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Mapping a Polymer Product's Lifecycle | SOME SIMPLE STEPS

Creating Vision Across the Polymer Lifecycle

From plastics and composites, to foams, elastomers and adhesives, polymers are one of the most widely used materials in the life science industry. Despite widespread application, the importance of polymer properties and product lifecycle are often understated. As polymers flourish because of their diverse application potential, workers in R&D, product development, engineering, or laboratory environments must take responsibility for ensuring the quality of materials across the product lifecycle. Team members must identify critical questions needed to develop product requirements, map steps in the product lifecycle, and understand how individual contributions affect performance of the final product.

There are numerous strategies used by industry to improve efficiency, design, and lifecycle management, but such strategies can become unwieldy when team members want to ask questions and understand the "big picture" or the product lifecycle. As such, gaps become apparent when individuals ask common questions like, "If I modify the manufacturing process or surface features, will my device still perform as intended?" or "If I change to a different polymer, will my product behave in the same way?".

These gaps in understanding can create frustration and inefficiency at the team level, but may have even greater consequences for the manufacturer and final product. Due to United States regulations, like the Biomaterials Access Assurance Act of 1998 (BAAA), gaps in material understanding can pose significant liability issues for product manufacturers. According to the BAAA, manufacturers are required to ensure the quality of materials purchased from their suppliers and used across the product lifecycle. By taking a simple, proactive approach to mapping the material lifecycle, identifying key questions, and knowing regulatory requirements, all parties can work together to form vision across the life of the product.

Steps involved in creating a lifecycle vision

Creating vision across the lifecycle should be a straightforward, information-building exercise and not an overwhelming, acronym-filled burden. The first step in creating a vision for polymeric materials is to define and map each step in the product lifecycle. Typical steps begin with the raw material supply chain followed by materials acceptance, and then formulation, manufacturing, packaging and performance of the final component. Steps will vary for different products and materials and should be defined by the team or contributors.

After defining these steps, establish a comprehensive list of all requirements for the final component by engaging relevant stakeholders and identifying critical factors such as regulations, specifications, modeling, and testing. The comprehensive list for the component should include regulatory requirements, operational requirements, expectations, form, fit, and function. Building the list can be a simple or complex exercise depending on how well these requirements are understood. In all cases, creating a list helps to cultivate the team's understanding of the component and how it must perform. The list should also include key questions about specifications, modeling, and testing for the final component; for example:

- Specifications: "What specifications exist, or are needed, to demonstrate the requirements?"
- Modeling: "Is modeling being used to predict material properties, and what data is being used in the models?"
- Testing: "Is more testing now required to demonstrate safety and achieve or maintain approval?"

Once this exercise is completed for the component, it should be repeated for each step of the lifecycle (for example materials acceptance, mixing, moulding, sterilisation, and so on). This process results in a comprehensive list of requirements for the final component as well as each step within the lifecycle. Creating a list early on will have a profound effect on establishing project schedules, addressing materials selection, identifying testing needs, meeting regulatory requirements, and minimising potential liability. Not only can this simple strategy aid in product design, but it also helps with engineering evaluations, troubleshooting, process improvement, failure analysis, and product liability risk assessment.

Case study: polystyrene cell culture containers

Without proper context, "mapping the material lifecycle" and identifying critical factors and questions may seem abstract. The following case study provides an example of how to create vision across the product lifecycle to address a failure analysis investigation.

This case study deals with polystyrene cell culture containers. Scientists use these products to grow cell lines for biological research. The containers come in various forms and undergo sterilisation and surface modification. The surface characteristics such as chemistry, roughness, hydrophilicity, and so on, are critical for culturing success. Chemical and biological contaminants can also impact culture success.

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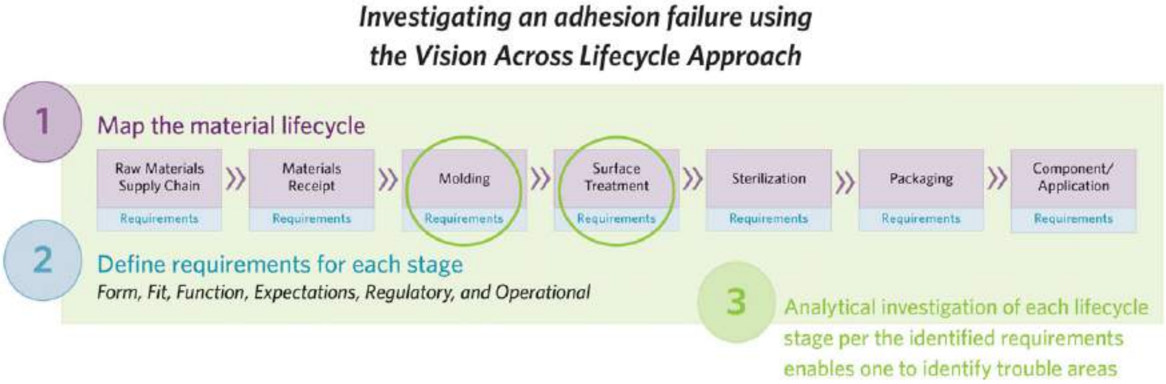

<< Figure 1: Map of the lifecycle for a cell culture container. **We used a "vision across lifecycle" approach to map the material lifecycle, identify material and process requirements, and then analyse the material at each stage of the lifecycle. We were able to identify the point of failure (moulding and surface treatment). This process gave us a comprehensive understanding of the material lifecycle and allowed us to proactively implement testing to mitigate future failures. >>**

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In this study, the cell culture containers were part of a failure analysis or manufacturing anomaly analysis investigation. Although failure analysis was not intended to be part of the product lifecycle, understanding the lifecycle was critical to conducting the investigation, identifying potential failure points, and proposing a comprehensive, proactive testing plan to prevent future issues. The investigation started by mapping and defining the steps in the process. Additional information about the materials, research studies, product information, and requirements of the component from the manufacturer were compiled.

<< Table 1: Defining Requirements and Expectations. >>

Function:	Containers used to culture and transfer cells.
Form:	Transparent polystyrene bottles, flasks, dishes. Surface area. Can have septa, ports, etc.
Fit:	Design must accommodate additional surface modification and sterilisation procedures. May integrate with stacking or automated system.
Regulatory Requirements:	Manufacturer-specific.
Operational Requirements:	Normal temperatures, atmosphere. Must be capable of sterilisation and surface modification. Optimal level surface characteristics for cell adhesion. Consistency and reproducibility are critical.

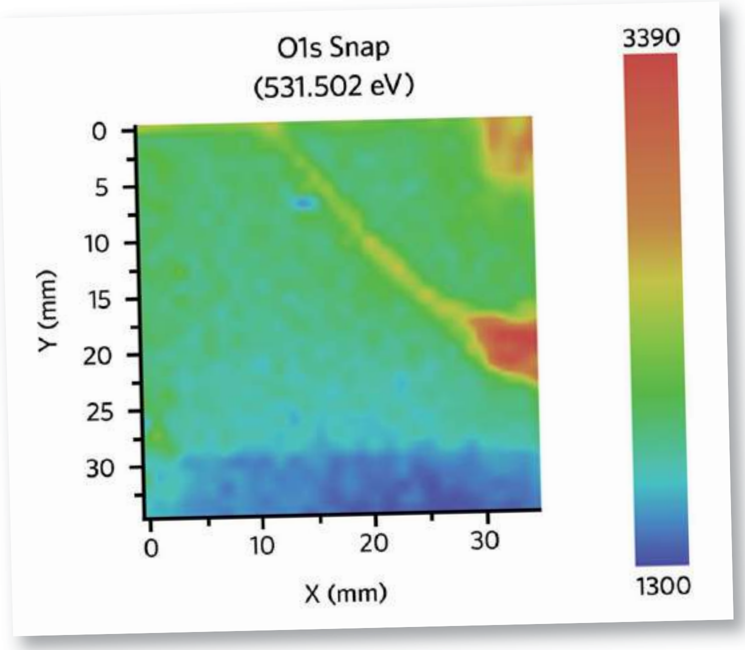
The requirements of the containers were largely based on surface oxygen content determined from x-ray photoelectron spectroscopy (XPS) spot scans. Based on our understanding of the issue and requirements for the component, our team embarked on an extensive analysis of the surface characteristics of the container samples. Extensive XPS studies on container surfaces included survey scans, variance assessment, spot-to-spot variability and scan-to-scan variability. XPS surface mapping studies were also conducted. Using surface mapping, significant oxygen content heterogeneity was observed on the surface. This heterogeneity was more difficult to observe with simple spot scans. The surface oxygen content has a direct impact on the performance of cell culture containers because of the cell adhesion interaction on the surface.

Because our team established a map of the lifecycle and a requirements list, we could identify trouble spots within the manufacturing process, define better material and process requirements, and incorporate comprehensive testing to eliminate this failure in the future.

Conclusion

The simple strategy of creating vision across lifecycle can have a significant impact on product success and materials understanding. The simple strategy allows team members to:

- Address tough questions and ask the right questions;
- Map steps within the product lifecycle from raw material to final component;
- Create a list of regulatory, operational, and other requirements that will affect the final product;
- Define critical factors such as modeling and testing during each lifecycle step;
- Ensure testing plan aligns with requirements and performance; and
- Ensure products are compliant, avoid potential liability issues, and minimise product failure.



<< **Figure 2: XPS O1s surface map on 40 mm x 40 mm section of polystyrene cell culture container.** **Extensive XPS studies on the cell culture container surface enabled us to determine the point in the material lifecycle where the failure occured. With this information we were able to implement comprehensive testing into the manufacturing process to eliminate this failure in the future.** >>

About the author

Crystal G Morrison Densmore, PhD, Macromolecular Science and Engineering, is currently a principal investigator and senior material scientist at RJ Lee Group, where she provides project management and technical direction for analysis supporting multiple industrial sectors. These areas include failure analysis, materials characterisation, product development, performance optimisation, and manufacturing quality assurance.

Dr Densmore specialises in the areas of polymers, foams, elastomers, adhesives and composites. She has conducted studies on carbon nanotube separation methods and spectroscopy and has done extensive work developing synthetic optimisations of materials for industrial scale-up. Dr Densmore has also served as a peer reviewer for the Journal of Applied Polymer Science and the American Chemical Society journal Organic Process Research and Development.

Dr Densmore presented "Polymeric Materials in Life Sciences: Creating Vision Across Lifecycle," at the Biomanufacturing Education and Training Center (BTEC) in North Carolina in September 2013. The presentation identified critical factors at each step in the product lifecycle and discussed proactive techniques to ensure products meet requirements, perform correctly, and satisfy stakeholder needs. Case studies involving medical elastomers and plastics were used to illustrate the role of critical factors.