



Medical Products and ISO 13485-2016 Gap Analysis, Certification and Audit Services



- Does your ISO 13485-2016 certification enable you to sell into new markets?
- Will your Medical Customers require you to be certified as a supplier in the future?
- Would your management system benefit from a rigorous review and a systematic approach?
- Do you have the resources in house to get certified, perform internal audits and Manage your system?
- Have you let your existing ISO 13485 Certification lapse? What needs to be updated to meet the new requirements of ISO 13485-2016?



When it comes to ISO 13485-2016 standards, WMEP has you covered. We can perform a Gap Analysis, work with your team to the extent you require to achieve certification and conduct Internal Audits. WMEP personnel can work either as a coach or can roll up their sleeves and get the work done.

BENEFITS OF ISO 13485-2016:

- ▶ A management system suited to your organization's needs
- ▶ Integration of top management into the system to ensure alignment with strategy and accountability
- ▶ Flexibility in documentation
- ▶ Ability to align with other key management system and regulatory standards
- ▶ A systematic approach to risk through your entire management system to prevent issues and ensure continuous improvements and complaint management



WHO WE ARE

As a private non-profit corporation, we focus fully on generating positive results for our clients.

Our team of manufacturing experts work side-by-side with hundreds of manufacturers each year, helping them develop and implement effective solutions that address their biggest challenges.

We closely monitor trends and best practices in manufacturing, and proactively develop solutions that meet the existing and emerging needs of manufacturers.

WMEP Manufacturing Solutions is part of the MEP National Network™, a public-private partnership that advances U.S. manufacturing. MEP Centers are located in all 50 states and draw on the talents of over 1,400 trusted advisors and experts.

WE HELP MANUFACTURING COMPANIES BECOME MORE PROFITABLE & VALUABLE

WHAT WE PROVIDE

WMEP Manufacturing Solutions recognizes that manufacturers face various challenges and we provide proven solutions to these challenges in the following areas:

- Operational Excellence
- Growth & Strategy
- Industry Certifications
- Human Capital
- Automation & Technology
- Sustainability

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