

Using Statistical Science to Optimize Quality across the Medical Device Life Cycle

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The global medical device market is expected to reach an estimated \$409.5 billion by 2023.¹ Manufacturers of implantable devices, wearable devices, drug delivery systems, and devices for use in point-of-care (POC) hospital settings are all investing in continued innovation and technological development. Two trends currently at the forefront of medical device innovation are 1) the development of new materials that are lightweight, strong, flexible, and durable and 2) the embedding of smart technologies. While both innovations offer important patient benefits, they can also pose risks that lead to adverse safety problems.

Manufacturers of implantable medical devices must ensure that the high-performance polymers, metal alloys, or medical plastics placed inside a patient's body will be effective and durable. Challenges can include the risk for extractables and leachables, lack of biocompatibility, and device failure due to fatigue from the cycles of the body. Many implantable devices, including implantable cardioverter-defibrillators (ICDs), neurostimulators, joint replacements, stents, and cochlear implants, have embedded technology that enables them to receive and generate data. Smart devices worn outside the body, such as continuous glucose monitors and insulin pumps, include similar technology. All are open to potential errors in data transmission and data security that can affect the safe use of the device and pose a risk for adverse user consequences.

Medical device manufacturers are increasingly leveraging statistical science to solve complex problems. Statistical science can support product quality, reliability, and safety across all stages of the product life cycle, including early development studies, manufacturing to scale, and post-market surveillance.

Early Development Projects:

Statistical science can play an important role in upstream or early development projects for medical device manufacturers by helping to more precisely frame research questions for product concept testing. It can also help inform the design of surveys, observational studies, and experiments to evaluate the efficacy and safety of products for clinical use. To answer these critical questions for medical device manufacturers, Exponent's team of statisticians often collaborate with science and engineering teams to predict the survivability of newly developed medical devices in the body. This process involves first deriving information from available predicate devices and then testing the new device's susceptibility to fatigue, corrosion, and MRI heating, as well as its overall survivability. Because of the long service lives sought for implantable devices, test engineers may accelerate aging by applying more stressful conditions than the device would experience under normal use. By providing guidance on the specimen quantity, testing conditions, and test duration, statisticians can help ensure that the team draws the most effective inferences possible matched to the resources expended.

¹ <https://www.lucintel.com/medical-device-market-2018.aspx>

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Manufacturing Quality Control:

Statistical science can also guide midstream projects where medical device manufacturers are producing at scale. This scope includes the development of systems to monitor product quality during the manufacturing process and support necessary process improvements. Statisticians may also design quality control programs to help manufacturers ensure the quality of materials received from suppliers.

When evaluating a manufacturing problem that has resulted in unacceptably large variability, understanding the root cause of variability is critical, as industry regulators can mandate a halt to manufacturing until the variability issue is fully resolved. In these instances, our team first engages engineers and scientists to understand the variability from a physical point of view. Our statisticians then evaluate data streams on raw materials and other inputs, manufacturing process steps, and end-of-line (EOL) measures. At this time automated learning algorithms to complement regression-based approaches may be deployed. If variation in the inputs or in-process metrics matches variation in the outputs, that finding may provide a clue into what is causing the problem. If statistical correlations are identified, Exponent can recommend further areas of investigation to confirm whether or not the potential cause identified is responsible for the variation in the manufactured product.

Post-Market Surveillance:

Finally, statistical science can help inform downstream projects that monitor the performance of approved medical devices. Medical device manufacturers have an obligation to monitor the safety, efficacy, and reliability of their product in the field. Exponent often assists manufacturers who have received feedback regarding potential reliability and/or safety issues. In addition to performing root cause analysis, we can mine field performance data to prepare communications for regulatory agencies that convey the scope of the problem and potential implications. If the problem is the subject of litigation, we can also evaluate field performance with respect to potential claims that may be made against the manufacturer by adverse parties.

Exponent's Expertise:

Exponent's statisticians are experts in quantitative science and understand how the right assumptions and data analysis methods can come together to solve complex problems. Coupled with our multi-disciplinary team of engineers, materials scientists, and physicians, we can help manufacturers optimize product quality and safety across the entire product life cycle.



Duane L. Steffey, Ph.D.

Statistical & Data Sciences

Principal Scientist & Practice Director
Menlo Park

(650) 688-7262 | dsteffey@exponent.com

Exponent Office Locations

Atlanta, Austin, Boston Area (Maynard, Natick), Chicago Area (Downtown Chicago, Warrenville), Denver, Detroit, Houston, Miami, New York, Philadelphia, Phoenix, Northern California Area (Menlo Park, Oakland, Sacramento), Seattle, Southern California Area (Los Angeles, Orange County, Pasadena), Washington DC Area (District of Columbia, Maryland, Virginia)

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