

November 16, 2021

This press release refers to the press release by Associates of Cape Cod, Inc. published in November 16, 2021. Detailed information is available on its website. (<https://www.acciusa.com/about-us/news-and-notice/articles/>)

## Seikagaku Announces PyroSmart NextGen™ recombinant BET reagent receives the Pharma Manufacturing 2021 Innovation Award

Seikagaku Corporation (Tokyo, Japan; “Seikagaku”) announces today that its overseas subsidiary Associates of Cape Cod, Inc.\*<sup>1</sup> (Massachusetts, U.S.A.; “ACC”) received the Pharma Manufacturing 2021 Innovation Award for its recombinant BET reagent “PyroSmart NextGen™”.

The Pharma Manufacturing 2021 Innovation Awards recognizes innovation and those who distinguish themselves as technological leaders in the pharmaceutical and equipment technology space. Chosen by magazine editors and industry reviewers, the committee selects the most innovative pharmaceutical manufacturing technologies of the year. This year’s award winners are covered in detail in Pharma Manufacturing Magazine’s November 2021 issue, published by Putman Publishing.

ACC was selected for the award because its cutting edge PyroSmart NextGen™ BET reagent\*<sup>2</sup> uses innovative recombinant technology. This technology makes the new product sustainable while maintaining its ability to reliably detect the presence of bacterial endotoxins in water testing, medical device, pharmaceutical and biopharmaceutical applications. The new PyroSmart NextGen™ reagent also allows existing users of traditional LAL based reagents to retain their existing equipment, utilize the same preparation steps and maintain existing test methods, all of which minimizes the time, cost and risk in retraining lab analysts and reviewers.

“The team at ACC is very pleased to be recognized for this important innovation-centric award”, noted Dr. A.J. Meuse, President and CEO of ACC, “Our PyroSmart NextGen™ BET reagent took years to develop in partnership with Seikagaku, all with a goal of delivering the sensitivity of traditional LAL based reagents with the reliability of leading edge recombinant technology to produce a sustainable reagent option for our customers. We are grateful to be recognized for our team’s commitment to innovation and introducing new sustainable technologies to the market.”

Seikagaku has launched PyroSmart NextGen™ in Japan since May 2021. Since the product is manufactured without using blood harvested from naturally sourced horseshoe crabs, we will continue to contribute to the conservation of the environment and biodiversity through PyroSmart NextGen™ sales and horseshoe crab conservation programs in which juvenile horseshoe crabs are raised and then released.

### < Reference Information >

\*1 Associates of Cape Cod Inc. (ACC)

Associates of Cape Cod Inc. (ACC), a wholly owned subsidiary of Seikagaku, was the first FDA-licensed LAL manufacturer. ACC was established in 1974, became a Seikagaku subsidiary in 1997, and currently plays a central role in the global Bacterial Endotoxin Testing (BET) and clinical glucan detection sectors. ACC’s reagent production facility, located at their campus in Falmouth Technology Park in Massachusetts, is vertically integrated with an end-to-end manufacturing operation that extends from harvesting horseshoe crab blood cells, a reagent raw material, to manufacturing, testing, packaging/labeling and distributing endotoxin and glucan in vitro diagnostic agents. From that location, ACC also offers customers in-house contract testing services for BET and clinical glucan product testing.

\*2 Bacterial Endotoxin Test (BET) reagents

Endotoxins are a component of gram-negative bacteria. Since endotoxins exhibit strong pyrogenic activity even in minute amounts and serious side effects can be triggered by endotoxin contamination of pharmaceuticals and other products, they must be rigorously controlled pursuant to regulations in the manufacture of pharmaceutical products and medical devices. BET reagents used worldwide in the quality control of pharmaceuticals, medical devices, biopharmaceuticals, and in water quality control in dialysis at hospitals.

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