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ACC Position Statement on USP Chapter <86> Inclusion of Recombinant BET Reagents

The recent update to USP Chapter <86> to include recombinant bacterial endotoxins test (BET) reagents—specifically recombinant cascade reagents (rCR) such as ACC’s own PyroSmart NextGen®, and first-generation recombinant Factor C (rFC) - marks a significant and welcome milestone in the evolution of endotoxin testing technologies.

As the pioneer in endotoxin detection with over 50 years of innovation, ACC proudly recognizes and supports the scientific and regulatory validation of recombinant technologies within the BET landscape. We believe recombinant reagents represent an important advancement, offering sustainable alternatives that align with the industry’s increasing focus on principled sourcing and environmental responsibility.

ACC has been at the forefront of this shift, having introduced the world’s first commercially available rCR reagent, PyroSmart NextGen®, four years ago. Since then, we have actively supported peer-reviewed studies and customer-driven comparability data to demonstrate that rCR reagents can match—and in many cases exceed—the performance and consistency of traditional LAL-based methods.

That said, it is important to emphasize that regulatory evolution does not immediately equate to industry-wide adoption. The inclusion of recombinant reagents in USP <86> is the beginning of a broader transition. Real-world implementation will require a phased, multi-tiered approach that takes into account the complexity of global regulatory expectations, the diversity of testing platforms, and the validation resources needed by manufacturers.

We caution against the misconception that the industry can or should move away from traditional LAL overnight. While innovation must be embraced, health and human safety must remain the primary driver. Traditional LAL reagents will continue to play a critical role in ensuring compliance and safeguarding public health as the industry gradually adapts to these new technologies.

ACC remains committed to supporting this transition through education, data transparency, and the continued development of robust, reliable solutions for endotoxin testing. We are proud to be a trusted partner to our customers and regulators as we navigate this next chapter - together.

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