



MDSAP. A success story: Auditing Organizations and Industry Perspective

Baja California's Perspective: MDSAP as a Practical Model for
Regulatory Reliance



Baja California: A Global Medical Device Manufacturing Hub

80+

Manufacturers

Medical device manufacturers in the cluster

100+

MedTech Establishments

Medical technology establishments operating in the region

100k+

Direct Jobs

Specialized direct employment positions

- ✓ Baja California is the largest medical device cluster in Latin America, exporting to the United States, Canada, Europe, Asia, and other global markets.
- ✓ As a globally integrated manufacturing ecosystem operating under multiple regulatory frameworks every day, regulatory convergence is not a future aspiration, it is part of our daily reality.
- ✓ Home to many of the world's leading medical technology manufacturers.



A Practical Success Story of Reliance

From Baja California's perspective, MDSAP is one of the most successful examples of Reliance implemented globally, **one audit leveraged by multiple regulatory authorities.**

Impact on our region

- A significant portion of multinational manufacturers in the cluster already participate in MDSAP
- Reduced duplication of audits
- Greater predictability
- More efficient use of quality and regulatory resources
- Increased confidence from global corporate headquarters

Why MDSAP Matters to Baja California

- Export-oriented industry
- Global product portfolios
- Multi-jurisdictional regulatory requirements
- Mature quality systems

One audit. Multiple regulators. A shared model of trust.



Why Adoption Has Been Successful

Our companies did not start from scratch. Virtually all medical device manufacturers in Baja California already operated with mature systems — making MDSAP a natural evolution, not a transformation.

ISO 13485-Certified QMS

Certified Quality Management Systems already in place across the cluster.

FDA Compliance Programs

Established regulatory compliance programs aligned with U.S. requirements.

Global Product Portfolios

Products commercialized in multiple international markets with mature regulatory organizations.

Early Program Participation

Several companies operating in Baja California adopted MDSAP during its early implementation stages.

For mature export manufacturers, MDSAP formalized, aligned, and streamlined practices that were already essential to competing in global markets.



From Challenges to Long-Term Benefits

For Baja California, MDSAP is proof that Reliance works. When regulators trust a common assessment process, manufacturers can focus on innovation, quality, and patient access, rather than regulatory duplication.

Initial Challenges

- Cultural transformation
- Understanding multiple regulatory frameworks
- Stronger documentation and traceability requirements
- Initial investment in resources and training

Long-Term Benefits

- Stronger quality systems
- Reduced audit burden
- Greater regulatory predictability
- Improved operational efficiency
- Facilitated market access across multiple jurisdictions

MDSAP vs. ISO 13485? Not a choice. ISO 13485 remains the foundation. MDSAP builds upon it through a multi-jurisdictional regulatory approach.



Thank you

