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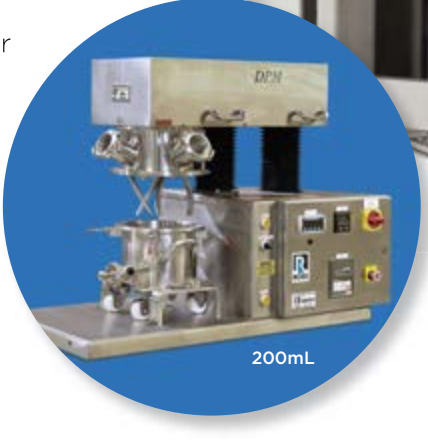

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Karen Langhauser
Chief Content Director

Shedding stigmas

How pharma can help obesity lose its shame — and keep it off

Two years ago, I found myself sitting in an endocrinologist's office, holding a color-coded portion plate and wondering if I was supposed to put the tomatoes in the 'fruit' section or the 'vegetable' section.

It took me close to a year to get the coveted appointment slot and I thought I was going to walk away with some answers as to why I couldn't lose any of the weight I had gained. Instead, I was being lectured about eating too much. Even though I was seeing a nutritionist, tracking my food and working out daily, I left the office convinced my excess weight was entirely due to my own personal failing.

For better or for worse, weight has always carried meaning.

History offers a capricious narrative about body size. In the 19th century, 'plumpness' was not only fashionable but also associated with power, good health and prosperity. Yet the tables turned with the century, and people suddenly began to equate excess weight with being inconsiderate, unintelligent, lazy and even promiscuous.

While social stigmas can be bitter pills to swallow, medically, stigmas can be dangerous. With obesity widely perceived as something that can be controlled with diet and exercise alone, patients are less inclined to seek treatment and doctors are less inclined to prescribe medication.

But the problem isn't going away. Obesity rates are expanding with our waistlines and currently, two thirds of America is overweight or obese.

Up until recently, the issue was compounded by a lack of long-term, effective pharmacologic treatment options. This can be partially attributed to an obesity space that's never been overly fruitful for the pharma industry. Phentermine has been the most commonly prescribed anti-obesity treatment for decades, and yet the entire U.S. phentermine industry, brand and generics combined, is estimated to generate just over $200 million annually.

For comparison, Novo Nordisk's GLP-1 receptor agonist, Wegovy, brought in $1.1 billion in the second quarter of 2023 alone.

But to be sustainable, weight loss gains need to go further than the bank. The rise of incretin mimetics in chronic weight management has the potential to change the look of obesity care. Not only can the drugs help people lose upwards of 20% of body weight when used in conjunction with diet and exercise, but the public buzz has given drugmakers a platform to educate on the multiple health risks that come with obesity.

In short, it's time for obesity care to shape up — and pharma holds the key to shedding stubborn stigmas.

Of course, some very big issues loom large for the pharma industry. Chief among them, a demand that is massively outstripping supplies, and a U.S. price point that much of the country can't afford. But as you will read in this month's cover story, drugmakers are advancing new drugs through pipelines and pouring billions into manufacturing capacity for existing drugs. Further clinical evidence in indications like cardiovascular health is making a strong case for incretins with payers.

Obesity has been viewed as many things throughout history but perhaps with modern-day medications, it can simply be viewed as treatable. We aren't there yet, but for those of us who have exhausted all options only to be fat-shamed while wondering why paper gowns only come in one size, the weight may be close to over.

Andrea Corona
Senior Editor

The Medicare ten

The highly-anticipated list of drugs selected for price negotiation has been revealed

After months of speculation and litigation, the Centers for Medicare & Medicaid Services has unveiled the initial 10 medications designated for Medicare price negotiations in accordance with the Inflation Reduction Act (IRA).

Broadly, the legislative measure was designed to tackle inflation, reduce the federal fiscal deficit, promote investments in domestic clean energy production and cut down on prescription expenses— but much of the pharma industry has noted flaws in the government's approach to drug pricing, with some companies even taking grievances to court.

The medications identified for negotiation belong to a group of "high-cost, exclusive-source drugs with no generic or biosimilar alternatives available." Medicare, which provides coverage to 66 million people, will now work with drugmakers to obtain better pricing for these drugs.

1. Eliquis — BMS, Pfizer

Approved in 2012, the anticoagulant, prescribed to prevent strokes and blood clots in individuals with conditions like atrial fibrillation, generated $18.2 billion in sales last year for its co-marketers, making it one of the top-selling drugs in the world.

The FDA approved the first generic apixaban applications from Mylan (now Viatris) and India's Micro Labs in late 2019, but extensive litigation has staved off the generics' arrival until 2028.

2. Jardiance — Boehringer Ingelheim, Eli Lilly

First approved in 2014, Jardiance is an SGLT2 inhibitor for the management of type 2 diabetes. Currently, the drugmakers are looking to expand the drug's indication to include chronic kidney disease. The list price of a 30-day supply of Jardiance oral tablets can vary, but typically is around $600.

India-based Alembic got the nod for a generic version in 2020 but with patent disputes pending, the generic likely won't hit the market until 2029.

Per CMS data, more than 8 million people covered by Medicare used these drugs between June 2022 and May 2023.

3. Xarelto — Bayer, J&J

Xarelto, approved in 2011, is an anticoagulant used to lower the risk of blood clots, strokes and deep vein thrombosis. The drug, which has a list price of over $600 for a 30-day supply, brought in $7.5 billion in sales last year. The earliest date for generic versions to enter the market is projected to be December 2024.

4. Januvia — Merck & Co.

Januvia, first approved in 2006, is utilized for the treatment of type 2 diabetes, aiding in the regulation of blood sugar levels. Merck has now reached settlement agreements with more than 20 generic drugmakers, deferring launch plans for generics until 2026.

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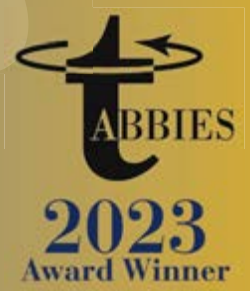
Pharma Manufacturing celebrates Eddies, Ozzies and Tabbies

While b2b journalism is about more than winning awards, here at Pharma Manufacturing, we don't mind adding a few trophies to our case.

The Folio: Eddie and Ozzie Awards are the magazine industry's largest and most prestigious contest, celebrating excellence in print and digital media. This year, all of Pharma's submissions — single article, full issue, overall art direction, and graphic art — were named finalists. The winners will be announced live at the awards gala in New York City this October.

TABPI, through its annual Tabbie Awards program, celebrates journalism professionals worldwide who cover their industries with passion, skill and creativity. This year, Pharma Manufacturing took home its first Tabbie for the May 2022 front cover design.



5. Farxiga — AstraZeneca

Farxiga's original approval in 2014 for adults with type 2 diabetes was later expanded to cover heart failure and more recently, chronic kidney disease. The expanded approvals ballooned sales to $4.4 billion in 2022. The drug's list price is around $550 for a one-month supply.

In 2018, Farxiga became eligible for patent litigation, and although there are 16 protecting the drug, U.S. patents are set to expire in 2024. Beating out over a dozen ANDA hopefuls, Zydus Cadila was the first to score FDA approval for a generic version last year.

6. Entresto — Novartis

Initially approved in 2015, Entresto is a heart failure medication that enhances heart function in individuals with certain heart conditions. Last year the drug brought in $4.64 billion in sales. An approval in HFpEF in 2021 extended its exclusivity period and there are currently no approved generic versions.

7. Enbrel — Amgen

Enbrel was first approved for rheumatoid arthritis back in 1998 and over the years has picked up approvals in five additional indications. Without insurance, the drug can cost as much as $8,000 per month. In 2016, the FDA approved Sandoz' biosimilar version of the TNF inhibitor, but following a federal court decision, it won't be available until 2029.

8. Imbruvica — AbbVie, J&J

Imbruvica was first approved in 2013 for a rare form of non-Hodgkin lymphoma. The kinase inhibitor now has approvals for various forms of lymphoma and leukemia. AbbVie is no stranger to patent walls, and following a similarly aggressive tactic, has 88 patents for Imbruvica. With the granting of pediatric exclusivity in 2022, the company fended off generic competition until 2032.

9. Stelara — J&J

After some initial obstacles, Stelara was approved in 2009 to treat psoriasis and since then has accumulated approvals in ulcerative colitis, arthritis and Crohn's disease. The drug saw a price hike in 2019, which sent its out-of-pocket costs surging to close to $25,500 for an 8-week treatment. J&J recently struck a deal with Amgen, delaying the launch of a proposed biosimilar until 2025.

10. Insulin — Novo Nordisk

The largest insulin maker in the world, Novo has built its business on diabetes care. Under fire for high prices, the drugmaker, along with its competitors, has sought its own ways of lowering list prices in the U.S. Earlier this year, the company said it would be discounting its insulin by 75%, effective on January 1, 2024.

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Margaret Fuller
Journalist and women's rights activist
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PHARMA'S WEIGHT LOSS CHALLENGE

Can the industry rewrite the script for obesity care?

Karen Langhauser
Chief Content Director

From William the Conqueror's alcohol-only regime in the Middle Ages to Lord Byron's 19th century vinegar diet to Lucky Strikes' 'smoking for weight loss' campaigns in the 1920s, history is heavy with questionable methods of weight management.

Ancient Greek physician Hippocrates, considered the 'father of medicine,' recognized excess weight as a health risk nearly 2,500 years ago, recommending lifestyle modifications such as diet and exercise. And according to Dr. Ethan Lazarus, past president of the Obesity Medicine Association, not much has changed in terms of modern-day treatment plans.

"The majority of doctors that I know still think that obesity is a function of willpower. I regularly have patients with BMIs as high as 50 or 60 who have been told that the treatment for their obesity should be eating more vegetables," says Lazarus, who began his career in family medicine before taking over a specialized obesity management practice close to 20 years ago.

Despite the American Medical Association officially recognizing obesity as a disease in 2013, medical and societal stigma has persisted — and so has obesity. Today, more than two-thirds of U.S. adults are either overweight or obese — a growing problem that adds over $170 billion to the country's health care costs each year.[1]

It's an epidemic that has long lacked safe and effective pharmacologic solutions — until now.

A fast-growing class of drugs known as incretin mimetics, originally developed to treat type 2 diabetes, may rewrite the script for obesity care.

"These drugs are not silver bullets," warns Dr. Marcus Schabacker, president and CEO of ECRI, a global independent authority on health care technology and safety. "Obesity is a multifactorial issue and you need to take a multifactorial approach, but in that context, the drugs are very effective and could truly be a turning point."

Faced with a sizable potential patient population and a global market now projected to hit $100 billion in sales by 2030, pharma has the opportunity to raise the missing pillar in comprehensive obesity care.[2]

But there's a hefty caveat. Treatment options come with a high price tag and right now, pickings are slim.

> "The majority of doctors that I know still think that obesity is a function of willpower."
>
> — Dr. Ethan Lazarus

So slim that Novo Nordisk currently owns the entire incretin obesity market with the only two FDA approved drugs. In the absence of options, off-label demand for incretin-based diabetes treatments, specifically Novo's Ozempic and Eli Lilly's Mounjaro, has triggered ongoing shortages.

The hunger for Novo Nordisk's pricey new anti-obesity drug, Wegovy, is so great that the drugmaker's CEO recently said it could take "some years" for the company to meet the demand.[3] Even as the drugmaker scrambles to fill orders, lack of competition has padded its pockets; Novo Nordisk is now valued more than the entire Danish economy.

Continued momentum in obesity care will be predicated on access to new drugs. In order to truly transform obesity into a treatable disease for all patients, pharma must overcome current supply and pricing issues and get more drugs through development and within reach of those who need them most.

The incretin effect

While they don't date back to antiquity, incretin mimetics are not as new as their recent TikTok popularity implies.

The term 'incretin' is credited to Belgian physiologist Jean La Barre, who in 1932 proposed that diabetes could be treated with naturally occurring human hormones. The two main incretin hormones released by the small intestines, glucose-dependent insulinotropic peptide (GIP) and glucagon-like peptide-1 (GLP-1), were officially identified back in the 1970s and 1980s, respectively.[4]

In what is now known as the 'incretin effect,' scientists discovered that in healthy individuals, glucose responsive receptors in the gastrointestinal tract trigger the release of GIP and GLP-1 hormones in response to food — but in people with type 2 diabetes, this effect is blunted.

From those new advances in diabetes understanding came the idea that long-acting stable receptor agonists of the GLP-1 hormone could be used to stimulate insulin secretion. As their name implies, incretin mimetics work to mimic the glucose-lowering actions of incretins.

In 2005, the FDA approved the first incretin mimetic, developed by Amylin Pharmaceuticals and Eli Lilly, as an add-on therapy for patients with type 2 diabetes. By binding to GLP receptors in the pancreas, the drug, branded Byetta, triggered the effects of the GLP-1 hormone.

Byetta's weight loss properties, which were consistently demonstrated in clinical trials, were used to position the drug against other type 2 diabetes drugs, many of which were commonly associated with weight gain. But Byetta's ability to stimulate weight loss set the stage for the exploration of incretin mimetics in obesity care.

Nourishing an obesity market

As more incretin mimetics advanced through pipelines for type 2 diabetes, their weight loss properties began to shift from a nice perk to a lucrative opportunity.

"The drugs were proving very effective in managing non-insulin dependent diabetes. Then secondarily, as pharmaceutical companies often do, they looked for additional indications for the drugs, to quite simply, make more money," points out Schabacker.

Profits (and judgment) aside, there is a verifiable health link between obesity and type 2 diabetes, which are often referred to as 'twin epidemics.' It's estimated that 90% of type 2 diabetes patients are overweight or obese, and people battling obesity face the highest risk of developing diabetes.[5] The risk of many of the common complications faced by patients with diabetes, such as kidney disease and cardiovascular issues, can be lessened by losing weight.

Long-time diabetes giant Novo Nordisk wasted no time getting out of the anti-obesity gate. By 2006, the Danish drugmaker was testing its GLP-1 agonist, liraglutide, in both type 2 diabetes and obesity.

In 2009, the drug ran into some safety delays on its road to approval in type 2 diabetes and Novo temporarily halted the phase 3 obesity studies while working with regulators to resolve concerns over pancreatitis and a rare type of thyroid cancer.[6] The following year, Novo secured approval for

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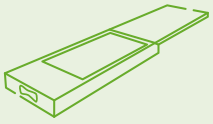

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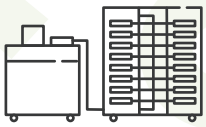

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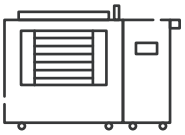

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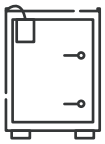

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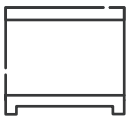

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Drug Product

Figure: Safe Handling of biopharmaceuticals with Single Use Support's End-to-End Process Solution

FDA approved GLP-1 receptor agonists

2005 Byetta (exenatide)
Amylin/Eli Lilly (now AstraZeneca)
type 2 diabetes

2010 Victoza (liraglutide)
Novo Nordisk
type 2 diabetes

2012 Bydureon (exenatide)
Amylin/Alkermes (now AstraZeneca)
type 2 diabetes (discontinued, reformulated 2017)

**first once-weekly treatment for type 2 diabetes*

2014 Tanzeum (albiglutide)
GSK
type 2 diabetes (discontinued)

2014 Trulicity (dulaglutide)
Eli Lilly
type 2 diabetes

2014 Saxenda (liraglutide)
Novo Nordisk
chronic weight management

**first GLP-1 approved for obesity/overweight*

2016 Adlyxin (lixisenatide)
Sanofi
type 2 diabetes (discontinued)

2017 Ozempic (semaglutide)
Novo Nordisk
type 2 diabetes

2019 Rybelsus (semaglutide)
Novo Nordisk
type 2 diabetes

**first oral GLP-1*

2021 Wegovy (semaglutide)
Novo Nordisk
chronic weight management

2022 Mounjaro (tirzepatide)
Eli Lilly
type 2 diabetes

**Mounjaro is a dual GIP/GLP-1 receptor agonist*

liraglutide, branded Victoza, for type 2 diabetes and was able to confidently resume its trials in obesity.

Other drugmakers, including Amylin, GSK and Eli Lilly began grabbing up approvals of GLP-1 analogues in type 2 diabetes, and with each approval, conviction — and data — in the drug class was mounting.

In 2014, the FDA approved a higher dose version of Novo's liraglutide, branded Saxenda, marking the first GLP-1 receptor agonist to get the green light as an obesity treatment — and the start of a pharmacologic shift in obesity care.

"For the first time, there was something with manageable side effects that seemed to be relatively safe even in the long term because diabetic patients had been using it for years," notes Schabacker.

Celebrities weigh in

While Novo Nordisk's Saxenda had the distinction of being the first anti-obesity incretin, it was the drugmaker's next-gen GLP-1s that catapulted the drug class into weight loss stardom.

The FDA approved semaglutide, branded Ozempic, for diabetes in 2017 and a higher dose version to treat obesity, branded Wegovy, in 2021. The drugs' effectiveness when it came to weight loss — in some cases up to a 20% reduction in body weight — along with some unsolicited celebrity endorsements on social media and even at the Oscars, sent prescriptions soaring.

The therapies have stolen the show financially too. When Novo Nordisk rolled out its recent second-quarter results, diabetes and obesity care sales had increased by 36%, driven predominately by the demand for GLP-1 therapies.[7] Following the drugmaker's early September launch of Wegovy in the UK, Novo usurped luxury brand company Moët Hennessy Louis Vuitton to become Europe's most valuable firm.[8]

Novo's anti-obesity drug is also racking up accolades in the clinic. The results from two international trials reinforced Wegovy's potential to enhance cardiovascular care. In the larger SELECT trial, the drug reduced the risk of major adverse cardiovascular events by 20% in adults with overweight or obesity.

Martin Holst Lange, the drugmaker's executive vice president of Development, heralded the SELECT results as a major pharmacologic breakthrough, saying that Wegovy now "has the potential to change how obesity is regarded and treated." Many doctors, including Ethan Lazarus, agree — but there is a catch.

"The treatment with pharmacotherapy is now becoming more compelling both because of the safety profile and potential benefits, but also the magnitude of the weight loss," says Lazarus. "But right now, we have a significant problem in that we only have one highly effective drug approved for obesity, and Novo Nordisk can't come anywhere close to meeting the demand for that drug."

Wegovy first hit the FDA drug shortage list in March 2022 and currently remains there. It is joined by sister drug Ozempic — a supply issue that many attribute to off-label use of the drug for weight loss. One recent analysis found that 56% of patients

newly prescribed Ozempic or Eli Lilly's type 2 diabetes drug, Mounjaro, did not have diabetes.[9]

For Novo Nordisk, manufacturing snags have further worsened the shortages. On two separate occasions, the FDA cited quality control issues at the CDMO plant that fills Wegovy syringes, later revealed by Reuters to be a Catalent facility. Novo has responded by ramping up production to 24/7, investing up to $4 billion a year to expand capacity and signing a second CDMO.[10]

The incretin frenzy isn't limited to Novo Nordisk drugs either. Between the drug's impressive ability to reduce glucose levels in those with type 2 diabetes and off-label demand presumably inspired by weight loss, Eli Lilly has run into shortages with Mounjaro as well.

In May 2022, tirzepatide, branded Mounjaro, earned the distinction of becoming the first and only FDA-approved medicine that activates two different incretin receptors, GLP-1 and GIP, which the drugmaker says contributes to superior blood sugar control. The dual agonist also produced incredible results in a late-stage obesity trial, with patients losing as much as 22.5% of their weight.

With the treatment's anti-obesity approval fast-tracked and in the hands of regulators, Eli Lilly has been ramping up supply efforts.

"We continue to invest and add manufacturing and supply capacity around the world," says an Eli Lilly spokesperson. "With the addition of our manufacturing facility in North Carolina, coupled with additional actions and expansions at other sites, we are on track to achieve the goal we shared in November 2022 to double our incretin capacity by the end of this year."

Despite extraordinary promise, for now, supplies of incretin drugs are limited — which means so is their impact on the obesity epidemic.

Nearly 1 in 3 U.S. adults are overweight. More than 2 in 5 U.S. adults have obesity.

— National Health and Nutrition Examination Survey

A hefty price tag

Shortages aren't the only issue that manufacturers must lean into if the industry wants to upend the obesity epidemic.

According to ECRI, the biggest barrier to weight loss drug adoption is pharma's familiar nemesis: price. Currently, Wegovy injections list for $1349 per month. The price tag means that most Americans can only access the next-gen medication through health insurance — and right now, coverage is a work in progress.

While most private insurance companies will cover the new incretin medications for patients with diabetes, those seeking out treatment for obesity are still battling historical biases in the form of plan exclusions.

On the public side, only nine states have placed GLP-1 weight-loss drugs like Wegovy on their Medicaid preferred drug lists.[11] Medicare, however — under the Medicare Modernization Act, which passed in 2003 in the shadow of the Fen-Phen fallout — is prohibited from covering medications used for weight loss.

"Insurers' unwillingness to cover weight-loss medication puts it out of reach, especially for people with low incomes who experience obesity disproportionately," says Schabacker. "It's really important to stress the point that the non-payment further drives the inequity in our health care system."

Lawmakers recently reintroduced the Treat and Reduce Obesity Act (TROA), an 11-year-old bipartisan piece of legislation which, among other improvements, would expand Medicare Part D coverage to include FDA-approved anti-obesity medications. The bill has been endorsed by a host of medical groups including the Obesity Medicine Association and, not surprising, pharma companies such as Boehringer Ingelheim, Novo Nordisk and Eli Lilly.

With many private insurers modeling their benefits after Medicare coverage, the passage of a bill like TROA would have effects beyond just the senior population covered by federal insurance. But legislation still faces an uphill battle because the large potential patient population requiring long-term treatment translates to enormous government payouts. One NEJM perspective piece from health policy researchers at Vanderbilt University Medical Center calculated that if all Medicare beneficiaries with obesity were to be prescribed Wegovy, the cost would exceed the entire Medicare Part D budget.[12]

The onus of course, can't be placed entirely on payers. "Price is not determined by production cost. Price is determined by what the market bears," reminds Schabacker. Yet with demand skyrocketing and supplies dwindling, patients are unlikely to see price reductions until more drugs are commercialized and competition ramps up.

As is typically the case with any new category of drugs, the pharma industry's focus has been on payer coverage. The versatility of incretin mimetics and their potential to prove effective in additional conditions that are often linked to excess weight has helped upped the odds for pharma. Having learned lessons from the drugs that hit the market first, manufacturers are building their case in the clinic.

Obesity advanced pipeline snapshot

Regulatory review

- Eli Lilly, tirzepatide
  dual GIP/GLP-1 receptor agonist

Phase 3

- Eli Lilly, orforglipron
  oral GLP-1 receptor agonist
- Eli Lilly, retatrutide
  GIP/GLP-1/glucagon receptor agonist
- Novo Nordisk, cagrilintide
  +semaglutide (CagriSema)
  amylin analogue plus GLP-1
  receptor agonist
- Novo Nordisk, semaglutide
  oral GLP-1 receptor agonist
- Novo Nordisk, semaglutide (7.2 mg)
  high dose GLP-1 receptor agonist
- Boehringer Ingelheim/Zealand
  Pharma, survodutide
  GLP-1/glucagon receptor agonist

Phase 2

- Amgen, maridebart cafraglutide
  GIP/GLP-1 receptor agonist
- Structure Therapeutics, GSBR-1290
  oral GLP-1 receptor agonist
- Pfizer, danuglipron
  oral GLP-1 receptor agonist

One example is Boehringer Ingelheim's experimental once-weekly injectable, survodutide, born out of a longstanding partnership with Zealand Pharma and now advancing into phase 3 clinical studies in obesity. While the drugmaker says it's too early to comment on pricing, Ioannis Sapountzis, global head of Therapeutic Areas at Boehringer Ingelheim advocates a more comprehensive view of treatment value.

"It is important to consider the long-term costs associated with obesity especially since it is a leading risk factor for several cardiovascular, renal and metabolic conditions," says Sapountzis. "We are convinced that conversations with payers will evolve given the changing perception of obesity."

In addition to obesity and type 2 diabetes, survodutide is also being tested in liver diseases such as non-alcoholic steatohepatitis (NASH). NASH, one of the major causes of liver fibrosis and cirrhosis, is especially prevalent in people with metabolic disorders such as obesity.

Eli Lilly is also studying Mounjaro as a potential treatment for NASH, as well as in sleep apnea and HFpEF, the most common form of heart failure.

Grabbing the obesity approval hasn't stopped the research for Novo Nordisk, with the drugmaker's 17,600-person SELECT trial proving a major win for semaglutide and GLP-1 agonists in general in terms of cardiovascular indications.

As drugmakers push to expand their incretin drug labels, their findings lend more evidence to the case for obesity as a serious medical condition in need of pharmacologic treatment.

"Studies like the SELECT trial are going to change this discussion," says Lazarus. "Let's say a patient comes to see a family doctor and has sky high blood pressure — ignoring it in this day and age would be malpractice. Similarly, I think we are getting to a point where we are going to have to address weight."

Full pipelines

Whether attributed to the temptation of a looming $100 billion market or the genuine hunger to fill an unmet need for millions of patients, drugmakers have taken a seat at the obesity care table.

Citeline's Pharmaprojects database found that globally, there are 51 active drugs in development with incretin mimetics as the mechanism of action. Within these compounds, 22 are being explored in obesity.

While the first drugs on the market were limited to single GLP-1 agonists, new drugs are pushing boundaries in incretin pathways as drugmakers pursue drugs with dual modes of action.

Boehringer Ingelheim-Zealand Pharma's phase 3 drug, survodutide — which has demonstrated up to 19% weight loss in trials — is a dual agonist that activates both GLP-1 receptors and receptors for glucagon, a hormone that plays a role in energy balance through receptors in adipose tissue (body fat) and the brain.

"Survodutide has the potential to become the first anti-obesity medication to induce significant weight loss by reducing

appetite while increasing energy expenditure through direct action on the liver to help people with overweight or obesity reduce their body weight," says Boehringer's Sapountzis.

Eli Lilly has a triagonist in phase 3 trials for obesity and diabetes. The asset, known as retatrutide, activates receptors for GLP-1, glucagon and GIP.

"The incretin-based treatments that are currently approved to treat obesity only activate the body's receptors for GLP-1. We believe combining glucagon receptor agonism with GIP and GLP-1 receptor agonism may contribute to higher levels of reduction than that seen in trials for single- or dual-receptor agonists," says an Eli Lilly spokesperson.

Another trending area in the clinical space has pharma squaring off against a long-established challenge — converting injectable drugs to shelf stable, oral medications. Currently, the only GLP-1 medication offered in oral form is Novo Nordisk's Rybelsus, a once-daily pill version of semaglutide, approved for type 2 diabetes.

In 2020, Novo acquired Emisphere Technologies and its proprietary drug delivery technology known as Eligen sodium N-[8-(2-hydroxybenzoyl) amino] caprylate (SNAC). The technology, used in the Rybelsus formulation, is an acylated amino acid designed to improve the oral bioavailability of parenteral drugs. SNAC enables the transport of therapeutic molecules, including large peptides and proteins, across biological membranes, such as those of the gastrointestinal tract — a notorious stumbling point for oral biologics.[13]

Both Novo and Lilly are advancing once-daily oral GLP-1 receptor agonists in phase 3 trials for obesity and Pfizer has a twice-daily oral obesity drug in mid-stage trials.

The oral formulations have shown comparable efficacy to their subcutaneous counterparts and the needle-free administration is a major selling point with patients. But the drugs still come with some hurdles. Novo Nordisk's oral semaglutides, for example, must be taken on an empty stomach with only a sip of water, and patients must wait 30 minutes before intake of food or other medications.

However, for drugmakers, oral formulations have established manufacturing, storage and distribution advantages that will not only result in lower costs but could ultimately facilitate a more global availability of much-needed anti-obesity drugs.

The big reveal

"The standard of care for the treatment of obesity in primary care has essentially been to do nothing," says Dr. Lazarus. "Ignoring the problem is really missing the mark in terms of offering patients evidence-based treatments."

But after hundreds of years of stagnating treatment, a critical moment for obesity care hangs in the balance — and incretin mimetics could tip the scales in a very big way.

"People living with obesity deserve action, not just hope. The stakes are too high to let another 10 years go by without more change," wrote Eli Lilly in a recent blog post.[14]

With the final piece of the multifaceted approach needed to combat obesity in its hands, all eyes are on the pharma industry. What the industry does next in terms of facilitating access to this innovative new class of anti-obesity treatments has the potential to not only better the health of millions, but forever transform the way the world views obesity.

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Modernizing equipment qualification

How cutting-edge technologies can streamline and enhance equipment validation processes

It is critical to operate manufacturing equipment properly to ensure product quality and process stability. Current good manufacturing practice (CGMP) requirements stipulate that the manufacturing process must be performed on qualified equipment before being validated. It is a regulatory expectation that pharma manufacturing facilities, systems, utilities and equipment are designed, constructed and qualified to suit their intended purpose.

In their guidelines, regulatory authorities indicate that organizations must build quality into their processes and products. As an example, in 1962, the FDA dedicated Subpart D of FDA 21 CFR Part 211 to equipment regulation. With the advancements in technology, the regulation was further enhanced in 1978 through 43 FR 45077 to include automatic, mechanical and electronic equipment.

EXHIBIT 1

Traditional qualification flow

Equipment qualification was performed to meet user requirements but was more of a formality.
A standard course of equipment qualification was as follows:

The equipment the pharma industry used to use was basic. Major activities, such as adding ingredients to the manufacturing process, setting machine parameters, and transferring in-process or intermediate-stage materials and finished goods to manufacturing sites, were predominantly carried out manually.

When we think of equipment today, we do not visualize a simple piece of equipment but rather a complex system that is not only efficient, consistent, compact and compliant but also autonomous (with minimal human intervention) and connected (with IIoT, data lakes, smart analytics technologies and more). The idea of equipment sitting stationary on the shop floor has been replaced by equipment that can change manufacturing dynamics.

Therefore, the traditional validation method (see Exhibit 1) for complex systems can be redundant, time-consuming, costly and could pose challenges in real-time monitoring. To address these issues, the industry should be turning to cutting-edge technologies to streamline and enhance equipment validation processes.

The future of equipment qualification

Historically, industry held a more cautious approach towards adopting technology, appreciating the potential of change but hesitant to fully embrace it. Equipment and instruments were designed with simplicity in mind, relying on hard-wired connections or with minimalistic computer control (basic PLC). Industry reluctance stemmed from a limited understanding of the advantages offered by the newer systems, as well as limited clarity from regulators on how to navigate the transition from manual to automatic systems while preserving data and its integrity.

However, with a growing emphasis on patient safety in ISPE's GAMP guidance and the ISPE Baseline Guide: Commissioning and Qualification guidelines, a fundamental structure is being ratified that ensures that safety is built into every stage of the equipment life cycle. This is an ideal time to innovate in the field of equipment technology.

The idea of equipment sitting stationary on the shop floor has been replaced by equipment that can change manufacturing dynamics.

While there is an upsurge in demand for equipment connected to the internet or within a company's data servers (data lake), there is also an uptick in the workload added to the validation team at manufacturing sites to deliver the equipment on time for commercial operations. As equipment continues to increase in complexity, its qualification becomes more complex. It is crucial to ask some obvious questions about managing the commissioning and qualification of such systems. For instance:

1. How can we reduce costs and save time during product design?
2. How complicated would it be to qualify such equipment?
3. How do we simulate the failure mode of the equipment or its computer system?
4. How do we tap into the potential of process optimization, reducing variance and predicting maintenance?
5. How do we simulate test conditions without impacting the delivery schedule?
6. How do we ensure that equipment does not fail during real-time operation?
7. Can the system provide auto-generated data for the tests that were predefined during system design while managing all the iterations that have taken place?

The answers to these questions lie within one of the more recently recognized technologies of our time — the digital twin.

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Best practice digital twin approach for pharma equipment qualification

Identify equipment and requirements: Identify the pharmaceutical equipment to be qualified; list the regulatory requirements and standards that need to be met.

Data collection and model creation: Gather relevant design and operational data for the equipment; create a digital twin model using the collected data.

Calibration and validation: Calibrate the digital twin model to ensure it accurately represents the real equipment; validate the digital twin's performance against historical data and real-world measurements.

Simulation and testing: Use the calibrated digital twin to conduct virtual simulations and tests; evaluate the equipment's performance under different scenarios and conditions.

Deviation analysis: Analyze any discrepancies between the digital twin's predictions and real-world data; identify potential causes of deviations and areas for improvement.

Optimization and adjustment: Make necessary adjustments to the digital twin model to improve accuracy and alignment with the real equipment; optimize the digital twin's parameters for better predictions.

Verification and approval: Verify the updated digital twin model against real-world test data; obtain approval from relevant stakeholders for the qualified digital twin.

Ongoing monitoring and maintenance: Implement a system for ongoing monitoring of the digital twin and real equipment; perform regular maintenance and updates to keep the digital twin accurate and up to date.

Equipment qualification report: Generate a comprehensive equipment qualification report that includes the digital twin's capabilities and performance validation.

Integration with operations: Integrate the qualified digital twin into the pharma manufacturing process and quality assurance procedures.

Continuous improvement: Continuously gather new data and feedback to improve the digital twin's accuracy and predictive capabilities; use insights from the digital twin to drive continuous improvement in equipment and processes.

A digital twin is a virtual representation of a physical asset, system or process. It involves using real-time data from sensors, advanced analytics and modeling techniques to create a virtual counterpart of the physical equipment. This twin can be used to monitor, analyze and optimize the equipment's performance, troubleshoot issues, or simulate various scenarios without affecting the actual system.

Digital twins in equipment qualification

There are several applications of this technology for qualification and validation in the pharma industry, such as:

- **Design and simulation:** During the initial design phase, a digital twin can be created to simulate the equipment's behavior and performance under various conditions. This allows engineers to optimize the design and identify potential issues before the equipment is physically built, reducing the risk of costly errors and rework.
- **Virtual qualification:** Digital twins can undergo a virtual qualification process where they are subjected to the same tests and criteria as the physical equipment. Comparing the performance of the digital twin to the actual equipment can help verify if the equipment meets regulatory and quality standards.
- **Process validation:** Digital twins can be integrated into the pharma manufacturing process to monitor and validate critical parameters and performance. By comparing real-time data from the physical equipment with the digital twins' simulations, deviations or anomalies can be quickly identified and addressed.
- **Predictive maintenance:** Digital twins can facilitate predictive maintenance by continuously monitoring the performance of the equipment and predicting potential failures or maintenance needs. This proactive approach can minimize downtime, improve equipment reliability and extend its lifespan.
- **Regulatory compliance:** Digital twins can assist in maintaining compliance with regulatory requirements by providing a detailed and accurate representation of the equipment and its behavior. This helps in demonstrating the equipment's reliability and adherence to regulatory standards.
- **Training and optimization:** Digital twins can be used for training operators and engineers, allowing them to virtually interact with the equipment and gain valuable experience without the risk of operating the actual equipment. Additionally, digital twins help to optimize processes by running simulations to identify the most efficient operating parameters.

By incorporating data and information throughout the lifespan of the equipment, it is possible to exchange data with other digital twin simulators and programs.

This is an ideal time to innovate in the field of equipment technology.

These connections and interactions allow the digital twin to be a vital decision-making source during the equipment's lifetime. Although this technology is gaining popularity in many sectors, it is still in its early stages of adoption in the pharma industry.

Digital twin benefits

By utilizing digital twin technology for qualification and validation, pharma manufacturers can see several benefits, including:

- **Real-time monitoring:** Digital twin technology allows pharma companies to continuously monitor equipment during the validation process. This real-time monitoring enables the detection of deviations and anomalies, ensuring prompt corrective actions and reducing the risk of manufacturing defects.
- **Enhanced data analytics**: By integrating various data streams into the digital twin model, the pharma industry can gain deeper insights into equipment behavior and performance. Data analytics help identify patterns, predict potential failures, and optimize equipment settings for improved efficiency and reliability.
- **Cost and time savings:** Traditional equipment validation processes involve considerable time and expenses. Digital twin technology reduces the timeline for creating physical prototypes, accelerates the validation timeline and minimizes the need for costly trial-and-error approaches.
- **Risk reduction:** Pharma companies must adhere to strict regulatory requirements. The use of digital twin technology can help lower risks by ensuring that equipment complies with the necessary regulations and guidelines from the outset.
- **Simulating various scenarios:** Digital twins enable the simulation of different operational scenarios without interrupting actual production. This capability allows manufacturers to assess how equipment responds to varying conditions, helping to optimize processes and avoid potential downtime.
- **Predictive maintenance**: By continuously monitoring equipment performance, digital twin technology can predict when maintenance is required, thereby reducing the chances of unexpected breakdowns and unplanned production interruptions.

A working example

A pharma company can adopt digital twin technology to validate a critical blending machine used in the production of oral solid dosage forms. The machine's sensors can collect real-time data on variables like temperature, pressure and mixing speed. This data can be fed into the digital twin model, creating a virtual replica of the blending machine.

During the validation process, the digital twin should accurately mirror the behavior of the physical machine. Deviations from standard operating conditions would be detected promptly, allowing the company's engineers to make the necessary adjustments in real time. The virtual model should also help identify optimal operating parameters, leading to improved blending efficiency and product quality.

Digital twin technology offers significant advantages for equipment validation in the pharma industry. By providing real-time monitoring, enhanced data analytics and the ability to simulate different scenarios, it streamlines the validation process, reduces costs and improves the overall reliability of manufacturing equipment.

As the technology continues to evolve, its adoption is expected to become more widespread, transforming how pharmaceutical companies validate their equipment and ensuring they remain at the forefront of compliance and quality standards.

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Decentralizing data

How data mesh can help pharma free data from silos

The pharma industry can unlock a wealth of advantages by tapping into the capabilities of data analytics.

Pfizer, for example, uses data to create an efficient manufacturing and supply network that streamlines the way it delivers medicines to patients. Roche employs data analytics to advance its personalized medicine initiatives, provide holistic care and drive better patient outcomes. But there's a catch.

Given that many global pharma companies have teams in different regions, establishing a centralized data system to power analytics throughout their organizations becomes challenging. This is primarily due to the diverse regulatory environments in each region, as well as the distinct sub-organizational goals, priorities and IT budgets. Global teams own and manage different data hubs, leading to data silos.

At its core, a data silo occurs when there is a lack of connectivity between data sources, meaning that other groups in the same organization struggle to easily or fully access data. When critical data becomes trapped, users are forced to rely on partial or incomplete information, negatively impacting the decision-making process across the entire organization. According to a recent survey, 68% of knowledge workers — pharmacists, engineers, architects, scientists and academics — report that not having visibility into cross-functional projects adversely affects their work.[1]

Data silos exist throughout the modern pharma industry, from databases to shared network folders. They even exist between research colleagues at the same company. And even though data silos often emerge within large pharma organizations, any pharma business — regardless of size — may find itself facing data silos if there is no carefully planned data management strategy.

Now is the time to take a closer look at the impact of data silos on the pharma industry and how data mesh, a modern approach to data management based on decentralized data architecture, can help companies address this issue.

The problem with data silos

Effective cross-functional collaboration plays an important role in pharma organizations, as each department brings a unique set of skills, knowledge and perspectives to the table. That's why collaboration is crucial when it comes to improving information flow, identifying potential risks before they escalate, reducing bottlenecks and adapting to ever-changing market demands and regulatory requirements.

However, a recent Aspen Technology survey highlighted

that nearly half of the senior decision-makers from drug development or manufacturing companies agree that data silos significantly hinder cross-functional collaboration and efficiency within their organizations.[2] For this reason, removing data silos and barriers to data integration and sharing can help pharma companies enable faster processes, improve overall efficiency and save valuable time and resources.

In addition to that, pharma companies accumulate massive volumes of data throughout the drug development life cycle, from preclinical research, clinical trials, manufacturing and marketing. On average, phase 3 clinical trials alone produce approximately 3.6 million data points. This is three times more than the data gathered during late-stage trials a decade ago, according to a 2021 study from Tufts CSDD.[3] The same report also suggested that clinical trial designs are poised to become more complex and generate even greater data volume and diversity in the future.

The heart of the matter is that many data silos are not consistent with other data sets due to information stored in various systems or scattered throughout different departments. When data from one silo does not perfectly align or match with data from another silo, companies cannot integrate and analyze information effectively, leading to inaccurate results or incomplete insights.

On top of that, regulatory agencies, such as the U.S. FDA, have strict requirements for the quality, accuracy and integrity of data submitted in drug applications. Therefore, inconsistent data makes it difficult for pharma organizations to comply with regulatory requirements, which increases the chances of rejection and results in fines and even legal consequences.

For example, in 2012, GSK pleaded guilty and agreed to pay $3 billion to settle criminal and civil charges, covering issues such as failure to report safety data, unlawful drug promotion and alleged false price reporting practices.

A data silo occurs when there is a lack of connectivity between data sources, meaning that other groups in the same organization struggle to fully access data.

Eliminating data silos and enabling seamless information flow can also allow pharma companies to significantly improve data accuracy and ensure that sensitive data is well-protected. This, in turn, helps reduce the risk of unintentional data breaches, increases compliance efforts, streamlines regulatory inspections and prevents potential noncompliance penalties.

"Even the unintentional release of sensitive medical information is a serious breach of consumers' trust," highlighted J. Howard Beales, director of the Federal Trade Commission's Bureau of Consumer Protection back in 2002 after Eli Lilly had settled charges concerning a security breach.[4] "Companies that obtain sensitive information in exchange for a promise to keep it confidential must take appropriate steps to ensure the security of that information."

How data mesh can help pharma

The solution to problematic data silos lies within modern decentralized data architectures like a data mesh. Acting as a unifying force, a data mesh is a transformative approach to data management, creating a data-first community that seamlessly connects data providers with data consumers in a secure manner.

A data mesh's value goes beyond just fostering efficient communication: It also helps reduce complexity by granting users access to relevant information instead of all available datasets, which is particularly beneficial for pharma companies navigating large amounts of data. Thanks to this capability, teams are able to make quick decisions and enhance overall operational efficiency.

However, implementing a data mesh approach may be easier said than done, as there are numerous technical challenges to overcome. For starters, following the domain-driven, self-service data mesh infrastructure can involve a significant investment in hardware and software resources, requiring databases, messaging systems and application programming interfaces.

Creating a mindset change within the business domain where the members are the owners of the data and responsible for its quality and processing capability presents another hurdle. This is primarily because traditional business hierarchies often place data-related responsibilities in the hands of IT departments or data specialists. But regular communication about the significance of data ownership and its direct correlation to better decision-making, drug development and patient outcomes can help pharma companies emphasize the importance of this transformation and speed up the process.

The fruits of implementing a data mesh can be significant, especially in the pharma domain, where data is more diverse, global and covered by more regulations. Creating ownership fosters bottom-up accountability and a data-first mindset that can be crucial to unlocking exponential business value from data.

Building a data mesh strategy

Here are eight steps pharma companies can follow in order to establish and implement a data mesh strategy.

Step 1: As-is assessment
Organizations must gain a deep understanding of their existing business challenges, data infrastructure, processes and systems. Businesses can achieve this by defining key objectives, performing a business analysis, assessing data infrastructure, and cataloging and categorizing all collected data. The as-is assessment needs to be aligned according to the various business domains. This way, companies can identify and prioritize the data gaps that require immediate attention.

Step 2: Identify business domains
Each domain — whether research and development, clinical trials, manufacturing, supply chain, sales or marketing — has its own data needs and stakeholders. Therefore, pharma organizations need to make sure to identify the different business domains existing within their company, focusing on the ones highlighted in Step 1 as the most important areas to address.

Step 3: Formulate cross-functional domain teams
This involves working with domain experts, data engineers, data scientists and analysts. These teams will be responsible for managing the data within their respective domains and aligning it with an organization's overall strategy.

Step 4: Assign data product owners
Data product owners on each domain team can focus on the quality, availability and usability of the data products within their domains. Moreover, they can collaborate with other domain teams to define data product boundaries and ensure consistency and interoperability. These owners would also own the compliance of data with the specific regulatory frameworks governing it.

Step 5: Implement decentralized data infrastructures
There are several decentralized data infrastructures that support the data mesh approach, such as data vaults. This typically involves implementing a data warehouse that serves as a centralized storage repository for the data products.

Step 6: Enable data product discovery
Develop mechanisms for data product discovery and access. This may include a data catalog or data

marketplace that provides information about available data products, their owners and relevant metadata, which is important to ensure data privacy, security and compliance.

Step 7: Foster a data-centric culture
In order to promote a data-driven culture, companies can start by encouraging collaboration among employees. By doing so, team members can learn from each other's experiences, best practices and challenges, accelerating the learning curve. Companies can provide training programs and resources to assist employees in developing data literacy skills.

Step 8: Monitor and iterate
Regularly monitoring the data mesh implementation and seeking feedback from domain teams and data users are essential practices. Based on the valuable insights received, organizations can continue to iterate and improve data products, infrastructure and processes. Given that pharma companies operate in an environment influenced by regulatory changes, clinical advancements, and shifting patient expectations, regular evaluations can enable them to maintain agility and stay relevant.

The bottom line

By harnessing the power of data analytics, pharma companies can open up numerous opportunities, such as accelerating drug development, improving patient safety and streamlining business operations.

Varying regulatory demands and organizational priorities can result in different departments having their own data hubs, which leads to data silos. Not being able to access information seamlessly impacts collaboration within a pharma company, compromises the accuracy of data and even affects compliance efforts.

As a data mesh approach securely connects data providers and users while facilitating streamlined communication, it enables pharma companies to overcome these hurdles. While challenges still exist, the benefits of adopting a data mesh approach can be substantial.

For the full list of references visit PharmaManufacturing.com

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Elevating cold chain logistics

How the pandemic spurred a technology evolution for temperature-sensitive products

Cold chain logistics plays a vital role in the pharmaceutical industry. One of the most notable ways is in the transportation and storage of temperature-sensitive products like vaccines, blood products and biologics.

Without a doubt, the pandemic brought challenges to the pharmaceutical cold chain — many for which the industry was not prepared. The urgent need to distribute vaccines and other perishable supplies highlighted the vulnerabilities of the existing supply chain.

The regulations governing cold chain logistics have undergone major shifts in recent years, aiming to maintain the quality and safety of the critical raw materials essential for delivering lifesaving therapies. Shipping these materials in certain locations or by certain modes — particularly air transport — increases vulnerabilities due to air pressure and temperature fluctuations. Improper packaging could lead to heat or cold exposure outside of acceptable temperature ranges and potentially compromise the quality of the product.

To safeguard the integrity of pharmaceutical products throughout the supply chain, organizations are adopting Good Distribution Practices (GDP) and Hazard Analysis and Critical Control Points (HACCP) principles. GDP guidelines outline the necessary processes, infrastructure and controls needed. HACCP, on the other hand, focuses on identifying and managing potential risks and hazards in the cold chain process.

In addition to the adoption of GDP and HACCP guidelines, advancements in technology and monitoring and the development of smarter preservation methods have played pivotal roles in safeguarding temperature-sensitive pharmaceutical products.

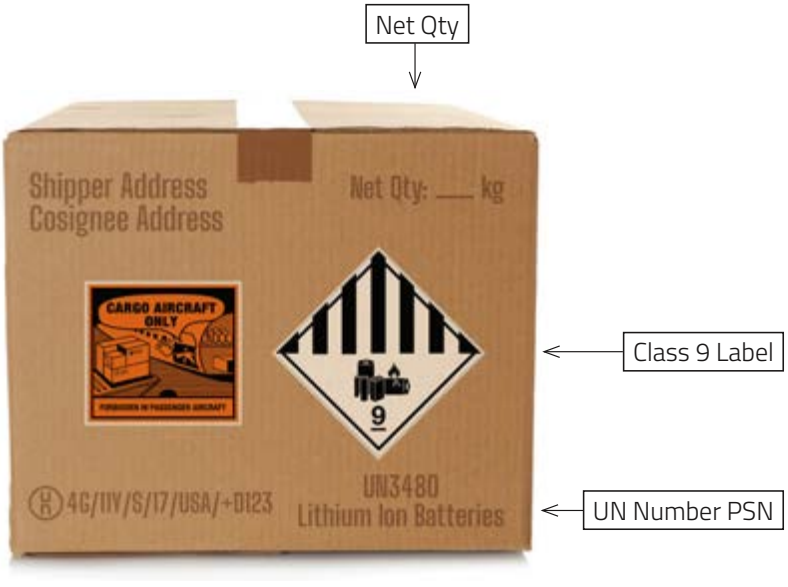
Finding the right preservation methods

Preserving goods throughout the cold chain has been an ongoing challenge. However, the industry has been actively exploring smarter preservation methods to ensure product quality. One notable development is the increasing use of dry ice for shipping temperature-sensitive products.

Dry ice, which is solid carbon dioxide, has excellent cooling properties and is commonly used as a coolant during transportation. It sublimates directly from a solid to a gas, eliminating the need for melting ice or refrigeration units. This feature makes it a smart choice for maintaining the required temperature conditions during transit.

But shipping cold chain products using dry ice comes with certain limitations. For instance, traditional methods of using dry ice may result in inconsistent insulation and temperature control, potentially jeopardizing product integrity. To overcome this challenge, some companies are investing in packaging solutions that provide enhanced insulation, better temperature control and longer-lasting cold conditions. These advancements minimize temperature variations and ensure the safe delivery of temperature-sensitive pharmaceutical products.

Lithium ion battery packaging



Evolution of technology

The evolution of technology for shipping cold chain products has produced significant advancements in recent years. Manufacturers and logistics providers have continuously strived to enhance insulation, temperature control and overall product integrity.

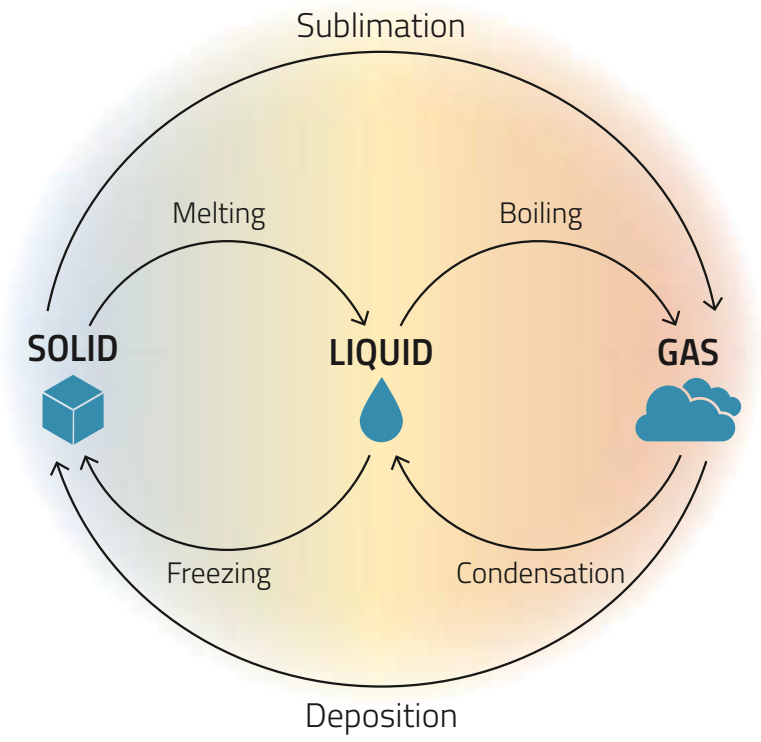
One of the key areas of improvement has been the development of more efficient packaging solutions. Insulated shipping containers with enhanced thermal properties help minimize heat transfer and temperature fluctuations during transportation. These containers are designed to withstand varying ambient conditions and can maintain the required temperature range for extended periods.

Furthermore, innovative temperature-monitoring devices have been integrated into the packaging, allowing real-time monitoring and data logging of temperature conditions. This enables stakeholders to track and analyze temperature data throughout the journey, ensuring compliance with regulatory standards and identifying any potential temperature excursions.

To further address the limitations of traditional dry ice packaging, companies have also introduced advanced phase-change materials (PCMs) and thermal wraps. These technologies enhance insulation and provide longer-lasting temperature control, thereby extending the shelf life of temperature-sensitive products.

A PCM is a substance that absorbs energy at the phase transition to provide cooling. A simple example of using PCM would be ice in a drink. Two of the most used PCMs in transportation are water-based gel packs and dry ice (solid carbon dioxide). Dry ice is regulated as a hazardous material in transport because the sublimating carbon dioxide gas displaces oxygen. Advanced PCM gels are used to replace dry ice and have a phase

Phase changes



Melting ——> Solid to a liquid
Freezing ——> Liquid to a solid
Boiling ——> Liquid to a gas
Condensation ——> Gas to a liquid
Sublimation ——> Solid to a gas
Deposition ——> Gas to a solid

change around -1 degree C or -20 degrees C. Replacing a hazardous material in transport with a non-regulated gel provides some transport restriction relief.

Thermal wraps are enhanced insulation that provide longer-lasting temperature control, protecting temperature-sensitive products from extreme temperature shifts during transport. These can be added to the existing thermal protection during extreme situations.

A global pandemic meant global solutions

The global supply chain disruptions, transportation restrictions and increased demand experienced during the pandemic put immense pressure on pharma companies and logistics providers to find alternative solutions to deliver critical products to health care facilities and patients in a timely manner.

Companies and industry stakeholders rapidly adapted to the challenges by implementing agile strategies and leveraging technology to ensure uninterrupted cold chain operations. This included optimizing transportation routes, enhancing inventory management systems and establishing dedicated cold storage facilities.

Moreover, collaborations between pharma companies, logistics providers and government agencies played a crucial role in streamlining the distribution process, prioritizing high-demand regions, and reducing bottlenecks. Examples include the transport industry and regulators quickly adjusting to provide solutions and regulatory relief for new companies producing and transporting hand sanitizer (hazard class 3). Amazing collaboration also occurred between air carriers, regulators and pharma logistic providers to move the large quantities of dry ice (hazard class 9) needed to maintain frozen vaccines during transport.

There are several dangerous goods (DG) transport associations, such as the Council on Safe Transportation of Hazardous Articles (COSTHA), Dangerous Goods Advisory Council (DGAC) and Dangerous Goods Trainers Association (DGTA) working to streamline transport requirements and prevent regulations from impacting pharma companies. One example would be recent work by several organizations at the UN to simplify the requirements for lifesaving medical devices containing lithium batteries in transport.

Steps to ensure compliance

Another challenge when it comes to the pharmaceutical supply chain is that many of the items being shipped — from clinical specimens and medical devices to dry ice and temperature monitors containing lithium batteries — can be classified as DG and have strict regulations around how they should be packaged, handled and transported.

To ensure successful shipping and proper handling of goods across the cold chain, it is important to keep the following strategies in mind:

Gel packs contain phase change material designed to maintain the recommended temperature range inside a cold box or carrier.

1. Know the regulations

Stay updated on the specific items being shipped and their classification, especially if they are considered dangerous goods. Familiarize yourself with the regulations governing the transportation of these items, including any shipping restrictions.

It's also important to establish processes and infrastructure to ensure compliance throughout the supply chain. This includes staying informed about evolving DG shipping regulations in the U.S. and globally, and effectively communicating relevant information within your organization and with supply chain partners.

A notable example is the change in regulations regarding the transport of lithium batteries as a hazardous material. The lithium battery found in a medical device, temperature recorder or laptop is regulated in transport. New hazard communication and modal restrictions could stop shipments (affecting consumers) and subject companies to significant fines and penalties for noncompliance. The Pipeline and Hazardous Materials Safety Administration (PHMSA) offers a lithium battery guidance document to guide U.S. companies in safe and compliant lithium battery transport.

2. Seek expert guidance

DG shipping regulations can be intricate and change constantly. Consult various attorneys and compliance experts to ensure compliance with the regulatory requirements for shipping pharmaceutical products across different modes of transport. These experts can help assess your facilities and compliance programs, identify any gaps, and integrate compliance into aspects of your organization and supply chain partnerships.

3. Use appropriate packaging

Proper packaging is crucial to safeguard the integrity of goods during transportation. Utilize only materials that are UN-certified for DG packaging. Supply chain issues have been devastating to many suppliers of UN-certified packaging since substitutions are often not allowed in certified packaging.

One hotly discussed topic recently in life science packaging is the UN requirement for fiberboard boxes used in limited quantity packages to be able to pass the Cobb water absorption test. This test is difficult for some recycled fiberboards to pass, which comes at odds with the sustainability requirements to use recycled materials that many companies are implementing.

4. Provide effective training

Training is vital in ensuring safe and compliant shipping practices. Ensure that all employees involved in shipping and handling DGs receive the necessary training, not only to fulfill training mandates but also to equip them with the skills to perform their duties correctly. Incorporate digital and e-learning tools as well — these can facilitate remote training for new employees and offer interactive and effective learning experiences.

5. Foster a compliance-oriented culture

Pharmaceutical companies have a direct impact on people's lives. It is crucial to maintain accountability and uphold the highest standards. Any indication of cutting corners, noncompliance, or inadequate processes can negatively affect customers or patients, brand reputation and business outcomes. Therefore, strive to create a culture that prioritizes compliance and embraces the necessary measures for ensuring safe and compliant shipping practices.

A promising future

Although the pandemic posed challenges, it has also spurred innovation and resilience within the supply chain, driving the evolution of technology in shipping cold chain products. As industry continues to adapt and improve, the future of cold chain logistics holds the promise of even greater efficiency, reliability and safety for the delivery of critical medical products.

Devin Bertsch
Project Director, Project Management Advisors (PMA)

Meeting new sustainability targets

Sustainability in pharma is complex, but there are opportunities for drugmakers and building developers to meet green goals

In the last five years, commercial property owners and building developers have stepped up to rein in their environmental impact and promote more sustainable operations. With a federal regulatory push, they are advancing toward net-zero building emissions by 2045, with a 50% reduction by 2030.

It's an ambitious goal, but pharma properties will be especially challenged to transform into net-zero environments, as lab spaces inherently require more robust power and water sources than traditional buildings.

Sustainability in pharmaceuticals is a complex issue, but there are opportunities for pharma companies and building developers as they work to meet new standards.

Pharma considerations

Unlike typical commercial offices, pharma buildings require specialized construction buildouts and benchtop equipment supported by energy-demanding mechanical, electrical and plumbing infrastructure. Energy usage is driven by various needs, like higher equipment driving system capacities, the frequency of air changes, water usage, or the additional backup power required to operate state-of-the-art equipment.

Although not all labs are the same, all life sciences properties produce a disproportionately larger environmental footprint than a standard office building, with little flexibility to use less energy. As one report from JLL notes, although the life sciences sector accounts for just 1% of real estate, it uses 10 times the energy and four times the water of a standard commercial building.

Although stakeholders are all working to make transformative changes to upgrade traditional lab operations and systems, many companies are playing a balancing act between what is affordable and what is implementable to maintain normal lab function.

Large pharma companies are leading the way by adopting ESG and efficiency standards internally and occupying buildings that complement their goals. These companies are testing out alternatives to evolve toward the creation of standardized sustainable industry practices that don't derail scientific progress.

Net zero vs. all-electric

While often used interchangeably, net zero and all-electric are two very different concepts. Net zero is the most comprehensive goal in building sustainability, addressing efficiencies in energy, water and waste with the goal of reducing or eliminating a building's carbon emissions.

Net zero is a lofty goal for pharma properties, but labs have an alternative solution that still helps achieve sustainability goals. All-electric energy labs will be able to operate with a net zero energy output as soon as the electrical grid that supports the lab is operating at net zero. This takes some of the onus off the lab operator and it puts the lab in a position to meet net zero goals as soon as the local infrastructure is updated.

It's been reported that Longfellow Real Estate Partners is building a 315,000-square-foot all-electric lab in the Bay Area. Known as the Avia Labs at Millbrae Station, it will be the first all-electric life sciences campus in California. This is a significant accomplishment that could be a model for future sustainable life sciences development in the state.

Reaching for sustainability

Outside of aiming for the lofty goal of net zero and all-electric labs, there are smaller steps that can reduce a building's carbon footprint.

Biofuels, which are renewable and burn cleaner than fossil fuels, offer a big win for companies that need natural gas but are aiming to increase sustainable operations. They are also a great option to support emergency generators without derailing broader environmental targets.

Sustainability can be enhanced during the building process as well. Pursuing standard green building practices, such as sourcing local materials, helps to reduce the property's carbon footprint. The use of sustainable building materials like recycled metals, plastics and wood helps offset the environmental impact of development.

Pharma companies, whether startups or household names, are looking for spaces in which they can do groundbreaking work. Lab spaces need to support a scientific use but companies are also concerned about the environment. The bar may be high, but many building development teams and pharma companies are already pushing forward to meet regulatory green goals.

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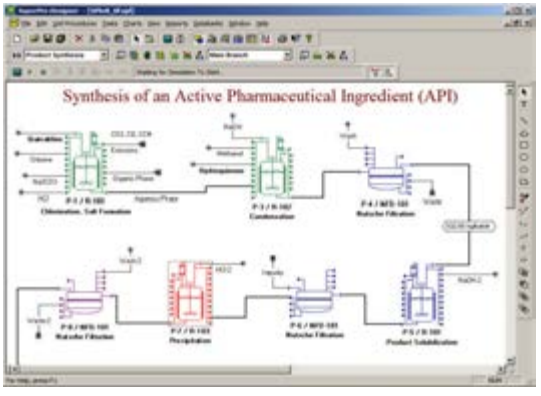

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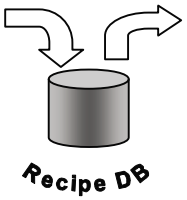

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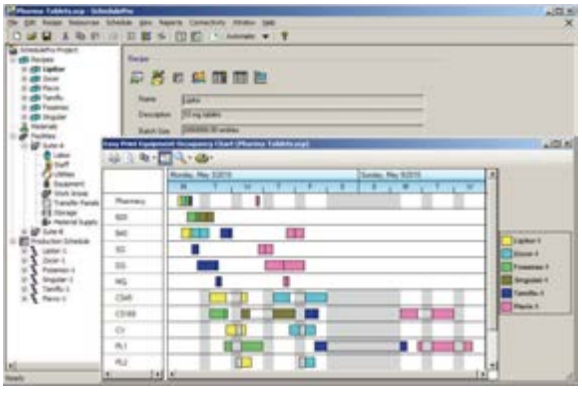

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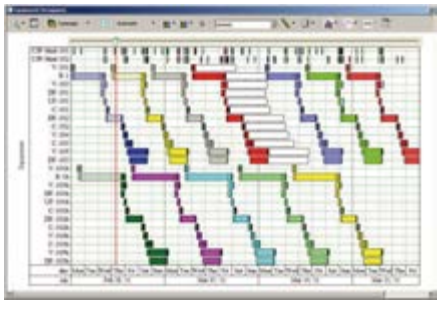

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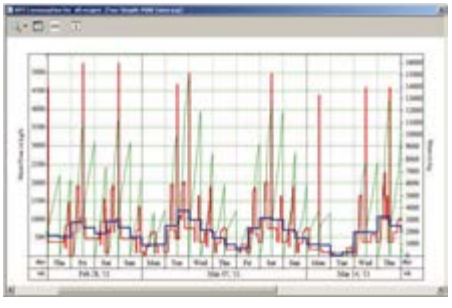
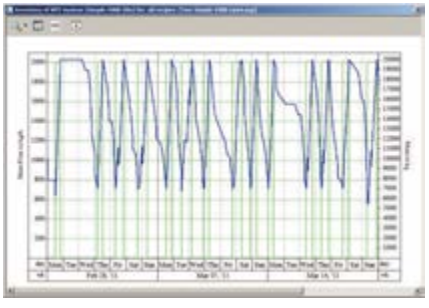


Tracking demand for resources (e.g., labor, materials, utilities, etc.)



Managing inventories for input, intermediate, and output materials

SuperPro Designer is a comprehensive process simulator that facilitates modeling, cost analysis, debottlenecking, cycle time reduction, and environmental impact assessment of integrated biochemical, bio-fuel, fine chemical, pharmaceutical (bulk & fine), food, consumer product, mineral processing, water purification, wastewater treatment, and related processes. Its development was initiated at the Massachusetts Institute of Technology (MIT). SuperPro is already in use at more than 500 companies and 900 universities around the globe (including 18 of the top 20 pharmaceutical companies and 9 of the top 10 biopharmaceutical companies).

SchedulePro is a versatile production planning, scheduling, and resource management tool. It generates feasible production schedules for multi-product facilities that do not violate constraints related to the limited availability of equipment, labor, utilities, and inventories of materials. It can be used in conjunction with SuperPro (by importing its recipes) or independently (by creating recipes directly in SchedulePro). Any industry that manufactures multiple products by sharing production lines and resources can benefit from the use of SchedulePro. Engineering companies use it as a modeling tool to size shared utilities, determine equipment requirements, reduce cycle times, and debottleneck facilities.

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Chief Executive Officer, eschbach

Ready for the next revolution?

How pharma can build a truly people-centered approach to technology integration

Every organization has both explicit and tacit knowledge. Explicit knowledge includes documented processes, SOPs, training materials and automated systems. These knowledge forms are objective, reusable and transparent. They are also relatively easy to capture.

But documented data and processes are only the tip of the iceberg when it comes to an organization's knowledge ecosystem. Tacit knowledge includes skills, experience, observations and expertise gained on the job — and is usually undocumented. Long-time employees tend to accumulate a wealth of tacit knowledge that makes them go-to resources. They can answer questions that aren't addressed in official documentation and help troubleshoot out-of-the-ordinary situations.

Capturing tacit knowledge can be difficult, especially since its value is often unrecognized until a situation arises. But these unspoken rules and problem-solving strategies are critical to the safe and smooth operation of a pharma plant.

A centralized knowledge management system designed to capture both explicit and tacit knowledge can help pharma improve efficiencies, reduce risk and drive innovation. New solutions will help move pharma from Industry 4.0 to Industry 5.0 — a truly people-centered approach to technology integration.

Managing knowledge

Knowledge management is a dynamic process — especially when it comes to tacit knowledge. A knowledge management system must be able to generate the right information at the time that it's needed, communicate that information in a usable form, help employees apply knowledge to the situation, and preserve newly generated knowledge for future use.

Capturing, communicating, applying and preserving knowledge gained through experience moves knowledge from the tacit realm to the explicit realm. Efficient knowledge capture and dissemination ensures that tacit knowledge is not locked up in the heads of a few key employees, but instead can be accessed and utilized by anyone who needs it.

AI-powered knowledge management

An effective plant process management (PPM) system includes a knowledge-capturing component that empowers employees by giving them the right information at the right time to do their jobs effectively. Tapping into the existing knowledge dispersed across the organization enables better decision-making, reduces duplication of effort, saves time and decreases human error. Knowledge sharing across departments also generates new insights and enables the discovery of new efficiencies and innovations.

A centralized, digital knowledge system for data, observations, notes, tasks and activities across the plant captures the tacit knowledge that is hidden in shift handover notes, equipment inspection observations, maintenance logs and ad hoc email communication between employees. But capturing knowledge is just the first step. Keyword-based search methods may return hundreds or thousands of hits, with varying degrees of applicability. This is where recent technologies based on artificial intelligence like natural language processing (NLP) and machine learning (ML) help.

Building AI into the knowledge management platform enables new, transformative digital applications such as smart search and solution suggestion. Instead of sifting through a multitude of hits generated by traditional keyword search, people can ask questions or request information in their natural language, just as if they were talking to a colleague.

Using NLP and ML, the system understands what the user is looking for and finds the answers hiding in data. With ML, the system can predict which answers or solutions are most relevant based on the context of the question or even synthesize information to develop new suggestions. Soon, extracting knowledge from digital systems may be as easy as asking a colleague, "When was the last time the color of the product was out of specification?"

Smart search and solution suggestion will help the pharma industry transition from Industry 4.0 (basic automation) to Industry 5.0. AI-powered shift handover and PPM systems work with people, giving them tools and information needed to perform their jobs more effectively, and collaborate across areas of responsibility.

Combining the strengths of people and technology will allow pharma manufacturers to discover new process efficiencies and accelerate discovery and innovation.

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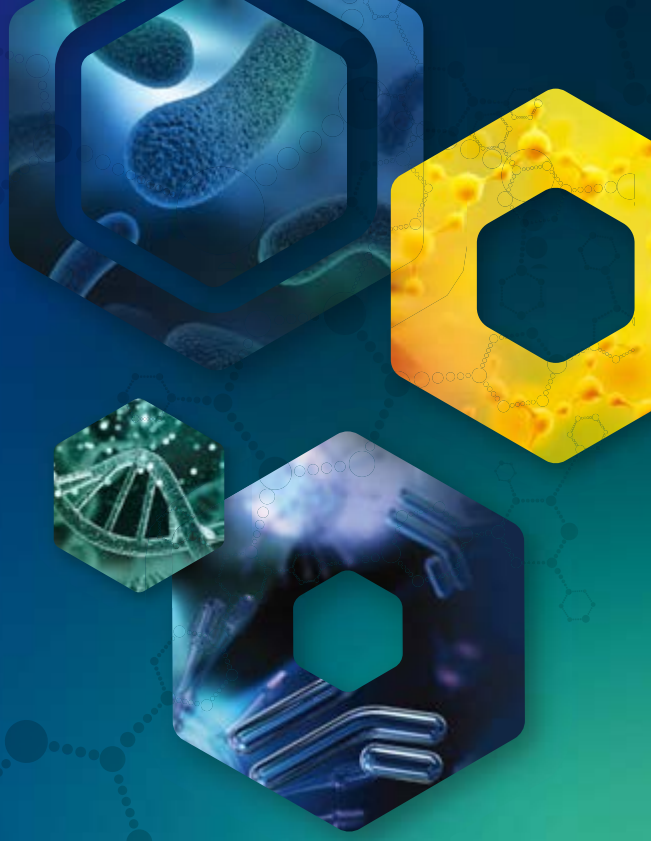

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