



PHARMA PRESCRIBED .COM

NEWSLETTER · IN CONVERSATION WITH HELENE QUIE

It used to be the Wild West

Helene Quie — MedTech regulatory strategist — on how far medical-device regulation has come, why risk should drive the rules, and the cell biologist's mission to help the people who actually build things.

Helene Quie is a MedTech specialist — her own preferred label — with more than twenty-five years at the intersection of science, regulation and commercial strategy, and the founder of the consultancy Qmed. A cell biologist rather than an engineer, she's candid that she can't build products herself; her mission is to help the people who can get them safely into the hands of the patients who need them.



I can't build products. But I can help the people who can.

— Helene Quie, on Pharma Prescribed

Out of the Wild West

Helene is vivid on how much medical-device regulation has changed. Not so long ago, she says, it was 'cowboy land' — the Wild West — and Europe has since built a far more demanding regulatory landscape. That maturing is uncomfortable for companies used to the old freedoms, but it's the price of

taking patient safety seriously in a field that puts material into people's bodies.

Diverse by nature

The defining feature of MedTech, she stresses, is diversity — a bandage and an implantable device share a regulatory universe but nothing about them is alike. That's why she's an advocate of risk-based regulation: match the scrutiny to the risk, and build it all on documentation. It's a market — companies want to sell — but it's also people's health, and both have to be held at once.

Plan for the system you're entering

Her practical counsel is strategic, not just regulatory: a device's path depends on where it's going, and the US and Europe are two different hospital systems with different evidence expectations. Designing your clinical and market strategy around the real system you're entering — rather than a generic one — is what separates a breakthrough idea from a product that never reaches patients.



Listen to the full episode

Helene Quie on Pharma Prescribed — at pharmaprescribed.com and wherever you get your podcasts.

Helene Quie is the founder and CEO of Qmed Consulting, a global MedTech consultancy, with over twenty-five years in medical-device strategy and regulation.