DuPont™ Tyvek® Medical Packaging Transition Project (MPTP)—Executive Overview

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The DuPont™ Tyvek® Medical Packaging Transition Project (MPTP) is a plan to transition Tyvek® 1073B and Tyvek® 1059B to the latest flash-spinning technology to help ensure greater continuity and flexibility of future supply. The MPTP is a collaborative effort involving sterile packaging manufacturers (SPMs), medical device manufacturers (MDMs), regulatory authorities, testing laboratories and contract sterilizers around the world. The DuPont™ Tyvek® MPTP would not be possible without this industry collaboration.

Commercialization

DuPont™ Tyvek® 1073B and Tyvek® 1059B produced on the newer manufacturing lines are anticipated to be fully commercial in 3Q 2015. Production will be from two global locations—with two polymer supply sources for the Richmond, VA, USA facility and two supply sources for the Luxembourg facility.

Controlled sales

Controlled sales of Transition Protocol material began in July 2013. Transition Protocol material is manufactured and released under quality systems and standards for current medical packaging styles.

Goal of MPTP

Our goal with the MPTP is to prove that the Transition Protocol material is functionally equivalent in performance to our current product in an effort to help mitigate requalification. This can reduce the amount of testing that each medical device manufacturer (MDM) will have to perform and will demonstrate that all of the six possible line/polymer combinations are interchangeable for both Tyvek® 1073B and Tyvek® 1059B.

Unparalleled data set

DuPont has generated an unparalleled data set on the properties of all polymers, as well as Developmental material and Transition Protocol material. Material test results include samples from all six possible line/polymer combinations for styles 1073B and 1059B. All data generated is posted on our website (www.Transition.Tyvek.com) as it becomes available.

Specification and miscellaneous properties

Samples from all six possible line/polymer combinations for styles 1073B and 1059B were used to determine specification and miscellaneous properties. Data demonstrates that all possible line/polymer combinations are interchangeable.

Biocompatibility, Food Contact and Pharmacopeia Testing

Polymer testing has met the requirements for U.S. Food Contact 21 CFR 177.1520 and European Pharmacopeia EP 3.1.3 and EP 3.1.5. Broader testing on Transition Protocol material has been completed and all materials have passed. Results are available on our website (www.Transition.Tyvek.com). Additional sterilization data is being generated for extractables and leachables and 5- and 10- year accelerated aging studies are in progress for cytotoxicity.

U.S. FDA Transition Protocol

The U.S. FDA Transition Protocol has been agreed to by the U.S. FDA Center for Devices and Radiological Health (CDRH) as seen in the letter from Jeffrey Shuren, M.D., J.D., Director, CDRH, which is posted on our website.

In this study, more than 60,000 packages made with current Tyvek® and Transition Protocol material represent 60 different medical devices (cells) manufactured by more than 40 global MDMs and sterilized by EO, gamma or electron-beam irradiation. All six line/polymer combinations are included in the Transition Protocol.

Packages undergo visual inspection and are tested for package integrity (dye penetration testing), seal strength and microbial barrier at pre-sterilization, post-sterilization, accelerated aging equivalent of 1, 3, 5 years and real-time aging of 1, 3, 5 years.

A description of the study design, the materials of construction of the packages and the sterilization process parameters, as well as updates and milestones can be found on our website (www.Transition.Tyvek.com). This website also has letters of guidance and/or position statements from the U.S. FDA, six European Notified Bodies, Health Canada, Japan and China.

Phantom Protocol

The Phantom Protocol is additional testing of applications and technologies that are outside the scope of the Transition Protocol but have been requested by the industry to support risk assessments.

There are 18 additional packages from more than 12 global MDMs in the Phantom Protocol. Sterilization methods include: steam, dry heat, low-temperature H_2O_2 and low-temperature $C_2H_4O_3$. The packages are subjected to the same testing described for the U.S. FDA Protocol.

Packages from some of the cells in the Phantom Protocol, as well as some of the cells in the U.S. FDA Transition Protocol, will also be subjected to 7- and 10-year accelerated aging and 10-year real-time aging.

Additional data to be generated per industry requests includes: particle generation; chemical resistance (ISO 11607); steam and low-temperature oxidative sterilization behaviors; dimensional stability study (steam–freeze–thaw–freeze–thaw); Differential Scanning Calorimetry (DSC); Attenuated Total Reflectance-Fourier Transform InfraRed spectroscopy (ATR-FTIR); surface energy; dynamic/static coefficient of friction; printability (flexo and thermal); low-intensity UV stability; Parker (surface) smoothness; baseline color and color after aging.

Some of this data has already been generated and the results are available on our website (www.Transition.Tyvek.com).

Conclusion

DuPont has developed the MPTP and made a significant investment in the development of a huge database of test results to provide the industry with information that can be used when performing risk assessments and change control procedures. If you have any questions or specific needs, please contact your DuPont representative.