

An Attorney's Guide to Evaluating a Medical Device Quality Expert Witness

By Denise Holliday

In the highly regulated field of medical device manufacturing, quality is not just a priority—it's a mandate. Medical devices must meet stringent safety and efficacy standards to protect patient health, and any deviation from established quality standards can result in severe consequences. When disputes arise in the courtroom, whether over product liability, regulatory compliance, or patent infringement, medical device quality expert witness plays an indispensable role. Attorneys need to know how to evaluate a medical device quality expert witness to ensure they receive the litigation support they need to win cases.

Several instances of poor-quality medical devices have caused severe harm or even death. Metal-on-metal hip implants, designed to provide a longer-lasting solution for patients needing hip replacements, are a well-known example. The design used a metal ball and socket to reduce wear compared to traditional plastic or ceramic implants. Unfortunately, widespread use revealed significant issues, including the release of metal debris into surrounding tissue and the bloodstream. These defects caused tissue damage, [Metallosis](#), and system toxicity. Thousands of patients experienced severe complications, including death, leading to recalls and lawsuits against manufacturers like [DePuy Orthopedics](#) (a subsidiary of Johnson & Johnson) and [Smith & Nephew](#).

Key Insights for Attorneys on Medical Device Quality Expert Witnesses

A [medical device quality expert witness](#) possesses deep knowledge of manufacturing processes, quality assurance, regulatory compliance, and risk management. Their expertise is not just theoretical; it is grounded in practical experience with the complexities of developing, manufacturing, and ensuring the quality of medical devices.

In litigation, a medical device quality expert is a critical resource for the legal team. They clarify complex technical issues, provide expert opinions on quality matters, and support the overall case strategy. Their insights can make the difference between winning and losing a case. For example, medical device quality expert witnesses have played key roles in the lawsuits involving the metal implants by providing expert opinions and reviews to establish critical information and [risk-based decisions](#).

How a Medical Device Quality Expert Witness Assists Attorneys

1. Clarifying Complex Technical Issues

The medical device industry operates under a web of regulations, including [Food and Drug Administration](#) (FDA) standards, ISO certifications, and other quality control measures. A medical device quality expert witness breaks down these complexities, making them understandable to judges and juries who may lack technical backgrounds. They explain how specific quality control processes work, what industry standards apply, and how deviations from these standards could lead to product failure or harm.

2. Assessing Compliance with Regulatory Standards

Medical device quality expert witnesses evaluate whether a device met regulatory requirements during its development and manufacturing. For instance, they determine whether a company adhered to [FDA's 21 CFR Part 820 regulations](#) or complied with [ISO 13485 standards](#). Their assessments reveal whether lapses in compliance contributed to a device's failure, which is often a key issue in litigation. Experts also examine the manufacturer's risk management processes, design controls, validation procedures, and post-market surveillance activities to determine if any deviations from established protocols or best practices contributed to defects, injuries, or patient harm. This comprehensive evaluation provides critical insights into the root causes of device malfunctions and help establish liability or negligence in legal cases.

3. Providing Expert Testimony

In the courtroom, a medical device quality expert witness [offers testimony](#) that shapes the outcome of the case. Their ability to present complex information clearly and persuasively influences decision-makers such as judges and juries. They discuss the adequacy of quality assurance processes, potential causes of device failures, or the standard of care expected within the industry. They offer critical insights into whether the device in question was designed, manufactured, and marketed according to regulatory standards and industry norms.

These experts also share opinions on whether alternative designs or safety measures could have prevented the failure or harm, which impacts negligence and liability determinations or compensatory damages.

4. Supporting Product Liability and Negligence Claims

In [product liability cases](#), attorneys must establish a link between a defect and harm caused to a patient. A medical device quality expert witness analyzes whether the defect resulted from failures in the manufacturing process, poor quality control, or inadequate risk management. Their analysis helps determine if manufacturers acted negligently and if the device's failure was foreseeable and preventable. They review design history files, corrective and preventive action reports, and internal audits to identify any deviations from regulatory standards or best practices. Their findings strengthen or challenge claims related to liability, causation, and damages.

5. Evaluating Damages and Financial Impact

Beyond technical expertise, a medical device quality expert witness assesses the financial impact of a product recall, costs associated with non-compliance, or future liability. By evaluating these factors, they help the court understand the broader implications of a case, especially when large settlements or damages are at stake.

Why Attorneys Must Choose the Right Medical Device Quality Expert

Selecting the right medical device quality expert witness is critical to the success of litigation. Experts must not only have technical qualifications but also communicate complex ideas effectively to a non-technical audience. Their credibility, experience, and ability to withstand cross-examination are essential to building a strong case.

Experts with hands-on experience in the [medical device industry](#) provide practical insights beyond textbook knowledge. They understand the real-world challenges of maintaining quality in manufacturing and speak authoritatively on how companies manage –or mishandle – those challenges. They draw upon their knowledge of industry best practices and regulatory expectations to provide context for alleged failures, helping the court understand whether the manufacturer's actions were reasonable or negligent. This combination of technical expertise and industry experience makes them invaluable in demonstrating both technical and practical aspects of a case, significantly influencing the outcome.

Medical Device Quality Testimony Attorneys Need to Win Cases

In medical device litigation, quality lies at the heart of the dispute. Whether the case involves allegations of defective products, regulatory non-compliance, or negligence, a medical device quality expert witness provides the expertise needed to navigate these complex issues. Their role goes beyond providing testimony; they bridge the gap between the technical intricacies of medical device manufacturing and the legal standards governing the industry.

By leveraging their knowledge and experience, attorneys can build stronger cases, protect patient interests, and hold manufacturers accountable for the quality of devices that millions of people rely on every day.

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[Capwell Consulting Group](#) is a nationally recognized litigation support and risk mitigation consulting firm specializing in highly regulated industries. Our firm provides industry-leading guidance, research, reporting, and expert witness testimony for legal proceedings involving background screening, HR and employee management, and medical device quality and regulatory compliance matters. With over 80 years of combined industry leadership, Capwell Consulting Group is a trusted advisor to employers, attorneys, and consumers around the globe.

About The Author

[Denise Holliday](#) leads the medical device regulatory consulting division at Capwell Consulting Group. She offers strategic support and expert testimony for medical device litigation. Ms. Holliday is widely respected for her deep expertise in quality management systems, international regulatory compliance, and medical device risk management.