VOLUME 23 • ISSUE 3

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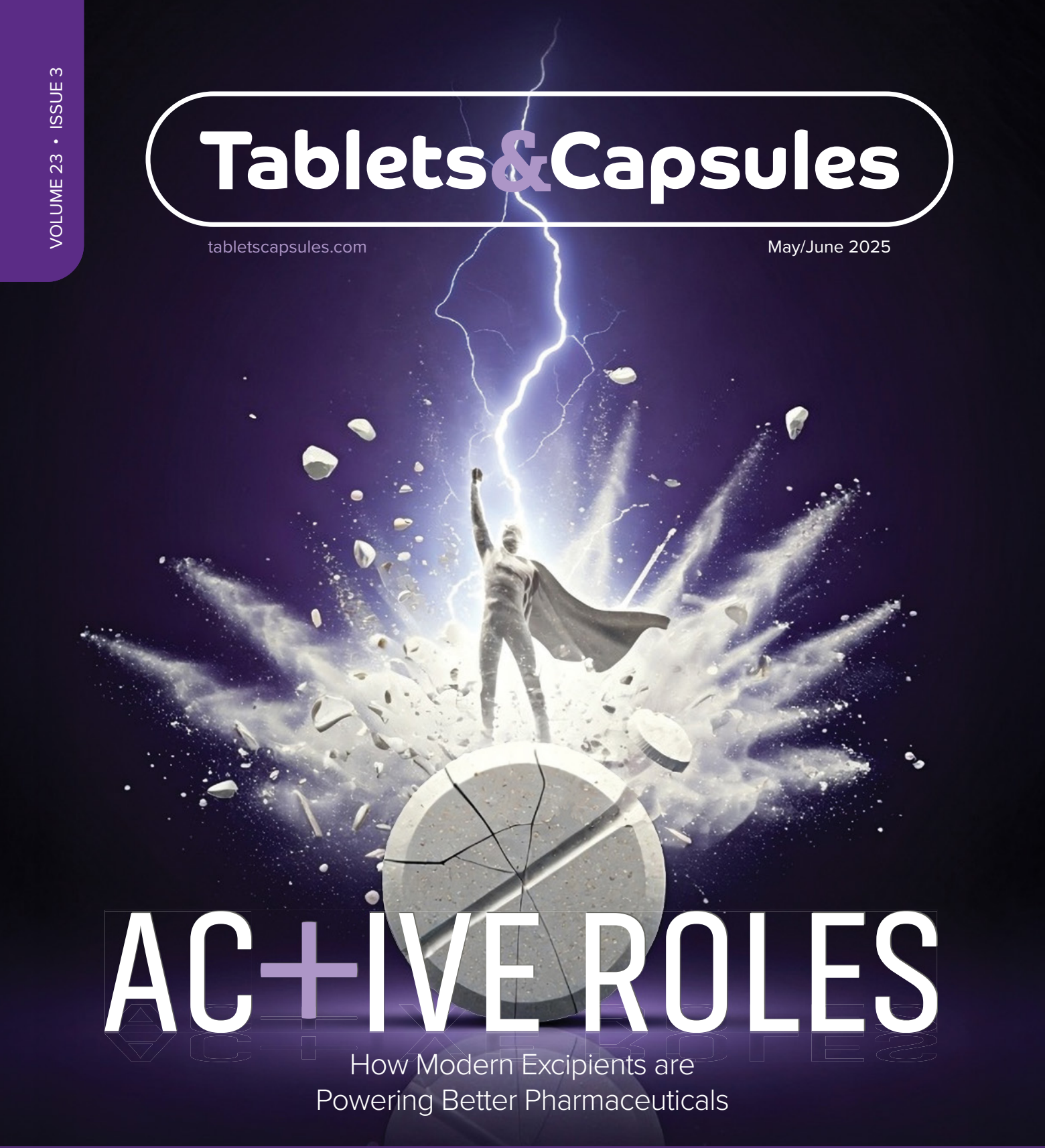
May/June 2025



AC+IVE ROLES

How Modern Excipients are Powering Better Pharmaceuticals

Taking on bRo5 Compounds

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ISSUE EXCLUSIVE: 2025 SOLID DOSE SOURCEBOOK

Active Roles

How Modern Excipients are Powering Better Pharmaceuticals

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Tablets & Capsules

Excipients and oral solid dose formulations have gone hand in hand since antiquity. Ancient Egyptians relied on inactive substances such as bread dough, honey or grease to bind together medicinal ingredients and form 'pills.' Roman medicinal tablets, recovered from a shipwreck, were found to contain starch grains, beeswax and olive oil.

The pharma industry has come a long way since ancient times, and excipients have helped manufacturers step up to the challenges of modern medicine. As drugs have become increasingly complex, manufacturers have leaned on excipients to help improve drug formulations. Advancements in formulation science are pushing excipient innovation to the forefront — especially when it comes to improving solubility, enhancing stability, and supporting more personalized approaches to drug delivery.

Balancing Function with Sustainability

Over the last five to ten years, excipients have become increasingly vital in helping the pharma industry meet new performance and drug delivery demands.

According to Colorcon, a global supplier of pharmaceutical film coatings and specialty excipients, one big driver of excipient innovation has been the need for

Image: Michael Annino | Shutterstock-AI

effective oral delivery of large molecule drugs. Delivering macromolecular drugs, which include both proteins and peptides, via oral routes has challenged the industry since the first attempts at oral insulin almost 100 years ago.

“Achieving delivery of large drug molecules through the oral route is considered the ‘holy grail’ of drug delivery, where many drugs that are currently available only via injections may be made available in tablet and capsule formats which are the preferred dosage forms for patients,” says Russell Prestipino, Global Business Manager – Immediate Release Excipients, Colorcon.

Getting these drugs across the gastrointestinal tract has proven particularly difficult, leading to poor absorption. That’s where next-gen excipients and coatings come in.

“A key focus has been to find polymers and other ingredients that can convert crystalline drugs into amorphous forms to increase their solubility and thus bioavailability. Additionally, it is critical to add stabilizing ingredients to ensure the drug remains stable over time in the gastrointestinal tract,” says Prestipino.

Sustainability has also been a major driver of innovation in the excipients market, as the pharma industry is under increased pressure from regulators and patients to develop high quality, biodegradable ingredients that enhance productivity and streamline manufacturing processes.

“The pharmaceutical industry’s shift toward more sustainable and environmentally friendly practices has made the incorporation of plant-based excipients a key strategy in developing new drug delivery systems,” says Anthea Rodoreda, a representative from specialty excipients and pharmaceutical coatings provider Mantrose-Haeuser.

Drugmakers and patients are also looking for clean-label ingredients and focusing on the use of natural, renewable sources that align with broader environmental goals. Excipient providers have stepped up, turning to more natural and biodegradable excipients, such as naturally occurring polymers.

“Advanced engineering processes are revolutionizing excipient capabilities by enhancing drug delivery, stability, and solubility, ultimately leading to superior and cleaner pharmaceutical products. In addition to improving product quality, these advancements are transforming manufacturing processes, making them more environmentally friendly, cost-effective, and efficient,” says Rodoreda.

Some manufacturers looking to meet the growing demand for cleaner, simpler formulations have turned to multifunctional and co-processed excipients — materials that can take on multiple roles in a formulation, reducing the need for additional ingredients. These excipients can improve processing efficiency and shorten development timelines because they require fewer ingredients and fewer steps, offering more functionality packed into a single component.

A Boost from Technology

Several emerging technologies are giving excipients more functional muscle.

“As there are many new medicinally active drugs which are poorly soluble, there has been great effort to find excipients that can improve their solubility and enhance their bioactivity,” says Bill Thonack, Senior Vice President at API and excipient provider Biddle Sawyer.

Nanotechnology, the manipulation of materials at the molecular or nanoscale level, is helping improve excipient solubility and absorption. Microencapsulation techniques, such as coating active ingredients in protective polymer shells, allow sensitive actives to be protected during processing and released more effectively where and when they’re needed.

Formulating drugs as amorphous solid dispersions (ASDs) is a common practice used to enhance the solubility and bioavailability of BCS Class 2 drugs, which are drugs characterized by high permeability but low solubility. In ASDs, the active ingredient is spread out within an excipient matrix in a non-crystalline form.

The two most common techniques for manufacturing ASDs are spray drying or hot melt extrusion. While hot melt extrusion tends to be less expensive, it is also not suitable for temperature-sensitive APIs. In spray drying applications, which help control particle size and enhance dissolution rates, excipients can also help with binding and compactability.

One alternative approach to ASDs gaining traction is the use of mesoporous silica as an excipient, which stabilizes APIs in non-crystalline form. Another potential alternative to ASD technologies involves a solvent-free, fusion-based process that combines frictional and shear energies with high-intensity mixing.

While 3D printing still sits on the fringe of pharmaceutical manufacturing, it holds potential for highly specific use cases. “3D printing is another tableting approach which I see as a niche – ideally for small batch clinical studies or in very remote locations,” says Thonack.

The ability to produce individualized tablets on demand makes 3D printing promising for orphan drug populations, where patient groups are small and traditional manufacturing isn’t always cost-effective. For now, though, its role remains limited to specialized applications rather than mainstream production.

Regulatory Constraints

Despite these advances, regulatory inertia continues to slow the introduction of truly novel excipients. Current approval pathways require that new excipients be introduced as part of a new or abbreviated drug application, a process that limits early adoption and discourages investment.

Certified USP/EP Pharmaceutical Glazes from Mantrose Group are used to coat pharmaceutical tablets for time-release and extended release profiles.

Colorcon's Prestipino explains that without a separate route to approval, excipient developers face long timelines and limited returns. "There are efforts underway by organizations like IPEC [International Pharmaceutical Excipients Council] to create a separate path for co-processed excipients, but progress has been slow," he says.

Thonack echoes this frustration, "Until a pathway is decided upon by the FDA this will continue to be a limiting force for new excipient approaches. Although the FDA is aware of this [restriction of novel excipient use] it appears the best efforts to piece together some route is being fostered by IPEC; however, I do not see a resolution near at hand."

As a result, many companies are leaning into optimization rather than invention. Pharma companies often choose well-established excipients to streamline product development.

"Without a clear pathway to get new excipients approved outside of NDAs or ANDAs, producers are modifying existing excipients to unlock new applications — often with a focus to use renewable sources and biodegradable aspects in excipient products," says Thonack.

Improving performance while staying within known regulatory frameworks has become a practical — and strategic — approach.

Supply Chain Resilience Amid Uncertainty

Like much of the pharmaceutical industry, excipient manufacturers are navigating a shifting and increasingly fragile global supply chain. Disruptions tied to geopolitical conflict, rising transportation costs, raw material shortages, and growing trade tensions have turned what used to be occasional challenges into ongoing operational concerns. As a result, supply chain resilience is no longer just a competitive advantage, it's a necessity.

"Disruption is the new norm," says Prestipino. "We've found it important to understand supplier risk profiles and to work with multiple suppliers or those with diverse locations and transportation routes. By building strong relationships with our suppliers, we foster resilience and trust, allowing us to offer location change options when necessary."

While the global availability of excipients has held relatively steady, logistics remain a pinch point. Biddle Sawyer's Thonack points to shipping constraints and vessel access as the most persistent bottlenecks.

"The current largest bottleneck in the supply chain for excipients imported into the U.S. has been the availability of vessels and their high shipping costs, some of which has been due to trouble spots throughout the globe. From my perspective, there are ample suppliers and availability of most excipients, maybe too many, but there are limited U.S. customers, many of whom have moved operations overseas," says Thonack.

Overseas operations could prove problematic, depending on how U.S. trade policies shakeout. While the anticipated impact on excipient sourcing should be minimal, companies are preparing nonetheless.

"One key adjustment is the expansion of domestic supply chains, which allows companies to reduce dependence on imported materials and shield themselves from tariff-related price increases. Mantrose, for instance, has ramped up production in the United States to meet growing demand, achieving record levels of output," says Rodoreda.

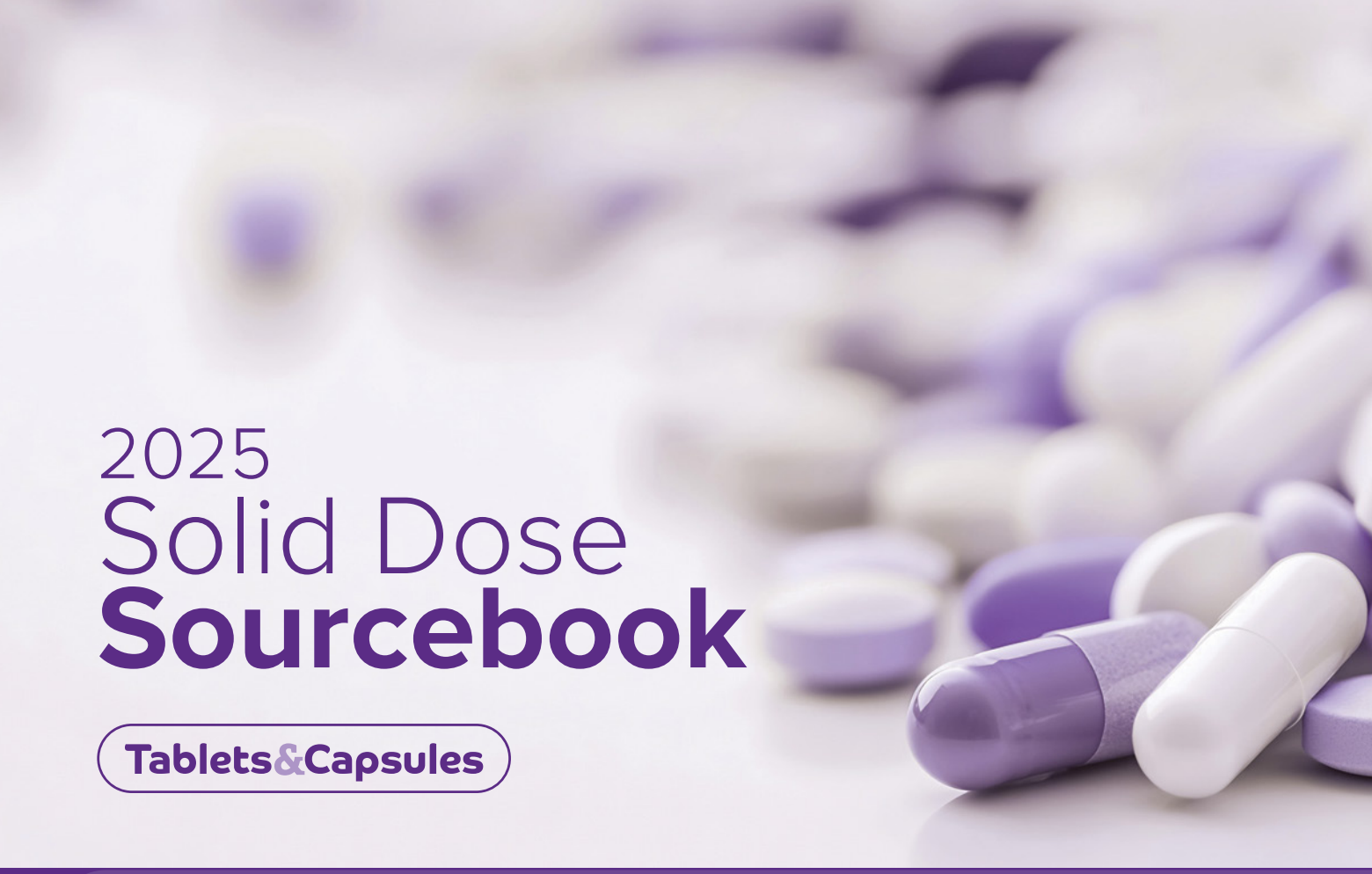
Domestic production also shortens lead times and enhances traceability — critical factors in today's regulatory and commercial environments. "By increasing domestic production capacity, Mantrose not only helps safeguard against tariff fluctuations but also ensures a more stable and responsive supply chain for its customers," says Rodoreda.

While Thonack says that tariffs on excipients are unlikely to raise drug manufacturing costs significantly, he cautions that tariffs on finished drug/nutraceutical products could have a ripple effect on pricing.

"Certainly, the on and off again tariff threats from the current administration could cause the public to cut back on spending for health care and nutritional supplement purchases. The latter being more vulnerable; however, many of the dietary supplement actives are cultivated in the U.S. which may moderate the impact," says Thonack.

Towards a Stronger Future

As the pharmaceutical industry pushes the boundaries of what's possible, excipients will continue to play a central role in shaping the future of medicine. The evolution of excipients alongside the pharma industry reflects a more significant trend: excipients are no longer support players. They're becoming strategic tools in modern drug development, helping formulators solve problems, streamline production, and bring better therapies to market faster.



2025 Solid Dose Sourcebook

Tablets&Capsules

PRODUCT INDEX

Colorcon®
Working Together for a Healthier World

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Phone: 215-256-7700
www.colorcon.com

COMPANY DESCRIPTION

Colorcon is a global leader in the development, supply, and technical support of formulated film coating systems, modified release technologies, core excipients and functional packaging solutions for the pharmaceutical, nutraceutical, and animal health industries. Our commitment to innovation, quality, and collaboration ensures that our customers' products go from concept to commercialization efficiently and effectively.

COMPANY BACKGROUND

For over 60 years, Colorcon has applied its deep scientific knowledge and extensive industry experience into providing exceptional products and services. Our people-centric approach and dedication to excellence has made us a preferred supplier for many leading pharmaceutical companies.

MARKETS SERVED

- **Pharmaceuticals:** Providing specialty excipients, film coating systems, and controlled release formulations.
- **Nutraceuticals & Dietary Supplements:** Developing clean label tablets, capsules, and gummies.
- **Animal Health:** Enhancing the palatability and effectiveness of medications and supplements for animals.

GLOBAL LOCATIONS

With over 40 technical laboratories and manufacturing facilities worldwide, we ensure that our expertise is within reach of any market or project. Colorcon's extensive global network provides local expertise and dedicated customer support. This global reach, combined with a deep understanding of local markets, allows us to offer exceptional value and innovative solutions tailored to meet the unique needs of our customers.

PRODUCTS

- **Core Excipients:** Essential for drug stability and delivery.
- **Controlled Release Technologies:** Optimizing therapeutic effectiveness and patient compliance.
- **Film Coatings:** Protecting medications from environmental factors and improving their appearance and taste.
- **Controlled Atmosphere Packaging:** Maintaining medication integrity by preventing degradation.

SERVICES/CAPABILITIES

- **Technical Support:** Our customer-focused team puts us at the forefront of formulation design, development and production.
- **Regulatory Compliance:** Ensuring products meet global regulatory standards.
- **Strategic Partnerships:** We are the exclusive representative for LOTTE Fine Chemical's AnyCoat-C and AnyCoat-P Hypromellose polymers.
- **Training and Education:** Colorcon Academy offers a range of schools and webinars to keep customers informed about the latest industry trends and technologies.

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