2019 Kilmer Conference Recap

Collaborate to Innovate

By Sopheak Srun
MPH, SM(NRCM), CISS-EO, CISS-RAD

Introduction

I had the pleasure of attending the 10th Kilmer Conference in Dublin, Ireland. The Kilmer Conference is an invite-only event hosted by Johnson & Johnson and is a global forum for exchanging ideas within the sterility assurance community. Concepts and research presented at previous Kilmer Conferences have helped to shape many of the standards for assurance of sterility that we all use today.

Collaborate to Innovate

The theme of the 2019 Kilmer Conference was *Collaborate to Innovate*. We are all facing a number of common challenges in our industry, and we must collaborate if we want to overcome them in an effective manner. In addition to the concepts and research presented, the conference included several collaborative activities to address some of these challenges.

Challenges Within the Sterilization Industry

One of the biggest issues we are facing today as an industry are constraints with sterilization capacities. Manufacturing volumes are continuing to go up, but sterilization capacities are either remaining the same or decreasing. As of 2017, approximately 50% of medical devices are sterilized by ethylene oxide (EO), 40% are sterilized by gamma irradiation, 5% are sterilized by e-beam, and 5% are sterilized through other modalities. EO sterilization capacities have recently decreased due to the closure of the Sterigenics facility in Willowbrook, IL, and the Viant Medical facility in Grand Rapids, MI. Regulations aside, it is extremely difficult to obtain approvals for expanding or building new EO sterilization facilities due to the public perception that any ethylene oxide emissions are harmful and can cause a spike in cancer in surrounding communities. Gamma irradiation facilities are also running into capacity constraints due to shortages in cobalt-60. In order to address these constraints in capacity, there are a number of x-ray sterilization facilities that are currently being planned or are under construction in the United States, but there will be numerous technical and regulatory challenges to overcome as part of the migration process to different sterilization modalities.

These issues with sterilization capacity are partly our own fault due to how we all conduct business. When introducing a new product to market, there are often tremendous business pressures to complete validation activities as quickly and as inexpensively as possible. For example, the EO sterilization cycles that the industry uses are typically much longer and use much more ethylene oxide than may be necessary, which is done to ensure the highest chance of a passing validation. Designing and validating an optimized EO sterilization cycle can take

significantly longer and will cost significantly more. Until these recent concerns with emissions arose, there has not been much of a business need to try to optimize EO sterilization cycles.

7 Focus Areas

Based on the theme, *Collaborate to Innovate*, presentations at the 10th Kilmer Conference focused on the following areas in order to address the common challenges that we are facing as an industry:

- ***Innovation for Sterility Assurance:*** How do we adapt our quality systems, validation approaches, and process controls for new technologies such as patient-specific 3D-printed implants or novel therapeutic treatments that have a very short shelf life?
- ***Customer Centricity:*** What can we do as an industry to change what we do for the ultimate benefit of the patient? For example, packaging is often designed in a manner to ensure that it passes all required tests and validations to keep the sterile barrier intact until the point of use. If this packaging is difficult to open for the end user, resulting in compromised sterility due to how the package is being opened, what good are our test results and validations?
- ***Enablers of Future Manufacturing:*** What can we do to work together to innovate and keep pace with the changing world around us? For example, how can we study and learn more about existing sterilization technologies in order to broaden their applicability for more products? How can we improve our standards to foster innovation and implementation of novel validation methods and sterilization technologies? How can we use robots and artificial intelligence to improve aseptic processing?
- ***Novel Gaseous Processing:*** With the advent of new products that are sensitive to established methods of sterilization (e.g. radiation and ethylene oxide), and with the challenges surrounding emissions concerns with the use of ethylene oxide, the importance of novel sterilization methods such as vaporized hydrogen peroxide, nitrogen dioxide, chlorine dioxide, etc., is increasing every day. As much is still unknown about these novel sterilization technologies, how can we foster industry collaboration so that we can all learn more and begin to use these technologies?
- ***Analytical Methods:*** How can we work together to develop and implement new analytical methods that can overcome the drawbacks of current methods? How do we overcome the barriers to advancing new analytical methods?
- ***Safeguarding Our Network:*** How can we collaborate to study differences in material effects between gamma, x-ray, and e-beam in order to make it easier for companies to shift from gamma irradiation to either x-ray or e-beam? What are best practices during the initial sterilization validation that can help to minimize the impact of potential supply disruptions? What can we do to minimize or reduce EO usage in order to reduce public concern over emissions?
- ***Career Development:*** Many of our colleagues in sterility assurance who were instrumental in developing the standards and test methods we use today are aging and retiring. How can we pass their knowledge and skills to the next generation? What can we do to foster curiosity and innovation, and to encourage our peers to publish their findings for the benefit of everyone in our community?

The intent of the 10th Kilmer Conference was not to simply conclude on the final day of the conference, but to promote further collaboration within the industry to address our common challenges. Cross-functional teams have been identified to continue working on the following challenges:

- How do we simplify sterilization modality changes and process optimization?
- How do we balance sterility assurance innovation and regulatory risk?

Our collaboration extends beyond the medical industry. Many of the methods and concepts in sterility assurance that we all use today are based on work performed by NASA. NASA is now collaborating with the sterility assurance community on its next Mars mission – to go to Mars and bring back samples to Earth for study, but without contaminating Mars with microbes from Earth, and without contaminating Earth with any potential microbes from Mars.

To encourage further collaboration, the following tagline was developed at the Kilmer Conference for use by all within the sterility assurance community:

I was honored to have the opportunity to attend such an exciting and prestigious event filled with passionate, innovative experts in sterility assurance. I look forward to seeing the long-term impacts and implementation of the ideas shared.

About the Author

Sopheak received his B.S. in Genetics, Cell Biology, and Development from the University of Minnesota. He also holds a Master of Public Health degree with a concentration in Epidemiology from Saint Louis University, and is a certified Specialist Microbiologist in Pharmaceutical and Medical Device Microbiology through the National Registry of Certified Microbiologists. Sopheak is also a Certified Industrial Sterilization Specialist in ethylene oxide and radiation sterilization through AAMI.

Sopheak has been with QTS for over ten years and currently holds the position of Principal Sterilization Specialist. He leads a team which is responsible for various sterility assurance functions, including validation and control of sterilization processes, microbiological control of manufacturing processes, and environmental monitoring. Sopheak is an active member of a number of AAMI Sterilization Standards Committee working groups. As part of his work in WG15, Sopheak has co-authored papers on alternate sterility assurance levels (SALs). These papers have been instrumental in gaining international support for alternate SALs, which has led to the publication of ISO/TS 19930:2017.

Sopheak W. Srun
MPH, SM(NRCM), CISS-EO, CISS-RAD
Principal Sterilization Specialist

Quality for Life

Quality Tech Services (QTS) is a Medical Device Outsourcing company that provides the expertise, responsiveness and exceptional quality required to rapidly bring medical devices to a highly-regulated market. We specialize in developing innovative solutions for a wide range of Medical Device manufacturing scenarios. Our services include package design expertise, materials sourcing, engineering validations, critical inspection, cleaning and passivation, device assembly, kitting and packaging, labeling, sterilization and lab testing services, as well as supply chain management. As an FDA registered, ISO 13485 certified, and J-PMDA compliant company, QTS holds the highest in quality standards when assisting medical device companies with their packaging and assembly needs. Our certified Class 7 cleanrooms provide controlled and monitored work areas to ensure the cleanliness and quality you require for your medical devices.

Cretex Medical Family

QTS is privately owned by Cretex Companies and is a proud member of the Cretex Medical family, which specializes in a broad range of manufacturing solutions for medical device OEMs. Cretex Medical's capabilities include: metal and plastic machining, additive manufacturing, plastic injection molding, metal stamping and fabrication, laser processing, finished device assembly, packaging, and sterilization management.