

Foreword

Members of the sterility assurance community come from a wide variety of backgrounds with a shared passion to safeguard and improve the quality of life for our patients, customers, and consumers. When we look at the future of sterility assurance, we see a very different landscape for healthcare products (e.g., medical devices, pharmaceuticals, combination products). The availability of new, more powerful technologies will allow for more effective and efficient processes. The fast evolution of healthcare products (e.g., individualized care products and products that are 3D printed in a supply chain) will allow our industry to address unmet patient, customer, or consumer needs. Our current strategies for assuring sterility through aseptic processing or terminal sterilization may no longer be fit for the purpose, and this will change how we deliver healthcare in the future.

The 2019 Kilmer Conference theme, *Collaborate to Innovate*, was intended to accelerate and facilitate an enhanced way of solving the issues that the sterility assurance community needs to overcome for the products of today *and* the future. To define the needs of the community, we asked participants prior to the conference to complete two surveys—the first to identify current industry challenges, and the second to prioritize them. The surveys resulted in the following top priorities:

1. Regulatory: How do I balance sterility assurance innovation and regulatory risk?
2. Sterilization: How do I streamline the move from ethylene oxide/gamma to E-beam/X-ray? (How do we simplify sterilization modality changes and process optimization?)
3. Rapid microbiology: How do I move from a traditional test to a rapid microbiological test and what barriers do I need to overcome?
4. Product process analytical technologies (PATs): What PATs would eliminate the need for finish product testing?
5. Process PATs: What PATs would allow for real-time (in-process) environmental monitoring?
6. Sterilization technology: How do I learn from others in the industry about alternative sterilization technologies (nontraditional) and how to benefit from them?

As a way to demonstrate how—as a community—we might collaborate to innovate on these topics, we initiated “Kilmer Collaboration Events” prior to the conference. The teams assembled were based upon the topics, a mix of individuals with different backgrounds and competencies, and volunteers identified during the survey process. The initial teams assembled were tasked to address the two highest priorities. The collaboration teams met and identified opportunities to publish the concepts and ideas that will establish the foundation for future innovation.

Industrial Sterilization: Process Optimization and Modality Changes includes some of these ideas for publication by the Collaboration Event Team and focuses on simplifying the move from one sterilization modality to another and optimization of current sterilization processes, as well as other important research from the field.

During the 2019 Kilmer Conference, the community continued the conversation and explored how together we may *Collaborate to Innovate* for current and future products, and how collaboration across the industry adds value. We defined innovation as “executing an idea that addresses a specific challenge and achieves value for both the company and customer.” We imbedded innovation into our community definition of collaboration, which is “a diversified team working together inside and outside a company with the purpose of executing an idea by addressing a specific challenge and creating value for patients/customers/consumers and our companies while leveraging technology for effective interactions in the virtual and physical space.”

To share our passion for what we do and help explain why we are passionate about “collaborate to innovate” for current and future products, we decided to use the conference as a means to create a tagline. This tagline provides a tool that everyone can use to promote a unified passion for working together to innovate for the future. During the conference, the community collaborated “real time” via crowdsourcing technology to identify themes for our tagline, and to create an industry tagline that we all can use.

The Kilmer 2019 Conference Industry Advisory Board (IAB) is pleased to share that new tagline for the community:



Please feel free to use this tagline to express the passion we share as an industry. Use it as a tool to start a conversation on why we are collaborative: about the end-to-end support we provide our supply chains, for new product development activities, and for connections with our customers. Use it on your e-mails, presentations, and communications to share with others our clear and compelling vision for what we do each and every day.

Collaboration among industry, academia, contract suppliers, regulatory authorities, and professional associations is key to innovation. To support this means of collaboration across the community, we are continuing to sponsor additional Kilmer Collaboration Events and recently initiated teams to work on the two PAT topics identified. Together we have the ability to support the development and manufacture of products that help improve the lives of the patients, customers, and consumers.

Joyce M. Hansen
Chair, 2019 Kilmer Conference

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