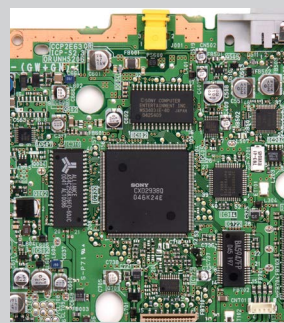
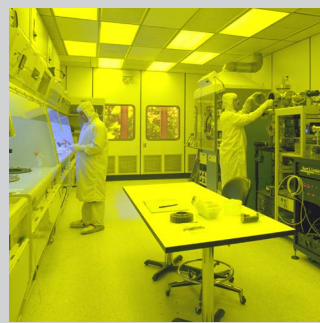




Medical Products and ISO 13485-2016 Gap Analysis, Certification and Audit Services



- 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



WMEP brings a wealth of manufacturing experience and a deep knowledge base in achieving a successful, on-going ISO certification.

- ▶ WMEP can systematically assess gaps and areas of non-compliance via an **ISO 13485 Gap Assessment**
- ▶ We can lead, assist or conduct a full **ISO Certification Implementation Project**
- ▶ WMEP can perform a complete **ISO 13485-2016: 2015 Internal Audit**

WMEP CAN

- ✓ Identify gaps in your system with the ISO standard (ISO Gap Assessment)
- ✓ Deliver a full ISO 13485-2016 Implementation
- ✓ Do a full upgrade to the new ISO 13485-2016 standard
- ✓ Perform internal ISO Audits

WMEP's Value Proposition

012419

How we're different	Why it matters	How clients benefit
We are an end-to-end solution. From supply chains to sales, we have the capability and networks to positively impact your business.	We understand the contributions of the pieces to the whole and use this understanding to help you optimize your enterprise.	We can identify the most impactful enhancements to make to your business to help you achieve your objectives.
We have extensive experience across all major manufacturing industry sectors in Wisconsin.	Our breadth and depth of experience working on projects and companies similar to yours increases our speed and effectiveness.	It takes less time for our staff to learn your business and objectives. We apply proven solutions to your business challenges.
We are all about manufacturing. We work with everyone and anyone who is committed to the success of manufacturing in Wisconsin.	We get manufacturing, and we're ready to roll up our sleeves and get to work to help you be successful and achieve your objectives.	In addition to our talented staff of experienced manufacturers, we provide access to our extensive national networks of industry experts.
We are evaluated by the results we produce for your organization. Your success is our reward.	Our objectives are aligned. We only recommend solutions that will help you achieve your business objectives.	Since the year 2000 we have generated over \$3.0 billion in total financial impact for our state economy, averaging slightly over \$450,000 per project.

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