

ASK THE EXPERTS: EAGLE ANALYTICAL



How Eagle's Approach Gives Its Customers a Huge Advantage



Ashley Trueheart, former Director of Product Design and Development at Eagle Analytical.

As an industry leader in analytical testing and consulting services for 503A compounding pharmacies, 503B outsourcing facilities, and pharmaceuticals, Eagle Analytical embraces a philosophy called the 'Eagle Shield' to help customers get product to market faster, safely and with full compliance.

bioMérieux had the opportunity to sit down with Ashley Trueheart, former Director of Product Design and Development at Eagle Analytical (Eagle) to discuss how they provide customers the fastest time-to-results using SCANRDI®, a safe and proven method for sterile product release.

Eagle is an FDA-registered analytical testing and consulting service for 503A compounding pharmacies, 503B outsourcing facilities, and pharmaceuticals. Eagle's scientific experts excel at helping sterile and non-sterile facilities identify risks, challenges, opportunities, and implement cost-effective, science-based solutions to resolve the needs of pharmaceutical companies.

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Before her transition to another leading biotechnology research company, Ms. Trueheart was with Eagle for 7 years, starting as a microbiologist and advancing to microbiology manager, and then on to Director. As Director, she led product design, assisting customers in navigating regulatory compliance requirements and acted as the subject matter expert on SCANRDI – a rapid microbiology solution with patented universal cell labeling and solid phase cytometry with the ability to detect bacteria, yeasts, molds, and spores.

Recognized by the FDA as an alternative method for sterile product release, SCANRDI® revolutionized rapid microbial detection when it was first introduced. Today its speed and sensitivity differentiates SCANRDI as a leading alternative method in the industry. Eagle adopted the technology to provide its customers an edge by reducing the actionable sterility results to 4 hours or less, down to 1 microorganism of sensitivity.

Our Motto and Commitment to Customers

Question: How is Eagle dedicated to being the one-stop-shop for the industry?

Answer: Ashley Trueheart (AT): Our motto is Eagle Shield – it's a philosophy – whether we are following GMP or building certifications, regulatory responses, environmental monitoring, and sequencer processing. We also provide services on how to better control your lab environment. We offer testing throughout the entire process – from the raw material and API testing all the way to finished production testing.

Question: Q: What is the average number of samples tested per day?

Answer: AT: With SCANRDI – we test 40 to 50 samples a day or 1,000 samples a month.

Question: Q: What are the minimum sample requirements for testing?

Answer: AT: It depends on what the test is. We break that down following USP<71> guidelines to determine how much testing is required.

Adopting SCANRDI Technology

Question: When did you first learn about SCANRDI?

Answer: AT: We bought a unit in 2013. I was introduced to it through Eagle. I instantly loved the unit, loved the technology and the process. So I really gravitated towards it and toward testing the products with it.

Question: What was your objective or primary driver for adopting SCANRDI?

Answer: AT: Traditionally, the pharmaceutical industry follows USP <71> for sterility testing. Rapid microbiological testing is a newer alternative method, so Eagle's hope for adopting the technology is to offer

customers quicker turnaround time so they can release the product faster to their patients. The SCANRDI not only allows for quicker response so our customers can release their products quicker, but it's also more sensitive and it's not dependent on growth.

Question: What were the results from the method validation with the SCANRDI?

Answer: AT: Eagle does a lot of method validations and product validations. We have almost 300 unique formulations on file that we've done for people on method suitability. We are a big proponent of that and we help troubleshoot others when they're doing their validation studies.

Question: How is SCANRDI a powerful technology and how can it support your customers?

Answer: AT: Its more sensitive than the USP <71> compendial sterility test, and it's extremely supportive for the pharmaceutical industry because it allows you to get results in just hours rather than 14 days.

Question: Based on the technology and personnel at Eagle, what unique value do you provide to customers?

Answer: AT: Our unique advantage is that we're very familiar with the SCANRDI platform in a real world experience which has allowed us to understand the technology and troubleshoot, and it has allowed us to see variations of microorganisms or particles. So our unique value to our customers is we're very good at this methodology and we are subject matter experts on it.

Question: What specific advantages can be gained by leveraging the SCANRDI?

Answer: AT: The business advantage to the customer is its improved turnaround time. This allows customers to get product off the shelf quicker – you're not making money if product is sitting on the shelf.

Helping Customers Better Navigate their Environment

Question: Eagle also provides consulting services. How can Eagle help sterile and non-sterile facilities looking to identify risks, challenges, and seize opportunities?

Answer: AT: We have a whole consulting department devoted to this, and we do gap analysis, audits for sterile and non-sterile facilities. We help with compliance, or state regulations. We will also go into facilities and do a mock FDA audit. We have several experts on staff, that range from Dr. Ross Caputo, who has over 40 years of microbiology experience, and we have Dr. David Hussong, our Chief Technical Officer at Eagle, who was with the FDA at the Center for Drug Evaluation and Research (CDER) for 30 years and served as the chair of the USP Microbiology Expert Committee for the 2015-2020. We also have Dr. Burn who is a PhD chemist. So we have significant experience on staff that helps the customers in a variety of areas and capacities.

Question: How can Eagle assist customers with cost-effective science-based solutions?

Answer: AT: As I said before, our motto is what we call Eagle Shield – a philosophy we have to help protect our customers. It comes down to what the issue actually is. First we identify the issue – is it a processing issue or compounding or a systems issue? Then we can offer an assessment on what steps can be taken to improve the issue.



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SCANRDI® is an industry leader in sensitivity and speed, providing your business a competitive edge. With a turnaround time that delivers results in just hours, this state-of-the-art technology helps you to confidently release your products into the market fast.