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MARCH 2023, ₹ 40

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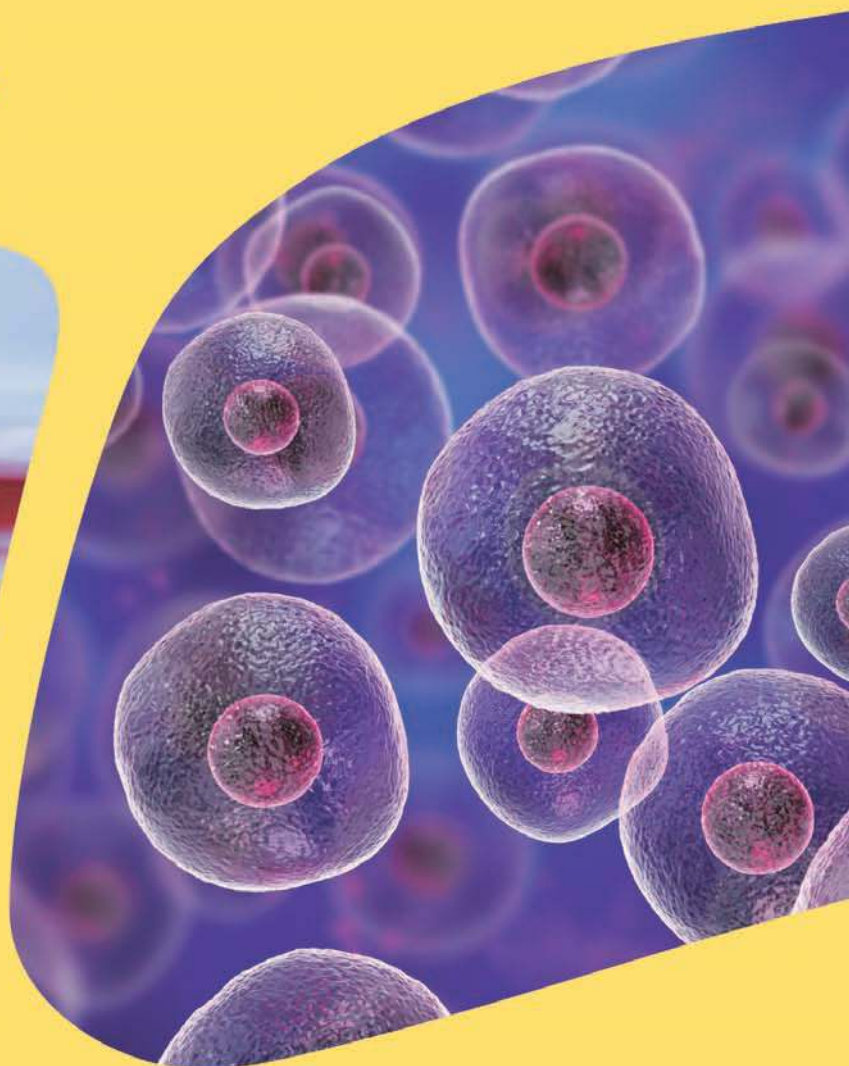
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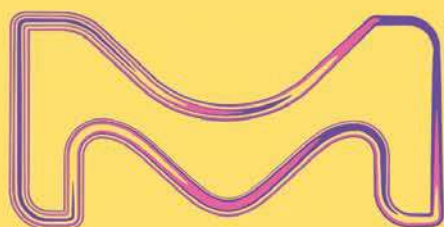
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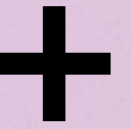
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### Express Pharma®

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# Top of ANDA approvals list, low on IP index

**I**n a sign of the times, 10 of the top 15 companies receiving the highest number of ANDA approvals in 2022 are Indian. An analysis of 2022 ANDA approvals shows that Indian companies once again dominated the ANDA approvals, with 355 or 48 per cent of total ANDA approvals. This further improves their share from 42 per cent (267 approvals) from last year, a 33 per cent growth of ANDA approvals for Indian companies versus 2021. India was followed by the US, China, Europe, and Israel, in that order, in the number of ANDA approvals.

The analysts, Meenu Grover Sharma, Partner, Business Associates Consultants and Dr (Prof) Harvinder Popli, Director, School of Pharmaceutical Sciences, Delhi Pharmaceutical Sciences & Research University further point out that 42 per cent of first-time-generic approvals and 38 per cent of Competitive Generics Therapies (CGT) approvals were garnered by Indian companies. This was close to the score by US-based companies, which received about 50 per cent of all CGT approvals and 21 per cent of first-time-generic approvals.

The authors conclude that significant filing costs of almost a quarter million dollars per ANDA, increasing programme fees, and continuing pricing pressure with increasing competition have not dampened the interest in participating in the US generics space, especially for Indian players.

Moreover, over 11 per cent (86 of 742) ANDAs approved this year (including nine ANDAs approved through the CGT route) are already listed as discontinued, driven by the FDA guidance to notify significant disruption in availability or permanent discontinuation. Going by the trend observed in previous years, the authors estimate that if 18 per cent of this year's ANDAs are discontinued by next year, it would represent approximately \$32 million of sunk cost across all companies.

The question is, will companies look at reducing ANDA filings to curtail sunk costs? Or will the FOMO factor (fear-of-missing-out) continue to drive ANDA filings as a strategic competitive necessity?

The ANDA approvals also indicate that India, except for Biocon/Viatris, do not feature in biosimilar filings. Similarly, oral formulations dominate the ANDA filings from India (69 per cent of approvals) with little less than 20 per cent coming from injectables. The ratio is reversed for arch rival China (69 per cent injectable products and 26 per cent oral formulations.) These trends could represent missing links in India's therapeutic offerings, which will need rectifying in the years ahead.

While India tops the list of ANDA approvals for the



**India's dominance of ANDA approvals juxtaposed with the continued low ranking in the US Chamber of Commerce's International IP Index signals that any tweaks in India's IP regime will be for the country's benefit and not overtly influenced by diplomatic and trade pressures**

US market, it is near the other end of the US Chamber of Commerce's International IP Index. Which is another sign of these times. India maintains a fairly low ranking of 42 out of 55 countries in 2023 International IP Index report, with the innovation score remaining unchanged from 2021 at 38.64 per cent.

The IP Index lists various weaknesses of India's IP ecosystem, with the dissolution of the Intellectual Property Appellate Board in 2021, combined with the 'long-standing issue of an underresourced and overstretched judiciary', leading the list. India's 'limited framework for the protection of biopharmaceutical IP rights', lack of regulatory data protection or patent term restoration for biopharmaceuticals and 'lengthy pre-grant opposition proceedings' are also cited. India's first and only compulsory license granted way back in March 2012 for 'commercial and nonemergency situations' still figures as a weakness area as does 'limited participation in international treaties.'

The IP index report does acknowledge some of the country's areas of strength and measures deemed IP friendly, like 'generous R&D and IP-based tax incentives', and the fact that the country is a 'global leader on targeted administrative incentives for the creation and use of IP assets for SMEs.' It also mentions that there have been 'strong awareness-raising efforts regarding the negative impact of piracy and counterfeiting.'

India's dominance of ANDA approvals juxtaposed with the continued low ranking in the US Chamber of Commerce's International IP Index signals that any tweaks in India's IP regime will be for the country's benefit and not overtly influenced by diplomatic and trade pressures. India will continue to forge its own IP policy.

Thus the country continues to be a very vocal advocate for the proposal to waive IP rights for COVID vaccines and diagnostics, not just COVID therapeutics. Conversely, the IP index cautions that these negotiations with the World Trade Organization (WTO) and World Health Organization (WHO) to waive IP rights 'will undermine the innovation ecosystem that was pivotal to combatting COVID-19 and threaten the ability to respond effectively to the next major global public health threat.' Balancing market expansion strategies with IP policy will remain a recurrent theme for India pharma for the foreseeable future.

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## ANDA approvals in 2022: Unrelenting interest again boosts numbers

**Meenu Grover Sharma**, Partner, Business Associates Consultants and **Dr (Prof) Harvinder Popli**, Director, School of Pharmaceutical Sciences, Delhi Pharmaceutical Sciences & Research University inform that Indian companies again dominated the ANDA approvals, with 355 or 48 per cent of total ANDA approvals, further consolidating their share from 42 per cent (267 approvals) from last year

As we write the 2022 edition of ANDA approvals analysis, the most striking observation is the reversal of the declining trend witnessed over the last couple of years. As a testimony to the unrelenting interest in the area, a total of 742 ANDA approvals were granted during the calendar year 2022, registering a growth of 17 per cent over last year. Additionally, 136 Tentative Approvals were also granted, again a similar growth over 2021 numbers (117) as seen for final ANDA approvals. Indian players contributed a large proportion of the incremental number of approvals this year with 88 more approvals than last year.

**Regional trend: Indian companies further consolidate their share; Chinese companies retain the same pace as last year**  
Similar to our analysis last year, ANDA applicants were mapped to the parent company as recorded in the FDA database and the location/headquarters of the parent company was used for analysing the regional trends. It was no surprise that the Indian companies again dominated the ANDA approvals, with 355 or 48 per cent



Meenu Grover Sharma

of total ANDA approvals, further consolidating their share from 42 per cent (267 approvals) from last year. This represents a 33 per cent growth of ANDA approvals for Indian companies versus 2021. India was followed by the US, China, Europe, and Israel, in that order, in the number of ANDA approvals. Chinese companies (without Taiwan) gained 61 approvals during the year (vs 66 last year), maintaining their interest in the US formulations space. Our prediction of increasing interest of Bangladeshi companies in this area started showing up in numbers with five different companies garnering a total of nine approvals, up from one approval for Beximco last year. We



Dr (Prof) Harvinder Popli

expect a steadily increasing two-digit representation of Bangladesh in the future years as well. Notably, there was one approval from Malaysia as well this year with Novugen Oncology SdnBhd getting approval for Abiraterone acetate tablets.

### Expectedly, oral dosage forms take the lion's share of approvals, followed by injectables and topicals

With 445 approvals, oral dosage forms held about 60 per cent of ANDA approvals granted in 2022, followed by injectables with 206 and topicals with 40 approvals. Within the oral dosage forms, 69 are extended-release/delayed-release formulations and 78 approvals for liquid

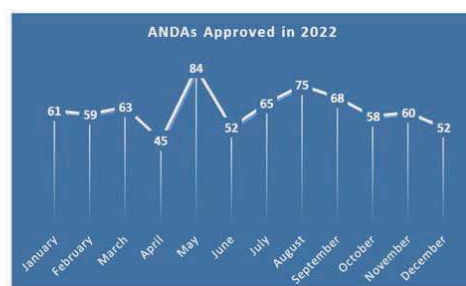
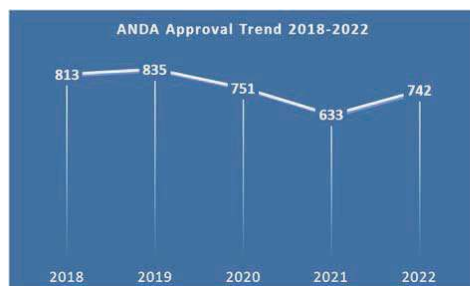
formulations (including powder/granules for solution/suspension). Separately, one buccal film (Buprenorphine) and three chewable tablets also got approval (two for Lanthanum carbonate and one for Meclizine) of which two were for Cipla. Two sublingual tablets (one for Nitroglycerine and one for Fentanyl) were also approved but both have been stated as discontinued. One chewing gum (Fertin) and one lozenge (Aurobindo) for Nicotine Polacrilex also got approval this year. Diatrizoate meglumine and Diatrizoate sodium oral/rectal liquid for contrast imaging is one of the most notable oral liquid approvals this year. Cetrorelix, succinylcholine chloride PFS, ganirelix and liposomal amphotericin B are some of the notable injectable product approvals. Approval of Breyna metered dose inhalation product of Viatris (the generic equivalent of Symbicort) is arguably the most notable complex product among all approvals this year. Methylphenidate extended-release transdermal film (Daytrana generic) is another one worth mentioning.

Notably, 69 per cent of approvals received by Indian companies were for oral formulations and a little less than 20 per cent for injectables. On the other hand, Chinese companies' approval basket was represented by 69 per cent injectable products and 26 per cent oral formulations. The preponderance of injectable product approvals for Chinese players could be stemming from the synergies they may desire to

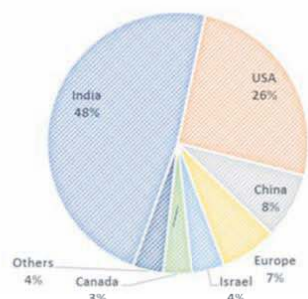
leverage in the domestic market based on US ANDA-approved products.

### First-time generics and CGT approvals: Indian companies and injectable formulations dominate

A total of 106 approvals are classified as first-time-generic approvals in 2022 and 63 approvals were granted through the Competitive Generic Therapy (CGT) route. 42 per cent of first-time-generic approvals and 38 per cent of CGT approvals were garnered by Indian companies. US-based companies received about 50 per cent of all CGT approvals and 21 per cent of first-time-generic approvals. Looking at the formulations spread, injectables dominated with 48 per cent of first-time approvals and 36 per cent of CGT approvals. Pemetrexed with 14 approvals, lacosamide tablets with eight approvals (of a total 11 this year) and Bortezomib with eight approvals (of a total 17 this year) listed as first-time-generic approval formed a significant proportion of multiple ANDAs getting first-time-generic designation for the same product. Some of the first-time-generic approvals were also for products with innovator brands still under patent protection such as dapagliflozin, empagliflozin and metformin, brivaracetam, sofosbuvir etc.; the status of many such ANDAs is expectedly stated as discontinued. Teva and Apotex with eight approvals each followed by Zydus and Fresenius with seven approvals each lead the table



Regional breakdown of ANDA Approvals in 2022

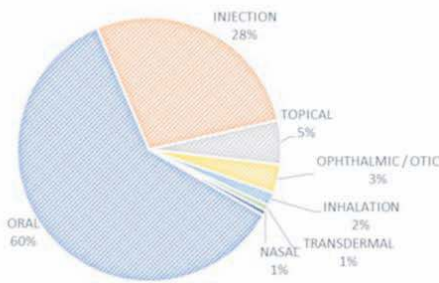


for first-time generic approvals. Amneal with six approvals, Zydus with five and DRL with four approvals gained are the leading players for the number of ANDA approvals through the CGT route. 30 ANDAs were also granted 180-day CGT exclusivity of which five had the exclusivity relinquished or forfeited. Since the FDA started the CGT initiative, about 185 ANDAs have been approved through this route and there are still about 500 innovator NDAs listed for products that are off-patent, off-exclusivity but without an approved generic alternative; these represent a potential opportunity for 180-day exclusivity. However, many of these being only small opportunities, selective filing and approvals are likely to continue in this space.

## Discontinuation trend is maintained at the same pace

In line with our earlier analysis, over 11 per cent (86 of 742) ANDAs approved this year are already listed as discontinued, driven by the FDA guidance to notify significant disruption in availability or permanent discontinuation. This also includes nine ANDAs approved through the CGT route. About 18 per cent of ANDAs approved in 2021 and a similar proportion of ANDAs approved in 2020 are now listed as discontinued. If 18 per cent of this year's ANDAs are also discontinued by next year, it would represent approximately \$32 million of sunk cost across all companies (estimated at the current rate of ANDA filing fee and disregarding apportioned programme fee, development costs and cost incurred on ANDAs that do not return a positive ROI). While some of these products await the loss of

ANDA Approvals in 2022, Dosage Forms



the only Indian company making an appearance in the approval list for the first time.

## Biosimilars

In 2022, seven biosimilars were also approved, taking the total number of biosimilars approved thus far to 40. Additionally, two interchangeable biosimilar products were also approved meet additional requirements and may be substituted for the

their presence in biosimilar approvals, except Biocon with its partnered/acquired programmes with Viatrix.

## Conclusion

Significant filing costs of almost a quarter million dollars per ANDA, increasing programme fees and continuing pricing pressure with increasing competition have not dampened the interest in participating in the US generics space, especially for Indian players. Companies have not only maintained the momentum but also accelerated filings, even during the ongoing waves of the COVID-19 pandemic, resulting in a higher number of ANDA approvals this year across all dosage forms, competition levels, and product complexity including drug-device combination products. We may see a higher number of approvals through the CGT route in the future as the list of open opportunities gets expanded and companies gain experience. One important trend that generics players are mindful of is the type of new molecular entities getting approved these days, with 54 per cent of those approved in 2022 targeting orphan diseases (meaning much smaller volumes) and a significant proportion being biologics. As we start seeing more interchangeable biosimilars, the interest in that area is definitely increasing but given the enormously larger outlay required for those products, only a handful of traditional generics players are currently planning to foray into that area.

*(If you are interested in getting the consolidated dataset used for this analysis in MS-Excel, you may contact the author at meenugrover14@gmail.com)*

## KEY HIGHLIGHTS

- ◆ 742 ANDA approvals granted by the US-FDA in 2022, up from 633 in 2021
- ◆ Additionally, 136 tentative approvals were also granted and seven biosimilars approved this year
- ◆ Indian companies account for 48 per cent of total ANDA approvals, with an increase of 33 per cent compared to the ANDA approvals Indian companies received last year
- ◆ Oral dosage forms made up 60 per cent of overall ANDA approvals, and 70 per cent approvals for Indian companies
- ◆ 106 ANDA approvals are classified as First-time-Generic approval and 63 approvals granted through the Competitive Generic Therapy (CGT) route
- ◆ 11 per cent of ANDAs approved this year are listed as discontinued already; 18 per cent of approvals from last two years have a discontinued status
- ◆ ~34 per cent of ANDAs approved this year have <5 active therapeutically equivalent ANDAs listed and ~28 per cent of ANDAs have 10 or more
- ◆ 10 of the top 15 companies receiving the highest number of approvals are Indian
- ◆ Aurobindo + Eugia Pharma received 44 approvals, followed by Zydus with 36 and Hetero with 33 ANDA approvals in 2022

exclusivity of the innovator brand for commercialisation, most companies are invariably always deliberating strategies to minimise loss arising from such real discontinuations, so it will be interesting to see if we witness any stemming of this trend in the years to come.

## 10 of the top 15 companies are from India

Zydus with 36 approvals topped the overall list of companies getting final ANDA approvals in 2022 followed by Hetero (including its affiliate Annora pharma) with 33 and Amneal with 31 approvals. This year Aurobindo has separately listed Eugia Pharma as a distinct entity, seemingly as the non-oral ANDAs holding company of the group but not listed as an affiliate by the FDA, which it was till last year. If both these entities are viewed together, a total of 44 approvals have been received by the group this year, which would take it to the top of the table if listed together.

Nanjing King-friend and Fosun (Gland Pharma) are the leading Chinese parent companies with 15 and 14 approvals respectively, which are mostly

injectables.

## Leading companies by number of ANDA approvals in 2021

Among the top 15, Apotex and Teva have the highest number of first-time generic approvals (eight each) followed by Zydus with seven.

A total of 171 companies globally and 47 Indian companies were among those receiving at least one ANDA approval this year. The top 15 companies received 44 per cent of overall ANDA approvals in 2022, while the top 15 Indian companies received 76 per cent of approvals obtained by all Indian players.

Optimus Pharma (one ANDA – Aminocaproic acid tablets) is

reference product at the pharmacy without the intervention of a prescriber. The seven biosimilars approved are bevacizumab (2), pegfilgrastim (2), ranibizumab (1), adalimumab and filgrastim. Fresenius Kabi (2 biosimilars) and Amneal (1 biosimilar) are the only traditional generics players with biosimilar approvals this year. Overall, Pfizer (along with Hospira) with eight biosimilars, Viatrix (4), Sandoz (4), Fresenius Kabi (2) and Amneal (1) are the only traditional generics players with approved biosimilars, accounting for about 50 per cent of all biosimilars. Indian companies have established their unequivocal dominance in the traditional generics space but are yet to show

Parent Company	ORAL	INJECTION	TOPICAL	OPHTHA	INHALATION	NASAL	OTHERS	Total	1st time Gx	CGT
1 ZYDUS PHARMACEUTICALS USA INC	24	8	3			1		36	7	5
2 HETERO LABS LIMITED	33						1	34	3	-
3 AMNEAL PHARMACEUTICALS LLC	13	9	5	1		3		31	4	6
4 TEVA PHARMACEUTICALS USA	22	1	3	1	1			28	8	-
5 AUROBINDO PHARMA LIMITED	25	1						26	1	2
6 ALEMBIC PHARMACEUTICALS LTD	9	4	8		1			22	1	1
7 MSN PHARMACEUTICALS INC	14	5						19	3	-
8 PRINSON PHARMACEUTICAL INC	17	2						19	1	-
9 DR REDDYS LABORATORIES LTD	9	8		2				19	4	4
10 APOTEX INC.	10	5	1	3				19	8	-
11 EUGIA PHARMA SPECIALITIES LIMITED	2	14		2				18	2	1
12 LUPIN LIMITED	11		2		2			15	4	1
13 NANJING KING-FRIEND BIOCHEMICAL PHARMA		15						15	1	-
14 MANKIND PHARMA LTD	6	4		2	2		1	15	-	1
15 ACCORD HEALTHCARE INC	7	7						14	4	-

Yellow shaded companies are from India- Parent Company considered for all ANDAs

## Trainings in pharma: Challenges and solutions

**Subrata Chakraborty**, GxPFont Consulting, INOVR Trainings explains how VR-based training environments can simulate actual shop-floor environment and provide an auto guided immersive training platform in pharma



If we look at the trend of recent regulatory citations, to me, most of them could be directly or indirectly attributed to personnel capability or practice-related issues. Obviously, human performance variability and its impact on product quality have clearly grabbed the attention of regulators world-wide. This is also evident from the newly published EU annexe-1, which has such an elaborate section on 'Personnel' as compared to its last update in 2003, with an increased reiteration of the word 'training' from 5 to 10 times in the current revision.

This is apparently leading to increasing focus of the pharma organisations to make training an important pillar of their quality systems. However, many top leaders of such organisations still wonder - why do so many people in the company fail to perform in the right way, even after going through the training programmes each year?

This is an obvious question, but the answer lies deep



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inside our current training systems in the pharma industry. A lot of previous research on this subject points towards the following reasons for training not being effective:

- ◆ Trainees do not receive the intended message fully because of barriers like language, attention or prior knowledge on the subject.
- ◆ They are not able to understand the criticality or usefulness of the subject they are trained on.
- ◆ They do not believe that the new methodology will work for them or it is any better than the current practice.
- ◆ They are also hesitant to try new ways as they are afraid it might increase their workload or cause any inconvenience.
- ◆ Current facility and process design doesn't support the implementation of new learnings.

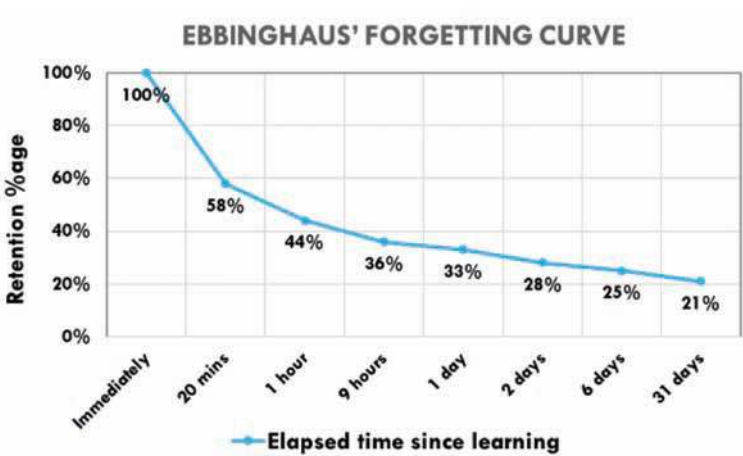


Figure 1

◆ New learnings are lost very fast due to the unavailability of opportunities to practice on the ground. In such

cases, it's unable to overcome the existing habits.  
◆ There is no mechanism to accu-

are theoretical. This is due to obvious reasons of contamination of critical areas or possibility of loss of costly products and machine downtimes.

So how do you expect your trainings to be effective and trainees retaining what they are taught for long time?

This is like the 'chicken-and-egg story'. On one hand, you cannot expect the trainees to gain reliable skills/knowledge without practicing what they learnt or applying their new learnings on the ground – on the other, you cannot allow them to practice/perfor-

form at actual shop floor before they are fully trained and certified. Then, what is the solution?  
There could be only two options to solve this puzzle:  
◆ Creating a training facility where all the required infrastructure is present

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Figure 2

rately evaluate the trainees' competency before deployment on a job.

The experiment by the German psychologist, Hermann Ebbinghaus, well known as the "Ebbinghaus forgetting curve", demonstrates the information received is forgotten over time very fast when no systematic efforts are made to retain it (Figure 1).

A similar research by the National Training Laboratories (NTL) Institute finds that the effectiveness of training can be highest when you teach someone else or use the training immediately or practice what you learnt. On the contrary, it is least effective if it is class room training or you learn by self-reading (Figure 2).

The challenge today in the pharma industry is that we over rely on class room trainings and SOP readings with limited scope for on-the-job trainings for critical processes. In most of the cases, trainees do not get the opportunity to use their learnings immediately or practice their newly acquired skills/knowledge before they are actually qualified for a job role. Further, most of the post training assessments

similar to an actual commercial facility with provision for test materials and experienced trainers. Although this could be an ideal scenario for training associates on people dependent critical operations like in aseptic manufacturing or sterility testing, but it needs a huge investment to maintain a parallel facility with utilities and material supplies, hence not always a good option.

◆ The second option is virtual reality (VR)-based training environments. Virtual Reality offers a huge opportunity to simulate an actual shop-floor environment near to real and provide

an auto guided immersive training platform that solve all the problems discussed above. VR as a training mode offers several advantages over the conventional trainings in pharma. Some of them are listed below:

**a) Practice options:** Once the right way to perform a task is explained, VR offers the opportunity to practice in a risk-and pressure-free environment, without any equipment downtime, environmental contamination or material wastage.

**b) Instant correction:** It provides instant feedback for all errors along with direction for correction. Participants get multiple opportunities to correct a practice till they are perfect on the task.

**c) Auto-guided trainings:** VR based training do not need a human trainer to communicate the message or evaluate the performance post trainings. The entire program is auto-guided with final evaluation of training results. This allows participants to take this training at their own convenience without waiting for any trainer.

**d) Better understanding:** Visualisation of mistakes or error situations and its impact on the product and patients offer a deeper understanding of the 'why' behind each process and practice. This increases employee buy-in on the new subject.

**e) Better knowledge retention:** Since VR trainings work on audio-visuals, demonstrations and practicing options, it boosts knowledge retention several times higher than conventional training modes.

**f) Better employee engagement:** With participants enjoying the whole experience and able to get aligned to the communicated message, the overall performance improves, which results in better employee engagement.

**g) Better efficiency:** The end result is increased efficiency of training, reduction of overall training expenditure, reduction of human errors and related regulatory citations.

### Conclusion

It's the need of the day to change the current training systems in pharma industry to move beyond a check box exercise to a real value-adding tool. The regulatory push that we are seeing in recent days is clear indication towards that.

However, we won't be able to bridge this gap due to the inherent limitations in this industry, unless we adopt new technologies like virtual reality. VR has already a time-tested history in many industries, but still remain a huge untapped opportunity for pharma. Once

leveraged to its full potential, it can be a game changer.

### References

1. Easygenerator blog - "How to beat the forgetting curve" by Kasper Spiro
2. NNE article on Digitalization - "Virtual reality boosts daily

operations in pharma manufacturing"

3. Pharmaceutical Online article - "Reviewing FY2017 FDA 483s: Training Failures Or A Learning Paradigm?" By Troy Fugate
4. EU GMP Annex-1 - "Manufacture of Sterile Medicinal Products"

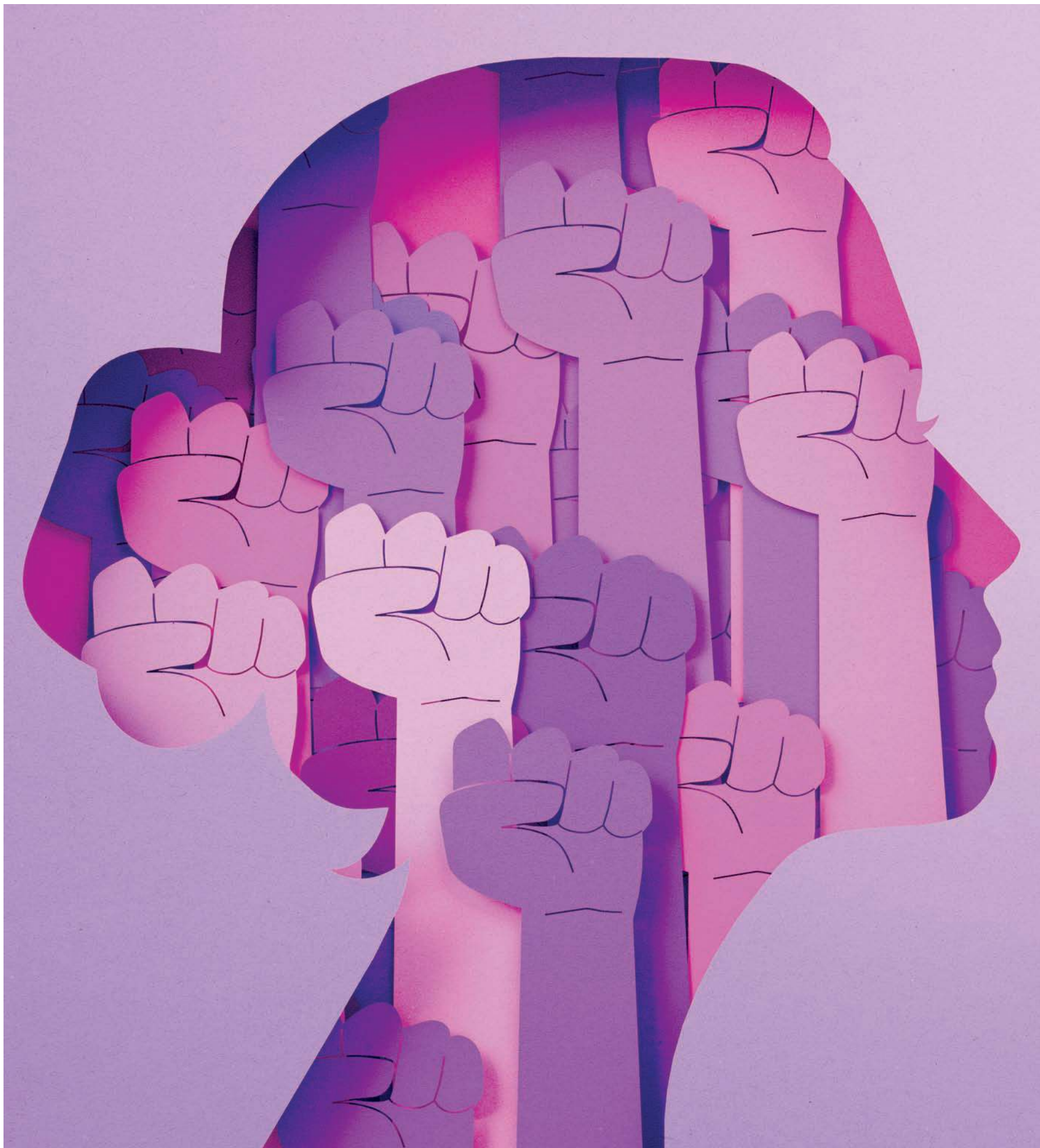


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# WOMEN'S HEALTH: ON THE CUSP OF A REVOLUTION?

In this Women's Day Special issue, **Lakshmipriya Nair** explores the growth potential, challenges and white spaces in the women's health segment as it evolves and advances

Considered as a mere subset of healthcare, women's health has often been overlooked and underserved. Studies inform that modern medicine was developed with male physiology in mind and as a result, women have been underrepresented in clinical trials too. Social and cultural taboos that limit and hinder conversations on sexual and reproductive health have also acted as barriers to women's health.

However, in the recent past, we have been witnessing a gradual shift, leading to the creation of an ecosystem which is more conducive to women and geared towards their better health outcomes. Novel products with superior routes of administration are being designed and launched specially for the female physiology.

Reenita Das, Partner, Senior VP, Healthcare and Life Sciences, Frost & Sullivan informs, "The market for female health products has received a wave of publicity recently. There is strong momentum in the larger market toward the 'Sheconomy' and the impact of women as consumers and commercial entities. Because of this wave of social trends, the focus on women's health is center stage today."

Expressing similar views in an earlier article covered in **Express Pharma**, titled, '*Is Women's Health Gaining Momentum*', Suchi Ray, Partner, Deloitte says, "In today's times, pharma companies in the women's healthcare space are expanding their R&D base and increasing the efforts to expand beyond reproductive health into key women's health areas."

The industry seems to agree with these views. Yash Singh, Founder & CEO of Frimline, a company which recently launched a toothpaste specially designed to address oral issues of women, explains, "Addressing the unique healthcare needs of women has been gaining traction. The industry too is more conscious of the trend now."



Source: Frost & Sullivan

### Winds of change

There are strong tailwinds spurring progress in this segment. A report from Fortune Business Insights informs that the India women's health therapeutics market is projected to grow from \$2.22 billion in 2022 to \$5.98 billion in 2029, at a CAGR of 15.2 per cent in forecast period. While there are several factors contributing to the evolution of this segment, some of key drivers of this transformation are:

◆ **Growing health awareness among women:** A changing mindset led by education is helping women break taboos surrounding their health and enabling them to seek diagnosis and subsequent treatment for their illnesses at the right time. Women are now learning to prioritise their health and create a demand for healthcare products and services that are better suited for their well-being.

Singh outlines, "There is a growing awareness on health and well-being among the Indian women resulting in a rise in the demand for

products that can help address their health issues. Even in the daily lives of women, there is significant opportunity to introduce self-care products that positively impact their well-being. For example, we recently launched Dente91 She, India's very first toothpaste designed exclusively to address oral issues of women. The correlation between various hormonal changes women go through their lives, and its impact on women's oral health is not widely known. This prompted the inception of product."

◆ **Advancements in R&D:** A report from McKinsey on '*Unlocking Opportunities in Women's Healthcare*', states, "A suite of scientific advances can now be harnessed in women's health. Recent advances in genomics, tissue engineering, and cell and gene therapy are ushering in a new wave of healthcare innovations that can be applied to underserved female-specific conditions. For example, researchers are studying transcriptomics (the study of all RNA molecules in a cell) for

treating otherwise elusive conditions such as preeclampsia or preterm birth. Others are now using tissue engineering to create uterine organoids in order to push the knowledge frontier on endometriosis. The potential is vast to redefine a host of conditions, including endometriosis, preeclampsia, and unexplained infertility, and to achieve advances to the degree that researchers are already achieving with oncology and immunology. Investors, researchers, and companies alike have an opportunity to participate in this rising wave of innovation and to deliver a new era in women's health."

◆ **Rise in FemTech:** FemTech, a word to describe tech-enabled solutions addressing women's health, has gained a lot of prominence in the recent times. A report from McKinsey called, '*The dawn of FemTech revolution*', reveals, "FemTech's current market size range from \$500 million to \$1 billion. Forecasts suggest opportunities for double-digit revenue growth. On the digital health front,

FemTech companies currently receive three per cent of all digital health funding. In our scan of hundreds of FemTech companies, we found concentration in maternal health patient support, consumer menstrual products, gynecological devices, and solutions in fertility. Funding reached \$2.5 billion by early December 2021."

Express Pharma's article on '*Is Women's Health Gaining Momentum*', also quotes Arvind Sharma, Partner, Shardul Amarchand Mangaldas and Co, who says, "With 50 per cent of the population as target customers, and with the women's healthcare market expected to reach \$50 billion by 2025, FemTech is the key focus area in the women's health market, and this is the right time for pharma companies to increase presence in this sector. In this tech-dominated scenario, connected devices and mobile applications will provide key and timely solutions to women. New business models such as telemedicine and remote monitoring platforms will emerge and are expected

to play a key role in the women's health segment. There is a lot of potential in the women's healthcare segment in India, and this will attract top global investors."

Das from Frost & Sullivan enlightens, "Trends toward using digital technologies for monitoring, prevention and personalisation through apps or digital devices are becoming commonplace. Patients are getting empowered about their health and starting to use online forums and chats to get information. There is the emergence of a new woman who is highly influenced by social media. In fact, 80 per cent of all decisions that women make today are driven by social influencers."

FemTech is definitely bringing about a revolution in women's health.

#### Rapid growth

Existing and emerging companies have begun expanding their offerings to cover a wide range of women's health issues like menstruation, skin and hair care, PCOS, mental health, sexual health, reproductive issues, fertility and pregnancy.

Let's take a look at some of the subsets where we are seeing phenomenal growth:

◆ **Feminine hygiene and menstrual health:** A report by Mordor Intelligence predicts that India's feminine hygiene market witness a CAGR of 14.7 per cent over the next five years. As per market analyses, rising awareness about intimate hygiene and innovations in menstrual products like sanitary pads, tampons and panty liners, are contributing towards the growth of feminine hygiene market in India. Government initiatives to promote menstrual awareness among women and adolescent girls have also helped.

As a result, a lot of newer entrants in this segment such as Avni, Milder Cares, Nua, Padcare, The Woman's Company etc. Leading brands are also entering and expanding

their offerings in this space. For instance, Cipla unveiled 'Evexpert', its range of feminine hygiene products in March last year, while FMCG major Dabur forayed into this

space with its new brand 'Fem' in December 2022. Piramal Pharma also forayed into the feminine intimate care category in 2021. Existing products like J&J's

Stayfree and P&G's Whisper have also introduced product variations and innovations to deal with growing competition.

Sujata Pawar, Co-founder

& CEO at Avni, a feminine hygiene and menstrual healthcare startup, shares more details about the growth drivers in this space. She points out, "Over the last decade,

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the feminine hygiene market has experienced consistent growth. The key growth drivers are increasing female literacy, rising disposable income among women, growing awareness of intimate health issues, and better access to menstrual products. The acceptance and prominence of new-age sanitary products have also contributed to the elimination of many menstrual taboos.”

“The availability of safe and affordable menstrual and reproductive products reduces their risk of infection. This has the potential to have a cascading effect on overall sexual and reproductive health, such as lowering teen pregnancy as well as aiding in maternal decisions, and reproductive success,” she adds.

“The market for feminine hygiene is now characterised by continuous expansion. Menstrual cups, sanitary pads, toilet hygiene, tampons, and other feminine products are the most often used products that fall under the disposable category. A highly dynamic market has resulted from customers' recent shift in behaviour towards environmentally friendly options. The market for feminine hygiene is characterised by a variety of novel goods, including tampons and menstruation cups made of organic or biodegradable materials,” reiterates Sandeep Vyas, Founder of Mild Cares and GynoCup.

◆ **Female contraceptives:** As Indian women get empowered to own certain choices about their health and body, there is a growing demand for safe, sustainable contraceptive tools as well. So, we are seeing the emergence of several options in this space such as female condoms, intrauterine contraceptive devices (IUDs), wider range of birth control pills, injectable contraceptives, hormone-releasing contraceptive devices like implants and vaginal rings, patches that can prevent pregnancies etc. Some of the players in this space

include Bayer, Pfizer, Merck & Co, CooperSurgical, Reckitt Benckiser, AbbVie, Johnson & Johnson, Lupin Pharmaceuticals, Viartis (Mylan Laboratories), Church & Dwight, The Female Health Company, Mayer Laboratories, Durex, Mankind etc.

A study published in *The Lancet* on worldwide contraceptive use last year reveals, that women of reproductive age (15-49) in India who need to prevent pregnancies but have no access to contraceptives have come down by over 13 percentage points between 1970 and 2019. The study also informs that over 160 million adolescents (15-19 years) and women (20-49 years) “remain with unmet need for contraception worldwide”, however ‘demand satisfied’ category has increased from 55 per cent in 1970 to 79 per cent in 2019.

◆ **Infertility treatments:** The demand for fertility

treatments and services is growing in India.

Das reiterates, “Infertility is becoming a big issue globally, including in emerging markets, where the rates are increasing drastically. Because of this, access to infertility treatments and monitoring is going to become very important, with lots of focus on wellness, diet and nutrition.”

According to a report published by Allied Market Research on India's in vitro fertilisation market, “Women comprise the largest market share of nearly two-thirds of the total market revenue in 2020, and are expected to exhibit prominent growth during the forecast period, 2021-2030.”

Growing incidence of male and female infertility, late pregnancies, technological advancements in ART procedures, increasing rates of success in IVF, and rise in

disposable income in India etc are contributing to advancements and growth of this market. While reports inform that while the paradigm of fertility drugs haven't witnessed drastic change, the market today definitely has better versions of the original fertility drugs. Moreover, rising number of fertility clinics and opportunities in emerging markets are expected to help market expansion in future.

### Women's nutrition

The women's nutrition market in India is also seeing a boom. Alongwith major players such as Abbott, GNC Holdings, Amway India, Bayer, Danone, Unilever, Nestlé, GSK, etc., this field also has seen a lot of new entrants such as Kapiva, Sudeep Nutrition, Chicnutrix, Oorah Nua and others offer products that serve women's needs ranging from PCOS to pregnancy, menopause and motherhood.

Swelling demand for healthy lifestyle choices and growing vitamin deficiencies in women are also driving robust growth in the women nutrition market.

In Express Pharma's earlier article titled, ‘*Evolving landscape of Women's Nutrition*’, Shanil Bhayani, ED, Sudeep Nutrition informs, “Women are growing aware of the importance of consuming essential nutrients in the right quantity. As it stands, many women have incorporated nutraceuticals in their daily lives to treat menstrual disorders as it has anti-inflammatory and smooth muscle relaxing properties. We are witnessing a growing trend for cranberry and bearberry-based nutraceuticals that are preferred by young adults to treat urinary tract infections, a common bacterial infection in women. We have seen many women who have turned to nutraceuticals to stimulate

## Approximately 1 percent of healthcare research and innovation is invested in female-specific conditions beyond oncology.

### Share of investment in female-specific conditions

\$ Annual R&D spend size

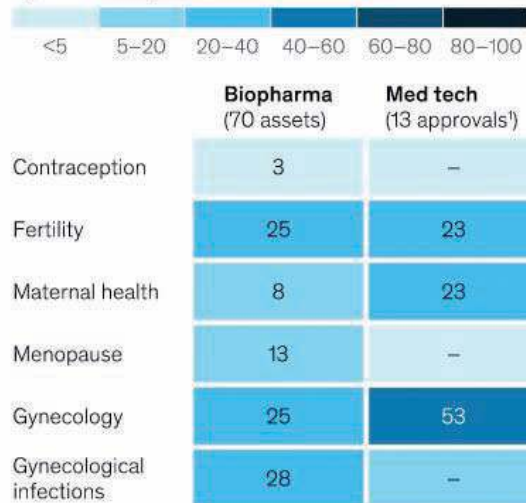
Biopharma, clinical-phase assets, 2020



Med tech, novel approvals, 2011-21



### Distribution of female-specific assets, by condition, %



<sup>1</sup>Excludes 4 breast implant assets.

Source: Evaluate Medtech (accessed July 2021); Global Burden of Disease Study 2019, Institute for Health Metrics and Evaluation, 2021; Pharmaprojects (accessed July 2021); Report of the Advisory Committee on Research on Women's Health, Fiscal Years 2017-2018; Office of Research on Women's Health and NIH Support for Research on Women's Health, National Institutes of Health, Office of Research on Women's Health, October 2019

McKinsey  
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milk production in pregnancy. A lot of women are opting for nutraceuticals such as melatonin, vitamin E, chasteberry, flaxseed, etc. to manage life-altering symptoms of menopause."

Also quoted in the article is Ameve Sharma, Co-founder, Kapiva, who states, "To say that the women's nutrition market is ever-evolving would be an understatement. Every year, we see a new selection of ingredients and trends rise to prominence in this industry. With each passing day, women are becoming more and more conscious towards their lifestyle choices."

### White spaces in women's health

Though women's health segment is clearly poised to grow and evolve, challenges continue to exist. But, the challenges faced by the women's health as a segment can also present opportunities to create value and serve women's healthcare needs through innovative solutions.

Frost and Sullivan recently forecasted the growth opportunities in this field. (See the

top 10 in Figure 1)

The McKinsey report on 'Unlocking Opportunities in Women's Healthcare', also highlights, "The current global innovation pipeline reveals mismatches between health investments and health needs. The gap highlights some remarkable opportunities for improving women's health within female-specific conditions (See Figure 2)"

So, industry stakeholders outline some measures to optimise the growth potential in this segment.

◆ **Ramping up awareness and education:** Recommending awareness and education as the tools to deal with the issues and challenges women face today, Das says, "Many women suffer for almost two decades from menopause, and they are not even aware of or prepared for these debilitating symptoms. It is important to provide systematic education. Second, governments and the private sector need to provide tools that women can access easily. Regular screening is also important, along with monitoring. Infertility insurance needs to be updated, and employers

need to include it in plans so that employees can access infertility treatments easily."

◆ **Increase in clinical research on women-centric diseases:** "Traditionally, women's health has been viewed as being synonymous with gynaecology and motherhood. However, the healthcare needs of women go much beyond. For example, heart diseases, joint health, oral health etc. have very different implications for women as compared to men. An increase in clinical research on women-centric diseases and introduction of appropriate treatment options and products that fill the whitespaces will help drive growth in this segment. It also requires replacing the gender-agnostic approach with a gender-specific lens," says Singh.

He adds, "Women are most affected by non communicable diseases (NCDs) such as heart diseases and cancer besides gynaecological and fertility related issues. Anemia is also a major concern for women across all age groups while osteoporosis and osteoarthritis are more prevalent among

older women. While there are numerous products available in the market, there is still an immense scope to introduce more products to address these issues."

◆ **Investments and policies to promote women's health:** There is a clear uptake in investments in women's health and many start-ups have sprung to cater to this segment. Many leading pharma companies have also expanded their offerings in this segment.

To cite a few examples:

◆ Bharat Serums and Vaccines (BSV) acquired Tidilan (Isoxsuprine hydrochloride), a brand in women's health, from Jagdale Industries in 2022

◆ Dr Reddy's and Mayne Pharma have signed an agreement in February 2023 to buy the latter's generic products portfolio which includes about 45 commercial products, including a number of generic products focused on women's health.

However, despite a few measures in the right direction, we need a lot more investment both at the public

and private stakeholder level.

There are significant white spaces that need to be filled to expand access and availability of women's health. Adequate 'gender budgeting' is also an imperative to enable sustainable progress in women's health.

As a report from Emcure released in 2021 finds, "There is a need for women, organisations and the society at large, to become proactive when it comes to managing their health and nor malise conversations around critical aspect of women's health. For every being, physical, mental and sexual health is inter-related. Greater investment is required in women's health including more research to unlock new insights that could lead to new and innovative solutions for women."

### Protecting the future

Since the link between women's health and economic growth of communities and countries is undeniable, it is time to prioritise women's health and wellness through investment, and research.

*lakshmi priya.nair@expressindia.com*

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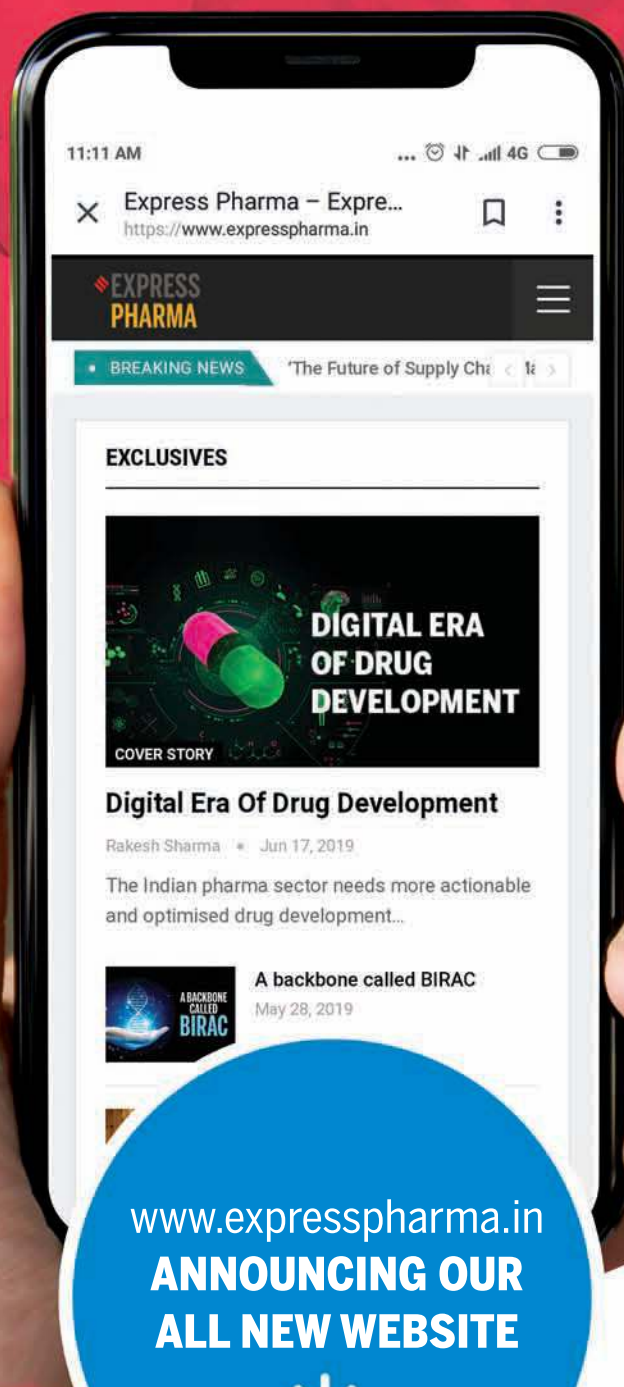
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Daman Pharma Summit brought leaders, experts and veterans of the pharma sector together to deliberate upon the opportunities and challenges in the Union territory and discuss strategies for India's pharma industry

**E**xpress Pharma, a leading industry publication from The Indian Express Group, recently the Daman Pharma Summit on January 20, 2023, at The Deltin Hotel, Daman under the theme, 'Sustaining and spear-heading growth: Through pandemic and beyond.'

Daman, with its proximity to major cities like Mumbai and Surat, good connectivity via road, rail, air and water, growing infrastructure and conducive business climate, is key to the pharma sector. Consequently, a plethora of pharma companies has set up bases in the union territory.

Daman Pharma Summit



2023 witnessed leaders and veterans of the life sciences in-

dustry come together to discuss the strengths and advan-

tages that Daman brings to the table, as India Pharma Inc

charts its blueprint for progress. Experts from the UT's pharma sector also deliberated upon the discuss strategies to optimise growth potential and shared learnings from the COVID-19 pandemic to enable sustained progress in a rapidly changing global milieu.

Daman Pharma Summit 2023 focussed on key topics such as strategies to make and innovate in India; emerging opportunities and growth drivers in Daman, sustaining cost leadership with product excellence, Making quality cornerstone for growth, Best practices for regulatory compliance and growth etc..

### Effective implementation of Lean Six Sigma and 5s in pharma manufacturing

**R**ajkumar Shiroadkar, Sr VP, Sovereign Pharma spoke on effective implementation of Lean Six Sigma and 5s in pharma manufacturing at Daman Pharma Summit 2023. Shiroadkar, a Black Belt in Lean and Six Sigma, drew from his experience in delivering significant financial benefits under lean and six sigma methodology and expertise in 5S concept and process excellence, and shared several valuable insights with the audience.

He explained that the concept of lean production was pioneered by Toyota in the 60s and adopted by other Japanese manufacturers. Discovered later by western manufacturers in the 80s, it is known by many names: Toyota Production System, Just-In-Time, Lean Production etc. Though it was originally focused on manufacturing, now it is also ap-



Rajkumar Shiroadkar, Sr VP, Sovereign Pharma

plied to transactional and service environments.

He informed that Six Sigma is a disciplined, customer-cen-

tric, data-driven approach and methodology for reducing

process variation and eliminating defects. Speaking on 5S, he explained that it is actually systematic organisation of the working space with goal of eliminating *muda*.

He went to explain the various tools, methods and applications of these concepts. He also elaborated on quantitative and qualitative benefits of adopting these concepts in the pharma industry such as increase in employees' productivity, reduction of cycle time, production time and cost of purchased material, reduction of machines breakdowns, increase in quality and process stability, improvement in material control and health & safety, increase in available space for workplace etc. He also highlighted that a clean and tidy workplace leads to greater well being, increased motivation and improvement in the company's image.

## Role of active packaging in drug development

The role and importance of active packaging in drug development was covered very well by Dhairy Sharma, Technical Sales, Cilicant, through an insightful presentation at Daman Pharma Summit 2022. Accentuating packaging's pivotal role in drug development, he detailed how active packaging acts as a smart packaging solution to enhance the shelf life of a package system, when used in a scientific manner.

He also informed that as the names suggests, active packaging is functionally active and helps to maintain and manage some key aspects of the drug which helps to protect its efficacy and effectiveness. He explained that the volume of the bottle, oxygen transmission rate (OTR), moisture vapour transmission rate (MVTR), RH, temperature condition and the shelf life are very crucial considerations. Sharma also elaborated on the vital connection between moisture content and water and informed that moisture content is quantitative in nature, and a driving force that decides how one can choose the right packaging.



Dhairy Sharma, Technical Sales, CILICANT

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ture content is quantitative in nature, and a driving force that decides how one can choose the

right packaging.

Giving more details about his company and its active

packaging solutions that help pharma companies' to protect and preserve their drugs, he explained about Accuflip, an equilibrium relative humidity (ERH) regulator. Giving more details about the solution, he said that it regulates the ERH to 20±5 per cent RH within the enclosed primary packaging, thereby preventing over-desiccation of capsule cells and protecting the product. He also explained how over-desiccation can adversely affect the efficiency and efficacy of pharma products.

Speaking further, he pointed out that Accuflip has a specialised sorbent which adsorbs and deabsorbs the moisture at the same time. He elaborated on the relation between water activity and ERH accentuated that active packaging should be used wisely to get optimal outcomes, since the right solution at the right time is really important.

## Sustaining cost leadership with product excellence

Tapas Kumar Mahapatra, VP-Operations (Daman & Indore), Alkem Laboratories spoke on a very pertinent and interesting topic, 'Sustaining cost leadership with product excellence', at Daman Pharma Summit 2023. At the outset of the presentation itself, he established the importance of balancing cost and quality. He pointed out that organisations either tend to overspend to deliver their services or compromise on quality if adequate budgets are not allocated to each function, unless costs are managed properly.

Then, he went on share insights on the economics of innovation and explained how rising operational costs, diminishing returns on products, pricing pressures, changing consumer demands, new entrants in the market etc., affect the



Tapas Kumar Mahapatra, VP-Operations (Daman & Indore), Alkem Laboratories

growth of life sciences organisations. Emphasising that it is essential to strategise very care-

fully to survive and thrive in this dynamic and competitive landscape, he pointed out that bal-

ancing cost with product excellence requires integrated systems, optimised processes and

best practices.

His session covered several vital aspects such the need and approaches to ensure better overall equipment efficiency and measures to control and sustain costs in the long run while enabling quality. Some of the steps recommended by Mahapatra to control costs included integrated lines, mass production, automation, predictive maintenance, multi-skilling, energy management and optimum utilisation of resources.

He also spoke on improving quality for product excellence through steps like effective technology management, cross functional development, supplier quality management, layout optimisation, functional integration etc.

Thus, his session had several takeaways for the audience at Daman Pharma Summit 2023.

## Presentation by Omega Scientific Instruments

**N**VS Vishal, BD at Omega Scientific Instruments gave a presentation on his organisation's offerings and solutions for the pharma industry. He said that as technocrats with a passion for pharma and biotech modules, Omega Scientific Instruments has strong design capabilities, excellent biopharma installation capabilities, provides unmatched service support, and enables cost effective flexible modules of service support alongwith top notch fabrication skills for SS-316L application.

Sharing details about their product profile, he informed that it can be split into mainly two categories: bioprocess equipment for asptic processing for FR&D purposes and industrial production purposes (mixing vessels, pressure vessels, compounding vessels, holding tanks, receiving vessels, fermenters etc), and purified water and WFI generation and distribution systems along with



NVS Vishal, Business Development, Omega Scientific Instruments

PSGs and MCDP.

Giving an overview on the company's abilities to manufac-

ture customised FR&D vessels, he said that Omega specialises in tailor made-manufacturing

of products for various processes like simple mixing, mixing with heating/mixing

**Omega Scientific Instruments provides new-age bioprocess equipment for aseptic processing, FR&D and industrial production**

with cooling, particle reduction, dispersion and suspension mixing and scale up models and scale down models. He ended his presentation by assuring the audience that Omega Scientific Instruments is fully geared up to be a good partner for the industry's progress.

## NEXT Gen Lab Water Purification Systems

**M**eenu Bansal, Field Marketing Expert, Merck Life Sciences delivered a very interesting session on Merck's new product Milli-Q at Daman Pharma Summit. Through simple yet pertinent questions which informed and educated the audience about Merck's recent innovation which will help the pharma industry to tackle their day-to-day needs for purified water in their operations.

She informed that Merck Life Sciences' Milli-Q Lab Water portfolio offers a broad range of sustainable pure and ultrapure water purification systems designed for scientists working in pharma, clinical, academic, industrial, research, and government laboratories — in both validated and non-validated environment.

This latest launch has a lot



Meenu Bansal, Field Marketing Expert, Merck Life Sciences

to offer in terms of consistent water quality that can be adapted to every user's application requirements and comes with unique delivery design to dispense water in an optimal way.

Speaking more about the features of Milli-Q EQ 70XX Ultrapure water purification system, Bansal also informed that it has got three manual flow rates, check and dispense lights, one-check volumetric dispense, 'at-a-glance' quality monitoring, and rapid data and access management, among other qualities. It has 20 per cent reduced plastic weight, 33 per cent smaller and lighter purification cartridges, and provides >10 per cent overall energy savings and paperless data management. In addition, in the lab close mode, it optimises the rinsing process.

## Training strategies for compliance and growth in pharma and life sciences

**D**ynaneshwar Gawade, Head-Technical Training, USV gave an informative presentation on a very vital topic, 'Training strategies for compliance and growth in pharma and life sciences.' He kickstarted his session by highlighting the various challenges faced by pharma companies such as need for rapid launch of new drugs, exploring new markets, poorly written SOPs, high rate of attrition etc. Then, he accentuated the importance of training and the need for right strategies to deal with the above mentioned challenges. He also informed about the training guidelines by various regulatory agencies like European Commission and US FDA. His session also covered how training programmes



Dyaneshwar Gawade, Head-Technical Training, USV

can enable better quality and regulatory compliance as well.

Gawade pointed out that training is key to create Workforce 4.0 which can navigate and thrive in Pharma 4.0.

He also addressed a vital question: Is training an investment or cost? He said that looking at the benefits received from training such as employee satisfaction, better efficiencies, financial gains, capacity to adapt to new technologies and processes etc, training should definitely be looked at as an investment.

Stressing that training and skilling are vital to thrive and survive in the life science industry, he said that training initiatives should be synced with the strategic business goals of organisations.

## Polymeric product solutions for pharma industry

**P**rabhat Balyan, Assistant Manager, Ami Polymer and Dhruv Borda, Assistant Manager Sales & Marketing, Ami Polymer gave a very detailed presentation on polymer solutions for drug manufacturing process at Daman Pharma Summit 2023. The speakers shared vital information about the company's journey and its various achievements and milestones. Then they shared details about different kinds of tubings and polymers, their features, advantages and applications in the life sciences industry. The speakers explained how different drugs and dosage forms require different kinds of solutions are suitable for different drug products. They explained why these products are most suited for certain applications as well.

The speakers also addressed how polymeric products can ensure regulatory



Prabhat Balyan, Assistant Manager, Ami Polymer

compliance explained about the factors that need consideration to achieve regulatory compliance.

Listing down various factors to be considered while

choosing tubing solutions, the speakers said that the material of construction and components, class of the clean room, method of sterilisation used or to be used, absorption, adsorp-



Dhruv Borda, Assistant Manager Sales & Marketing, Ami Polymer

tion and compatibility to products, extractables and leachables, validation package, regulatory standard tested, sealing, welding capabilities, pump pressure, etc are very crucial.

The presentation ended with an assurance to the audience that Ami Polymer can help them with the right polymer solutions for their drug manufacturing process.

## Sterilisation and Isolator Technology

Daman Pharma Summit 2023 also comprised technical sessions which are relevant to life sciences industry. One of them was given by Sunil Karpe, Sr VP-Production & Projects, Sovevax Biologics. His topic at the event was sterilisation and isolator technology.

He began his presentation by explaining the process of sterilisation and need for it in the life sciences industry. Then, he went on to explain each type of sterilisation i.e. physical sterilisation, chemical sterilisation, sterilisation by radiation and sterilisation by filtration. He explained each process, their applications and their need in detail.

Karpe also spoke about different barrier systems such as open restricted access barrier system (ORAB), closed restricted access barrier system



Sunil Karpe, Sr VP-Production & Projects, Sovevax Biologics

(CRAB) and isolator system. In this session, he focussed on the different types of isolators and

how they operate using negative pressure or positive pressure.

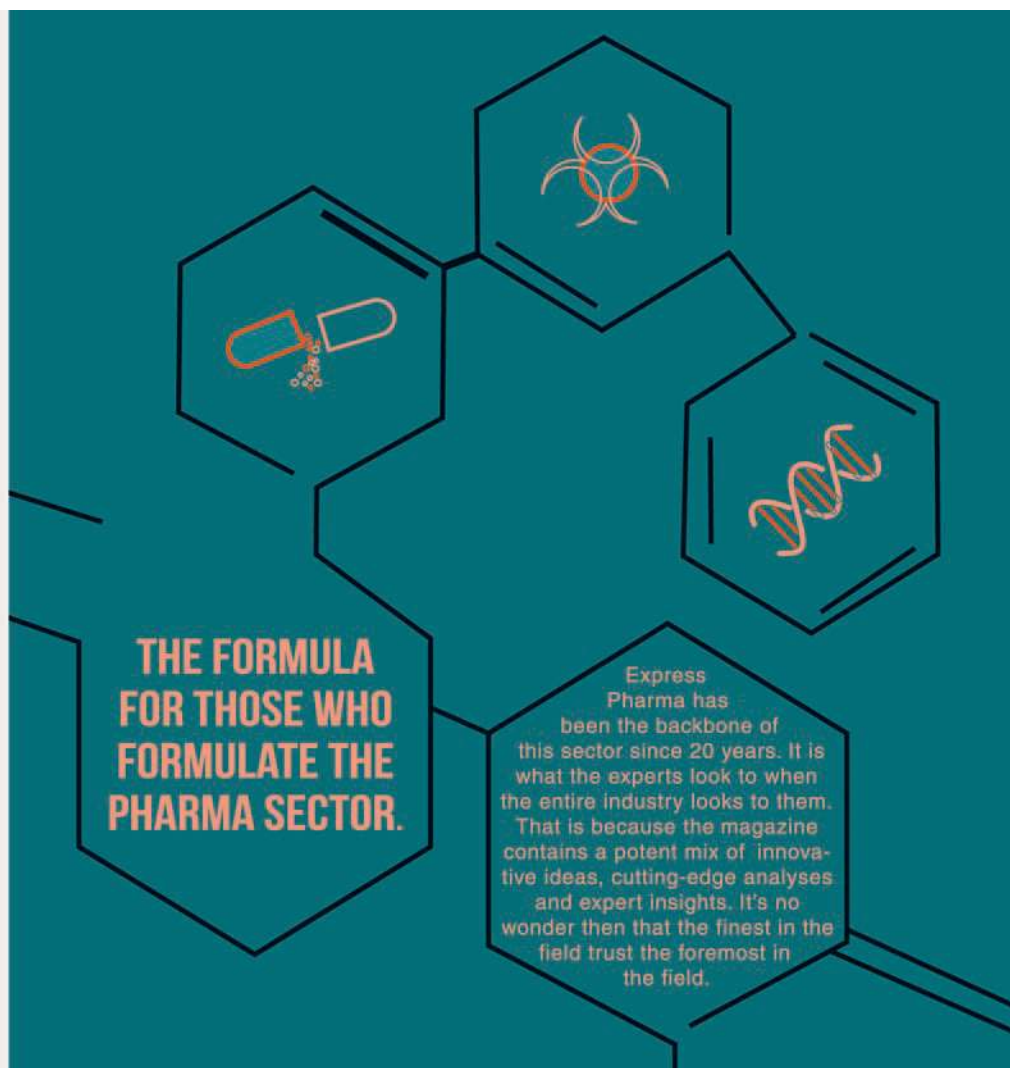
He informed that isolators

using negative pressure are used for oral solid dosage forms to handle toxic powders during

sampling, dispensing, process, testing. They are also used for non aseptic compounding in case of injectables. Positive pressure, Grade A, VHP sterile isolators are used for handling of all aseptic activities like filtration, filling, lyo etc.

Elucidating on the usage of isolators, he said that they are used to create a physical barrier between two different environments, i.e. background environment vs actual Grade A environment, wherever aseptic injectable products are handled. He said that they provide high assurance on sterility, make it easy to handle toxic products, hormonal products and steroidal products, as well as ensure that biotech products are safe from contamination due to humans or background environment.

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# Formulation and development of diclofenac sodium enteric coated tablets 50 mg using ECOPOL L30D-55

**Deepak Yadav** and **Dr Jitendra Amrutkar** from Ideal Cures, Mumbai present a study that demonstrates that aqueous enteric coating with ECOPOL L30D-55 system is an easy and economical approach for preparing stable delayed release formulations

Diclofenac sodium is a non-steroidal anti-inflammatory drug (NSAID), widely used to control pain and for the treatment of rheumatic arthritis<sup>1</sup>. The conventional immediate-release diclofenac sodium tablets make the drug immediately available for absorption in upper part of gastrointestinal (GI) tract resulting in local GI toxicity<sup>2</sup>. The usefulness of NSAID is sometimes limited by gastrointestinal side effects, such as indigestion, mucosal erosion and ulceration. It has been reported that the gastrointestinal track toxicity is not only caused by the inhibition of the prostaglandin synthesis but is probably also due to direct contact of the drug with the mucosa<sup>3</sup>. Diclofenac sodium is a phenylacetic acid derivative with pKa of 4.0, whose solubility as low as 1 mg/mL in acidic solutions is markedly dependent on the pH of the medium<sup>4</sup>. Diclofenac sodium shows better solubility above pH 6.5 and it is also important to protect the salt of diclofenac from gastric juice degradation to avoid the loss of drug bioavailability<sup>5</sup>. Enteric coating of solid dosage forms containing diclofenac sodium are recommended to prevent such side effects without negatively affecting the availability of the drug.

Several polymers can be used for enteric coating, coming from animal origin: Shellac for example (ester of aleuritic acid), synthetic origin: poly (methacrylic acid-co-methyl methacrylate), Polyvinyl Acetate Phthalate (PVAP), or based on cellulose: Cellulose Acetate Phthalate (CAP), Hydroxypropyl Methylcellulose Phthalate (HPMCP) and Hydroxypropyl Methylcellulose Acetate Succinate (HPMCAS).



Deepak Yadav

The pH-sensitive copolymers, such as methacrylic acid/methyl methacrylate copolymers ECOPOL enteric polymers are commercially available. ECOPOL L30D-55 is aqueous dispersion of anionic polymers with methacrylic acid as a functional group. It is a low viscosity liquid of white colour with faint characteristic odour. It is obtainable in the form of aqueous dispersion (30 per cent).

The aim of present study is to evaluate the enteric property of ECOPOL L30D-55 polymer on diclofenac sodium 50 mg tablets.

## Materials and methods

Diclofenac sodium purchased from Aarti Drugs Limited Mumbai, Lactose Monohydrate (K.P. Manish Global Ingredients Pvt. Ltd.), Sodium starch glycolate (Prachin Chemicals), Magnesium stearate (Scope Ingredients), Talc (Udaipur Minerals Development Syndicate Pvt Ltd), ECOPOL® L30D-55 (Ideal Cures Pvt Ltd). All the other used chemicals and reagents were of analytical grade and obtained from commercial sources.

## Preparation of diclofenac sodium tablet



Dr Jitendra Amrutkar

Diclofenac sodium tablet prepared by direct compression method. The required quantity of diclofenac sodium, lactose monohydrate, sodium starch glycolate and talc weighed according to Table No. 1 and passed through sieve # 60. The sifted mixture was transferred into rapid mixer granulator for dry mixing. Weighed quantity of magnesium stearate was sifted through sieve # 60 and added to the mixture. This blend was then transferred to octagonal blender and lubricated for two to three minutes. The lubricated blend was then compressed into tablets using 8 mm standard convex punches plain on both sides.

## Evaluation of core tablets

### a. Pre-compression

The powder blend was evaluated for pre-compression parameters such as angle of repose, bulk density, tapped density, Carr's index and Hauser's ratio.

### b. Post compression

#### i. Tablet physical properties testing

The compressed tablets were evaluated for average weight, thickness, hardness, and friability test.

#### ii. Assay

Drug assay was determined in accordance with the USP monograph for diclofenac sodium tablet<sup>6</sup>.

#### iii. Disintegration testing

The time taken for all the tablets to disintegrate completely in 0.1 N HCl at temperature  $37 \pm 2^\circ\text{C}$  was noted.

#### iv. Dissolution testing

Dissolution testing of diclofenac sodium core tablets was carried out in pH 6.8 phosphate buffer using USP type 2 apparatus (paddles) at 50 rpm. Sample aliquots were withdrawn at 10, 20, 30 and 45 minutes time interval and analysed for amount of diclofenac released<sup>6</sup>.

## Subcoating

Diclofenac sodium core tablets were seal-coated to a three per cent weight gain with INSTACOAT Universal reconstituted at 10 per cent solid in purified water. The coating process parameters employed in the coating operation are listed in Table No. 2.

## Preparation of subcoating dispersion

1. Weighed quantity of purified water was taken in a mixing vessel.
2. Using the mechanical stirrer,

stirred the purified water to form a vortex.

3. Required quantity of Insta-coat Universal was added to the center of the liquid vortex in a slow steady stream, avoiding clumping and maintaining a vortex.

4. After addition of Insta-coat Universal, stirrer speed was reduced to eliminate the vortex. The mixing was continued for 45 minutes.

## Enteric coating of diclofenac sodium tablet Preparation of enteric coating dispersion

1. Homogenised the weighed quantity of Titanium dioxide, Talc, Polysorbate 80 and plasticizer into 1/3 of purified water for 30 minutes.
2. Sodium Hydroxide solution was prepared by dissolving it into remaining quantity of purified water.
3. Under continuous stirring, sodium hydroxide solution was then added in ECOPOL L30D-55 dispersion and the stirring was continued for 30 minutes.
4. Homogenised colloidal dispersion was then added into ECOPOL L30D-55 dispersion under continuous stirring.
5. The final enteric coating dispersion was then filtered through sieve # 60 and used for enteric coating of seal coated diclofenac sodium tablets. The enteric coating dispersion was continuously stirred throughout the process to avoid settling. Sample were taken after 10 per cent of weight gain<sup>7</sup>.

## Coating process parameters

## Evaluation of enteric coated tablet

### a. Assessment of acid uptake

Diclofenac sodium enteric coated tablets were individu-

Table No. 1: Formulation of Diclofenac Sodium Tablet

Sr. No.	Ingredients	Quantity	
		Percent	mg/Tablet
1.	Diclofenac Sodium	25	50
2.	Sodium Starch Glycolate	8	16
3.	Lactose Monohydrate	65	130
4.	Magnesium Stearate	1	2
5.	Talc	1	2
	Total	100	200

Table No. 2: Process parameters of seal and enteric coating

Coating process parameters	Seal coating	Enteric coating
Equipment	Conventional coating pan	Conventional coating pan
Pan size (inch)	12	12
Nozzle bore (mm)	1	1
Inlet air temperature (°C)	45-50	40-45
Bed temperature (°C)	40-42	30-35
Spray rate (gm./min)	1	1
Atomizing air pressure (Bar)	1	1
Pan RPM	20-30	20-30
Curing	45 min at 40 °C at low RPM	45 min at 40 °C at low RPM

ally weighed and reciprocated for two hours in the test media, 0.1 N HCl solution in a USP disintegration apparatus at  $37 \pm 2^\circ\text{C}$ . At the end of this time interval, all the tablets were removed from the disintegration bath and inspected for any defects (bloating or swelling). Any excess surface moisture was gently blotted dry using a tissue paper, and the tablets were reweighed individually. The percent liquid uptake for a tablet was calculated according to the formula given below. It should be less than 10 per cent liquid uptake has shown to correlate to acceptable enteric protection for tablets<sup>6</sup>.

#### Whereas:

$$AU (\text{per cent}) = [(T_f - T_i)/T_i] \times 100$$

**AU (per cent):** Percent liquid uptake

**T<sub>f</sub>:** Final tablet weight (mg)

**T<sub>i</sub>:** Initial tablet weight (mg)

#### b. Acid resistance

The amount of diclofenac sodium drug released in the 0.1 N HCl after two hours is calculated in acid stage, and it is commonly limited to 10 per cent or less of the labeled content.

#### c. Disintegration testing

Diclofenac sodium enteric coated tablets that were observed to be physically intact following the liquid uptake test in 0.1 N HCl were then reciprocated in the disintegration apparatus using pH 6.8 phosphate buffer maintained at  $37 \pm 2^\circ\text{C}$  as the immersion liquid. The time taken for all the tablets to disintegrate completely was noted<sup>6</sup>.

#### d. Assay

Drug assay was determined in accordance with the USP monograph for diclofenac sodium delayed release tablets. The USP specification states

that the tablets contain not less than 90.0 per cent and not more than 110.0 per cent of the labeled amount of diclofenac sodium<sup>6</sup>.

#### e. Dissolution testing

Dissolution testing was carried out in accordance with the USP monograph for diclofenac sodium delayed release tablets. Drug release was determined using a USP compliant, Apparatus type 2 (paddles) at 50 rpm. At the end of the acid stage, (two hours in 900 mL 0.1 N hydrochloric acid), an aliquot was withdrawn and tested for the amount of diclofenac sodium drug released. The specification for the acid phase is not more than 10 per cent diclofenac sodium released. The acid (0.1 N HCl) was then drained from the vessel and replaced with pH 6.8 phosphate buffer. Sample aliquots were withdrawn from the phosphate buffer phase at 10, 20, 30 and 45 minutes time interval and analysed for amount of diclofenac released. The USP specification for the buffer phase is not less than 75 per cent drug released after 45 minutes<sup>6</sup>.

#### f. Stability studies

Stability studies of diclofenac sodium enteric coated tablets were carried out as per ICH guideline. The tablets were packaged in 100cc HDPE bottles and charged into stability chamber. Stability was monitored via acid resistance, drug release and assay of enteric coated tablets<sup>6</sup>.

### Result and Discussion

#### Evaluation of Core Tablet

- Pre-compression
- Post compression

#### Evaluation of enteric coated tablet

Table No. 3: Pre-compression parameters

Test	Result
Angle of repose (°)	28
Bulk density (gm/ml)	0.59
Tapped density (gm/ml)	0.69
Hauser's ratio	1.1
Carr's index	14

Table No. 4: Evaluation of Diclofenac sodium core tablets

Test	Result
Avg. weight (mg)	204
Hardness (kg/cm <sup>2</sup> )	3-4
Thickness (mm)	3.7-3.8
Friability ( per cent)	0.09
Disintegration time (minutes)	1
Assay ( per cent)	103
Drug release ( per cent)	More than 90 per cent in 45 minutes

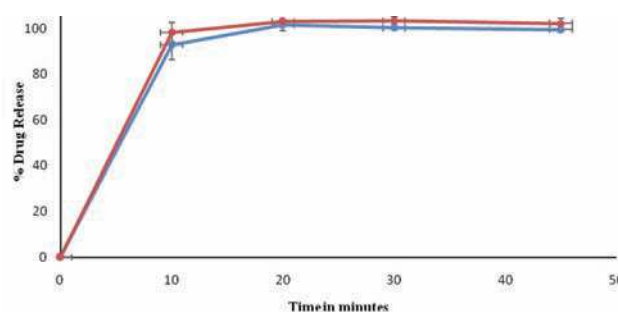


Figure No. 1. Dissolution of Diclofenac sodium core tablets in pH 6.8 phosphate buffer, n=2

Table No. 5: Tests of enteric coated Diclofenac sodium tablets

Test	Result
Acid uptake	3.78
Disintegration time (minutes)	4-5
Assay ( per cent)	105
Acid resistance ( per cent)	1.96
Drug release ( per cent)	More than 90 per cent in 45 minutes

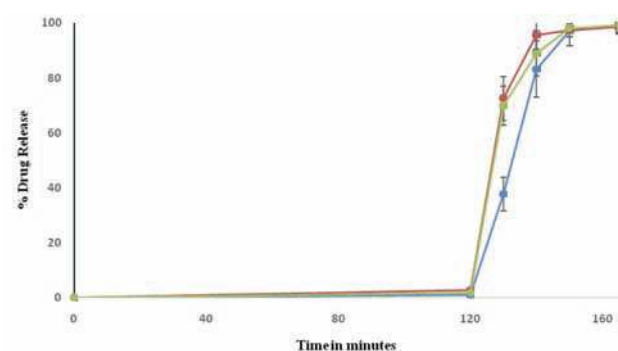


Figure No. 2. Dissolution profile of Diclofenac Sodium enteric coated tablets in 0.1 N HCl followed by pH 6.8 phosphate buffer (initial), n = 3

### Drug Release

Enteric coated Diclofenac sodium tablets passes the acid stage of the dissolution test for two hours in 0.1N HCl. More than 90 per cent Diclofenac was released in the pH 6.8 phosphate buffer within 45 minutes.

### Stability Studies

#### a. Acid resistance

Acid resistance of coated tablets stored at three months  $40^\circ\text{C}/75$  per cent RH is found to be less than three per cent of labeled content.

#### b. Drug release

Drug release testing indicates that the enteric coating continued to provide good protection in acid phase and more than 90 per cent diclofenac released in 45 minutes when stored for three months at  $40^\circ\text{C}/75$  per cent RH.

#### c. Assay

Assay of coated tablets stored at three months  $40^\circ\text{C}/75$  per cent RH met the USP requirements 90 per cent - 110 per cent of the labeled amount of diclofenac tablets.

### Result

The purpose of this study is to assess the enteric performance of ECOPOL L30D-55 on diclofenac sodium model drug<sup>5</sup>. In order to achieve good coating results, uncoated tablets should have good parameters to withstand the coating process. The obtained dry and appropriately lubricated blend had good flowability resulting in low tablet weight variation. The lubricated blend was compressed without any problem and the prepared tablets were free from tablet manufacturing defects such as capping and lamination. Tablets of good mechanical strength (3-4 kg/cm<sup>2</sup>) and low friability (0.09 per cent) were obtained. Physical appearance, hardness, friability, weight variation and drug content evaluation of the uncoated tablets were found to be satisfactory under pharmacopeial standards of tablet evaluation. In fact, tablets used in enteric coating process must be sufficiently hard to support mechanical stresses and should show a very low potential for powder loss and edge

Table No. 6: Tests of enteric coated Diclofenac sodium tablet at  $40 \pm 2^\circ\text{C}$  &  $75 \pm 5$  per cent RH

Period (months)	Acid resistance (per cent)	Drug Release (per cent)	Assay (per cent)
0	1.96	98.97	101.8
1	1.92	99.26	101.97
3	1.53	97.4	104.18

Note – Avg. of three batches were taken for acid resistance, drug release and assay.

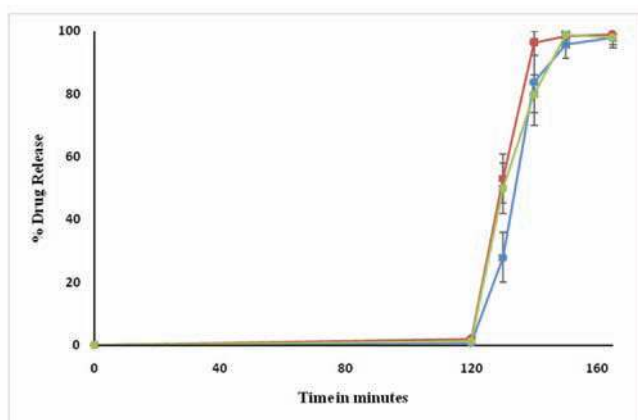


Figure No. 3. Dissolution profile of Diclofenac sodium enteric coated tablets in 0.1 N HCl followed by pH 6.8 phosphate buffer at  $1\text{ M } 40^\circ\text{C}$  /75 per cent RH,  $n=3$

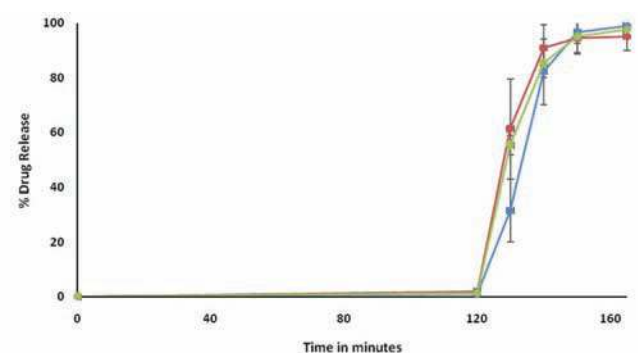


Figure No. 4. Dissolution profile of Diclofenac sodium enteric coated tablets in 0.1 N HCl followed by pH 6.8 phosphate buffer at  $3\text{ M } 40^\circ\text{C}$  /75 per cent RH,  $n=3$

chipping. Any defect in the uncoated tablet may result in localised weakness of the obtained enteric film coat. The core tablet was seal coated with INSTACOAT Universal. The seal coated tablet was enteric coated with the ECOPOL L30D-55. Although traditional aqueous functional coating formulations may require few component mixing steps before starting the coating process, this new formulation was dis-

persed in the minimum amount of time and produced desired percentage weight gain. The enteric coated tablets were without having any film coating defects such as roughness, orange peel appearance, chipping, tacking or other unacceptable flaws. The efficiency of the obtained enteric coat was determined by subjecting the coated tablets to gastric pH, and drug release, assay was analysed. In fact, the dis-

integration test of enteric coated tablets was satisfactory since Diclofenac sodium tablets enteric coated with ECOPOL L30D-55 showed complete acid resistance for two hours. The enteric coated tablets were completely disintegrated within 10 minutes when they placed in buffered solution at pH 6.8. In vitro drug release studies were carried out since these are considered the best tool for assessing in vivo drug behaviour. A passing result for the in-gastric (acid) portion of the test is equal to 10 per cent dissolved. A passing result for the intestinal (buffer) portion

avoid the presence of any clumps that could result in gun blockages or alteration of the smoothness of the enteric coat. The dispersion was continuously stirred during the period of the coating process to avoid sedimentation and coalescence of particles. Tablet coating was carried out in conventional coating pan using spray coating technique. During coating, all the parameters kept at optimum level in order to obtain the desired smoothness and uniformity of film coat. The enteric coated tablet coated with ECOPOL L30D-55 provides complete acid resistance with

gest that aqueous enteric coating with ECOPOL L30D-55 system is an easy and economical approach for preparing stable delayed release formulations.

## References

1. Brogen RN, Pakes GE, Speight TM, Avery GS. Diclofenac sodium: a review of its pharmacological properties and therapeutic use in rheumatic diseases and pain of varying origin. *Drugs*. 1980;20:24–48.
2. Carson J, Notis WM, Orris ES. Colonic ulceration and bleeding during diclofenac therapy. *N Engl J Med*.

**Diclofenac sodium tablets enteric coated with ECOPOL L30D-55 showed complete acid resistance for two hours. The enteric coated tablets were completely disintegrated within 10 minutes when they placed in buffered solution at pH 6.8**

of the test is equal to 75 per cent dissolved. The diclofenac sodium release met the criteria outlined in this study i.e., less than 10 per cent dissolved after 120 minutes in acidic conditions and higher than 90 per cent dissolved after 45 minutes in buffer solution at pH 6.8 as shown in. *Figure No.2*. Stability studies conducted were satisfactory, showing no significant variation in physical characteristics, colour, disintegration time, drug release and assay of the coated tablets. Percent dissolution and assay were within the acceptable limits of USP as shown in *Table No. 6*.

## Discussion

ECOPOL®L30D-55 is the aqueous dispersion of anionic polymers with methacrylic acid as a functional group. It is a low viscosity liquid of white colour with faint characteristic odour. It is obtainable in the form of aqueous dispersion (30 per cent). The preparation of the aqueous dispersion consists of a simple addition of the powder formulations, plasticizer, and anti-tacking agent. The obtained dispersion was sieved to

10 per cent weight gain. The enteric coated tablet met all USP specifications at three months accelerated stability condition. The obtained enteric coated tablets were stable, indicating high compatibility between Diclofenac sodium tablet and used ECOPOL L30D-55. All data indicated that the enteric coat was essentially unchanged and provided the desirable enteric protection.

## Conclusion

Delayed release diclofenac sodium was developed using ECOPOL L30D-55 system. Aqueous enteric coating was successfully conducted under lab-scale facilities. ECOPOL L30D-55 system provides acceptable enteric performance in terms of appearance, characteristics, stability and in vitro drug availability. The analytical testing results for all tested tablets, including both those stored at room temperature and those stored under accelerated stability conditions were within the specified criteria for passing results. Therefore, these findings sug-

- 1989;323:135–7.
3. Carson J, Notis WM, Orris ES. Colonic ulceration and bleeding during diclofenac therapy. *N Engl J Med*. 1989; 323:135–7.
4. L. Yang, R. Fasihi, Modulation of diclofenac release from a totally soluble controlled release drug delivery system, *J. Control. Release* 44 (1997) 135–140.
5. W.V. de Castro, M.A. Pires, M.A. Oliveira, C.D. Vianna-Souares, E.A. Nunan, G.A. Pianetti, L.M. Moreira-Campos, S.U. Mertens-Talcott, H. Derendorf, The influence of formulation on the dissolution profile of diclofenac sodium tablets, *Drug Dev. Ind. Pharm.* 32 (2006) 1103–1109.
6. United States Pharmacopeia 43/National Formulary 38 Online, 2020. <http://www.uspnf.com/uspnf/login>.
7. ECOPOL®- Pharma Acrylic Polymer- solutions, [https://www.idealcures.com/solutions/pharma\\_acrylic\\_polymers](https://www.idealcures.com/solutions/pharma_acrylic_polymers)
8. ICH Guidelines. Stability testing of new drug substances and products, Q1A(R2). Available at: <http://www.ich.org/cache/comp/o/363-272-1>.

# The digital dependency of genomics

**Anumodh K Sreedharan**, Senior Account Manager, Wipro highlights how organisations that offer services in Big Data & Analytics, AI/ML, cloud computing, and cybersecurity with expertise in genomics and life sciences will be uniquely positioned to be instrumental in the future of the life sciences industry

Genomics is the study of the genome, an organism's complete DNA set, and the interaction of genes with one another and their environment. Unlike genetics, which studies individual genes, genomics is interdisciplinary and focuses on the collective characterisation and quantification of all the genes in an organism.

DNA sequencing highlights the genetic information carried by a particular gene, while genomic sequencing provides information on genetic variations that contribute to the development of disease.

## Sync with Big Data and data analytics

Genomics data is a great example of the size and complexity of Big Data. In a perfect world, the entire genome can be encoded in about 700MB to 800MB of data. However, in the real world, it can require up to 200GB of storage to sequence the whole human genome.

The growth in genomics with its increased use of next-generation sequencing results in an exponential need to leverage Big Data analytics to identify clinically actionable genetic variants for precision genomic medicine. While integrating diverse genomic data with electronic health records poses challenges, it also provides an opportunity to develop an effective and efficient approach to identifying actionable genetic variants for personalised diagnosis and therapy.

## AI/ML in genomics

A key challenge to incorporating genomic data is the lack of standards for NGS data generation, data sequencing/processing, data storage, and clinical



Organisations in India that provide an end-to-end array of services for life sciences, from genomics labs to digital services through domain experts, will be the game changers for India's march toward leadership in genomics

decision support. Due to the frequent evolution of tools in NGS technology, it has been hard to establish standards. A lack of standards has led to difficulty in interoperability regarding data quality. These data management and analysis challenges can be overcome using AI/ML algorithms.

AI/ML also promises to simplify and speed up genome interpretation by integrating predictive methods. This opens a whole range of possibilities in

terms of predictive risks of diseases, not limited by generations. At the next level, this shall help identify the precise medical interventions that can prevent or treat such ailments.

While the use of AI/ML is very promising, it should be approached with caution as its analytical insights and results will have direct clinical impacts on patients.

## Ubiquity of cloud

Cloud computing is the perfect

fit for analysing genomic datasets quickly without maintaining and upgrading servers. Simply put, the pay-as-you-go model the cloud offers flexibility to scale up and down the computational power and storage as needed. This flexibility in computing is desirable for small and medium businesses in life sciences.

Despite the clear utility of the cloud to genomics, wide adoption of the technology is yet to be seen. The primary reason for the lack of adoption is the hesitancy of businesses regarding long-term costs. While storage is charged per gigabyte, the cost of computational power in the cloud can sometimes be five times the cost of onsite computation.

As more players come to the market, prices will become more competitive, and cloud technology in genomics will be here to stay.

## The security angle

As the British mathematician Clive Humby says, "data is the new oil." And just like oil over the past century, players across the spectrum, both public and private, are vying for data. The more complicated the data is to gather, the greater demand for it in the market. Genomics data is a perfect example of this making it a target of cyber threats. A potential attack on genomic data can significantly affect the confidentiality, integrity, and availability of the relevant systems.

According to the National Center for Biotechnology Information, some possible attack scenarios include biological substance attacks, malicious hardware/firmware implantation, and NGS software compromise. Along with strong

policy development, the cybersecurity community will play a significant role in thwarting attacks and maintaining the integrity of genomic data and systems.

The digital technologies mentioned above are critical to the success of the genomics industry and its impact on the world of medicine. Organisations that offer services in Big Data & Analytics, Artificial Intelligence/Machine Learning, cloud computing, and cybersecurity with expertise in genomics and life sciences will be uniquely positioned to be instrumental in the future of the life sciences industry. The rapid growth and stabilisation of digital technologies is a precursor to a transformation in the application of genomics that will change every individual's life within the next few years.

India has a tremendous ecosystem and significant support from government organisations. The Genome India Project, initiated by the Department of Biotechnology, is an example of the Indian State's interest in this field. Similarly, the IndiGen Project founded by the Institute of Genomics and Integrative Biology under CSIR can be bolstered through AI-based solutions. With multiple use cases for genomics in public health, such as cancer research and precision medicine, the digital ecosystem, along with India's genomic labs, can be leveraged to advance such genomics projects. Organisations in India that provide an end-to-end array of services for life sciences, from genomics labs to digital services through domain experts, will be the game changers for India's march toward leadership in genomics.

# Pharma's path forward: From driving drug launches to improved patient outcomes

**Subhro Mallik**, SVP and Global Head Life Sciences, Infosys emphasises that an end-to-end ecosystem enabling data orchestration and meaningful is essential to drive true digital transformation across the life sciences value chain and enhance enterprise-wide performances

The healthcare and life sciences ecosystem is rapidly evolving under the influence of various environmental factors. The commercial ecosystem for pharma companies is increasingly complex and interlaced with multiple dependencies influencing care management decisions. Therefore, decision-makers must consider complex data sets to make more precise and timely decisions.

Data proliferation in life sciences is happening faster than the time taken by the industry to consume the data and draw meaningful insights. Pharma companies have invested heavily in large data warehouses and building pipelines to ingest external data. Yet, they have managed to build disconnected data platforms at best. They must still rely on considerable manual intervention to interpret the data and put it to real use. The problem is exacerbated by the lack of a one-size-fits-all solution to address this challenge of managing commercial data.

## Current challenges in commercial operations

When drug launches do not go as per plan, there is an impact on productivity. When a drug is introduced, pharma companies are hampered by lengthy onboarding processes and the need to buy data from multiple sources. They must also build point solutions and reporting engines for each brand. These investments force pharma companies to stretch their budgets often without achieving desired returns and satisfactory brand performance.

Drug launches can be long-winded. The company must navigate countless complexities of regulation, cost, and intense competition stemming from speciality therapeutics. As the pa-



Currently, life sciences companies are experiencing complex patient journeys, which call for tech interventions to deliver value along the continuum of care

tient population is typically small and spread out for pharma companies, they need an end-to-end insight platform that can handle these challenges while being flexible enough to repurpose existing investments of clients. Despite years of studying the drug, its potential market, and strategic planning, more than a third of newly launched drugs tend to underwhelm in terms of sales performance. This could be because of factors such as incorrect targeting of patient population or ineffectiveness in measuring field sales performance KPIs.

It makes sense for pharma companies to work on building

an effective data marketplace and understanding end-user well ahead of a drug launch. Plus, they need the data discovery process to enter a self-service mode to speed up their insights and innovation capabilities. While several commercial insights solutions exist, they are isolated and limited to providing partial truths that result in costly investments without actually addressing the larger problem. The data they get is not the data they need.

## Closing the data-to-insights gap for new drug success

While pharma companies have

invested in various technology capabilities, an end-to-end ecosystem enabling data orchestration and meaningful insights eludes them. Such an ecosystem will help commercial teams do more with less while driving agility, innovation, and real-world data focus to improve patient outcomes. A single version of the truth is essential to drive true digital transformation across the life sciences value chain and enhance enterprise-wide performances so that they get insights that are faster and adaptable to their unique needs.

## Such an ecosystem must be guided by:

**Real-world data:** Studies show that the more mature and effective the field force, the greater their contribution to sales performance. The right data can help drive patient outcomes, optimise commercial spend, and improve forecasting and effectiveness of the field force, which remains a vital promotional channel. Companies also recognise the need for better market segmentation and understanding of customer needs.

**End-user-centricity:** Data onboarding time can be shortened by identifying specific commercial personas that are targeted in the drug launch and understanding their needs. This will facilitate better collaboration and communication of patterns and other user insights between brand marketing, commercial operations, data scientists, and other partners involved.

**The collective power of the ecosystem:** Leveraging insights and capabilities from pharmacies, buyers, suppliers, and other ecosystem players can help build an effective commercial insights solution. This

can help right from data discovery to democratisation to enhancing patient outcomes and boosting the drug's commercial acceptance. Overall, this gives pharma organisations a greater chance of success.

Currently, life sciences companies are experiencing complex patient journeys, which call for tech interventions to deliver value along the continuum of care. End-users too increasingly prefer virtual communication channels that facilitate specialised disease conversations. Therefore, the uni-dimensional approach of driving business through field forces has morphed into a more segmented approach that leverages multiple channels to capture target users. Personalised and omnichannel engagements are required and therefore, data must be captured along all user touchpoints to stitch the narrative together.

A drug launch remains a pivotal event for pharma. Its success involves multiple factors such as market insights, access to patients, understanding of prevalent market forces, and competitor intelligence. All of these must align and contribute to the strategic planning of the roll-out. Robust tech capabilities backed by comprehensive advanced analytics capabilities can help address these evolving needs and enable the success of new drugs.

## References

<https://www.technologyreview.com/2022/02/15/1045405/streamlining-pharma-drug-launches-with-data-and-analytics/>  
[https://img1.wsimg.com/blobby/go/1651eb46-a148-4180-836e-3cb99822cb3e/downloads/Mentor%20Group\\_WP\\_Field%20Sales%20Force%20Effectiveness.pdf?ver=1626130082785](https://img1.wsimg.com/blobby/go/1651eb46-a148-4180-836e-3cb99822cb3e/downloads/Mentor%20Group_WP_Field%20Sales%20Force%20Effectiveness.pdf?ver=1626130082785)

## Impact of robotic process automation, AI in pharma

**Ranjit Barshikar**, CEO-QbD International, cGMP/QbD Consulting, United Nations Adviser elaborates how emerging technologies like RPA and AI are finding application in diverse areas of the pharma industry such as regulatory/compliance, clinical trials, manufacturing, and supply chain

**D**igitalisation and emerging technologies have revolutionised the pharma industry. These technologies are very useful from the perspectives of quality and compliance, based upon Industry 4.0/Pharma 4.0 concepts.

Robotic Process Automation (RPA) and Artificial Intelligence (AI) are no longer small operations as manufacturers are using these technologies to maximise quality and compliance. Many companies are already using AI to analyse huge scientific data in an effort to speed up and improve the drug discovery process.

These technologies have new applications in diverse areas like regulatory/compliance, clinical trials, manufacturing, and supply chain. RPA automatically handles manual, repetitive, time-consuming, and highly structured tasks such as data entry, reviews and back-office functions. RPA solutions can improve regulatory compliance because bots do not deviate from programmed steps and audit trail history can be tracked. They provide comprehensive, unchangeable, and time-stamped activity logs, reducing risks and errors through the automatic execution of repetitive and routine manual activities.

There are several applications of RPA/AI in the pharma industry from quality and compliance perspectives such as:

**Data integrity compliance:** Achieved through RPA audit trails review of various chromatography data generated during laboratory analysis. When reviews performed with RPA detect no anomalies, the reviews can autonomously be closed and logged by the bot.



**AI and robotics operations are a boon to the pharma industry in ensuring speed of product availability, quality, safety and efficacy of products in the interest of patients**

However, if the bot detects any inconsistency or discrepancy that requires human evaluation, RPA can be programmed to report the issue to one or more users before proceeding with the next steps of the process.

**Ensuring quality, predictive quality analytics (PQA):** AI-enabled LIMS-QMS, automates time-consuming, error-prone, manual inspection tasks. Predicting the quality of a batch is another big advantage of newer technologies as they help to standardise quality monitor-

ing processes. They analyse data, predict quality, deal with complaints handling process and make remedial suggestions to mitigate the risk of failure of a batch.

**Clinical trials:** AI and RPA are used to speed up the process of selecting the volunteers saving time from months to only a few days. AI is now being used in identifying the right candidate for clinical trials. Monitoring the pharmacovigilance activity is another area where RPA is of great advantage. It helps to

monitor huge amounts of adverse event data, as well as enable necessary communications to report and accumulate such data. RPA solution utilises bots to substantially reduce data processing time, improve reliability and mitigate risk by eliminating errors and improving accuracy in trial documentation.

The regulatory documents submission process is a huge and time-consuming activity where RPA solutions can speed up certain required activities, such as document status tracking and creating a records dossier, thereby reducing process time.

**Manufacturing:** AI helps to reduce manual oversight in manufacturing and allows tighter control of quality and operating costs by assessing manufacturing data from multiple batches and product lines, identifying process anomalies and predicting quality issues. This can direct staff to investigate only those batches most likely to have quality issues, saving time and resources. It proactively identifies anomalies, prioritises compliance risks, and improves operational efficiency.

**Sterile manufacturing:** The applications in pharma manufacturing are vast, including aseptic roller bottle processing, multi-format aseptic filling, aseptic cytotoxic compounding, packaging, warehousing and distribution. Robotic production lines that can provide flexible aseptic filling and closing of ready-to-use vials, syringes, and cartridges with a single machine, resulting in overall production speed are necessary to remain competitive and cost-effective. Several benefits in sterile manufacturing like minimis-

ing human errors (like foreign matter, hair etc. contaminations), maintaining air velocity, and sterile conditions in core areas, RPA enables closed systems to eliminate all sources of contaminations.

**Predictive maintenance:** Maintenance is simpler due to fewer parts, and if done properly, can result in significantly longer lifespans. Robots facilitate ongoing maintenance by self-monitoring and using programmed alarm scenarios to alert operators of issues. AI is being used to predict the failure of equipment in the near future. As soon as an alarm is known, preventive actions start, thus ensuring zero downtime.

**Packaging operations:** Robotic automation is being used in packaging operations to minimise defects by way of in-line checks along with several cameras for separating defective tablets, capsules, empty strips pockets, defective blisters etc.

AI is being used in R&D drug discovery, clinical trials, manufacturing, quality control laboratory and supply chain. Automation is already transforming the pharma industry in areas like product development and real-time monitoring. Many companies are increasingly turning to robotic process automation as a solution allowing them to enhance productivity, quality, operational efficiency, and customer satisfaction. Overall, AI and robotics operations are a boon to the pharma industry in ensuring speed of product availability, quality, safety and efficacy of the products in the interest of patients. Pharma operations will be completely AI-enabled, AR + VR towards paperless plants in near future.



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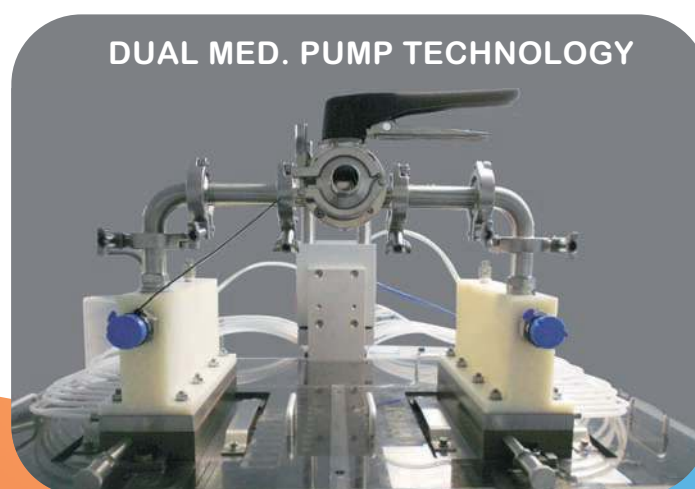
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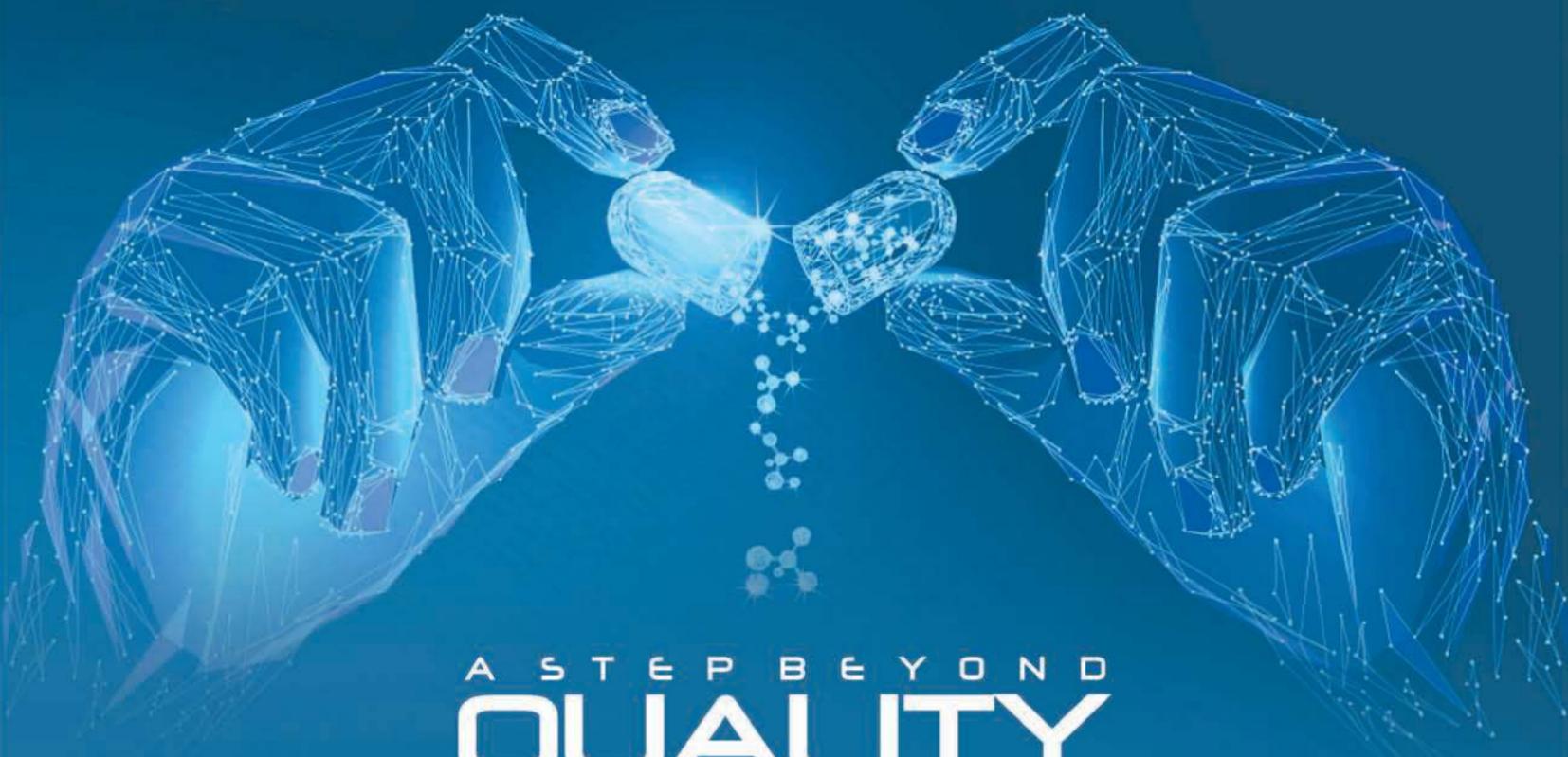
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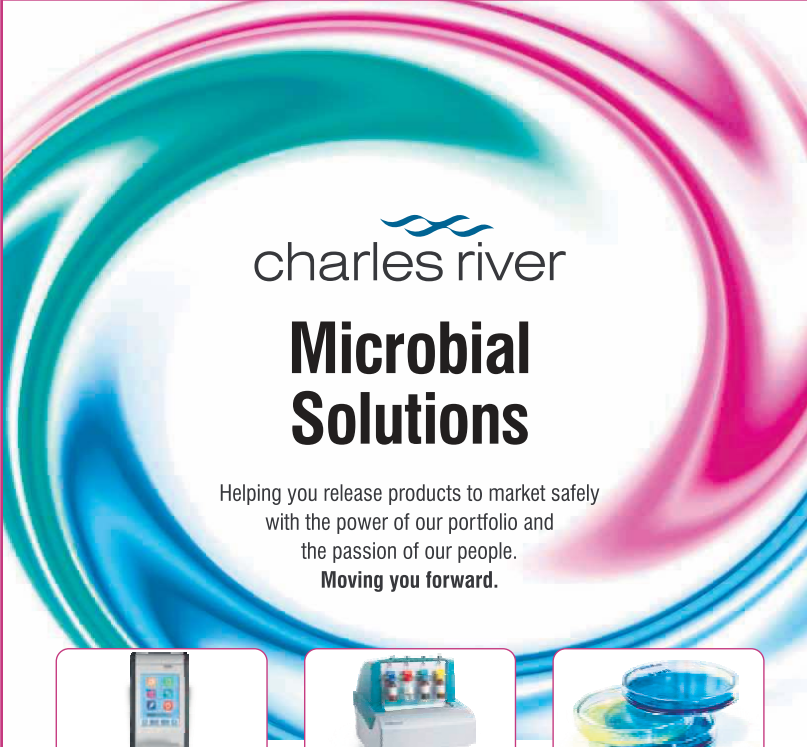
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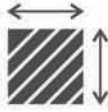
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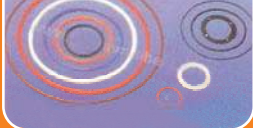
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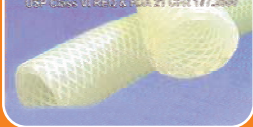
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# The growing importance of amino acids

**Christoph Zahner**, Senior Manager-Global Business Development, Biopharmaceuticals, DKSH emphasises on the role of amino acids in pharma industry

Amino acids are the building blocks of life and serve as natural compounds in various industries and applications. They are widely produced and utilised commercially, including as food seasoning, animal nutrients, pharma, and cosmetics. The term amino acid is short for alpha-amino carboxylic acid. Commonly used as supplements in cell culture media and metabolism research, they act as building blocks of proteins and as intermediates in metabolism.

According to Grand View Research, the global amino acids market size was valued at USD 26.1 billion in 2021 and is expected to expand at a compound annual growth rate of 7.4 per cent over the next 10 years. The market is anticipated to be driven by the increasing demand for amino acids from the food, pharmaceutical, and nutraceutical industries.

The Asia Pacific market is expected to be the fastest growing market in terms of revenue-growth due to the increased consumer spending in the region. Other influencing factors include the growing adoption of a healthy lifestyle, and rapid expansion of industries, including nutraceuticals, pharmaceuticals, personal care, and cosmetics.

### A closer look at amino acids

Today amino acids are used in several sectors, including the food industry as flavor enhancers. Glycine, cysteine, and D, L-alanine are also used as food additives, and mixtures of amino acids serve as flavor enhancers in the food industry.

Some products are often supplemented with certain amino acids to increase their nutritional value. Many plant-



**DKSH offers a broad range of amino acid solutions to cater to your pharma needs. Our international teams of technical specialists collaborate across borders to develop innovative solutions for companies looking to tap into the growing consumer needs**

based products are deficient in certain amino acids, which can be introduced to provide consumers with extra nutrients to improve health. For example, bread can be enriched with lysine, and soy products can be enriched with methionine. Lysine, methionine, and glutamic acid are widely used in animal feeds.

### Common uses of amino acids

Amino acids are used as precursors for chemicals used in various industries, such as pesticides and herbicides. For example, threonine can be used to produce the herbicide azthreonam and glycine can be used to produce glyphosate, another herbicide.

Amino acids are widely used in dietary supplements owing to their ability to treat muscle soreness, sprain, and mental fatigue. Several amino acids like leucine, valine, proline, alanine, cysteine, and isoleucine are used in supplements for muscle growth and bodybuilding. Amino acids are also commonly used as

preservatives in food and drink. Fruit juices are often preserved with the use of cysteine as an antioxidant.

Amino acids are used therapeutically for nutritional and pharmaceutical purposes. For example, patients are often infused with amino acids to supply these nutrients before and after surgical procedures. Treatments with single amino acids are part of the medical approach to control certain disease states. Examples include L-dihydroxyphenylalanine for Parkinson's disease, glutamine and histidine to treat peptic ulcers, and arginine, citrulline, and ornithine to treat liver diseases.

Certain derivations of amino acids, especially glutamate, are used as surfactants in mild soaps and shampoos. D-Phenylglycine and D-hydroxyphenylglycine are intermediates used for the chemical synthesis of  $\beta$ -lactam antibiotics such as synthetic versions of penicillin. Aspartame is a sweetener prepared from the individual component amino acids aspartic acid and phenylalanine.

DKSH offers a broad range of amino acid solutions to cater to your pharma needs. Our international teams of technical specialists collaborate across borders to develop innovative solutions for companies looking to tap into the growing consumer needs.

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### Sources:

<https://pubmed.ncbi.nlm.nih.gov/34906648/>  
<https://www.britannica.com/science/amino-acid>  
<https://www.sigmaaldrich.com/IN/en/products/chemistry-and-biochemicals/biochemicals/amino-acids>

# Ensuring pharma compliance with testo data measurement technology

Testo being a market leader in testing & measurement sector provides the best-in-class data loggers and data monitoring systems for the pharma division

Due to the crucial necessity and its direct impact on human health and welfare, pharma is probably the most important and critical sector among others. As a consequence of which, it becomes essential to store pharmaceuticals, vaccines, laboratory samples or units of blood at the right temperatures to ensure that they remain effective and that quality is maintained. Another reason for the pharma division to ensure safety measures & controlled environment is stringent regulations and inspection of the facilities. This elementary need for climate control can only be ensured with right data monitoring systems. Testo being a market leader in testing & measurement sector provides the best in class data loggers and data monitoring systems for the Pharma division.



EN 12830 and 21 CFR Part 11 compliant which ensure complete documentation of parameters, be it humidity, temperature or absolute pressure. They come with professional software where the data recorded cannot be modified and the audits can be easily complied with.

## Service & calibration made easy

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## Ensuring end to end climate monitoring-Testo Data Loggers

Pharma goods must be stored well in every situation as any deviation in the ambient temperature or humidity values may lead to deteriorated quality of the product. Testo data loggers can be used to test the optimum conditions for specific products or surroundings. Temperature & humidity data loggers are often used in Pharma industries to monitor the conditions in which drugs, medicines, vaccines are kept. Not only storage, but during the transit of goods, testo transport data loggers are useful to measure the transport conditions. The range of data loggers is very extensive. A temperature & humidity logger such as 174 T guarantees continuous monitoring in a storage or warehouse. Also, data loggers with multi chan-

nels for connecting external sensors & thermocouples, like testo 176 are available for ensuring secured work process in labs.

These data loggers are also critical for production quality assurance where the temperature has to be frequently checked at various points in production processes. Using thermocouple probes, data loggers can also record data in the kinds of extreme temperature ranges. The probe's fast response also contributes in the validation processes and quality standard optimisation in QA units & clean room applications. These instruments are the most convenient and pocket friendly solution for all pharma application areas.

The testo Saveris 2 WiFi data logger system is the simple, flexible and reliable solution to humidity and temperature monitoring in cold storage

area like blood banks. This innovative monitoring system is ideal for high product quality & eliminates manual work of reading out or documenting measurement data. With a secure online storage of all readings in Testo Cloud the data can be managed and analysed online by the user via smart phone, tablet or PC anywhere and anytime. In case of crises and deviations, it is provided with an alarm by e-mail, or optionally by SMS.

Another important and crucial application of a pharma industry involves validation of sterilisation and freeze-drying processes. Not only that, validating cleaning and disinfecting equipment is equally necessary. In order to allow a seamless operating procedure, the validation process and the documentation work must be as efficient and smooth as possible which could be easily

achieved with testo 190 data logger solution that has innovative data loggers for temperature & humidity, smart software and accessories.

## Data compliance for audits and inspections

Testo offerings are majorly related to the data security along with comprehensive analysis & evaluation of all the recorded measurement data. Testo data loggers ensure continuous monitoring of temperature and relative humidity of pharma products during production, storage or transit of goods. Real time data monitoring is important for the quality of Pharma goods and also enables the supplier to improve the life of the goods. Transportation trucks, warehouses, cold rooms etc. can now be remotely monitored via Testo data loggers & data monitoring systems. Our data loggers are

ited service & calibration LAB in accordance with the standard ISO/IEC 17025:2017, that takes care of the after sales support locally from Pune. Testo service & calibration facility is highly cost effective as it delivers international standards very conveniently within a week's time. Instruments of any brand/make can be calibrated and serviced locally maintaining necessary standards.

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# Waters Corporation to acquire Wyatt Technology

Accelerates next phase of Waters' strategy for growth and value creation through increased exposure in attractive, high-growth adjacent markets

**W**aters Corporation has announced that it has entered into an agreement to acquire Wyatt Technology, a pioneer in innovative light scattering and field-flow fractionation instruments, software, accessories, and services, for \$1.36 billion in cash, subject to certain adjustments. The transaction is expected to close in the second quarter of 2023, subject to regulatory approvals and other customary closing conditions.

Bioanalytical characterisation for new modalities including cell and gene therapies is a significant market opportunity, with a \$1.8 billion total addressable market and 10-12 per cent projected annual growth. By applying Waters' well-established business model, Empower informatics software, global reach and scale, Waters and Wyatt are well-positioned to build a high-growth bioanalytical characterisation business.

Based in Santa Barbara, Calif., Wyatt is a privately held family company with 2022 revenues of approximately \$110 million. With a worldwide workforce of more than 200 employees, Wyatt has been delivering world-class training and personal

service to a global base of scientific customers. Since Wyatt's scientists were the first to commercialise on-line multi-angle laser light scattering instruments more than 40 years ago, Wyatt has been defining and redefining state-of-the-art macromolecular characterisation instrumentation, software, and services to solve its customers' unmet needs. Over the years, Wyatt has added several complementary technologies, including well-plate based dynamic light scattering and field-flow fractionation for separating nanoparticles in solution. Together, its innovative product offerings are used across the value chain in discovery, product development, manufacturing, and QA/QC settings to determine the critical quality attributes of novel therapeutics such as cell and gene therapies, vaccines, and proteins, as well as synthetic polymers and nanoparticles.

Dr Udit Batra, President and CEO, Waters Corporation said, "Over the past two years, Waters has regained our commercial momentum, revitalised innovation and put an outstanding leadership team in place. Now we are entering the next phase of our strategy to accelerate value creation and gener-

ate faster growth. While biological therapies, including cell and gene therapies, can dramatically change the quality of life for a significant percentage of the population, the cost of delivering these therapies is a major barrier for broader adoption. We share a common mission to harness our technology and deep scientific expertise to increase the availability and affordability of life-changing therapies. We look forward to welcoming the Wyatt team to the Waters family."

Dr Philip Wyatt, Chairman and Founder of Wyatt Technology said, "For more than 40 years, our company has delighted its customers using the unique products and unparalleled personal service we deliver to support life-enhancing large molecule therapeutics. For decades, we have seen firsthand how closely Waters and Wyatt's scientific heritage, ethos, and values have been aligned. Becoming an integral part of Waters is a natural way for us to expand our business dramatically. Waters has the reach and scale to leverage Wyatt's successful legacy and extend the benefits of our offerings to many new applications and customers. We could not be more excited about the vast

growth opportunities we will have as part of Waters."

## Strategic and financial benefits

**Broadens Wyatt's global reach:** Waters will broaden Wyatt's global reach and scale, further expanding its footprint in Europe and Asia. The combination will accelerate deployment of Wyatt's light scattering technologies and techniques in downstream, high-volume, and recurring QA/QC applications, through Waters' well-established Empower informatics platform.

**Expands Waters' portfolio and increases exposure to large molecule applications:** Enhances Waters' portfolio of separation and detection, which will provide customers with an unmatched set of analytical solutions across a wide range of applications. With more than 80 per cent of Wyatt's revenue derived from large molecules, this will increase Waters' exposure to exciting new applications within the bioanalytical characterisation market.

**Immediately accretive to Waters' revenue growth and margin profile:** Wyatt has a three-year compound annual growth rate of 20 per cent, which is expected to grow

low-teens over the near- to mid-term and has an existing adjusted operating margin of approximately 40 per cent.

**Revenue synergies:** Waters is expected to generate over \$70 million in annual revenue synergies by the fifth year following transaction close.

**Accretive to EPS with high single-digit plus adjusted-ROIC:** The transaction is also expected to be accretive to Waters' adjusted earnings per share beginning in Q1 2024. The transaction is expected to deliver a high single-digit plus return on invested capital in year five, net of tax.

## Transaction details and financing

Waters will fund this investment through cash on its balance sheet and existing borrowing capacity available on its revolving credit facility. The company will temporarily suspend its share repurchase program through the remainder of 2023 and utilise free cash flow to pay down debt.

## Advisors

Kirkland & Ellis LLP is serving as legal counsel to Waters, while Wyatt's legal counsel is provided by Glaser Weil Fink Howard Avchen & Shapiro LLP.

# Lipids for LNP formulations – Flash chromatography purification options

To protect the mRNA and enable its effectiveness, pharma companies have worked with biotech companies to create more viable cell delivery options

**C**OVID-19 caused accelerated research into developing vaccine options. Some of the created vaccines are based on mRNA, which, if not protected, easily degrade in humans before their therapeutic benefits can be realised.

To protect the mRNA and enable its effectiveness, pharma companies have worked with biotech companies to create more viable cell delivery options. The most widely used is lipid nanoparticle (LNP) encapsulation. This technology uses microfluidics to combine the vaccine, lipids, other excipients and adjuvants into small spherical particles called LNPs.

The lipid mixtures used typically contain one that is cationic, one that is PEG-based, a phospholipid, and one that is neutral, such as cholesterol. Due to the nature of these molecules, many purification techniques such as distillation or crystallisation are either extremely difficult or impractical to use; so, the industry has faced a new challenge at scale. Luckily, lipid molecules tend to be well suited to off-the-shelf purification methods and platforms, such as Biotage automated flash chromatography development systems (Biotage® Selekt) and scale up (Biotage® Flash 400) platforms for rapid scale up – by both normal-phase and reversed-phase methods.

Historically, detection by UV was hindered since these compounds have little UV absorbance. This problem required alternative detection techniques (evaporative light-scattering, (ELS)), or just collection by volume with post-purification analysis by TLC with staining or charring. Modern flash chromatography systems

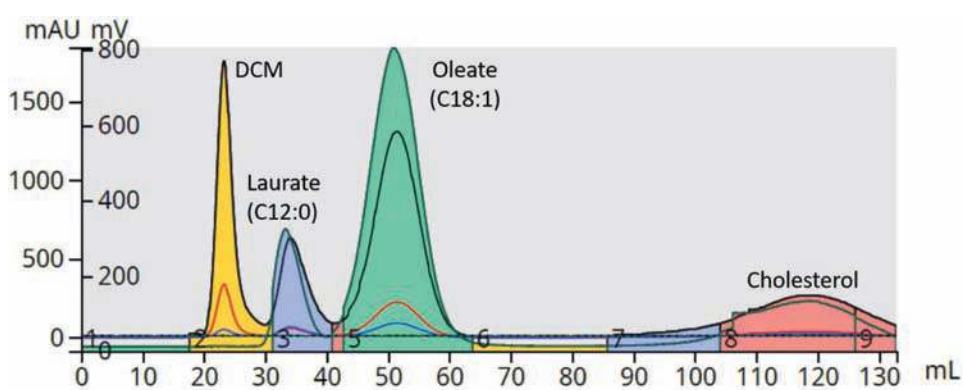
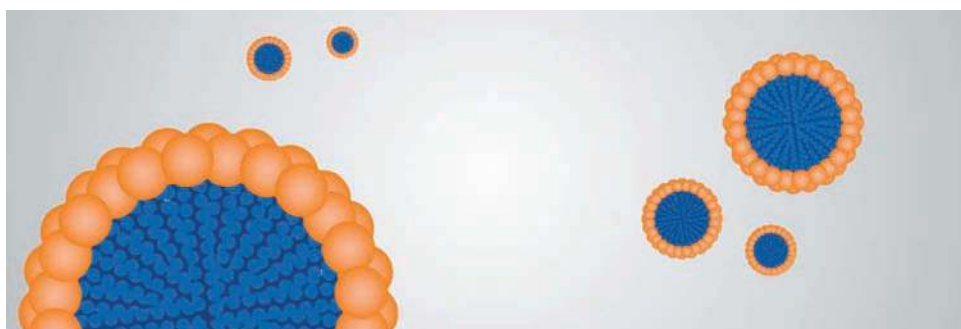


Figure 1. Reversed-phase flash chromatography purification of methyl laurate, methyl oleate and cholesterol in 100 per cent methanol with UV (198-210 nm) and ELS detection. All lipids are easily detected by both UV and ELS including the fully saturated methyl laurate

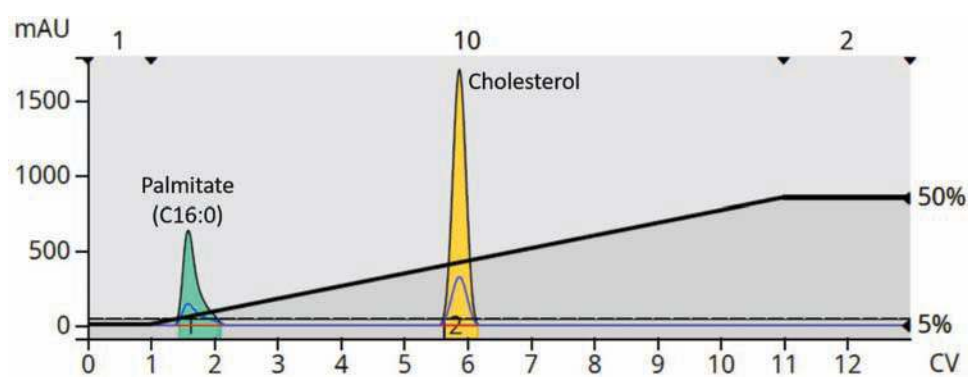


Figure 2. Normal-phase flash chromatographic purification of methyl palmitate and cholesterol. The fully saturated palmitate is too lipophilic to be retained while cholesterol, with a hydroxyl group, is well retained

now utilise photo-diode array UV detection, which can be focussed in the absorption range for the targetted molecules, thus, enhancing their detectability.

Reversed-phase flash chromatography separates compounds based on their hydrophobicity differences through a partitioning mechanism as seen with the lipid

chromatogram below where compound retention increases with the number of carbons in the molecule (Figure 1).

Normal-phase chromatography, on the other hand, separates

The lipid mixtures used typically contain one that is cationic, one that is PEG-based, a phospholipid, and one that is neutral, such as cholesterol

compounds based on polarity differences using an adsorption-desorption mechanism. Lipophilic compounds elute quickly and those that are more polar elute later. For lipid purification, this can be beneficial as fatty acid type compounds will only be marginally retained, while cholesterol and other more polar compounds will be retained better, (Figure 2).

These examples were performed a low scale (<100 mg) using small flash columns (10 gram), but the purification methods are easily scaled to 100s of grams to even kilogram-scale by using larger columns from Biotage up to 50 kg (Biotage® Flash 400L).

So, if you are involved in the world of lipid production and need to purify your lipids, consider your options. Depending on your goals, it is very likely either normal-phase or reversed-phase flash chromatography will help you attain them.

*Interested in learning more about fast-tracking purification? Learn more at [www.biotage.com](http://www.biotage.com), contact: [india@biotage.com](mailto:india@biotage.com)*

# Gandhi Automations: Ideal solution for all industrial and commercial needs

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# Merck launches new-age water purification system, Milli-Q® EQ 70XX Water Purification System at Pharma Summits in Sikkim and Daman

Milli-Q® Lab Water portfolio offers a broad range of sustainable pure and ultrapure water purification systems designed for scientists working in pharmaceutical, clinical, academic, industrial, research, and government laboratories

**M**erck, a leading science and technology company, recently launched the all in one Milli-Q® EQ 70XX Ultrapure (Type I) & Pure (Type 3) water purification system. This system was unveiled by eminent pharma dignitaries at the Sikkim Pharma Summit 2022 and Daman Pharma Summit 2023, organized by *Express Pharma* at Hotel Mayfair in Gangtok on Nov 18, 2022 and The Deltin, Daman on Jan 20, 2023.

Milli-Q® Lab Water portfolio offers a broad range of sustainable pure and ultrapure water purification systems designed for scientists working in pharmaceutical, clinical, academic, industrial, research, and government laboratories — in both validated and non-validated environment. The selection of the right water system for your laboratory will depend on several parameters such as feed water available, daily volume needs, monitoring requirements, validation levels expected and any other specific requirements you may have.

Considering Milli-Q® Lab water system, this latest launch has a lot to offer in terms of consistent water quality that can be adapted to every user's application requirements and comes with unique delivery design to dispense water in an optimal way.

Some of the key features of Milli-Q® EQ 70XX Ultrapure water purification system are as follows::

- ◆ The compact set up lets you position the dispenser where



Unveiling of Milli-Q® EQ 70XX Ultrapure water purification system at Daman Pharma Summit 2023



Unveiling of Milli-Q® EQ 70XX Ultrapure water purification system at Sikkim Pharma Summit 2022

ever is convenient for your lab (on the left or right side, and at the top or bottom of the system)

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To further connect with their expert team, Please write to [Labwatersolutions-India@merckgroup.com](mailto:Labwatersolutions-India@merckgroup.com).

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