint GxP search illustrated in this article, accepts multiple keywords that work in tandem with advanced search operators (AND (default), OR, NOT, NEAR and Wildcard"*") to deliver to pharma manufacturing stake-holders at any level across the enterprise a CONTEXT specific, richer set of narrowed-down search hit results not possible elsewhere with minimal customisation. It's a start now knowing QC can never be masters of their universe!By so doing, the customised Sharepoint list-based GxP search delivers to a diverse set of enterprise stakeholders a new level of cGMP predicate rules awareness and cGMP sophistication within timely reach for assimilation into their respective SOPs management and maybe –just maybe—well ahead of QC stepping in!!

VENDOR NEWS

OPTIMA pharma inaugurates CSPE Center

The new building, with an area of 4,600 square metres, creates the space needed for large-scale complete pharmaceutical systems

Optima Pharma's recently inaugurated its new assembly hall, which has been named as Comprehensive Scientific Process Engineering (CSPE) Center. Hans Buehler, MD, Optima Group, handed over the building to the staff of Optima Pharma. The new building, with an area of 4,600 square metres, creates the space needed for large-scale complete pharmaceutical systems and optimal working conditions for the employees. Optima has invested a double-digit million sum in the new building in Schwaebisch Hall's Solpark Industrial Estate.

Following the company meeting at Optima Pharma, Hans Buehler ceremoniously presented Gerhard Breu, Chairman, Optima Pharma Division, with a symbolic key. Breu has been Chairman of the Optima Pharma Division since July 2017. In his speech, Buehler underlined the building's importance for Optima Pharma and said, "This building will make it possible for us to build large pharmaceutical plants, some of them multi-storey."

In the past year, Optima Pharma has introduced CSPE, a technical and scientific approach that significantly shortens the delivery and commissioning times of complex turnkey plants. As a result of the new infrastructure, 'integrated acceptances' are now possible within the scope of the new, future-oriented CSPE processes. The entire system – consisting of isolator and filling and closing machine – has been fully tested and approved on site in Schwaebisch Hall.

The assembly hall, which is twelve metres high, provides 3,600 square metres of space to house the large pharma plants. This is adjoined on the north side by a three-storey office building, accommodating social rooms, office space and meeting rooms for customer visits. The building is heated and cooled by a concrete core activation system, which ensures pleasant temperatures year round. Cranes can be used up to a height of eight metres. These provide a high level of safety. "On the north and west sides, we will add a green strip of around three meters wide," says Rolf Blank, the chief architect. In addition, the adjacent courtyard was asphalted at ground level so that transportation from the new logistics centre to Optima Pharma can now be carried out on ground level. A covered container area will also be added.

Hans Buehler, MD, Optima Group handed over a bread plait in the shape of a key to Gerhard Breu, Chairman, Optima Pharma Division

On the occasion of the inauguration of the new assembly hall, Annette Walser-Schaeff, Production Manager, OPTIMA Pharma, Gerhard Breu, Chairman, Optima Pharma Division, Hans Buehler, MD Optima Group, Patrick Herr, Optima Facility Management, Ralf Horlacher, Chairman of the Works Council, OPTIMA Pharma and architect Rolf Blank ceremonially cut the ribbon

Buehler expressed his special thanks to Blank and emphasised the impressive performance of the companies involved in the construction work. Blank and his team completed the building in just seven months. Blank had already been entrusted with the new logistics centre and has already built several new buildings for Optima.

Breu thanked Buehler for the trust he had shown and wished the employees many successful projects in the new building. "Buildings such as this one demonstrate an orientation towards the future, confidence and trust. The hall has created an excellent new working environment for our employees," said Breu in his speech.

The preliminary planning phase for the new building began as early as 2016. Construction was originally scheduled to start in 2021, but was brought forward due to the high volume of orders received by Optima Pharma. The construction work began in October 2018, and the building was completed in April 2019.

EP News Bureau

PRODUCTS

Logistics: Choosing the right loading bay

MANY FACILITY supervisors look at their warehouses not from the outside, but from the inside. Let's face it, you get to work, go inside the warehouse and spend the rest of the day inside taking care of business.

Who is responsible for going outside and doing an actual equipment survey? Have you looked under your dock levelers, at your dock seals, checked the quality of your dock bumpers and wheel chocks or truck restraints (dock locks)? If you are responsible for 'safety', 'efficiency', 'productivity' and 'compliance' now is the time. Small repairs left unchecked can lead to huge expenses and sometimes –employee injuries.

The type of goods your logistic centre handles directly influences the types of vehicle and loading equipment you use, and, in turn, the types of distribution vehicle, the type of goods and the processes you use will determine the type of loading bay you should have. Here, we discuss a few considerations you should take into account.

What type of vehicle do you need to accommodate?

The size of the truck driving up to your loading bay will play a big part in which loading bay to choose. You need to choose a dock leveller that will ensure the smooth transition of goods between the docked vehicle and the loading bay and select a dock shelter and leveler that fits the vehicles you use. And if you work with a range of different sized vehicles, you should consider a dock leveler which is designed to work with vehicles of all sizes.

How are goods unloaded?

If you work in a small vehicle logistics centre which only deals with vans, you might use a small manual dock leveller suitable for personnel as they walk between the warehouse and the van. But if your loading and unloading process includes vehicles such as forklift trucks or electric pallet trucks you should choose a dock leveller with a high load capacity and which offers a smooth transition between the leveler and the vehicle bed.

What type of goods?

If you deal in goods that are temperature sensitive you should consider an insulated load house package or an insulated dock leveller with dock shelter and insulated overhead sectional doors. Whereas if you deal with heavy goods you will definitely need a dock leveler with a high load capacity. It is important to determine the needs of your goods when choosing your loading dock equipment.

Keeping a well-maintained dock area not only helps things run smoothly, it also shows that your company takes pride in its shipping and receiving area, is energy conscientious, and knows that safety is most important.

Gandhi Automations manufactures loading bay solutions like dock levellers, dock shelters, sectional overhead doors. Dock equipment are designed and factory-made in state-of-the-art manufacturing facility. Our dock equipment meet international safety standards like EN1398 for dock levelers and product is CE marked.

There are many things to consider when choosing a loading bay, but we recommend these as a good place to start.

Contact
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AAF Filtration Solutions provide highest levels of protection for cleanrooms

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A cleanroom is a contamination-controlled environment designed for specialized industrial production or scientific research. Specifically, the pharmaceutical industry follows strict requirements on air purity levels for aseptically prepared parenteral medicine, such as injectables and other formulations.

Contamination during manufacturing may lead to severe harm or life-threatening health risks to the patient. Anything that could come into direct contact with a pharmaceutical product is a potential risk of contamination. Hence, the quality of HEPA filter directly affects process performance and output. Therefore, it is very important to select the right product for the desired cleanliness. Industries like pharmaceutical labs, biotech labs, food & beverage facilities, microelectronics facilities, semiconductor facilities, optical labs are regulated to maintain these cleanliness levels for a foolproof product.

AAF pioneered many of the techniques and products used in cleanroom operations & processes. It recommends MEGAcel II – an ultra-high efficiency and ultra-low resistance eFRM membrane HEPA/ULPA filter for cleanrooms. MEGAcel II and eFRM media are manufactured, tested, and packaged in ISO 7 clean facilities to ensure the highest purity, quality and consistency. The company understands the critical nature of contamination-controlled environments and has played an active role in establishing new standards for cleanroom applications.

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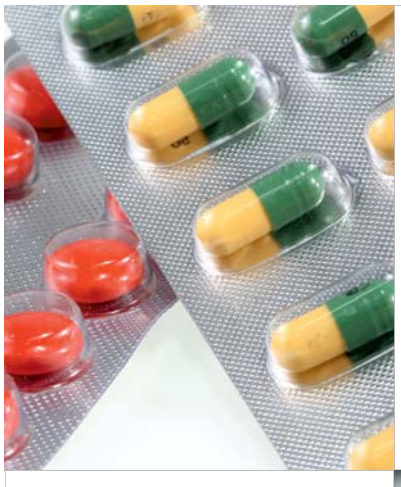

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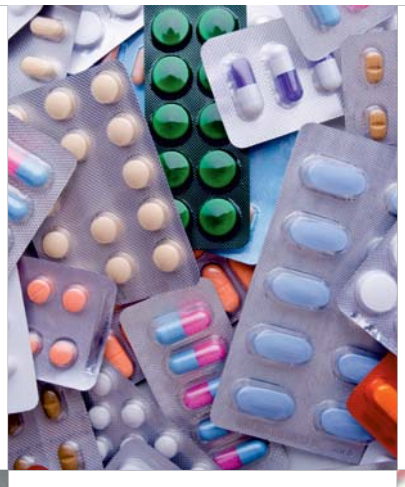

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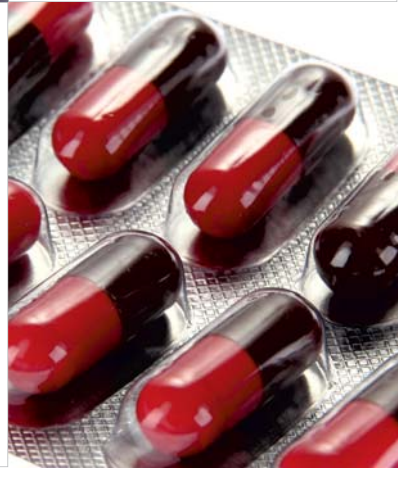

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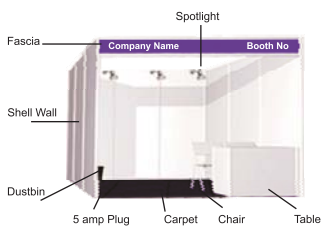

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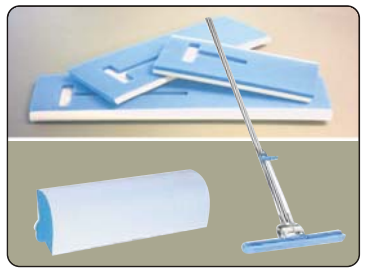

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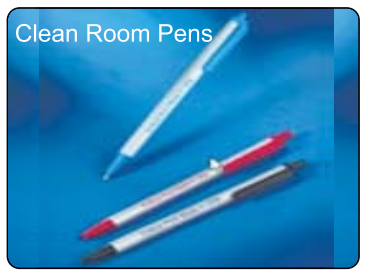

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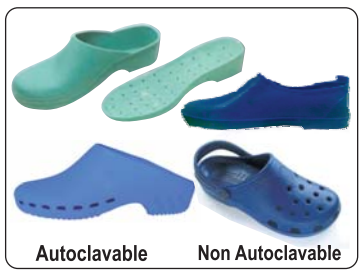

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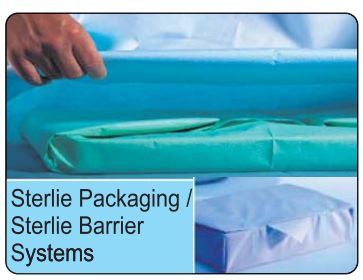

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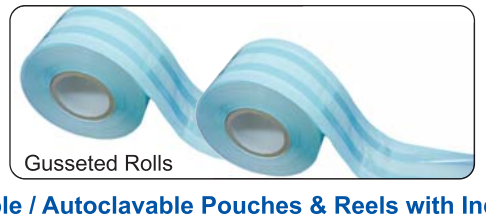

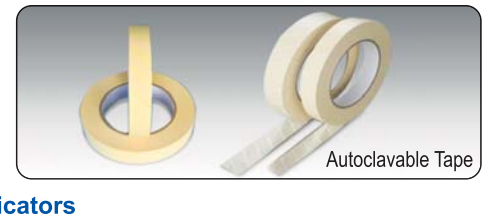

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Can pharmacy colleges act as big data enabler in pharmacovigilance?

Prof (Dr) Vandana Arora Sethi, Group Director, Lloyd Group of Institutions, talks about the rise in reporting on adverse drug reactions, and how institutionalising PV centres in the medical and pharmacy colleges of India can help the government and the healthcare industry overcome, or better tackle, this problem

Adverse drug reactions' reporting is on the rise due to pharmacotherapy, hence pharmacovigilance (PV) is the key topic of discussion in healthcare circles. There has been a national directive to institutionalise a PV centre in every medical college of India and the thought of having the same is ripe for pharmacy colleges. There is an urgent and crucial need to inform, educate, and enlighten the readers about the constitution and dynamics of a PV centre.

Efforts have to be accelerated to contain the damage before it looms large on the country and there is a pressing demand to better define the relationship between the pharmaceutical industry, healthcare professionals and medicine regulatory authorities so that deleterious effects of medicines in their routine use could be avoided and if at all this occurs, it should be effectively tackled.

PV is a central idea that will enable the country to examine drug safety data and arrive at tailor-made regulatory decisions for its population. For any drug, it is firstly desired by the users that the same should be absolutely safe and without any risk. PV envisions this at its core and scrutinises the drugs for their ADRs and sets a mechanism for noting drug effects to uphold the safety of people on priority.

Establishing a robust PV system in any country requires meticulous planning, continuing zeal, proactive approach and motivation of the concerned staff. PV has to ensure that future generations will not condemn the present one for its indifference and callousness to the gravity of the situation and no adverse effects should go unnoticed or unreported.

Roots of PV in history

In India, PV was conceived in 1986, which resulted in the proposal of 12 regional centres. Activities were insignificant for about a decade. Initially, three centres were assigned the task of ADR monitoring of marketed medicines — All India Institute of Medical Sciences (AIIMS) New Delhi, King Edward Memorial (KEM) Hospital Mumbai, JLN Hospital Aligarh Muslim University. These centres were to report to Drug Regulatory Authority of India. This too did not yield much. Finally, in 2005, the National Pharmacovigilance Program (NPP) was launched by the WHO and funded by the World Bank, with 24 PV centres at present under this programme.

India has woken up a bit late to its importance and is lagging in the implementation of the necessary systems and manpower to get it rolling. To address this concern, the Central Drug Standard Control Organization (CDSCO) launched the National Pharmacovigilance Program (NPP) in January 2005. To give it a further impetus, the Drug Controller General of India (DCG(I)) has announced the CDSCO's 'VISION 2020,' which proposes to create a PV centre in every medical college in the country which is an ambitious task keeping in view the fact that it is still at low ebb in many government medical colleges and the condition may be worse in the private institutes. It is likely that the proposal may have to face many bottlenecks to pay some dividends.

Need for PV

PV is defined as per the World Health Organization (WHO) as "Science and activities relating to detection, evaluation, understanding, and prevention of adverse drug reactions or any other drug-related problems." The scope of the definition has now been widened to include ethnopharmacological products and complimentary blood products, biological, medical devices and vaccines.

The human safety data that is extrapolated from only animal studies are often deviant in many aspects and not conclusively predictive. The surface clinical trials reveal a fair percentage of adverse drug reactions, but they may not always give the fuller picture due to various factors like the relatively fewer number of patients from a specified geographic location on trial, limited duration of the trial, differences in the conditions of use from clinical practice. Gross variations in the effects of medicines exist among populations of different countries and also various regions of the same country which may be attributed to the differences in prescribing practices and diseases, genetics, food habits, and pharma manufacturing protocols. This issue needs more attention in India as there is haziness on regulations for herbal remedies, which are widely used and may pose problems when used singly or in combination. India, now being a signatory to the World Trade Organization (WTO) and a hub of clinical trials, is fast becoming a market for new molecules whose safety data are not available from other countries. Therefore, it needs to exercise earnest efforts to remedy its lapses in this vital sector of healthcare and generate its own dependable data from long term use of medicines. In addition to these, clinical trials may not always pick up rare adverse reactions. Also with the prevailing heterogeneity in clinical practices in India - allopathy, ayurvedic, homoeopathy, unani, siddha and in view of the complex interplay among these various systems of medicine, the need for an efficient monitoring system is further underscored.

Advantage pharmacy colleges

◗ Expert manpower and facilities

To begin with, a PV centre can kick start with a part-time expert who can be a physician/clinical pharmacist with some secretarial support. Gradually, as the data traffic increases, a full time professional can be appointed to maintain the support. For the smooth functioning of a PV centre, professionals with expertise in pharmacology, clinical medicine, epidemiology, toxicology prove to be most useful.

Additionally, there could be a secretariat to handle phone calls, database, and documentation of literature and coordination of activities like interfacing with related or successful functioning of the centre.

An advisory committee serves to get funding and support for the centre, monitoring and evaluation, keeping a tab on the quality of the procedures relating to data collection and mining, data interpretation and publication information. The advisory committee may be represented by the disciplines of clinical medicine, pharmacology, toxicology, epidemiology, phytotherapy, pathology, drug regulation and quality assurance.

The pharmacy college could easily fulfil the few basic technological requirements for a PV centre — uninterrupted electric supply, intercom, multi-connection telephone, computer, printer, FAX, Internet, photocopier. Adequate backup facilities are also present so that work is not paralysed in case of sudden breakdowns.

◗ Tasks

Information service

The centre should have access to up-to-date and comprehensive literature database, which can be made available in the college's library. This is because one of the primary responsibilities of a centre is to make high quality credible and latest medicine information available to healthcare professionals.

Reaching out

Newsletters, medicine bulletins, columns from reputed medical or pharma journals may be chosen as routes of effective propagation of the latest developments in medical research and therapy to the healthcare professionals.

Appraisal

The ADR case reports obtained are evaluated by the centre staff, employing the collective know-how of clinical medicine, pharmacology, toxicology, and epidemiology.

Data processing

Data is best managed electronically by computer, wherein, data is entered in a hierarchical format according to the product name, medicine name or therapeutic category. The computer centre facility can serve this purpose.

Medicine regulation

The pharmacy faculty and experts can assist PV centre keep a close eye on the new medicines launched in the market and follow them up to look for newer ADEs, issue warnings, unmask newer indications or changes or to advocate withdrawal of medicines in extreme cases.

Technical knowhow

The pharmacy college can provide the required technical support and know-how for the reporting system. Reports of suspected ADRs are taken in case report forms (CRF) which in PV is defined as a notification relating to a patient with an ADE suspected to be induced by a medicine.

Healthcare professionals e.g. practising physicians, pharmacists, nurses, dentists, and midwives are reliable sources of information. Pharmacists at colleges and nurses can illuminate on concomitant medication and a history of medicine usage. It is imperative for pharma companies to report any ADRs of their products to regulatory authorities.

The college can provide

- Easy and free availability of prepaid reporting forms and other modes of reporting
- Duly acknowledging the receipt of ADR reports telephonically or through personal communication

- Providing journal articles, ADR bulletins, newsletters to reporters
- Actively involving the PV centre staff in scientific meetings, undergraduate and postgraduate education
- Collaborating with professional associations

Funding

The academia may provide the requisite financial support required for a particular PV centre and additional monetary support may be sought from health insurance companies, philanthropic organisations, and government departments with an interest in medicine safety.

India rates below 1 per cent reporting in PV as compared to the overall world average of 5 per cent. It could be remedied by training our technical manpower in the latest developments in PV, identifying, and supporting centres of excellence across the country which can impart quality training in PV to the healthcare professionals. And there could be no better manpower than pharmacy graduate and undergraduate students and faculty. Efficient communication both in sharing our own findings with the global database and reaching feedbacks and analysed reports to the prescribers well in advance should be ensured.

Planning for the study

The following requisites can be set up in the PV centre at Pharmacy College:

Communication process

Getting in conversation with health authorities and local, regional, national bodies and groups engaged in clinical medicine, pharmacology, toxicology, epidemiology, briefing them about the importance of the project and its applicability in modern therapeutics.

Data acquisition

Designing a template for ADR reporting and making available ADR reporting forms at all times, to hospital departments and general practitioners, on which they can furnish relevant information to the data bank of the centre.

Dissemination

Producing printed handouts as well as conducting meetings or workshops in hospitals and academia to acquaint healthcare professionals about the definitions, goals, scope, and methodology of the PV system to create awareness about its relevance in present times.

Establishment

Hiring the right qualified and interested staff, getting a suitable place for accommodating them as well as the centre, making arrangements for telephones, computers, printers, word processors, database management, bibliography support services and Internet.

Internal education

Ensuring proper education and frequent updating of the staff belonging to the PV centres by training them in data collection, filtration, mining, verification, interpretation and coding of ADRs, medicines coding, causality assessment, signal detection, risk management, and action in case of serious/fatal adverse drug events (ADE). Data mining is a relatively nascent interdisciplinary area which involves finding correlations and patterns among many fields in large databases with the aim of categorising the data and summarising identified relationships.

Database

Creating a safely stored, classified database which is retrievable and guarded by required degrees of confidentiality.

Promotion

To inculcate and promote the habit of reporting ADRs to the higher centre, medical journals, health bulletins and other professional healthcare publications

PV is all about drug regulation and rests on sound collaborative ties, coordination, communications, and public relations. The most suitable location for setting up a PV centre is dictated by the political governance and its healthcare priorities, including a willingness to do, law enactment, its enforcement, funding, organisation, staffing, training, and development. For national coordination of PV, governmental support and sustained monitoring is a must. A centre can be started in a college,a hospital or at any department, preferably in pharmacology, medicine, clinical pharmacy or clinical toxicology. The requisite of one hospital locally is a must in that case.

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APPOINTMENT

Syngene appoints Dr Mahesh Bhalgat as COO

Dr Bhalgat is recognised for his contribution to the commercialisation of diagnostic kits, biopharmaceuticals and WHO pre-qualification of vaccines

SYNGENE International announced the appointment of Dr Mahesh Bhalgat as Chief Operating Officer. Dr Bhalgat comes to Syngene from Shantha Biotechnics, a Sanofi company, where he was responsible for all manufacturing operations, supply chain, engineering projects, HSE, manufacturing excellence and administrative services.

Commenting on the new appointment, Jonathan Hunt, CEO, Syngene International said, "We are delighted to have Dr Bhalgat join the Syngene executive leadership team. Syngene has evolved to be a global scale scientific services provider and Dr Bhalgat's significant expertise in R&D, analytical development, technology transfer, regulatory sciences and quality will further enhance Syngene's position as a global CRO."

In a career spanning over 25 years in the field of biotechnology and biologics, Dr Bhalgat is recognised for his contribution to the commercialisation of diagnostic kits, biopharmaceuticals and WHO pre-qualification of vaccines. He has a rich experience in diverse areas of biotechnology such as biotherapeutics, vaccines, ag-biotech, and research reagents and has been associated with companies such as Amgen, Monsanto, Celera Genomics, Thermo Fisher, Biological E.

A PhD in Medicinal Chemistry from the University of Utah, he is the Co-Chair of CII's National Committee of Biotechnology as well as a member of the Biomeriux Scientific Advisory Board, France, United States Pharmacopeia, GCBA committee and the Indian Pharmacopeial Commission.

EP News Bureau

INITIATIVE

Lupin Foundation organises Dr Desh Bandhu Gupta Memorial Lecture in New Delhi

The event hosted over 200 dignitaries

LUPIN Foundation, the CSR arm of leading pharmaceutical company Lupin organised a memorial lecture to remember their Founder and Chairman, Dr Desh Bandhu Gupta on his second death anniversary. The lecture was held at the India International Centre, New Delhi on June 26, 2019.

Inaugurated and introduced by Sita Ram Gupta, Executive Director, Lupin Human Welfare & Research Foundation (LHWRF), the event hosted over 200 dignitaries. It was also graced by Sompal Shastri, Former Union Minister for Agriculture, Uma Suresh Prabhu, IC Shrivastava, Ex IAS Officer and Ex Collector of Bharatpur District and Yaduvendra Mathur, Special Secretary, NITI Aayog.

(L-R) Sita Ram Gupta, Executive Director, Lupin Human Welfare & Research Foundation; Sompal Shastri, Former Union Minister for Agriculture; Uma Suresh Prabhu, IC Shrivastava, Ex IAS Officer and Ex Collector, Bharatpur District, Yaduvendra Mathur, Special Secretary, NITI Aayog

Sompal Shastri addressed the audience with the first Dr Desh Bandhu Gupta Memorial Lecture wherein he spoke about the efforts undertaken to overcome rural distress.

Speaking about the event, Gupta said, "Lupin Foundation today remembers its guiding light Dr Desh Bandhu Gupta for his philanthropic and pioneering efforts in India's CSR space. His far-sighted leadership enabled us to touch lives of over 2.8 million people in more than 4371 villages across the country through a growth-oriented model of rural development. Our job is not yet over, we will continue to strive hard and keep his vision alive for betterment of rural development."

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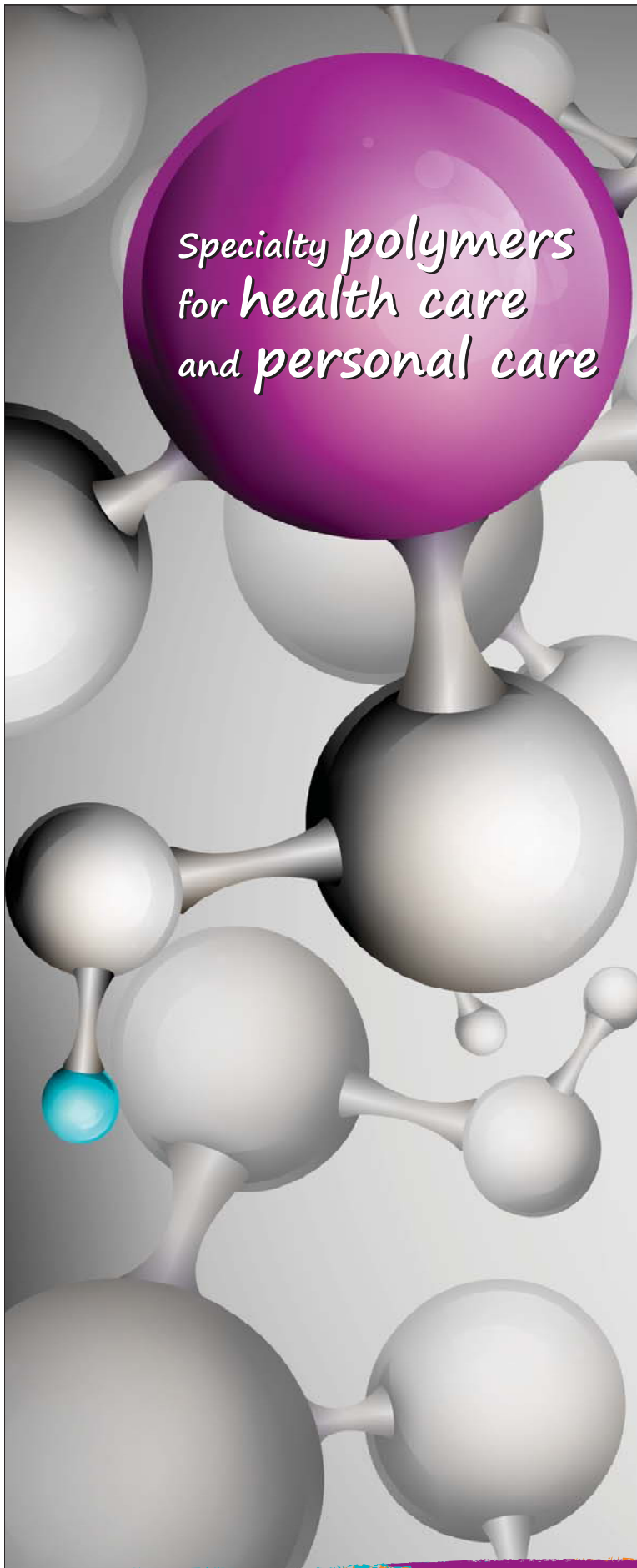

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