



U.S. Army Medical Research
and Development Command

Office of Regulated Activities



WHAT IS THE ORA?

The Office of Regulated Activities (ORA) is a multidisciplinary team of regulatory affairs and clinical compliance professionals dedicated to supporting the U.S. Army Medical Research and Development Command's mission of developing Food and Drug Administration-regulated medical products for the Warfighter.

WHO DOES THE ORA SUPPORT?

The ORA supports USAMRDC subordinate laboratories and Military Health System (MHS) facilities that conduct, contract, sponsor, support, or manage DOD's medical product research and development efforts. The ORA primarily supports integrated product teams, program, product, and science and technology managers engaged in FDA-regulated activities.

WHAT DOES THE ORA DO?

ORA provides full-service support, oversight, and consultation services in regulatory strategy, clinical monitoring and management, manufacturing, data management, biostatistics, product pharmacovigilance and safety management, regulatory and medical writing, publishing, submission, product technical operations, and document control.

ORA ensures the sponsor's responsibilities, such as selecting qualified investigators, ensuring proper monitoring, and maintaining an effective investigational new drug. Oversight of The Surgeon General-Department of Army (TSG-DA) sponsored products ensures study and data integrity, and trial subjects' rights, confidentiality, and welfare.

HOW CAN THE ORA HELP YOU?

Regulatory support starts with the regulatory strategy and continues through Product Development Support Management to mitigate risks and accelerate the delivery of Food and Drug Administration-regulated products to the Warfighter. ORA personnel provide:

- ▶ **Full support for TSG-DA sponsored products and research efforts:** providing defined regulatory and clinical deliverables
- ▶ **Oversight of TSG-DA sponsored products and research efforts:** ensuring FDA requirements are met on all regulatory and clinical deliverables
- ▶ **Consultation for non TSG-DA sponsored products and research efforts:** reviewing and advising customers with products research and development



FOR MORE INFORMATION

U.S. Army Medical Research and Development Command

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