

Pharma Solutions

Tracing Quality to the Source: A Look at DuPont's Raw Materials Supply

Dan Willwerth, Executive Buyer for DuPont Nutrition & Biosciences' Pharma Solutions platform, is responsible for implementing a global sourcing strategy to secure critical ingredients in support of various product lines, including Avicel® and METHOCEL™. This strategy includes the ongoing evaluation of DuPont's raw material suppliers to ensure quality, safety and regulatory standards are met.

1. How does the Pharma Solutions platform in DuPont Nutrition & Biosciences select its suppliers, and what criteria must they maintain?

As a major supplier into the pharmaceuticals space, it's our responsibility to uphold the most stringent standards of quality and reliability from our raw material suppliers. We select our suppliers based on their proven capabilities and the opportunities they present, including unique product attributes, production capacity, and both process and logistics capabilities.

We typically begin evaluations with a technical hypothesis: a raw material from a specific supplier could provide value to DuPont, whether that value be processability, functionality, price or some other attribute. The evaluation then proceeds to an assessment by a multifunctional team to determine potential impacts or advantages of the new materials to areas such as quality, regulatory, product stewardship and other functions. At this point, we thoroughly review supplier documentation, technical exchanges take place, and comprehensive laboratory or pilot scale testing is conducted.

One of the most critical standards we take into consideration is sustainability. We will only partner with suppliers that have established sustainability initiatives, as well as strong environmental, health and safety policies to actively improve their impact on the environment and the communities they serve. For example, all of our wood pulp sources have third party certifications for their forestry practices and/or wood sourcing chain of custody practices.

2. How does Pharma Solutions evaluate and qualify potential suppliers?

When bringing on a new supplier, we follow our strict change management process to avoid a negative impact on DuPont, our products and the customers we serve. All suppliers to DuPont must have a quality system suitable for supply of raw materials into a pharma excipients plant. Typically, we begin evaluating a supplier by reviewing all documentation pertaining to product specifications, test methods and quality procedures. We require all vendors to provide the necessary documentation and any requested samples for evaluation. We then perform an on-site audit to confirm a prospective supplier can meet our established quality, regulatory and performance expectations. Ultimately, the Pharma Solutions Quality Team determines whether a prospective supplier has become qualified to supply. This team also has the authority to disqualify any supplier at any time.

3. How does the platform ensure consistency between multiple suppliers to source high-quality pharmaceuticals?

To assure reliability of supply, we work with multiple suppliers around the globe. We are continually evaluating new suppliers to create alternative options that reduce the risk of any shortage of raw materials. Unfortunately, the qualification process can take many years to complete, and prospective suppliers are not always successful in passing our qualification

process, and therefore cannot supply. Because of this high degree of difficulty, we typically secure supply with our well-established sources through long-term contracts.

To maintain our product consistency with different suppliers, all suppliers must meet our stringent raw materials specifications and operate within the parameters documented through our auditing process. If there is any deviation from an operating parameter that could constitute a significant change, we require the supplier to notify us of the change, even if they believe the quality of their product is unaffected.

4. Does the platform consider both long- and short-term contracts? How do you evaluate suppliers to guarantee they deliver?

We have both long-term and short-term contracts in place, but they differ based on the type of raw material the suppliers are providing and the longevity of the need. Typically, the larger, critical suppliers have longer term and more complex contracts, while shorter terms are used for smaller needs that fit specific product lines. To consider a supplier for the long-term, we evaluate their financial viability, business plans, their commitment to DuPont and the markets we serve. Many suppliers start with short-term contracts in niche areas, which can evolve over time into long-term contracts, serving multiple purposes.

5. What contingency plans are in place to prepare for potential crises?

Although we have multiple high-quality sources for raw materials, my team is constantly assessing new suppliers so we are prepared whenever a crisis may strike. As one of the largest pharmaceutical excipient producers in the world, we've established long-standing, strong relationships with our suppliers to make sure they are there for us during a crisis.

For more information, please visit pharma.dupont.com.

The Pharma Solutions platform within DuPont Nutrition & Biosciences:



Works with 7 major vendors across the globe to source raw materials for its pharmaceutical products.



Sources wood pulp from 9 mills across 6 different countries.

- Avicel® is supplied by 5 mills in 4 countries
- METHOCEL™ is supplied by 5 mills in 3 countries



Is committed to sourcing raw materials from sustainable suppliers. All wood pulp suppliers are FSC (Forest Stewardship Council) and/or PEFC (The Programme for the Endorsement of Forest Certification) certified.



Audits suppliers at a frequency based on the risk they pose. Supplier audits typically include a review of sustainability programs, Environmental Health and Safety (EHS) performance, technical/commercial developments and multiple other topics.



Offers one of the broadest portfolios in the excipient industry to create innovative pharmaceutical formulation solutions utilizing the safest, most reliable raw materials.



Has more than 300 years of cellulosic experience across our portfolio, and an unrivaled network of expert scientists and engineers to fuel cross-functional innovations that solve all types of formulation challenges.



Nutrition & Biosciences
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