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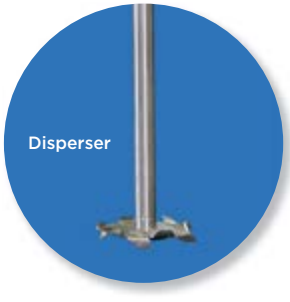

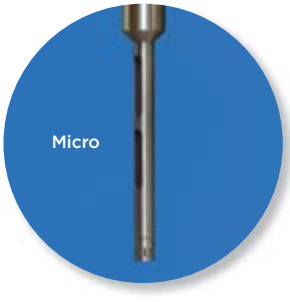

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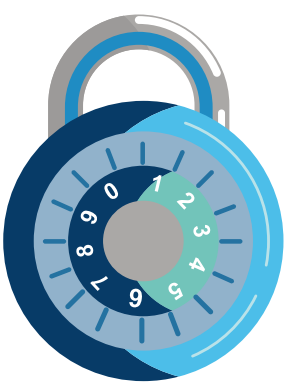

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Karen Langhauser
Chief Content Director

Hammering away at innovation

Here's to the tools that help build a better pharma industry

When it comes to examples of human innovation, the wheel is a fan favorite.

In a more simplistic telling of history, Homo sapiens invented the wheel and from there were empowered to advance both agriculture and transportation. However, most archeologists agree that the timeline is a bit more protracted than this succinct version of the wheel's origin implies.

While the details of the wheel's history aren't set in stone, excavations have led archeologists to believe that wheels first appeared in Mesopotamia around 3500 B.C. to help potters shape clay.

Which means, the first wheel was more likely a tool rather than an end product. Getting a wheel to rotate while supporting weight for the purpose of transport — and thus exist as standalone product — was a more complex undertaking and likely came much later in time.

Though the wheel is often heralded as the primordial example of humankind's ingenuity, tools, including knives, hammers and even sewing needles, were around far before the wheel began turning on its axle. And in my opinion, tools don't get enough credit for their roles in history.

To that end, this issue's cover story is dedicated to the tools — and the toolmakers who forged them.

Our annual Pharma Innovation Awards were fashioned over a decade ago in a conference room in Schaumburg, Illinois (archeologists recently found evidence of this in a 2013 print issue buried in the depths of my office closet). Inspired by product origin stories shared with us on tradeshow floors, the awards aim to tell the story-behind-the-story and celebrate the equipment and technologies that help drugmakers continue to produce lifesaving therapies.

Having overseen this award program for years, I've come to appreciate that most 'innovations' are not earthshattering. In fact, some of the best ideas that have rolled across our desks have offered incremental, yet sorely needed, improvements to existing technology. In much the same way that ancient tools evolved to meet the needs of their users, pharma equipment providers have adapted their technologies to serve the modern needs of the pharma industry.

From seamlessly automating previously manual tasks to easing the burdens of scale-up to tackling the unique complexities of today's advanced therapeutics, our winners have been hammering away with the end goal of putting stronger solutions into the hands of drugmakers.

Please join us in celebrating this year's winners, 13 products spanning across six different categories, highlighted for their robust contributions to keeping the wheels of pharmaceutical progress spinning forward.

Karen Langhauser
Chief Content Director

Andrea Corona
Senior Editor

High quality events

Pharma Manufacturing editors peek at the future of quality and data management

The next frontier in quality

Earlier this month, Pharma Manufacturing headed out to Salt Lake City to attend MasterControl's Masters Summit 2023. The annual event offers education and inspiration for quality and manufacturing professionals in life sciences and other regulated industries — whether they are MasterControl customers or not.

Keeping pace with QC evolution

MasterControl began as a document control solution provider, helping companies navigate ISO compliance requirements. The company's founding in 1993 pre-dated 21 CFR Part 11 regulations on electronic records. When the FDA released the regulations in 1997, enabling pharma companies to use software to create, update and store records, MasterControl pivoted to developing software solutions for quality control processes, ultimately transitioning to SaaS cloud-based solutions.

MasterControl CEO Jon Beckstrand recognizes the "astronomical challenge of getting to market" faced by today's pharma manufacturers. After 20 years of leadership from Beckstrand, the company remains laser-focused on helping its customers to deliver breakthrough technologies to the market faster and at a lower cost.

Right now, with the world abuzz about AI, Beckstrand says pharma companies are thinking carefully through the details. In a complex regulatory landscape where patient safety is prioritized, "the industry must figure out how to contextually incorporate AI in a compliant way," says Beckstrand— and MasterControl plans to be there to help along that journey.

Ultimately, AI can help pharma to use all the data it creates and collects to improve performance, safety and quality. And technology providers that can give pharma customers meaningful access to connected data and the insights that result, will prevail.

Chief Content Director Karen Langhauser participated on a 'real-world voices' panel at this year's Masters Summit. The panel, which also included moderator Jennifer Sefakis and Quality Digest's Jeff Dewar, discussed continuous improvement, manufacturing careers and practical AI applications.

Data can fool you

The summit also featured a colorful plenary session by famed astrophysicist, Neil deGrasse Tyson. Tyson spoke about objective truths of science and how easily things around us — such as internet searches and bad science reporting (no offense taken) — can lead us astray. Data is the path to objective truth, however data, said Tyson, "can fool you."

Tyson, with his trademark wit, seamlessly opined on news headlines touting astronomic events that are not astronomically significant (spoiler, 'super moons' are not all that super); the existence of aliens (Tyson wonders why, with 4 billion hi-res images and videos uploaded to the internet each day does all our alien footage look like "grainy tic tacs?"); and perhaps most importantly, why pineapple doesn't belong on pizza.

Championing innovation

In order to continue to facilitate lifesaving innovation in the pharma industry, technology providers also need to continually refresh and revamp their products. To that end, the summit features an annual Hackathon reception.

A fan favorite event, this year's Hackathon broke attendees into 15 'pods,' tasking each group to come up with 12 new ideas for features they personally wanted to see added to MasterControl software solutions. The top 16 ideas were put into a March Madness-like bracket, and the next day, attendees got to vote bracket by bracket in real-time from their apps.

MasterControl engineers were on-site and by the end of the event, they had coded 12 of the most popular features into the software. All of those features will be active in the next quarterly release of the product.

Sticking with the innovation theme, the North American Masters of Excellence Award winners were also revealed during the summit. The awards recognize MasterControl customers who have excelled in quality and manufacturing innovation. The winners included:

- The Quality Champion: Kate Selzman, director, Quality Assurance, Alcami
- Digital Transformation in Manufacturing: QuVa Pharma
- Excellence in Analytics: Pine Pharmaceuticals
- Innovation Excellence: Oncocyte

Top THREES of 2023

Most popular news headlines

1. FDA flags shortage of Eli Lilly diabetes drug (July 2023)
2. Sanofi is 'all in' on AI with new app launch (June 2023)
3. Roche wins FDA approval for bispecific lymphoma drug (June 2023)

Most anticipated drug approvals

1. Leqembi: Eisai/Biogen, Alzheimer's disease (Jan. 2023)
2. Elevidys: Sarepta Therapeutics/Roche, Duchenne muscular dystrophy (June 2023)
3. Roctavian: BioMarin Pharmaceutical, hemophilia A (June 2023)

Biggest pharma M&A deals

1. Pfizer announces $43 billion acquisition of Seagen (March 2023)
2. Amgen completes $27.8 billion acquisition of Horizon Therapeutics (Oct. 2023)
3. Merck completes $10.8 billion acquisition of Prometheus Biosciences (June 2023)

Best-selling drugs (first half 2023)

1. Merck's Keytruda ($12.1 billion)
2. AbbVie's Humira ($7.6 billion)
3. Bristol Myers Squibb's Eliquis ($6.6 billion)

Worst regulatory letdowns

1. FDA issues Eli Lilly a CRL for accelerated approval of Alzheimer's disease drug, donanemab (Jan. 2023)
2. FDA issues Biogen and Sage Therapeutics a CRL for Zurzuvae in major depressive disorder (Aug. 2023)
3. FDA issues Mesoblast a CRL for its resubmission for remestemcel-L for pediatric steroid-refractory acute graft versus host disease (Aug. 2023)

The future of data management is here, and pharma is ready

The 2023 Veeva R&D and Quality Summit took place in Boston from September 10-13, and Pharma Manufacturing was there to hear the scoop. Designed to serve as a knowledge-sharing platform, the annual Veeva event offers insights into the latest updates and technologies related to research, development and quality control.

Advancing innovation

Much like our annual Pharma Innovation Awards included in this issue, each year, Veeva honors exceptional people who have gone above and beyond to drive the industry forward. Announced during the keynote at the summit, the 2023 Veeva Hero Award recipients included Hanssar Chacón from CRISPR Therapeutics, Melissa Umbehauer Chiasson from Takeda, Denise Guerriero from Pfizer, Charles Johnson from CSL Behring, John Kelleher from Pfizer, Nick Kurkjy from Takeda, Matt Neal from Atara Biotherapeutics, Regina Norelli from Replimune, Ann O'Heney from Teva Pharmaceuticals and Jennifer Willhide from Emergent BioSolutions.

Celebrated for their commitment to advancing innovation and excellence within their respective organizations and the broader industry, these individuals were lauded for their roles in expediting clinical trials, driving transformative change in quality, regulatory and safety programs, and promoting cross-functional collaboration across the product development landscape.

A data-centric approach

At the summit, experts discussed the future of the pharma industry, placing emphasis on the increasing importance of data. Across several panels, industry experts echoed that the compass points towards a shift to a data-centric approach in response to evolving regulatory landscapes, marking a departure from traditional narrative-based submissions. Moreover, the potential for heightened collaboration among health authorities was underscored as a strategy for streamlining submissions and expediting approvals.

Data integrity also took center stage. Panelists spoke about how the task of ensuring data accuracy and privacy is becoming more complex given the diverse abilities of patients in tech-enabled data collection, requiring more comprehensive training and support, especially for clinicians and investigators transitioning to digital methodologies.

New technologies

Veeva also introduced two new products. The Veeva Vault Batch Release, a cloud application, was unveiled to streamline GMP release and market-ship decision-making by aggregating data and simplifying collaboration.

Attendees also got a glimpse at the Veeva Study Portal, a free cloud application, designed to simplify access to sponsor technologies for clinical researchers. The application enables the creation and sharing of study profiles with links to relevant sponsor technology systems, reducing the need for managing multiple usernames and passwords.

During the event, representatives from pharma companies including Amylyx, AstraZeneca, GSK and Minaris Regenerative Medicine shared insights on how these technologies are empowering them to directly confront the challenges they encounter in their respective fields.

"Veeva Vault Training has helped modernize our onboarding approach by seamlessly ensuring all read and understood training is completed before the on-the-job training," said Jennifer Diminni, director and global head of GxP Training, Learning and Development at Minaris. "Veeva has been very receptive to our feedback on how to automate training plans for personnel while eliminating manual tracking via spreadsheets from our technical trainers, and we're excited for curriculum sequencing to be launched in an upcoming release."

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A craftsperson's toolbox serves as a symbol of their skill, ingenuity, and dedication. It cradles a world of possibilities, unlocking tangible manifestations of imagination through the use of physical tools.

In a similar spirit, the pharma industry must continuously empower itself with cutting-edge technologies and equipment solutions in order to continue to produce lifesaving therapies. With drugmakers facing incredible pressures to get drugs to market quickly, safely and affordably, every addition to development and manufacturing efficiencies matters.

Now in their eleventh year, the Pharma Innovation Awards allow Pharma Manufacturing to acknowledge the investments that equipment and technology providers put into building and improving their products.

Please join us in celebrating this year's award winners, selected by our editors and reviewers, for hitting the nail on the head with their solutions to drugmakers' most pressing issues.

Data management and visibility

From ensuring product safety and efficacy to navigating complex global regulatory requirements, effective data management practices are central to maintaining the highest standards in drug manufacturing.

Based on worldwide estimates, more than two-thirds of all pharma manufacturing is now outsourced through contract manufacturing and packaging partners. As a result, the efficient management and exchange of data with supply chain partners throughout the product life cycle is no longer a nice-to-have capability, but a strategic imperative that all manufacturers must possess.

With an eye on enhancing supply chain visibility and enabling end-to-end process orchestration, **TraceLink's Multienterprise Information Network Tower (MINT)** is being recognized for its global supply chain impact. An end-to-end supply chain digitalization solution, MINT leverages TraceLink's proprietary data exchange model for sharing real-time information among supply chain partners, resulting in improvements in revenue, agility and resiliency, while reducing business risk.

The solution enables users to exchange a large catalog of transactional business information, including purchase orders, advanced shipment notices, and invoices, with 100% interoperability among supply chain partners without forcing any changes to any partner's enterprise business system.

In a landscape where many companies still grapple with the limitations of traditional communication methods like email-based file exchanges, MINT provides a flexible and streamlined solution that accommodates businesses at various stages of digital maturity.

Pharma's clinical trial processes generate a substantial amount of data and the ability to derive actionable insights from that data is powerful. Our second awardee, **DoseMe Analytics** by **DoseMe**, is designed to help support drug developers through phase 3 clinical trials and aftermarket enrollment.

Within this environment marked by intricate complexities and uncertainties, this cutting-edge solution harnesses real-time data to redefine precision dosing. The software incorporates a personalized, adaptive dose adjustment approach rooted in a drug's pharmacokinetics and pharmacodynamic properties to optimize efficacy and mitigate the risks of adverse drug events and toxicities. By seamlessly integrating into clinical trial infrastructures, DoseMe guides investigators away from traditional maximum tolerated dose trial designs and instead encourages a model-informed selection of patient-specific doses.

The dosing platform offers real-time support to investigators within their facilities, effectively reducing patient dropouts and potential study failure attributed to dose-related toxicities. Reviewers applauded DoseMe's innovation for its efforts to lead clinical trials towards a more successful and patient-centric future.

Process development and scale-up

Transitioning drug products from lab to commercial scale is one of the most vexing tasks in pharma. During this process, regulatory compliance demands increase and quality control methods must be robust

FlowInova platform
Quotient Sciences

enough to detect variations and defects. Selecting equipment suitable for large-scale production adds another layer of complexity, involving considerations like material compatibility and ease of maintenance.

Our first awardee in this category, **TriLink BioTechnologies' CleanCap M6** is an advanced mRNA cap analog designed to maximize the impact of mRNA therapeutics and vaccines. Used in the first commercially adopted mRNA vaccine, the CleanCap capping technology reduces immune responses, increases mRNA expression up to three times, and streamlines manufacturing, with an estimated cost savings of up to 40% compared to other capping methods.

The latest CleanCap M6 cap incorporates two key modifications of the CleanCap technology, 3'OMe on the m7-guanosine and an additional methyl modification on the +1 adenosine. These modifications improve mRNA potency and yields with purity exceeding 95%. The technology's single-pot reaction simplifies manufacturing, enabling quicker turnaround times and higher transcriptional yields. By driving down manufacturing costs and shrinking production times, the tool aims to help bring life-changing medicines to market faster.

Reviewers expressed optimism about the product, recognizing its promise as a valuable niche innovation that could enhance mRNA therapeutics — a relatively uncommon achievement in manufacturing processes. They commended the product as a great development and a useful tool, emphasizing its potential application in addressing global health care challenges.

Another major challenge faced in the development process for biologic drugs is protein aggregation. The next winner in this category, **SentrySciences' ParticleSentryAI software**, plays a crucial role in helping drug developers detect changes in the aggregation caused by stressors not easily detected by a human. The software utilizes AI and subvisible particle imaging to establish a robust aggregate control strategy. Traditionally, managing aggregates relies on flow-imaging microscopy, but the immense volume of data and human limitations in interpreting these images present obstacles.

By using deep machine learning, ParticleSentryAI evaluates morphological and textural details within images, establishing fingerprints that swiftly and quantitatively pinpoint root causes of subvisible particle morphological changes. In doing so, it provides a robust foundation for continuous process verification, addressing scale-up challenges head on.

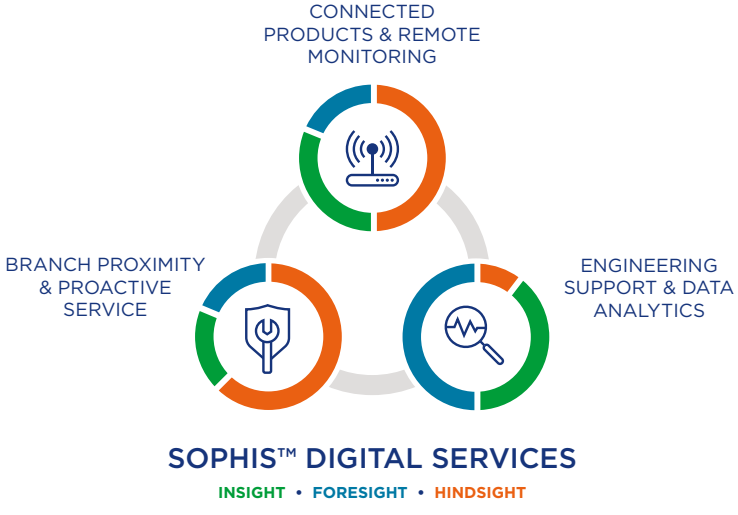
ParticleSentryAI overcomes limitations by leveraging image features to comprehend the causes of aggregation, delivering actionable data for mitigating their impact. By analyzing the images gathered, it can create a fingerprint for drugs under normal and stressed conditions, and detect significant changes in these fingerprints, supporting batch-to-batch consistency. Another favorite among reviewers, the product was applauded for its significance in addressing protein aggregation, with reviewers lauding its ability to automate a previously manual process. One reviewer called it an "innovation in dealing with a perennial issue."

As the pharma industry trends towards more targeted drugs, small molecule active pharmaceutical ingredient (API) candidates are becoming more potent. At the same time, the industry is looking to streamline development and scalability, with an end goal of speeding market entry. Continuous manufacturing has emerged as a possible solution to these challenges.

To that end, **Quotient Sciences' FlowInova platform** is being recognized for its ability to streamline the scale-up process for early-phase API development. By utilizing high-throughput experimentation and modeling, the platform significantly reduces the time and material quantities required for scale up within a laboratory setting, which translates to accelerated development timelines, cost savings, and greater productivity for drugmakers.

Born out of a collaboration with the University of Nottingham, the project also focuses on the informed decision-making aspect of development. It introduces automated reaction equipment and early-stage modeling, which leads to better decision-making for subsequent experiments. As data accumulates and process knowledge grows, predictive process models enable 'virtual design of experiments,' ultimately enhancing the overall efficiency and effectiveness of the development process.

Sophis Digital Services
Xylem



Plant operations

A once overlooked area of pharma manufacturing, the modern day plant floor is proving to be a prime place to capture efficiencies and cost savings. One crucial element of plant operations that can often go unnoticed is water management.

In the pharma industry, the significance of water purity cannot be overstated, as it directly impacts the quality and safety of all products. Holding down the category this year, **Xylem's Sophis Digital Services** — with an ambitious mission to redefine the way manufacturers manage critical water systems — is being recognized for its ability to mitigate risks through 24/7/365 remote monitoring and support while ensuring water quality and optimizing performance.

As a sophisticated water service solution, Sophis effectively prevents production-affecting problems by continuously monitoring vital water system data, including feedwater conductivity, membrane pressure, and permeate flow. Proprietary data models also identify anomalies that could disrupt production, triggering immediate alerts to the engineering team. Once an anomaly is flagged, a course of action is dispatched to the local service team, and upon completion, the event information is recorded for continuous learning. The result? Increased uptime and substantial capital savings for pharma manufacturers, along with the assurance of pharmaceutical-grade water purity.

Currently paired with the company's VRx High Purity Water System, Sophis Digital Services delivers an all-encompassing solution designed to meet and exceed the stringent requirements for compendial purified water and Water for Injection (WFI) production, aligning seamlessly with USP, EP and JP monographs. With its approach to water system management, the solution not only addresses crucial industry challenges but also plays a

vital role in ensuring the quality and safety of drugs for the benefit of patients worldwide.

Packaging and inspection

In an industry where regulations leave no room for error, the selection of both packaging materials and inspection methods plays a pivotal role in upholding the integrity of pharmaceutical products.

Our first awardee in this category, the **Eagle-LP (Lab Pack) Blister Machine** from **Maruho Hatsujyo Innovations (MHI)** alleviates two key pain points in pharmaceutical packaging: cost-effectiveness and space utilization. The unit is purpose-built to address persistent challenges in early-phase blister packaging, providing an economical alternative for stability testing, clinical trials and small-scale production, eliminating the need for expensive and space-consuming equipment.

The machine is specifically designed for small-scale processes, offering a unique, reliable and budget-friendly solution for various developmental phases. What distinguishes the Eagle-LP is its adaptability to newer, eco-friendly blister film materials, which are often more complex to shape and seal. The versatile unit seamlessly handles a variety of materials, including PVC, PVDC, PET, ACLAR, ALU and PP.

Reviewers expressed enthusiasm for the Lab Pack, describing it as a long-awaited remedy to a persistent issue.

In the charge for more sustainability in the industry, pharma packaging suppliers are at the forefront. In January 2018, the European Commission introduced the EU Plastics Strategy, which set the target of making all plastic packaging in the EU market recyclable by 2030, meaning that a certain portion of plastic packaging should be recyclable. The Packaging & Packaging Waste Directive currently mandates

Transparent Recyclable Mid-barrier Blister Package
TekniPlex Healthcare

that a minimum of 65% of all packaging waste by weight must be recycled by the close of 2025. While pharma sector is exempt from the EU Packaging & Packaging Waste Directive mandates until 2035, it's never too early to start preparing for this shift.

Taking a step in a greener direction, **TekniPlex Healthcare** takes the stage as our next honoree with its **Transparent Recyclable Mid-barrier Blister Package**. The company has introduced a groundbreaking solution — the world's first fully transparent, recyclable mid-barrier blister package. The innovative offering not only provides robust moisture barrier protection but also champions recyclability where the #5 (polypropylene) recycling stream is available.

TekniPlex Healthcare's mid-barrier blister pack pairs a polyolefin blister film with a barrier polypropylene lidding film, signaling a significant step towards achieving circularity in health care materials. It's a milestone that deserves recognition as the first certified recyclable combination of a formed blister

Eagle-LP Blister Machine
Maruho Hatsujyo Innovations (MHI)

MAVIS Combi
Stevanato Group

and lidding in the health care packaging sphere that's fully transparent. The transparency allows for vision systems to see through the package to detect a variety of potential quality control issues, including a damaged tablet or capsule, presence of any foreign substances, or closure integrity (making sure the blister is properly formed and sealed). The company's initial assessments of manufacturability have yielded highly encouraging results, underscoring the potential of this tool to revolutionize drug packaging.

In the packaging realm, visual inspection is another crucial quality control step that comes with its own unique set of challenges. Ensuring that drug products are free from defects and meet stringent quality standards is of utmost importance. But variations in container types, substances, and the need to detect particles, cosmetic imperfections and closure integrity issues pose significant hurdles. The demand for high-speed performance, adaptability and precision further complicates the process.

RoSS.pFTU XL
Single Use Support

Innovative solutions, like **Stevanato Group's MAVIS Combi**, have emerged to tackle these issues head-on, offering advanced performance, flexibility and speed to enhance visual inspection.

The inspection machine, part of Stevanato's MAVIS line, has the capabilities to handle a diverse array of glass-filled drug containers, including syringes, vials, ampoules and cartridges, making it a versatile asset for manufacturers navigating varied product formats. MAVIS Combi also showcases precision in identifying particles, cosmetic imperfections, and closure integrity issues, addressing paramount concerns for product quality and safety, and can process both bulk and ready-to-use containers.

In addition to its versatility, the MAVIS Combi offers a compact design that optimizes visual inspection efficiency. Its high-speed performance is a standout feature, processing up to 400 pieces per minute, outpacing industry standards. This efficiency boosts production throughput while maintaining quality control, providing a much-needed solution to meet rising demands in pharma packaging inspection.

Cold chain logistics

The pandemic proved definitively that as supply chain operations expand to larger geographic areas or larger volumes of sensitive goods, the complexities of managing temperature-controlled facilities and transportation increase substantially. Crucially, deep-cold medications, such as mRNA-based therapies and cell and gene therapies, demand specialized handling, containment and delivery systems.

SCHOTT Pharma's SCHOTT TOPPAC freeze prefillable polymer syringes are being recognized this year as effective packaging for these frozen or thawed medications, even those that require storage and

transport at extremely low temperatures, nearing -100°C.

The syringes, made from cyclic olefin copolymer, are break-resistant, biologically safe and equipped with advanced cross-linked siliconization technology to ensure drug stability. They also come with comprehensive data to verify container closure integrity, functionality and particulate generation after freezing and thawing.

SCHOTT TOPPAC freeze syringes support the safe and stable delivery of these extremely cold medications throughout the supply chain, provided to drugmakers in a standardized nest and tub configuration. This compatibility ensures easy integration into major fill-and-finish lines, helping pharma companies to efficiently and safely bring deep cold medications to the market using prefillable polymer syringes for the first time.

Our next winner in this category, the **RoSS.pFTU XL** from **Single Use Support** is an innovative plate-based freezing and thawing unit that addresses critical issues in biopharma cold chain logistics. It can freeze up to 10 single-use bags, each with a 50-liter capacity, setting a new standard for bulk freezing.

The technology rapidly freezes batches down to -90°C in under 10 hours while allowing for precise control of the freezing rate to suit specific product needs. The unit stands out as the only plate-based freezer for large volumes, offering fast and precise freezing. It helps minimize product quality loss due to cryoconcentration, preserving drugs' attributes during freezing or drying. This technology guarantees product integrity and efficacy throughout the freezing process while enhancing overall process efficiency.

The RoSS.pFTU XL also ensures reproducibility, meets regulatory standards (21 CFR Part 11) and eliminates manual handling concerns. Its modular design supports scalability and accommodates various

Gibco CTS DynaCellect Magnetic Separation System
Thermo Fisher Scientific

single-use bioprocess containers, making it a key component in the quest for a fully scalable end-to-end process for bulk fluid and cold chain management.

Cell and gene therapy

It's no secret that cell and gene therapies (CGT) represent a revolutionary approach to managing disease, with the potential to disrupt how patients are treated and eventually even cured. However, the promise of CGT hinges on drugmakers' ability to bring these lifesaving drugs to patients safely, effectively and affordably.

Chief among the challenges faced in the sector is scalability. Starting in small research laboratories, CGT processes must scale up to meet growing clinical and commercial demands. This necessitates innovative manufacturing methods that

SCHOTT TOPPAC freeze syringes
SCHOTT Pharma

Multienterprise Information Network Tower
TraceLink

balance product integrity with quantity, calling for advanced bioreactors, automation and a deep understanding of biology.

Leveraging the capabilities of large language models, cell and gene therapy developers can now, for the very first time, proactively analyze and mitigate crucial manufacturing risk factors before embarking on the journey of scaling up production. To this end, our next winner, **Form Bio's FORMsight^{AI}** has emerged as a pioneering tool, ushering in a new era of predictive efficiency and safety in the development of these groundbreaking therapies.

The comprehensive solution integrates advanced, customizable AI/ML models crafted to confront prevalent challenges encountered by developers. Specifically, it addresses issues like construct truncations and manufacturing contaminations, both of which significantly contribute to unsustainable low manufacturing yields, extended time-to-market, and potential therapeutic safety concerns.

FORMsight^{AI} has the potential to streamline manufacturing to save time, money and resources, which could ultimately accelerate the delivery of critical therapeutics to patients who need them.

Designed to address the labor-intensive, time-consuming, and inconsistency-prone nature of manual cell isolation and bead removal processes, our next award goes to the **Gibco CTS DynaCellect Magnetic Separation System** from **Thermo Fisher Scientific.** This system responds to a crucial need in the market for a closed, automated platform that effectively overcomes challenges while ensuring exceptional isolation efficiency, recovery rates and cell viability.

A favorite among our reviewers, one reviewer called it "timely and innovative," expressing that the system has the potential to become a standard in cell isolation. In comparison to alternative methods that often demand 4–5 hours for cell isolation, the CTS DynaCellect system reduces the processing time to approximately 100 minutes. Additionally, it significantly shortens Dynabead removal time from roughly five hours to less than one hour, accelerating the development and delivery of transformative therapies that have the potential to change lives.

The device's capacity to swiftly process 1,000-mL for cell isolation and offer continuous processing for bead removal positions it as a critical asset for successful scale up. Moreover, its modular design allows seamless integration into a variety of workflows, enhancing instrument efficiency and utility, making it a potentially transformative tool within the realm of pharma manufacturing.

With that, we conclude our 2023 Pharma Innovation Awards. We want to extend our appreciation and gratitude to all the participating companies and the hardworking suppliers that remain dedicated to advancing the industry. As we look to 2024, we anticipate even more groundbreaking developments, and we're excited to see how these innovations continue to shape the pharma industry.

Jessica Zhang
Technical Services Manager, Pharmaceutical Ingredients, Univar Solutions

Expediting drug development with innovative ingredients

Co-processed excipients can be a valuable solution in troubleshooting common product development issues

The U.S. population is currently undergoing unprecedented change. For the first time in history, adults aged 60 years and older will outnumber children by 2034 and the number of adults over 80 years of age is expected to triple by 2050.[1]

As the country's demographic heads rapidly toward an aging population, a variety of societal issues will come to light, including labor and supply shortages with a dwindling qualified workforce and increased expenses for long-term care. In tandem with this, there is a rising need for more specialized, custom medications and generic, cost-sensitive drugs on the market.

In order to meet these consumer and societal demands, the U.S. pharma industry must place an increased emphasis on implementing a more robust drug development cycle. Currently there are several bottlenecks in the product development cycle, including phases of research and development, supply chain, manufacturing and commercialization.

Although many potential solutions exist, the current rise in innovative ingredient solutions and ingredient technology pose as a strong contender, deserving of in-depth exploration.

Sourcing the right ingredients

Throughout the product development cycle, formulation scientists encounter common issues related to sourcing the right ingredients, cost savings and scaling up for commercialization.

Sourcing the right quality ingredients and utilizing them in the proper amounts in drug formulations plays a crucial part in the development and scale-up phases. A small variation in ingredient quantity within any drug formulation may vastly affect many aspects of the final product ranging from attributes such as texture, viscosity and hardness to delivery effectiveness for patients. For instance, for oral solid dosage forms, tablets may experience physical defects such as capping or lamination or simply may not be producible.

The same applies even if the ingredient chosen exhibits the same chemistry but does not adhere to the same quality standards. In these instances, the efficacy and potency of the active pharmaceutical ingredient (API) formulated within the tablet may not pass quality control tests such as dissolution or disintegration, which can ultimately cause failure to meet label claims. Adjustments as simple as the quantity, quality or type of ingredient can have significant downstream ramifications.

One solution to these challenges comes in the form of co-processed excipients (CPEs). In recent years, these excipients have risen to the forefront as a valuable solution in troubleshooting common product development issues, specifically in the oral solid dosage space.

The blended benefits of CPEs

What defines a co-processed excipient? The development consists of selecting several commonly used and established excipients that are then combined into a singular blend, which exhibits more uniformity than traditional excipients. Each excipient

within these blends is chosen for its individual ingredient characteristics and functions within a tablet formulation. Ingredient characteristics most typically desired during the preparation of CPEs exhibit properties and functions such as lubricants, flow aids, binders and diluents.

When co-processed together, individual excipient attributes can be enhanced and, at optimized ratios, allow for a more homogenous mixture in one single blend. Co-processing can be accomplished through a variety of methods such as spray drying, dehydration or granulation, and final blends have continuously proven better performance when compared to individual ingredients processed under standard manufacturing processes.[2] Some of the many advantages that co-processed excipients bring to a formulation include improved powder flow, lubrication and uniformity of particle sizes — all of which contribute to powder and tablet compressibility benefits.[2]

Additionally, co-processed excipients bring significant benefits to the product development cycle. Incorporating CPEs into drug formulations relieves pressures on ingredient sourcing, can lead to cost-savings and can ease challenges associated with scaling up from clinical trial phases into mass commercialization. No matter where drugmakers are in the manufacturing process, these benefits can be realized without compromising product quality or efficacy.

Cost savings today

During the ingredient sourcing stage, co-processed excipients also help reduce the number of ingredients required for sourcing and validation.

For example, in a single drug formulation, one co-processed excipient may accomplish the same, or better, functions of three or four ingredients. This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When co-processed together, individual excipient attributes can be enhanced and, at optimized ratios, allow for a more homogenous mixture in one single blend.

leads to less time R&D specialists must contribute to sampling and validation processes and can often expedite the formulation development stage.

Applying this to the overall drug development cycle, a shortened development stage results in less time weighing and manufacturing ingredients and less waste produced. Additionally, with less powder needed in the formulation, sustainability benefits arise with the realization of reduced cleaning solvents and operator time necessary in manufacturing.

When scaling up from benchtop to pilot and ultimately to commercialization, these benefits become even more noticeable and can make a real difference for pharma manufacturers and the industry as a whole. When specifically examining the advantages of CPEs in the benchtop testing phase, fewer ingredient quantities are used, further reducing time, waste, physical warehouse space for storage, and cleanup time needed to produce small batch quantities.

From a patient and packaging standpoint, drug formulations utilizing co-processed excipients may result in physically smaller tablets due to less powder being weighed and compressed — thus optimizing and decreasing the thickness and diameter of the final dosage form. As the world realizes an increased aging population combined with common challenges of patient pill fatigue, smaller tablet sizes present tremendous long-term benefits. This translates to smaller blister packaging and bottles required to store and transport tablets, saving costs with packaging materials and shipping while contributing to sustainability goals.

These ambitious standards allow pharma and health care industries to better serve

customers, employees and partners so that together, they can shape a better tomorrow.

Microencapsulation technology

Another innovative ingredient solution making its mark on the pharma industry is the process and technology behind microencapsulation. While this technology has been widely used in industries such as personal care, food and textiles for many years, more recently it has progressively advanced in pharma applications. One such instance involves sensitive APIs which may be easily susceptible to degradation when exposed to environmental factors such as heat, humidity, oxygen or light.[3]

Through the microencapsulation process, the API is coated with a protective outer layer designed to help prevent degradation or improve stability.[3] Recent advancements have taken applied microencapsulation even further to include a wide range of ingredients, ranging from vitamins and proteins to mammalian and stem cells.[4] These newly coated substances are continuously demonstrating increased stability and easier formulation capabilities and functions during the product development stages.

To illustrate the impact of microencapsulation, we can explore the common issue revolving around APIs that exhibit hygroscopic properties. When these APIs lack protective coating, the active ingredient is compromised the minute the original container packaging is opened and air or moisture is introduced. Furthermore, depending on the manufacturing process, that active ingredient may be exposed to the elements for prolonged periods of time, drawing in excess moisture from the air, and consequently changing the physical characteristics of the ingredient. In some cases, the powder may change from a free-flowing powder into a more crystalline structure leading to more time and complexity in the manufacturing process, contributing to increased ingredient waste, and the inability to guarantee quality and efficacy of the final drug product.

With a coated active ingredient, the hygroscopic characteristics are potentially negated, leading to improved ingredient and final

product effectiveness and stability. Additionally, commonly used excipients that function as moisture protectants or antioxidants may no longer be required in the formulation, circling back to the same key benefits discussed earlier such as time savings in the development cycle and sustainability wins.

Beyond this, additional applications for microencapsulation include improved taste masking for bitter APIs, controlled release for drug delivery, active ingredient protection from the upper gastrointestinal tract and more targeted mechanisms of action.[4] All these benefits help lead to an improvement in the bioavailability and therapeutic effects of the drug providing significant competitive advantages in the market and among the patient population.

Key considerations

While there are clearly many benefits of co-processed excipients and microencapsulation in the pharmaceutical space, we must acknowledge that no solution is perfect and there are some limitations to consider.

For example, with co-processed excipients, the ratio and type of excipient becomes fixed during co-processing stages. When formulating with unstable APIs, this means there may be cases where extra excipients are needed in the drug formulation as the existing ratio in the CPE may not be enough to provide stability — albeit the quantity of added excipients needed tend to be less than what would regularly be required without the use of co-processed excipients. Additionally, although the individual excipients used during the co-processing steps are monographed, the CPE blend itself may not yet be published in official monographs.

For microencapsulated ingredients, one potentially limiting and undeniable factor is the cost associated with the process. Outside of sourcing the proper active ingredient, there is an extra step in identifying the proper microencapsulation process to best suit the specific drug product qualities. Careful consideration is needed to evaluate the proper use in a formulation and optimization of the manufacturing cycle would be ideal in an effort to offset the upfront costs.

Innovative ingredients and technologies improve bottlenecks throughout the development cycle with the added benefit of improving the overall patient experience.

For both co-processed excipients and microencapsulated ingredients, any changes to the formulation will require reformulation and revalidation of the entire product development cycle. This proves particularly challenging and time-consuming when the drug product has already been commercialized. As a result, it is prudent to be aware of all the innovative solutions available during the initial drug development cycles so that the final drug product released onto the market can leverage competitive advantages.

Pharma innovation is here

As the world patient population and demographic continues to shift and grow, consumer factors such as ease of patient access, more palatable drugs, and pill fatigue play more important roles than ever in drug selection and administration. Fortunately, the rise in innovative ingredients and technologies brings with it a new wave of development for unique and desirable dosage forms. This is reflected in innovative dosage therapies such as mini tablets, bi-layer tablets, capsules in capsules, and more targeted cell and gene therapy applications. Previously unstable, poorly soluble or low bioavailability active ingredients may now be safely administered with less cost to the patient.

Ultimately, these innovative ingredients and technologies improve upon bottlenecks throughout the product development cycle such as research and development, supply chain, manufacturing and commercialization with the added benefit of improving the overall patient experience. The end-to-end drug development cycle is expedited and optimized, leading to the introduction of a more competitive and advantageous product to the market.

By optimizing and shortening the product development cycle through innovative solutions and technologies, manufacturers can realize positive benefits in the form of efficacy, quality and cost while developing and delivering more sustainable dosage forms that are better suited for the patient.

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Karen Langhauser
Chief Content Director

The smart factory future is now

For pharma, digitalization on the plant floor has become a hard-fought reality

The term 'Fourth Industrial Revolution' — or Industry 4.0 — was introduced as a German government initiative in 2011, but soon found its way into public discourse. The concept gained widespread recognition in 2016 when the World Economic Forum's annual meeting debuted 'Mastering the Fourth Industrial Revolution' as its theme.

"Since the 2016 Davos forum, when Industry 4.0 was essentially published in the social psyche, pretty much everybody has been trying to figure out how to make their buildings and manufacturing facilities more modern," says Laks Pernenkil.

Pernenkil, who now serves as principal and practice leader for Deloitte Consulting's Life Sciences Product, Supply and Manufacturing practice, has witnessed this manufacturing evolution firsthand.

"In the last half-decade, the focus of manufacturing organizations has been to shift from a legacy lean and Six Sigma operations efficiency paradigm to a digitally accelerated, next-gen technology-enabled smart manufacturing model," says Pernenkil.

But it hasn't been an easy victory for companies on the plant floor, and for pharma, it's been especially daunting.

"The curse of the manufacturing environment in general is that these are long range depreciated assets. So, you can't just flip a switch — it takes a lot of planning, even in a simple manufacturing environment," says Pernenkil. "When you add on the regulated manufacturing environment, the transformation is extremely difficult."

Yet with the pharma industry facing mounting pressure to bring high quality, cost-effective drugs to market faster, smart factory deployments are proving worth the effort, as companies are now realizing tangible improvements in manufacturing performance.

Pharma complexities

The pharma industry often faces a strange juxtaposition — it is tasked with making novel cutting-edge medications, using legacy equipment in aging facilities. This puts pharma in a position that is familiar to much of the broader manufacturing industry when it comes to digitalization: Companies have to decide between retrofitting existing facilities or building entirely new plants.

"The biggest challenge in front of the pharma industry is that they are almost always trying to balance the ROI of 'should I retrofit my existing site and increase the efficiencies?' or 'should I just go ahead and build a new site that is completely automated?'" says Pernenkil.

So which is the better option for pharma? According to Pernenkil, it depends. While companies will likely save on costs in a retrofitting project, the complexity can be significantly higher.

"And only 30% of that complexity is technology," says Pernenkil. "Most of it is humans, because you have to change the way that people work within that existing site."

The Smart Factory @ Wichita is one of several of Deloitte's global immersive experiences designed to accelerate digital transformation.

Technology's role, per Deloitte, is to enable smart factory capabilities in a compliant way. But the smart factory itself requires business functions to operate in a connected way — and this can't happen without employees embracing the evolution of the future of work.

The alternative to retrofitting, of course, is to start from scratch. According to Pernenkil, while new builds tend to be less complex, they are not without constraints. During the thick of the pandemic, for example, companies ran into issues with contractor capacity — and projects were sitting on the market for months with no bids.

The other big consideration for the pharma industry is time — often site success hinges on the efficient launch of a specific product looking to gain market share. Which means, even if a company has the best intentions — to build a brand new 'facility of the future' — tight timelines often ruin those plans.

"Because each new facility under construction is being built for some set of new products on the market, the timelines of product launches force pharma companies to commission and start the site, and not spend a lot of time and investment to 'future proof' effectively," says Pernenkil. "So all your beautiful visionary ideas of how it's going to be a no-touch, facility of the future go out the window pretty quickly because you have a certain timeline to maintain."

In Pernenkil's experience, most companies usually settle on middle ground — a combination of retrofitting some sites and then creating new builds featuring next-gen technology.

Smart factory ROIs

Regardless of how companies get there, the question on everyone's mind is what are the tangible benefits of going 'smart'?

Last year, Deloitte, in collaboration with Wichita State, opened the doors to a hands-on, experimental smart manufacturing environment known as The Smart Factory @ Wichita. In addition to helping leaders build a vision for smart manufacturing success, the program collects data that helps back the business case for the smart factory, demonstrating measurable improvements to asset efficiency, quality, safety and sustainability.

On the plant floor, smart factory technologies such as IoT, augmented reality and sensor-enabled monitoring can predict equipment problems before they happen and calculate available capacity based on demand, reducing downtime and increasing overall equipment effectiveness.

On the sustainability side, tools such as motion sensors, microclimate controllers and AI pattern detection optimize energy levels in real time, reducing costs. In the quality department, vision systems, smart sensors and real-time analytics can be used to accelerate quality inspections.

Pernenkil estimates that a smart factory can yield operating expenditures that are five to seven times lower than what might be typically seen in a traditional plant.

Because having pharma production lines go down is extremely costly, traditionally, much of the labor force expense on the production floor comes in the form of people who are supporting operators — maintenance technicians, quality technicians, sampling technicians, etc.

But a smart factory offers relief from those costs.

"The operating expense of a typical plant has a lot more overheads, whereas the smart factory will give you more leverage because you are proactively solving for issues," says Pernenkil. "Therefore, you are able to have a smaller pool of specialized technicians that can solve a wider array of problems because you have the plant telling you with data where to focus and what is happening on the production floor."

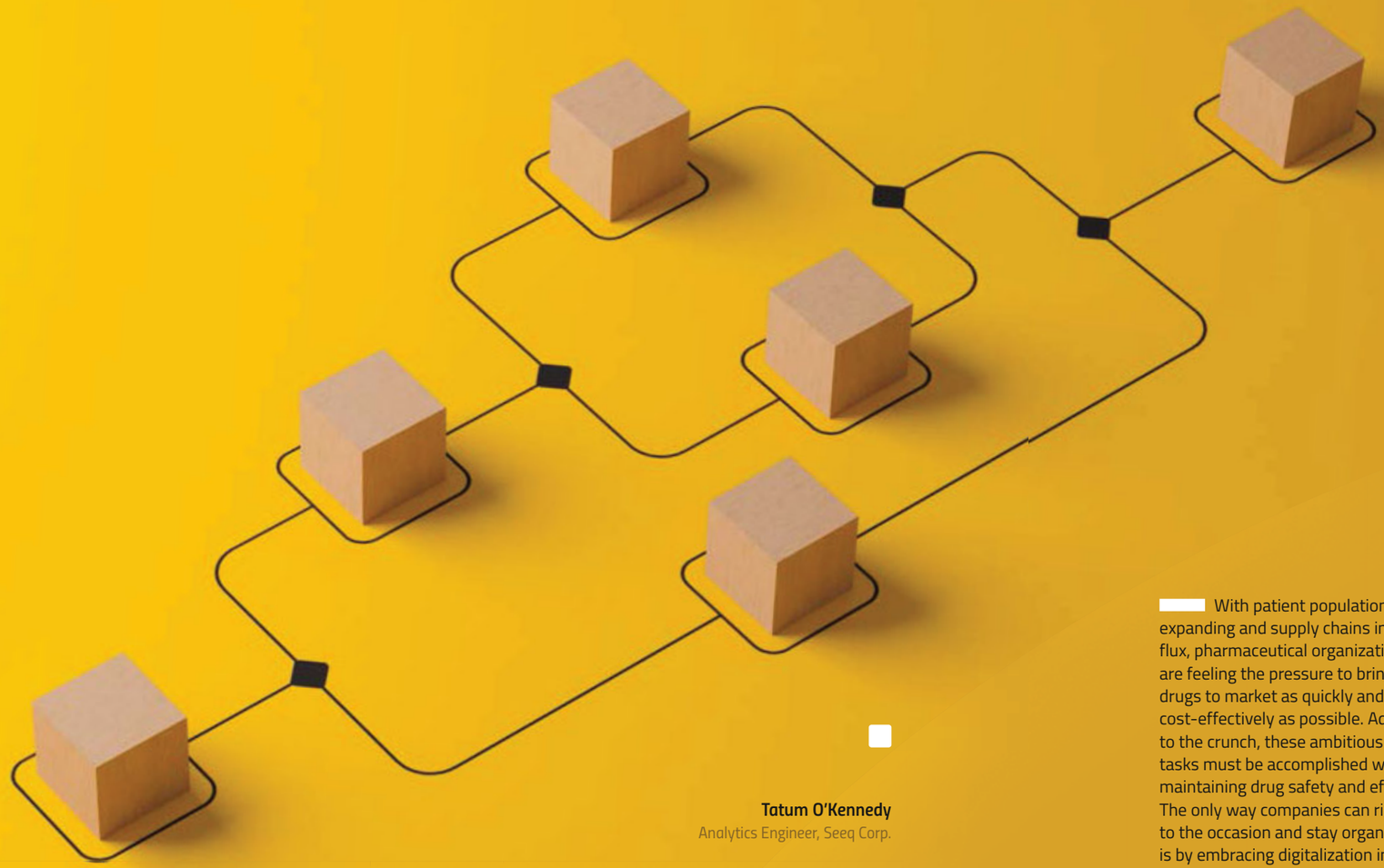
Where pharma stands

While the pharma industry has developed a reputation for being slow adopters of technology, over the past five years, Pernenkil has seen a commitment to foundational digital infrastructure across the industry.

"Almost every client that I know has made the commitment to invest in core systems and core capabilities," says Pernenkil. "There are very few companies, if any, that have not taken the leap into digitizing infrastructure."

A persistent obstacle for the pharma industry has been making sense of the tremendous amount of data it generates. Recently, Pernenkil has noted an increased emphasis on gathering data from the production floor — process data, quality data, equipment data, environmental data — and using it in ways that bring real value. Some Deloitte clients have built data fabrics that collect and contextualize data, and then generate insights using AI. These insights can then be used by operators to take the best action on the production floor.

"A manufacturing floor typically creates a terabyte of data per day, and barely 5% of that gets used at all in any form of decision-making. We are out to help our clients change that," says Pernenkil.



Tatum O'Kennedy
Analytics Engineer, Seeq Corp.

Streamlining workflows from development to commercialization

Digitalization with advanced analytics empowers pharma experts to speed lifesaving therapies to market

Pharma organizations across the industry are leaning on digital resources to monitor process data throughout the drug life cycle.

With patient populations expanding and supply chains in flux, pharmaceutical organizations are feeling the pressure to bring drugs to market as quickly and cost-effectively as possible. Adding to the crunch, these ambitious tasks must be accomplished while maintaining drug safety and efficacy. The only way companies can rise to the occasion and stay organized is by embracing digitalization in R&D, manufacturing and regulatory settings.

In this high stakes and highly regulated industry, therapeutic efficacy and integrity depend on efficient and data-based decisions. For this and other reasons, pharma organizations are improving and operationalizing workflows throughout the entirety of drugs' life cycles by implementing advanced analytics, which enables seamless automation of equipment health monitoring, calculation standardization, scale-out and multi-phase monitoring.

From formulation development through commercial production, drugmakers require analytics that can adapt to the changing needs of the industry. Flexible analytics platforms that can handle discrete, infrequent lab data at the R&D scale must evolve with manufactured products to gather data across hundreds of reactors at the production scale. Ultimately, empowering engineers to streamline common workflows across each phase of the drug product life cycle will allow for cost reduction and time improvements.

Process monitoring with advanced analytics

In drug development and production settings, a variety of processes are often at play. With batch, semi-batch and continuous processes all commonly used throughout the pharma industry, organizations require advanced analytics resources that can complement a variety of workflows.

These multiple process types are never more evident than in the world of small molecules, where fluid bed granulation, encapsulation and spray drying — among others — require dynamic analytics tools.

In a granulation case study shared by a top-five global pharma company, engineers were having trouble monitoring continuous and dynamic processes with conventional methods. However, leveraging an advanced analytics solution, the team incorporated key input parameters — such as roller gap, press force and roller speed — to model granulation performance of calculated parameters, including solid fraction (SF), SF error and gap error.

With a near real-time performance model in place, the team predicted deviations from process setpoints proactively, instead of relying on reactive measures. In one specific instance, engineers identified SF and gap irregularities occurring mid-manufacture, and as a result, they stopped processing immediately to proactively troubleshoot (Exhibit 1).

With continuously accessible near-real time data available, the models revealed refined setpoints and process improvements that can be fed into future campaigns. The team also noted reduced startup times and material savings during the granulation processes. With a reliable data-informed view into process variability, the company inadvertently improved quality assurance as well.

While the company's advanced analytics resources and digitalization initiatives helped improve its continuous manufacturing workflows, improvements did not end there. In another case study, the same team explored how to leverage advanced analytics solutions to understand process dynamics within a semi-batch wet granulation process.

With many cycles and unit operations in each batch, the task of gathering and parsing through the vast quantities of data was previously cumbersome and time-consuming. Driven by digitalization initiatives, the organization turned again to advanced analytics resources to standardize their analytics workflow for interpreting large datasets.

With dryer cell temperature, status, inlet temperature and humidity, and airflow inputs, the team developed an understanding of average batch values to gain insights into batch performance and variation across dryer cells. In one instance, the calculated averages indicated variant behavior in a specific dryer cell that led the team to optimize the drying parameters, including drying time and temperature difference.

Overall, this digitalization initiative created material savings and mitigated the need to reject material in future batches. With a streamlined analysis, the team automated the development of wet granulation monitoring views for sharing key insights across functional teams, and the team noted an improvement in product uniformity because of the better monitoring and data-based control strategy (Exhibit 2).

Near-real time monitoring and alerts

When subject matter experts (SMEs) are faced with competing priorities in addition to delayed and infrequent data reporting, a struggle to respond to process issues in a timely manner almost always ensues. Without even realizing it, organizations often waste precious time and resources by not leveraging the right analytics software solutions for the tasks at hand.

At a top-15 global pharma company, overworked engineers sometimes found themselves unable to respond to process excursions for weeks and months at a time. However, by automating process alerts using an advanced analytics solution, the organization reduced reaction time to hours, driving a production increase of more than 500,000 units annually.

With competing priorities impacting not just engineers but operations teams as well, advanced analytics platforms can be leveraged on the manufacturing floor for near-real time insights.

In another case study shared by the same organization, engineers developed real-time statistical process control charts to compare current hourly performance with past months of performance. By consolidating summary metrics in a dashboard accessible on the manufacturing floor, operations teams gained visibility into hundreds of potential deviations to focus on the highest priority variances.

The engineering team saw a subsequent increase in informed recommendations made by their newly empowered operations colleagues. By placing the power of data-informed decision-making in both engineers' and operations' hands, the organization noted productivity improvements and an increasingly collaborative culture.

Improved user experience with data infrastructures

It does not take much imagination to picture examples of advanced analytics tools helping improve batch quality, reduce downtime and support continued process verification efforts. However, digitalization efforts should not be constrained only to improving analytics workflows.

In a case study shared by a U.S. pharma company, an in-house team of engineers expressed difficulties onboarding new employees to their existing

EXHIBIT 1

Using Seeq, an advanced analytics solution, process engineers at a top-five global pharma company monitored for gap and solid fraction irregularities during active batches.

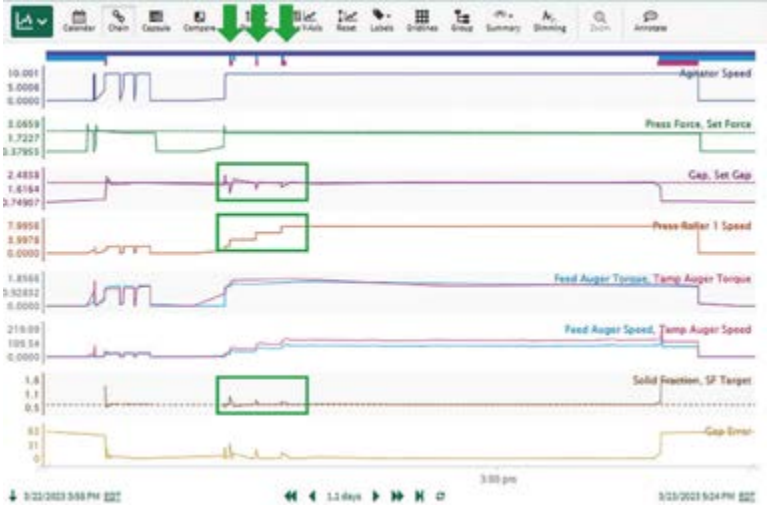


IMAGE COURTESY OF SEEQ

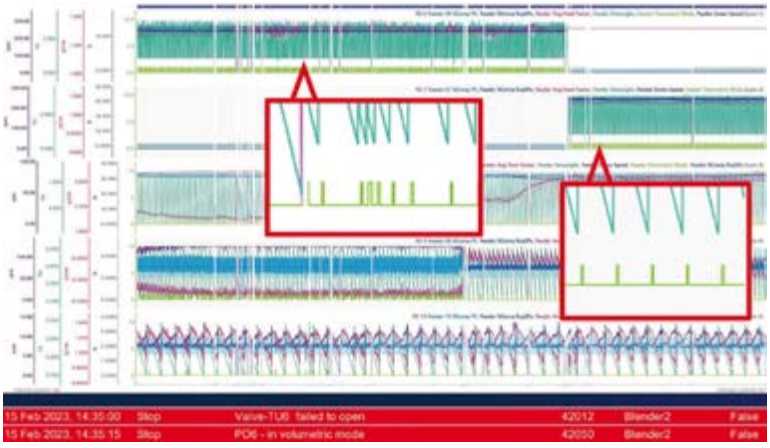


IMAGE COURTESY OF SEEQ

EXHIBIT 2

The team at a top-five global company was able to easily make out signal spikes associated with feeder behavior, providing preemptive identification of equipment issues.

data infrastructure with complicated equipment tag names and non-intuitive asset structures, which made accessing data burdensome. Similarly, the team experienced challenges onboarding new equipment to their facilities because each piece of equipment was often incorporated into the data framework in a completely new and unique way. Faced with mounting complexities from a variety of users and onboarding methods, the team decided to start from scratch and design a new data infrastructure altogether.

The engineers began by aligning on a series of goals: empower users to find equipment and tags easily, standardize calculations and visuals for similar equipment and assets across sites, and automate deployment of the revamped system for new equipment. Leveraging an advanced analytics platform with integrated programming capabilities, the data science leaders on the team developed user-oriented asset structures to mimic data infrastructure based on how employees visualize the plant resources.

After creating standardized, user-friendly tag names, the team moved to incorporating calculations into the asset structures. This process enabled not only calculation and visuals standardization, but more importantly, facilitated easy access to these standards across equipment and sites. With positive feedback from the broader team, the engineers enabled automatic deployment for future equipment by programmatically defining and deploying asset structures. Not only did existing data and advanced analytics users appreciate the transition, but the number of users accessing the newly available data doubled.

This case study exemplifies how accessibility barriers can prevent key stakeholders from interacting with data that is critical to their functions. With digitalization efforts driving user-base improvements, the process data was put to broader use. The engineering team in this case took to heart a bold refrain first published in 2017, although it is hardly a surprising truth in today's age of digital transformation: "The world's most valuable resource is not oil, but data."[1]

Increasing process efficiency

Pharma organizations face ever-mounting stress to manufacture drugs more rapidly, efficiently and cost-effectively, but in today's modern manufacturing environment, achieving such tall orders requires embracing cutting-edge digitalization solutions.

By leveraging advanced analytics software, users are discovering rapid insights from time series process data, with integrated lab and manufacturing data in a single location. SMEs from formulation development to commercialization functional teams are gaining the ability to optimize production and save time that would have otherwise been spent manually compiling and sifting through vast quantities of information.

With solutions made to evolve with processes at lab and commercial scales, including batch and continuous processes, organizations can devote digitalization resources, instead of precious engineering resources, to monitoring and alerting. And rather than waiting weeks — or even months — to notice process deviations, SMEs are now utilizing digitalization tools to identify developing issues and monitor process health in near-real time. These same resources streamline and automate the scale-out of facilities and equipment data accessibility, helping even brand-new process engineers get comfortable with the data they need quickly.

Batch-saving decisions on the plant floor are empowering companies to reduce waste and increase development speeds. And pharma organizations across the industry are leaning on digital resources to monitor process data throughout the drug life cycle, providing better insights for quality metrics and faster delivery of lifesaving drugs.

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Tiffany Overstreet
Innovation Director, MM Packaging Pharma and Healthcare

Pharma's enhanced security imperative

How a technology-driven packaging security strategy can help combat counterfeiting

As we head toward 2024, the pharmaceutical industry is at a critical juncture in its history, facing the daunting task of not only advancing science and innovation, but also safeguarding patient safety amidst the growing tide of counterfeit pharmaceutical products.

Counterfeit drugs present a multifaceted problem that demands a comprehensive and coordinated response, which is why packaging — the key touchpoint between pharma businesses and users — has a clearly defined place within this discourse.

For 2024, pharma companies need to think of packaging design as a focal point in patient security, because that's where it truly begins. To that end, new packaging security technologies, such as micro-optics, are helping pharma companies better protect end users and patients.

The counterfeiting threat continues

Counterfeit pharmaceutical products have become a pervasive global threat, ranking as the 10th most counterfeited category of products.

These illicit drugs, often failing to meet international safety and security standards, have an estimated global value of up to $4.4 billion. Beyond the economic repercussions, the ramifications of counterfeit pharmaceuticals extend to the very core of patient safety, making it a high priority problem to solve.

In some markets around the globe, it's estimated that around 10% of pharmaceutical products are counterfeit or illicit. Fake pharmaceuticals present a host of formidable challenges, each with far-reaching consequences — so the pharma market cannot afford to take its eye off the ball or slow down on progress.

The challenges of counterfeiting encompass economic ramifications, such as revenue losses and market distortions within the pharma industry, as well as severe health risks for patients. Illicit pharma products are not tested or regulated. Their ineffectiveness and the potential for adverse effects pose immediate threats to those in need of treatment. Moreover, counterfeit drugs can fuel drug resistance, making it harder to combat diseases at the individual level but also contribute to larger public health strategy concerns.

During pandemics and crises, counterfeit medications and vaccines can hinder collective efforts to control outbreaks, potentially leading to more extensive epidemics. Perhaps even more concerning for pharma businesses is the erosion of public trust. Counterfeit drugs undermine faith in health care systems, pharma companies and regulatory authorities, which can then translate into reluctance to seek medical care and reduced uptake rates in products such as vaccines.

Of course, these issues extend into the legal and regulatory environment, where involvement in the counterfeit drug trade carries severe legal consequences and the potential for lasting reputational damage. Furthermore, the strain on health care systems and the potential for cross-border issues amplify the global impact of this challenge, necessitating international collaboration and regulations to mitigate these risks effectively.

The protective role of packaging

In the battle against counterfeit drugs, the accelerated role of packaging and labeling technology cannot be overstated. It's central when it comes to creating transparency, validation and safety, particularly through the more intricate and complex supply chains apparent in today's globalized market.

Positioned at the forefront of the supply chain, pharmaceutical packaging serves to protect the efficacy and safety of medicinal products from the point of manufacture through to the hands of the end users, so naturally, we ask a lot of it in terms of performance.

Perhaps one of the most complex commercial routes today, the pharma supply chain typically includes numerous intermediaries, varying climates such as cold chain storage, and extensive transportation routes for multi-market access.

Here, we see how packaging is never 'just' packaging; it's the combination of materials and designs chosen to withstand diverse environmental conditions and protect the contents from adulteration or contamination. Robust packaging materials, when coupled with intelligent design, serve to uplift and enhance the security of pharmaceutical goods in new and potentially unexpected ways.

Serialization is the most widely employed anti-counterfeiting measure in packaging and is a requirement in many geographic regions. Assigning packs their own uniquely identifiable code creates a measurable and traceable data set that can be used to track product origin.

However, the complexity of the modern pharma landscape means that serialization alone is no longer enough to ensure effective anti-counterfeiting, as fake products are still being identified in the market, as well as genuine products appearing in grey markets. Instead, serialization is best employed alongside other security features.

Beyond serialization

One of the clearest opportunities to accelerate the role of pharma packaging is as a tamper-evidence solution, enhancing security and providing clear validation of any tampering or unauthorized access during transit.

Regulatory compliance is everything in the highly legislated pharma landscape, and packaging is key to enabling pharma manufacturers to meet stringent regulatory initiatives, such as current good manufacturing practices (CGMP) and good distribution practices (GDP).

We have seen enormous leaps forward in the development, scalability and accessibility of technologies in tamper evidencing and authentication. These technologies offer immediate at-a-glance visual confirmation of a product's authenticity, legality and safety, and can be effortlessly integrated into packaging.

Given the importance of flexibility in the changing pharma market, it is essential that brands consider as broad a range of anti-counterfeiting features as possible. Forensic, brand enhancement, consumer engagement and covert and overt technologies can be strategically combined with supplier expertise, allowing pharma businesses to access new tools and preserve the integrity of their products.

For 2024, pharma businesses are invited to explore security options with fresh eyes. Covert and overt security features both serve important purposes. Whereas covert features are designed for machine readability, overt features are designed for human visibility and are often the first thing we picture when thinking about anti-counterfeiting solutions. They employ visual markers and features that cannot be easily replicated by fraudsters. This can come in a number of different forms, including colorshift inks and Guilloche Print, which create intricate patterns that defy replication.

In a more complex pharma market, one standout feature that packaging providers can offer is micro-optics technology.

In fact, it's very likely you've already seen this innovation in action and held it, because it's rooted in the same technology used to safeguard the validity of valuable banknotes around the world. Micro-optics technology consists of millions of microscopic lenses, specifically shaped to focus on small, customizable icons applied to the substrate beneath them. This effect results in three-dimensional depth and movement, making it simple to quickly determine a product's authenticity at a glance — making it an ideal fit to support drug safety, security and transparency.

With an emphasis on ease of use, micro-optics enable straightforward product authentication while allowing for designs that not only enhance security but also reinforce brand identity. Distinctive 3D effects provide clear visual indicators of authenticity, and the technology's ability to manifest independent movement across multiple axes of tilt adds an extra layer of sophistication to product verification and security.

Micro-optic technology can be integrated with security inks, track-and-trace technologies and taggants, creating a well-rounded security ecosystem that safeguards pharma businesses against counterfeiting.

Micro-optic solutions enhance pharma packaging with secure origination while offering an intuitive way to check for authenticity.

Market adoption

In part due to the continued rise of counterfeiting and the innovation seen from suppliers, the market for anti-counterfeit packaging in pharmaceuticals is witnessing remarkable growth. Projected to reach $1.8 billion by the close of 2024, market growth has been accelerated by increasing adoption of anti-counterfeiting technologies.

As the pharma industry evolves and safety concerns mount, it's clear that packaging can assume a more prominent role in ensuring the safe and secure delivery of drug products.

In response to a growing list of challenges, a technology-driven security strategy will be key, making use of innovative solutions available in the packaging supply chain.

Tracy Nasarenko
Senior Director, Community Engagement, GS1 US

Aligning on supply chain visibility

How a cohesive 2D barcode strategy can drive operational improvements across the pharma ecosystem

The increasingly complicated business of sourcing and moving products is a pain point for many companies today. But when the products are essential for human health, supply chain visibility is crucial.

With stringent regulations, time-sensitive medications, and patient safety at stake, pharma stakeholders need comprehensive visibility into their supply chain to ensure the integrity, quality and availability of medicines.

The COVID pandemic exposed key weak points in pharma's supply chain. Fortunately, these weaknesses can be strengthened and possibly eliminated by utilizing an aligned strategy that leverages data made available in advanced barcodes.

The importance of visibility

Supply chain visibility involves the collection, analysis and sharing of data throughout the supply chain network. This enables companies to track the movement of goods, monitor inventory levels, and identify bottlenecks or disruptions within the supply chain, allowing for timely decision-making and problem-solving.

Pharma supply chain visibility encompasses various aspects, including tracking and tracing the movement of products from the manufacturer all the way to point of use. It involves monitoring temperature-controlled environments to ensure proper storage and transportation conditions. Visibility also extends to regulatory compliance, where pharma manufacturers must uniquely identify products, enabling traceability and recall management. One pressing example is the Drug Supply Chain Security Act (DSCSA) which requires unit-level traceability in an electronic, interoperable manner by November 27, 2023.*

By achieving supply chain visibility, pharma can optimize inventory management, improve recall management, reduce the risk of counterfeiting or tampering and prevent drug shortages.

Aligning on standards

Every trading partner in the supply chain needs to access, understand, utilize, add and share information about products' identification, location and status as they move from point of origin to point of use. Critical product information is being encoded in traditional linear or two-dimensional (2D) barcodes like the GS1 DataMatrix so it can be easily captured.

This information's usability lies in the use of global data standards to enable interoperability. Every product should be identified consistently across the supply chain, using a GS1 Global Trade Item Number (GTIN). DSCSA requires a "2D data matrix barcode" for packages and a "linear or 2D data matrix barcode" for homogenous cases. The use of 2D barcodes allows all four product identifiers — GTIN with embedded National Drug Code, serial number, lot number and expiration date — to be encoded, in addition to any information manufacturers need to include.

When all supply chain partners are using GS1 Standards and equipped with optical scanners, this data can be captured and automatically shared up- and downstream for effective collaboration. This becomes crucial in the event of a product recall or other safety issue where traceability and speed is paramount.

While recent surveys suggest that the majority of pharma stakeholders are developing capabilities around scanning, the consumption of enriched data elements is still in progress. It is recommended that pharma manufacturers discuss their 2D transition strategy with key trading partners including distributors, wholesalers, third-party logistics providers and end users as they create transition plans.

Perhaps the most important aspect of the entire operation is collaboration. Effective and timely communication enables faster, more targeted recalls, along with the reassurance that comes with knowing where a drug is at any point. Without standardization of homogenized information enabling a common language that all entities can understand, it would be virtually useless. With the DSCSA deadline approaching, the days of proprietary product identification schemes and databases are over. Interoperability is the only way forward.

In pharma's complex and interconnected global marketplace, supply chain visibility empowers companies to enhance collaboration with suppliers, distributors and customers — fostering trust and transparency throughout the entire ecosystem.

*The FDA recently announced an enforcement delay until November 27, 2024.

John Hatzis
Global Industry Technical Consultant, Life Sciences, Rockwell Automation

Effective OEM orchestration is music to pharma's ears

Adopting a holistic plan early in facility design can help harmonize equipment

OEM equipment forms the foundation of modern modular pharma manufacturing plants by providing the flexibility to choose and combine the best equipment solutions for specific processes.

Commissioning and validating OEM equipment is generally a faster process as manufacturers receive pre-assembled, purpose-programmed units. Furthermore, OEMs typically supply equipment in a validation-ready state, making it easy to qualify the equipment for use in CGMP facilities. There is no need to rely on internal resources or third parties for equipment construction and application code development.

However, challenges can arise from different connectivity standards and interfaces among various equipment vendors, making it difficult to integrate multiple pieces of equipment into a unified control system. This is where OEM equipment orchestration comes into play.

An orchestration strategy

Without a strategic approach and clear specifications, the use of OEM equipment results in fragmented islands of automation. This lack of a strategy is usually due to late collaboration with equipment vendors on the part of the end user.

When automation is not considered in the initial equipment procurement process, engineers often struggle to integrate equipment or rely on engineering firms to handle the integration. At best, this late-stage process of piecing equipment together as an afterthought can lead to limited interface capability within the plant. At worst, the whole process can backfire by being time-consuming and costly with no increase in digital maturity.

To solve these issues, pharma manufacturers can adopt a holistic plan for OEM equipment orchestration to automate and coordinate various components to work seamlessly together early in the facility specification and design phases.

Having comprehensive standards established before any equipment is purchased allows an end user to work collaboratively with equipment vendors, giving the OEM the opportunity to differentiate on how equipment can fit into a unified automation platform. For the end user, this simplifies cross-training and standardizes interfaces, alert systems, diagnostics and recipe management. This reduces costs, streamlines operations and results in faster construction, commissioning and qualification of the facility.

Standardized interfaces

End users are demanding OEM equipment that comes with plug-and-produce capability to integrate with any distributed control system (DCS) or supervisory control and data acquisition (SCADA) system.

This plug-and-produce capability standardizes core automation services such as equipment interfaces and recipe management, user interface screens, audit trails and alarm management across disparate equipment. It systematically connects all these elements and coordinates them using standardized interfaces, like the NAMUR module type package, and modern protocols, like OPC Unified Architecture. Integrating all these disparate platforms together brings consistency, saves time and effort on integration, and makes plug-and-produce a feasible technology for facilities of the future.

These technologies should be viewed as an augmentation to a cohesive strategy for OEM orchestration rather than replacing all the work done with collaboration between organizations and comprehensive specifications.

Although there is no magic button to integrate equipment seamlessly, vendors can play a big part in an effective OEM orchestration strategy. For example, a plant built entirely with black box equipment with a standardized interface might be fast to integrate but would be difficult and costly for an end user to support long term due to managing numerous support contracts, disparate spare parts, and a lack of consistency in or access to application software on the OEM equipment.

A multitude of benefits

Put simply, the orchestration of OEM equipment facilitates the work of creating a unified automation platform for a facility. This ultimately leads to a faster time to market and lower total cost of ownership.

Effective orchestration enables the integration of different OEM components in a way that allows for easy customization and scalability, new equipment addition into existing systems, and seamless integration of future upgrades and expansions.

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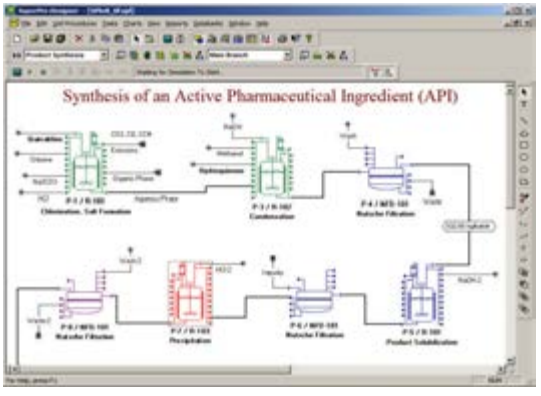

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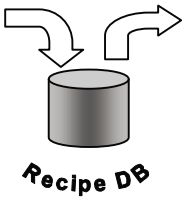

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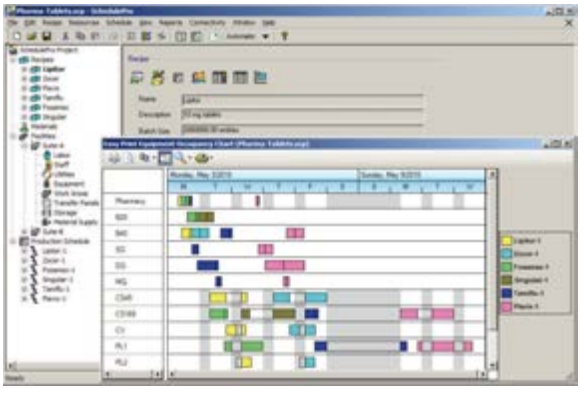

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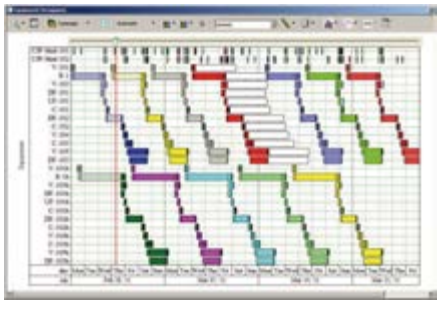

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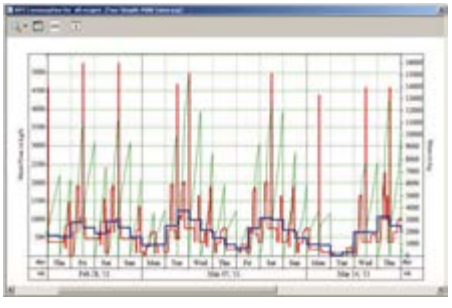

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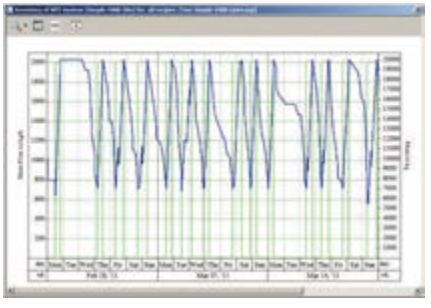

Managing inventories for input, intermediate, and output materials

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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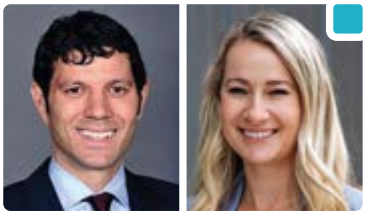

DPT laws: Don't be caught unexpecting

State drug price transparency laws are here to stay — and manufacturers need to be prepared to comply

Understanding the significance of state drug price transparency (DPT) laws requires an awareness of some recent history.

In 2015, Martin Shkreli, then CEO of Turing Pharmaceuticals, became a household name for his controversial price hike of Daraprim, a lifesaving infection treatment. Overnight, he raised the price per pill from $13.50 to $750. Around the same time, more people started to pay attention to the rising price of insulin, which had been steadily climbing as new analogs entered the market.

In response to the public's building frustration over high prices, several states have taken measures to pursue price transparency further: passing DPT laws, requiring additional information to support drug price trend monitoring, publishing databases on drug prices, or establishing review boards to make recommendations on costs.

DPT laws were designed to inform the public of which pharma manufacturers are increasing prices, why they are doing so, by how much, and how often. After the flurry of DPT laws that rolled out in the late 2010s, we continue to see new developments. This year, several states have already passed new laws, and other governors have bills on their desks. More than 100 DPT-related bills are pending at the federal and state levels.

Needless to say, you don't want to be caught unexpecting when it comes to DPT laws. Manufacturers should know what to expect, have the required information ready, and ideally, have someone on their team who can handle conversations with states in a timely and knowledgeable manner.

Today's DPT obligations

Some states are very clear that their goal is to 'name and shame.' Vermont and Maine, for example, publish lists of the top drugs the states are spending money on, effectively putting manufacturers on notice for the financial impact of their pricing strategies. Minnesota takes it one step further, publishing the number of reports expected and received from each manufacturer.

Specific to price increases, our clients usually ask one of two questions: 'What reporting requirements will this price change trigger?' or 'How much of a price increase can we take without triggering reporting requirements?'

In working with clients in real-time to think through DPT laws and implications, we have observed that the clerical burden that comes with these laws is prompting manufacturers to rethink moves they might have made without question 10 years ago. Today, they must explain why they are choosing to raise prices and provide all the context that factors into that decision.

When companies decide to go through with a price increase, the 'consequence' is a more administrative burden, which varies by state. However, all drug manufacturers are subject to DPT laws and will have some degree of reporting obligations.

Noncompliance can cost you

In addition to the added operational burden and potential for name and shame, there are also financial repercussions for failing to comply, as many states are doubling down on disciplinary efforts for failure to meet report requirements. California, for example, fines a manufacturer up to $1,000 per day per NDC.

Not only can the fines be strict, but so can the standard on the quality of information provided. If a state decides that a manufacturer didn't provide satisfactory information, it can push back. In Oregon, manufacturers can face a fine of up to $10,000 per day if the state doesn't believe they made a good-faith effort to provide a complete and accurate report.

DPT laws are constantly changing and vary from state to state. DPT activity doesn't need to start as early as state licensing, but it's important to know where you are likely to trigger a DPT law in your timeline. Companies should begin making plans for DPT reporting at least six months before a drug launch and then be ready for ongoing work since some reporting is done on a quarterly and annual basis.

There is a broad, ongoing push toward health care transparency. Drugmakers set out with the goal of bringing life-changing products to as many patients in need as possible. DPT laws are the result of states wanting to be more in tune and alert to how and why drug prices change. These laws are here to stay — and more are coming, so pharma needs to be prepared to comply.

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