Oriel STAT A MATRIX

Training and Consulting Services

FOR THE LIFE SCIENCES INDUSTRY

Training Programs to Mitigate Compliance Risk, Improve Quality, and Enhance Performance

Auditing, Staff Augmentation, QMS Implementation, and More

OVER **50** Years of Excellence

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Did you know? All of our training courses offer CEUs! Visit www.orielstat.com for more details.

Lead Auditor Training for ISO 13485

EXEMPLAR GLOBAL | RTP Certified Training

Prepare to lead audits with this course. Our expert instruction, engaging class discussions, and workshops use ISO 13485:2016 as the primary audit criteria. Workshops reinforce key skills with hands-on practice opportunities. Our course teaches the audit discipline according to ISO 19011:2018, the standard for auditing quality management systems, while providing a sector-focused learning experience for professionals in the medical device industry.

During this class, you will go through every phase of an audit, including planning the audit, conducting the opening meeting, performing the audit, documenting findings, recording the audit, conducting the closing meeting, and writing the audit report.

The course emphasizes the use of process and risk-based approaches to auditing, so you will be prepared to lead audits against the ISO 13485 standard more efficiently and effectively.

ATTENDEES MUST BRING THEIR OWN LAPTOP COMPUTER (preferred) or **TABLET** with current web browser and Microsoft Word installed, in order to complete required learning assignments and the final online exam.

WHO SHOULD ATTEND
This course is appropriate for attendees who lead audits and/or audit programs, either for their own organization or as part of a supplier quality assurance program. The course is intended for those who have ISO 13485:2016 auditing experience and/or have completed an internal auditor course.

COURSE REQUIREMENTS
All attendees must study the current published version of ISO 13485 before attending class. Evening study recommended. A 2-hour final exam is required.

This course is offered with both **IN-PERSON** and **VIRTUAL INSTRUCTOR-LED** training options. Check online for in-person and virtual dates and locations.

$2,595 ▪ Course Code: **LAF** ▪ 4.4 CEUs

Internal Auditor Training for ISO 13485

EXEMPLAR GLOBAL | RTP Certified Training

Begin your ISO 13485 auditor training here. Learn how to plan and perform internal audits of quality management systems (QMS) against the requirements of ISO 13485:2016. This active, hands-on class includes workshops tailored to the medical device industry.

This class covers auditing basics, using process maps and a risk-based approach to the audit, audit planning, audit conduct, and reporting and following up on the audit.

Topics of interest for newer auditors include preparing your working documents, the opening meeting, collecting and verifying information, sampling, interviewing, documenting findings, and conducting the closing meeting.

ATTENDEES MUST BRING THEIR OWN LAPTOP COMPUTER (preferred) or **TABLET** with current web browser and Microsoft Word installed, in order to complete required learning assignments and the final online exam.

WHO SHOULD ATTEND
This course is appropriate for people who will be conducting, managing, or participating in internal (first-party) audits or helping to develop an ISO 13485-compliant quality system.

COURSE REQUIREMENTS
All attendees should study the current published version of ISO 13485 before attending class. Evening study is recommended during the course. A 90-minute final exam is required.

This course is offered with both **IN-PERSON** and **VIRTUAL INSTRUCTOR-LED** training options. Check online for in-person and virtual dates and locations.

$2,195 ▪ Course Code: **IAF** ▪ 2.5 CEUs

Lead Auditor Training for ISO 9001

Are you looking to lead audits of quality management systems? If so, this course is for you! Our expert instruction, engaging class discussions, and workshops will teach you everything you need to know to lead audits against the ISO 9001:2015 standard.

Our course is based on ISO 19011:2018, the standard for auditing quality management systems. We will cover all phases of an audit, including planning the audit, conducting the opening meeting, performing the audit, documenting findings, recording the audit, conducting the closing meeting, and writing the audit report. You will also have the opportunity to participate in hands-on workshops in which you can practice your new skills.

The course emphasizes the use of process and risk-based approaches to auditing. This will help you to lead audits more efficiently and effectively.

EXEMPLAR GLOBAL | RTP Certified Training

WHO SHOULD ATTEND
This course is appropriate for quality, regulatory, and technical professionals in primarily device or pharma industries seeking to understand the integration of these sectors, as well as those currently working in combination product areas seeking to optimize best practices.

This course is offered online as **VIRTUAL INSTRUCTOR-LED** training. Check online for virtual dates.

$2,195 ▪ Course Code: **LAI** ▪ 4.4 CEUs

Internal Auditor Training for ISO 9001

If you are new to auditing to ISO 9001, this course is for you. You will learn how to plan and perform audits of quality management systems (QMSs) against the requirements of ISO 9001:2015. The class focuses on preparing your working documents, conducting the opening meeting, collecting and verifying information, sampling, interviewing, documenting findings, conducting the closing meeting, and reporting and following up on the audit.

Our internal auditor training courses are delivered in a hands-on, interactive format that allows you to learn by doing and apply what you learn to your own work.

EXEMPLAR GLOBAL | RTP Certified Training

WHO SHOULD ATTEND
This course is appropriate for regulatory personnel, design managers and engineers; manufacturing, service, quality assurance, reliability, R&D, internal auditors, and regulatory affairs professionals; and other cross-functional team members in combination product manufacturing. All attendees must have a basic familiarity with FDA 21 CFR Part 820 and ISO 13485.

This course is offered online as **VIRTUAL INSTRUCTOR-LED** training. Check online for virtual dates.

$1,295 ▪ Course Code: **IAI** ▪ 2.5 CEUs

Conducting Remote Medical Device QMS Audit Training

Remote auditing is not new. However, the need for remote auditing has become more evident over the last several years as organizations looked for ways to keep their audit programs on track without traveling on site. Over the long term, remote auditing is showing to be a tool that organizations will continue to leverage to save time and expenses while improving efficiency.

Designed for experienced auditors, in this class we'll teach you how to effectively complete all phases of the audit process in a remote format. We'll also explore common challenges of a virtual audit and ways to overcome them.

EXEMPLAR GLOBAL | RTP Certified Training

WHO SHOULD ATTEND
This course is appropriate for anyone managing, developing, reviewing, or engaging in the design of combination products. Recommended for those with direct engineering functions, QA/QC, production management, regulatory, and anyone else who has a role in building a robust regulatory–compliant environment.

This course is offered online as **VIRTUAL INSTRUCTOR-LED** training. Check online for virtual dates.

$1,195 ▪ Course Code: **RAF** ▪ 0.8 CEUs

EU MDR 2017/745 Implementation

This is your starting place for the EU MDR. Learn about the significant new requirements in the EU MDR, and practice applying them in exercises and discussions with an expert instructor.

Get up to date on the regulation's transition timeline and major roles and entities. Then examine EU MDR requirements related to the QMS, device classification, conformity assessment routes, technical documentation, clinical evaluation, UDI, postmarket activities, and Notified Body audits.

The course concludes with best practices for implementing the EU MDR requirements at your organization.

WHO SHOULD ATTEND
This course is appropriate for anyone who works for manufacturers that market medical devices in the EU. It is primarily intended for staff in the organization who participate in or support EU MDR transition activities.

This course is offered with both **IN-PERSON** and **VIRTUAL INSTRUCTOR-LED** training options. Check online for in-person and virtual dates and locations.

$2,995 ▪ Course Code: **EMF** ▪ 2.5 CEUs

EU MDR Training Course for Auditors

UPDATED

EXEMPLAR GLOBAL | RTP Certified Training

This course covers major EU MDR requirements, including device classification, economic operators, the PRRC, the QMS, GSPRs, risk management, technical documentation, clinical evaluation, PMCF, UDI, and postmarket surveillance.

Attendees will participate in interactive discussions and practical auditing-related exercises to help develop the skills and knowledge they need to conduct effective audits.

ATTENDEES MUST BRING THEIR OWN LAPTOP COMPUTER *(preferred)* or **TABLET** with current web browser and Microsoft Word installed. Participants must have practical experience in auditing and be familiar with the EU MDR, EN ISO 13485, and ISO 14971.

WHO SHOULD ATTEND
This course is appropriate for internal regulatory and QMS auditors, audit-related personnel, and those performing gap assessments to the new EU MDR.

This course is offered with both **IN-PERSON** and **VIRTUAL INSTRUCTOR-LED** training options. Check online for in-person and virtual dates and locations.

$3,595 ▪ Course Code: **LEF** ▪ 2.8 CEUs

Clinical Evaluation Report (CER) for EU MDR Compliance

Build CERs that meet the EU MDR's requirements. This course covers all aspects of assembling a CER from the ground up as well as improving your existing clinical evaluation to meet the more stringent requirements of the EU MDR.

Using workshops and real-life examples, your instructor will address all facets of clinical data, clinical evidence, and clinical investigations, explaining the requirements for each and detailing the stages of the clinical evaluation process.

WHO SHOULD ATTEND
This course is appropriate for anyone working in regulatory, quality, risk management, or clinical roles with responsibility for creating, reviewing, or auditing CERs. Participants are expected to have some basic knowledge of clinical evaluation reports, risk management, and medical device regulation in the EU.

This course is offered online as **VIRTUAL INSTRUCTOR-LED** training. Check online for virtual dates.

$3,895 ▪ Course Code: **ECF** ▪ 2.5 CEUs

EU IVDR 2017/746 Implementation

Ensure your company is at the head of the line for the EU IVDR. This regulation brings significant new requirements to IVD manufacturers – including Notified Body involvement for most IVDs. While there is an extended timeline for application of *all* the requirements, you must meet some requirements now and have others in place to even book a Notified Body (and there are few Notified Bodies available).

Start preparing in this class, which features instructor-led discussions and exercises. You will learn about the new requirements found in the IVDR, their impact on manufacturers, and how to plan an effective and efficient implementation of the IVDR at your organization.

WHO SHOULD ATTEND
This course is appropriate for anyone who works for manufacturers that market *in vitro* diagnostics in the EU. It is primarily intended for staff in the organization who participate in or support EU IVDR transition activities.

This course is offered online as **VIRTUAL INSTRUCTOR-LED** training. Check online for virtual dates.

$3,495 ▪ Course Code: **EIF** ▪ 2.5 CEUs

EU IVDR Training Course for Auditors

EXEMPLAR GLOBAL | RTP Certified Training

Designed for internal and second-party auditors with ISO 13485 experience, this course uses practical exercises and a case study to cover IVDR requirements related to IVD classification, conformity assessment routes, economic operators, the PRRC, the QMS, GSPRs, risk management, technical documentation, performance evaluation, PMPF, UDI and labeling, and postmarket surveillance activities.

ATTENDEES MUST BRING THEIR OWN LAPTOP COMPUTER (preferred) or TABLET with current web browser and Microsoft Word installed, in order to complete required learning assignments and the final online exam.

WHO SHOULD ATTEND
This course is appropriate for internal regulatory and QMS auditors, audit-related personnel, and those performing gap assessments to the new EU IVDR.

This course is offered with both **IN-PERSON** and **VIRTUAL INSTRUCTOR-LED** training options. Check online for in-person and virtual dates and locations.

$3,595 ▪ Course Code: **LIF** ▪ 2.8 CEUs

Performance Evaluation Report (PER) for EU IVDR Compliance

How will your organization handle the EU IVDR requirements for performance evaluation reports (PERs)? Required by Article 56 in the EU IVDR, this report is comprised of the clinical evidence (including your scientific validity report, analytical performance report, and clinical performance report) that demonstrates that your IVD fulfills its intended purpose and is both safe and effective.

In this interactive class, your instructor will cover the basic skills and knowledge you need to design and modify performance evaluation plans (PEPs) and execute performance evaluation reports (PERs).

WHO SHOULD ATTEND
This course is appropriate for anyone working in regulatory, quality, postmarket surveillance, marketing, R&D, medical/clinical affairs, and those who need to create, review, and audit performance evaluation reports.

This course is offered online as **VIRTUAL INSTRUCTOR-LED** training. Check online for virtual dates.

$3,495 ▪ Course Code: **EPF** ▪ 2.4 CEUs

QMS for Medical Devices:
FDA QSR and ISO 13485:2016

UPDATED

This is the cornerstone class for the medical device sector. It is perfect for new employees, experienced employees seeking to refresh their understanding, and members of senior management responsible for the implementation of requirements.

This course walks through the QMS requirements of both US FDA and ISO 13485 to help you create, support, or improve a harmonized quality management system that meets the requirements of both. Interactive discussions, exercises, and a case study keep the focus practical.

What about the FDA Quality Management System Regulation (QMSR)? While the industry waits for the proposed FDA QMSR to be finalized, the QSR requirements remain. FDA requirements are already very similar to ISO 13485 – this class will show you these similarities and highlight any differences.

WHO SHOULD ATTEND
This course is appropriate for anyone who needs to understand how to meet general quality management system requirements

This course is offered with both **IN-PERSON** and **VIRTUAL INSTRUCTOR-LED** training options. Check online for in-person and virtual dates and locations.

$2,495 ▪ Course Code: **GRF** ▪ 2.4 CEUs

Internal Auditing to MDSAP:
Concepts and Practices in Aligning the Internal Audit Program

UPDATED

EXEMPLAR GLOBAL | RTP Certified Training

Learn how to perform internal audits that support your organization's preparation for MDSAP. Using interactive discussions, exercises, and a case study, this class is for experienced auditors and emphasizes MDSAP's process-based approach.

You will examine MDSAP processes, audit tasks, process and task linkages, and nonconformity grading from the perspective of an internal auditor. The class also reviews the country-specific requirements found in the MDSAP Audit Approach as well as the topics covered in the Audit Approach's annexes, including auditing technical documentation, sterilization processes, and written agreements.

WHO SHOULD ATTEND
This course is appropriate for participants who have hands-on experience in medical device internal auditing and a working knowledge of ISO 13485:2016. **Note that this is an advanced auditing course.**

This course is offered online as **VIRTUAL INSTRUCTOR-LED** training. Check online for virtual dates.

$3,295 ▪ Course Code: **AMF** ▪ 2.8 CEUs

Medical Device Single Audit Program (MDSAP) Training: *Preparing for a Successful Implementation*

NEW

The Medical Device Single Audit Program (MDSAP) allows medical device manufacturers to consolidate compliance audits from five Regulatory Authorities (RAs) with a single audit. That's right, just one audit! The program is currently in effect in Australia, Brazil, Canada, Japan, and the United States.

Our course will teach you everything you need to know about MDSAP, including what to expect during an audit, the key regulatory requirements, how to apply the MDSAP process-based audit approach, and the scoring system that auditing organizations (AOs) will use during certification audits. Our interactive workshops and exercises include case studies that help identify best practices, and we'll share practical examples from our customers who have successfully passed their MDSAP certification audits.

WHO SHOULD ATTEND
This course is appropriate for quality, regulatory, engineering, manufacturing, and other professionals who plan, execute, report, maintain, review, or manage process validation activities and who have basic knowledge of statistics or statistical tools.

This course is offered online as **VIRTUAL INSTRUCTOR-LED** training. Check online for virtual dates.

$2,195 ▪ Course Code: **SAF** ▪ 1.6 CEUs

ISO 14971 Medical Device Risk Management

BEST SELLER

Risk management is center stage. The EU MDR, MDSAP, and ISO 14971:2019 have put a spotlight on risk management as a foundational process in your QMS. How companies manage device risk throughout the product life cycle is getting more scrutiny from regulators and Notified Bodies than ever before.

Through interactive workshops and group discussions, learn to apply the ISO 14971 risk management process requirements from planning through analysis and control to review, production, and postproduction activities, including benefit-risk analysis.

WHO SHOULD ATTEND
This course is appropriate for design manufacturers and engineers; manufacturing, service, quality assurance, reliability, R&D, and regulatory affairs professionals; and other cross-functional team members.

This course is offered with both **IN-PERSON** and **VIRTUAL INSTRUCTOR-LED** training options. Check online for in-person and virtual dates and locations.

$2,995 ▪ Course Code: **RMF** ▪ 2.5 CEUs

Medical Device Complaint Handling, Event Reporting, and Recall Management

Tighter timelines in the EU. Increased focus by FDA. Efficient complaint identification, investigation, and decision making have never been more critical.

This course uses guided discussions and exercises to cover the complete complaint-handling process: intake, triage, investigation, closure or escalation, recall management, and reporting. At the end of the class, you'll have the skills to improve the effectiveness and efficiency of your organization's complaint-handling process.

WHO SHOULD ATTEND
This course is appropriate for quality and regulatory managers in medical device companies or anyone who needs to understand and apply the regulatory requirements for complaint handling, event reporting, and recalls. All attendees must have a basic familiarity with FDA 21 CFR 820 and ISO 13485.

This course is offered online as **VIRTUAL INSTRUCTOR-LED** training. Check online for virtual dates.

$3,295 ▪ Course Code: **CHF** ▪ 2.4 CEUs

CAPA and Root Cause Investigation for Medical Devices

Stop struggling with repeat CAPAs. We've helped many companies assess the health of their CAPA systems and find that it often comes down to the basics: determining the need for CAPA and defining the problem.

This course provides a deep dive into the process, beginning with a solid problem definition statement, which is determined with data that can be used to verify the effectiveness of the implemented solution.

During exercises, you'll work through the entire root cause (RC) analysis process, from creating a data-based problem statement, applying RC tools, and conducting data analysis for verifying the cause to selecting the best solution and determining its effectiveness.

WHO SHOULD ATTEND
This course is appropriate for anyone in compliance/regulatory affairs, QA/QC, manufacturing operations, and document management, as well as anyone participating in root cause analysis investigations.

This course is offered with both **IN-PERSON** and **VIRTUAL INSTRUCTOR-LED** training options. Check online for in-person and virtual dates and locations.

$3,295 ▪ Course Code: **CRF** ▪ 2.5 CEUs

Design Control for Medical Devices:
Requirements and Best Practices

The pace of change and the iterative nature of most design processes makes understanding when and how to apply design controls even more important. Design controls are integrated management practices applied to the medical device development process, ensuring that the resulting device is safe, effective, and meets stakeholder requirements.

In this class, you'll learn strategies and best practices for managing these processes to ensure that your devices meet user needs, intended uses, and regulatory requirements. Instructor-guided discussions and exercises offer opportunities to practice applying what you learn.

WHO SHOULD ATTEND
This course is appropriate for anyone managing, developing, reviewing, or engaging in the design of medical devices. Attendees must have a basic familiarity with FDA 21 CFR Part 820 and ISO 13485.

This course is offered with both **IN-PERSON** and **VIRTUAL INSTRUCTOR-LED** training options. Check online for in-person and virtual dates and locations.

$3,295 ▪ Course Code: **DBF** ▪ 2.5 CEUs

Process Validation for Medical Devices:
Principles and Protocols

FDA and ISO 13485:2016 require process validation but don't offer much guidance. This class will show you how to interpret the requirements, identify which processes need validation, plan process validation, apply the principles of risk management, create qualification protocols (IQ, OQ, PQ), and identify statistical methods and tools used to implement and maintain process validation activities.

Interactive discussions and workshops provide realistic examples and opportunities for practice.

WHO SHOULD ATTEND
This course is appropriate for quality, regulatory, engineering, manufacturing, and other professionals who plan, execute, report, maintain, review, or manage process validation activities and who have basic knowledge of statistics or statistical tools.

This course is offered with both **IN-PERSON** and **VIRTUAL INSTRUCTOR-LED** training options. Check online for in-person and virtual dates and locations.

$3,295 ▪ Course Code: **PVF** ▪ 2.5 CEUs

Medical Device Supplier Quality Management

Poorly designed and executed supplier quality management systems can cost your company millions. With dozens or hundreds of suppliers to manage, you need a proven risk-based process that meets FDA and ISO 13485:2016 requirements.

On paper the requirements seem straightforward, but applying them can get tricky. You'll walk away from this training with a clear understanding of the various regulatory requirements and how to establish an effective and efficient system using a risk-based approach.

WHO SHOULD ATTEND
This course is appropriate for anyone involved in sourcing, securing, and maintaining critical suppliers and services that affect product quality and organizational reputation. Attendees must have a basic familiarity with FDA 21 CFR Part 820 and ISO 13485.

This course is offered with both **IN-PERSON** and **VIRTUAL INSTRUCTOR-LED** training options. Check online for in-person and virtual dates and locations.

$3,295 ▪ Course Code: **SQF** ▪ 2.5 CEUs

Usability Principles for Medical Devices:
Interpreting and Implementing IEC 62366

NEW

The topics of usability and human factors are receiving scrutiny from auditors because they directly relate the patient and user experience. It is important to understand how your users may interact with your device in order to ensure that the device functions properly and all potential safety issues are understood. Human factors studies are part of the design process and should be integrated into device risk analysis. This course provides an overview of the requirements of IEC 62366-1:2020, including the relationship with the risk management process.

WHO SHOULD ATTEND
This course is appropriate for anyone from the medical device and *in vitro* diagnostic device industries involved in development, including regulatory personnel. Recommended for staff with the specific responsibility of risk management, as well as quality engineering, technical services, operations, QA/QC, regulatory, and R&D.

This course is offered online as **VIRTUAL INSTRUCTOR-LED** training. Check online for virtual dates.

$3,895 ▪ Course Code: **UDF** ▪ 2.4 CEUs

Medical Device Postmarket Surveillance (PMS) Program Implementation

REVISED

How well is your organization handling the increased focus on postmarket surveillance? The expanded requirements in the EU MDR and IVDR and the new ISO standard for proactive PMS shine a bright light on your organization's PMS processes.

In this interactive class featuring discussions and exercises, you will learn how to collect, analyze, report, and apply postmarket data, as well as connect the PMS process to QMS and risk management processes.

This class uses the ISO/TR 20416:2020 guidance as a foundation to show you how to establish and maintain a medical device postmarket surveillance system that not only provides inputs to systems that conform to ISO 13485:2016 and ISO 14971:2019 but also satisfies the regulatory requirements of the EU MDR and IVDR, MDSAP, and other country-specific stipulations.

WHO SHOULD ATTEND
This course is appropriate for anyone who is involved in supporting the postmarket experience for medical devices in an organization. Attendees must have experience with or basic knowledge of quality management systems.

This course is offered online as **VIRTUAL INSTRUCTOR-LED** training. Check online for virtual dates.

$3,295 ▪ Course Code: **PSF** ▪ 2.5 CEUs

ISO 13485 Overview Training for Medical Device and IVD Manufacturers

NEW

ISO 13485:2016 is the de facto standard for quality management systems for medical devices. It's one of the most critical standards you'll need to understand and implement if you want to ensure the quality of your medical devices.

This course will help you not only know *what* is in the standard but will also give you the *why* and the *how*. You'll learn about the key concepts of ISO 13485, including management responsibility, risk management, customer focus, and continual improvement. Through interactive workshops, you'll have the opportunity to apply what you're learning in real-time. This will help you solidify your understanding of ISO 13485, so that by the end of the course you'll be able to implement the standard in your own organization.

WHO SHOULD ATTEND
This course is appropriate for anyone who is involved in supporting the postmarket experience for medical devices in an organization. Attendees must have experience with or basic knowledge of quality management systems.

This course is offered online as **VIRTUAL INSTRUCTOR-LED** training. Check online for virtual dates.

$2,195 ▪ Course Code: **QSF** ▪ 1.6 CEUs

FDA and EU Medical Device Labeling Requirements

NEW

Medical device labeling is a complex and challenging task. There are a lot of requirements to comply with, both from US FDA and the EU. And if you don't get it right, you could be putting patients at risk.

In this course, we cover the mandatory label content and accompanying information, as well as best practices for the elements that provide challenges, including symbols, translations, and unique device identification (UDI). We also cover the concepts that underpin medical device labeling (usability, risk, and misbranding), and the practicalities of implementing labeling processes.

With discussions, activities, and exercises in which you apply what you learn, you'll have a clear understanding of the regulatory requirements for medical device labeling and how to implement an effective and efficient labeling system.

WHO SHOULD ATTEND
This course is appropriate for anyone in a pharmaceutical organization responsible for managing procedures, approvals, and data in electronic form. Also helpful for all RA/QA professionals and other cross-functional team members.

This course is offered online as **VIRTUAL INSTRUCTOR-LED** training. Check online for virtual dates.

$2,195 ▪ Course Code: **LBF** ▪ 1.6 CEUs

Understanding Medical Device Classification and Regulatory Pathways

NEW

Bringing a new medical device to market in the US or EU? Need to understand how the process works in each market? These are important considerations when choosing which market to pursue first. Using interactive discussions and workshops, we will cover in detail the US FDA pathways, including 510(k) and premarket authorization (PMA), as well as the EU CE Marking process. You'll walk away with a solid understanding of how the two markets overlap, how they differ, and what will be required to gain US clearance or approval and/or CE Marking certification in Europe.

WHO SHOULD ATTEND
This course is appropriate for personnel involved in sourcing, securing, and maintaining suppliers for combination product manufacturers that ensure excellent product quality and organizational reputation.

This course is offered online as **VIRTUAL INSTRUCTOR-LED** training. Check online for virtual dates.

$2,895 ▪ Course Code: **WSF** ▪ 2.5 CEUs

SOP Writing and Process Mapping for Medical Device Regulations

NEW

Documentation practices are evolving, so to avoid FDA or Notified Body findings you must stay ahead of the curve in this critical area. Over 2 days you'll learn best practices and strategies to plan and improve a documentation control system and prepare for audits under the new EU regulations, ISO 13485:2016, and FDA's QSIT. Risk-based change management strategies – critical for FDA compliance and business efficiency – are a key focus in this course.

Document management is one of the fundamental cornerstones of an effective quality management system. Don't be left short!

WHO SHOULD ATTEND
This course is appropriate for any quality, regulatory, engineering, manufacturing, and other technical professionals in the pharmaceutical industry who plan, execute, report, maintain, review, or manage process validation activities, and who have basic knowledge of statistics or statistical tools.

This course is offered online as **VIRTUAL INSTRUCTOR-LED** training. Check online for virtual dates.

$2,195 ▪ Course Code: **DOF** ▪ 1.5 CEUs

Managing Medical Device Cybersecurity Risks

Cybersecurity is an area of growing concern for FDA. This training will introduce you to the process of ensuring that cybersecurity risks in connected devices are identified and managed throughout the software life cycle. You will build a sample threat model during the workshops in the course by incorporating the principles of cybersafety by design, information sharing, evidence capture, and incident response.

WHO SHOULD ATTEND
This course is appropriate for risk managers, quality assurance professionals, auditors, engineers/testers, product managers, and regulatory professionals working in medical device and *in vitro* diagnostic organizations.

This course is offered online as **VIRTUAL INSTRUCTOR-LED** training. Check online for virtual dates.

$2,495 ▪ Course Code: **CRS** ▪ 1.6 CEUs

Medical Device Non-Product Software Validation

Using software to automate a process required by FDA? If so, there's a good chance that you are required to validate that software. Validation demonstrates that the software accurately, reliably, and consistently meets the requirements for its intended use; ISO 13485 has similar requirements.

In this course, using hands-on exercises and case studies, you will learn how and when to implement a non-product software validation program that meets FDA and ISO requirements. We will also cover the role of risk management in non-product software validation.

WHO SHOULD ATTEND
This course is appropriate for anyone responsible for the development or use of non-product software used in any part of a company's quality management system.

This course is offered online as **VIRTUAL INSTRUCTOR-LED** training. Check online for virtual dates.

$2,995 ▪ Course Code: **NPS** ▪ 1.6 CEUs

Medical Device Data Integrity and FDA 21 CFR Part 11 Compliance

FDA is changing its approach to regulating software in quality systems. In the past, manufacturers could simply follow FDA's guidance to ensure compliance. However, FDA now expects manufacturers to take a more proactive approach by determining their own controls and justifying their effectiveness to regulators.

This course will provide you with the knowledge and practical application experience you need to ensure that your devices and regulated IT systems meet the high level of quality expected by FDA. Specifically, this course will focus on the ALCOA+ method of ensuring integrity, FDA 21 CFR Part 11 requirements for electronic records and signatures, and data integrity in software systems used in the medical device industry.

WHO SHOULD ATTEND
This course is appropriate for anyone who is involved in supporting the postmarket experience for medical devices in an organization. Attendees must have experience with or basic knowledge of quality management systems.

This course is offered online as **VIRTUAL INSTRUCTOR-LED** training. Check online for virtual dates.

$1,495 ▪ Course Code: **DIS** ▪ 0.8 CEUs

Medical Device Software Regulations and Standards

NEW

Get the big picture of the regulations and guidance covering software development in the medical device industry. Regulations for software in/as a medical device are evolving almost as quickly as the software itself. This course identifies similarities among global software guidance and regulations to help you comply across the globe.

You will learn the regulatory requirements from the EU, US, and MDSAP countries – including requirements for submissions and software-related guidelines – in addition to the standards associated with software (ISO 13485, ISO 14971, and IEC 62304). The course also provides an overview of cloud computing in a regulated environment, artificial intelligence, and machine learning within the regulations.

WHO SHOULD ATTEND
This course is appropriate for software developers and those involved in nonregulatory functions associated with software. That includes software QA engineers, program managers (managing software), software test engineers, scrum masters (leads of Agile development), and solution architects.

This course is offered online as **VIRTUAL INSTRUCTOR-LED** training. Check online for virtual dates.

$2,995 ▪ Course Code: **RAS** ▪ 1.6 CEUs

Medical Device Software Development Life Cycle

NEW

The software development life cycle (SDLC) covers all aspects of software from development to validation and change control. This course provides an in-depth look at the SDLC, using IEC 62304 as a basis for the course discussions. Exercises within the course provide opportunities for practical application of the concepts being taught. Learn how to map these phases, processes, and deliverables to US and global regulatory requirements/standards.

WHO SHOULD ATTEND
This course is appropriate for anyone managing, developing, reviewing, or engaging in the design of medical device software. Attendees must have a basic familiarity with FDA 21 CFR Part 820 and ISO 13485.

This course is offered online as **VIRTUAL INSTRUCTOR-LED** training. Check online for virtual dates.

$2,995 ▪ Course Code: **SLS** ▪ 1.6 CEUs

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DaySmart Classes

Need to get up to speed quickly, but don't have the time, need, or budget for a multi-day class?

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ALL ORIEL STAT A MATRIX DAYSMART CLASSES are taught by the same highly qualified instructors as our multi-day SkillsLab classes. The difference is that DaySmart classes are shorter in order to focus on a specific topic or provide a general overview of a broader topic. DaySmart classes offer:

- The same quality content but with a specific focus or higher-level overview
- Virtual and private in-person options
- Small groups with ability to ask questions

DAYSMART TOPICS INCLUDE:

- EU Medical Device Regulation (2017/745)
- EU *In Vitro* Diagnostic Regulation (2017/746)
- Risk Analysis Based on ISO 14971 Medical Device Risk Management
- ISO 13485 Overview for Medical Device and IVD Manufacturers
- Medical Device Single Audit Program (MDSAP)

Check **www.orielstat.com/courses/daysmart** for more information or call **1.800.472.6477**.

Combination Products:
From Regulatory Strategy to Postmarket Surveillance

This course provides an overview of combination products and explores the regulatory challenges of a product that combines a medical device with a drug and/or biologic. In this course, through exercises and case studies, you will learn how to identify and apply Good Manufacturing Practices (GMPs) to combination products. You will apply best practices in managing the product life cycle of combination products, from premarket through postmarket activities.

WHO SHOULD ATTEND
This course is appropriate for quality, regulatory, and technical professionals in primarily device or pharma industries seeking to understand the integration of these sectors, as well as those currently working in combination product areas seeking to optimize best practices.

This course is offered online as **VIRTUAL INSTRUCTOR-LED** training. Check online for virtual dates.

$3,295 ▪ Course Code: **CPP** ▪ 2.4 CEUs

ISO 14971 and Risk Management Training for Combination Products

Learn how to apply ISO 14971:2019 and ICH Q9 risk management from both a combination product focus and a process focus. The course also discusses how to select and apply risk management tools through all phases of a combination product's life cycle.

WHO SHOULD ATTEND
This course is appropriate for regulatory personnel, design managers and engineers; manufacturing, service, quality assurance, reliability, R&D, internal auditors, and regulatory affairs professionals; and other cross-functional team members in combination product manufacturing. All attendees must have a basic familiarity with FDA 21 CFR Part 820 and ISO 13485.

This course is offered online as **VIRTUAL INSTRUCTOR-LED** training. Check online for virtual dates.

$3,295 ▪ Course Code: **RMP** ▪ 2.4 CEUs

Design Control for Combination Products

Because of the additional complexity involved with combination products, once a manufacturer has determined that a proposed item has promise, it's important that a design control plan should start immediately. Once established, the plan can be used to determine the adequacy of the design requirements and confirm that there are no negative interactions between its individual parts. The plan will also provide assurance that those parts, when combined, result in a combination product that performs as expected. In this class, you will learn how to apply control to the design process to ensure that your organization's combination products meet user needs, intended uses, and specified requirements.

WHO SHOULD ATTEND
This course is appropriate for anyone managing, developing, reviewing, or engaging in the design of combination products. Recommended for those with direct engineering functions, QA/QC, production management, regulatory, and anyone else who has a role in building a robust regulatory-compliant environment.

This course is offered online as **VIRTUAL INSTRUCTOR-LED** training. Check online for virtual dates.

$3,295 ▪ Course Code: **DCP** ▪ 2.4 CEUs

FDA 21 CFR Part 11 Training:
Pharmaceutical Data Integrity, ALCOA+, and Electronic Records

FDA is changing its approach to regulating software in quality systems. Simply following their guidance has not been enough for the pharma industry to guarantee the high quality of systems that FDA expects. Manufacturers will now be responsible for determining their own controls and justifying their effectiveness to regulators rather than following explicitly proscribed guidance.

In this course, you will obtain the knowledge and practical application experience needed to ensure that your devices and regulated IT systems maintain or exceed the high level of quality expected by FDA. This course specifically focuses on appropriately maintaining electronic records, electronic signatures, and the data integrity of software systems used in the pharmaceutical industry.

WHO SHOULD ATTEND
This course is appropriate for anyone in a pharmaceutical organization responsible for managing procedures, approvals, and data in electronic form. Also helpful for all RA/QA professionals and other cross-functional team members.

This course is offered online as **VIRTUAL INSTRUCTOR-LED** training. Check online for virtual dates.

$1,495 ▪ Course Code: **DIP** ▪ 0.8 CEUs

Combination Product Device Supplier Management

This course will provide your organization with the knowledge and tools to manage a comprehensive, risk-based, cross-functional supplier quality management system for your combination product. As part of this course, you will identify recommendations for writing quality agreements with contract manufacturing organizations (CMOs) and auditing.

WHO SHOULD ATTEND
This course is appropriate for personnel involved in sourcing, securing, and maintaining suppliers for combination product manufacturers that ensure excellent product quality and organizational reputation.

This course is offered online as **VIRTUAL INSTRUCTOR-LED** training. Check online for virtual dates.

$3,295 ▪ Course Code: **SQP** ▪ 2.4 CEUs

Process Validation in the Pharmaceutical Industry

This course provides an in-depth look at the entire validation cycle in the pharmaceutical industry: planning, execution, and reporting of process validation activities. You will learn how to interpret the regulations, standards, and guidance documents; correctly apply the principles of risk management; and identify statistical methods and tools for implementing and maintaining process validation activities. You will practice identifying critical quality attributes, determining key operating parameters, writing qualification protocols, and identifying data analysis strategies.

WHO SHOULD ATTEND
This course is appropriate for any quality, regulatory, engineering, manufacturing, and other technical professionals in the pharmaceutical industry who plan, execute, report, maintain, review, or manage process validation activities, and who have basic knowledge of statistics or statistical tools.

This course is offered online as **VIRTUAL INSTRUCTOR-LED** training. Check online for virtual dates.

$3,295 ▪ Course Code: **PVP** ▪ 2.4 CEUs

Root Cause Analysis for Combination Products and Drug Delivery Systems

This course provides an overview of the essential investigation method to understand failures throughout a combination product's life cycle. Through exercises and case studies, you will learn the root cause analysis (RCA) process – from accurately identifying and defining a combination product problem to designing an effective intervention.

WHO SHOULD ATTEND
This course is appropriate for anyone participating in root cause analysis investigations for combination products containing a device constituent. Recommended for staff in quality engineering, QA/QC, manufacturing operations, CAPA management, and R&D.

This course is offered online as **VIRTUAL INSTRUCTOR-LED** training. Check online for virtual dates.

$3,295 ▪ Course Code: **RCP** ▪ 2.4 CEUs

Applying Usability Principles to Drug Delivery Systems with IEC 62366-1:2020

Whether you design the drug delivery system or contract with a medical device manufacturer, usability is key for your patients. It is important to understand how your users may interact with your drug delivery system to ensure the system functions properly and that all potential safety issues are understood. Human factors studies are part of the design process and should be integrated into risk analysis. This course provides an overview of the requirements of IEC 62366-1:2020, including the relationship with the risk management process.

WHO SHOULD ATTEND
This course is appropriate for anyone from the pharmaceutical and medical device industries involved in development, including regulatory personnel. Recommended for staff with the specific responsibility of risk management as well as quality engineering, technical services, operations, QA/QC, regulatory, and R&D.

This course is offered online as **VIRTUAL INSTRUCTOR-LED** training. Check online for virtual dates.

$3,895 ▪ Course Code: **UDP** ▪ 2.4 CEUs

FDA PAI, GMP Inspection, and For Cause Audit Training for Combination Products / Inspection and Audit Readiness for Medical Device Manufacturers

Managing an inspection effectively is an art. Oriel STAT A MATRIX has created a 9-day onsite learning experience that combines training and coaching with an immediate opportunity to apply new knowledge and skills.

THE FIRST 3 DAYS of the training course teach participants how to effectively set up a front-room/back-room audit approach. Hands-on exercises prepare participants for the logistics of an audit or inspection, including auditee behavior, site preparation activities, and documentation preparation. Attendees also gain an understanding of auditor/investigator techniques so they can effectively navigate the challenges that FDA and Notified Body audits/inspections present.

THE NEXT 2 DAYS of the training course are focused on coaching participants on auditee behavior and providing detailed performance support. This prepares participants for the final part of the experience, a mock QSIT audit.

THE LAST 4 DAYS of the experience are focused on a mock QSIT audit led by an OSAM Lead Auditor Consultant. This audit will uncover any nonconformances while also satisfying internal audit requirements. The initial instructor (now coach) provides support as participants apply their new skills and knowledge. This hands-on, guided practice audit reinforces what was taught, both improving retention and ensuring that participants are ready when FDA or their Notified Body shows up.

Course Code: **IRP/IMF** ▪ 2.4 CEUs

REGISTRATION

PHONE TOLL-FREE
800.472.6477 *(US and Canada)*
732.548.0600 *(Select option 1)*

EMAIL
customerservice@orielstat.com

ONLINE
www.orielstat.com/training

Visit us on Linkedin!

Registration Fees

For Public, In-Person Seminars

Registration fees are due and payable prior to the start of the course and include all course materials and lunch. Program schedules with start times will be sent with the registration confirmation.

For Virtual Instructor-Led Training (VILT)

Students will not be granted access to the link to access the virtual training classroom until full payment is received. The VILT session includes an eBook. Access to course materials is typically granted the Friday before the start of the class. Phone charges incurred if a participant uses a dial-in number to join the audio portion of the training are the responsibility of the student.

A personal device, such as a laptop or tablet, will make it easier to participate in some workshop activities and certain courses have online exams or other homework assignments that require a device to complete.

Payment and Purchase Orders

Personal checks, company checks, Visa, American Express, Mastercard, and purchase orders are all accepted.

Substitutions, Transfers, Cancellations Policy

Substitutions

If you cannot attend a course, you may send an alternate person to attend in your place. You can make a substitution at any time, at no additional charge. Email customerservice@ orielstat.com and tell us the alternate's name, the course name, and the session dates.

Transfers and Cancellations

You may transfer to a different course session (based on availability). Transfers and cancellations will be charged as follows:

- 22 or more days before the course start date: no charge
- 15–21 days before the course start date: 25% of the tuition
- 8–14 days before the course start date: 50% of the tuition
- 7 or fewer days before the course start date: 100% of the tuition

Please check website regarding COVID-19 related cancellation policy for in-person training.

Email your requests for cancellations, transfers, or substitutions to customerservice@orielstat.com.

Additional

In-person training follows the CDC and local health protocols at the time of the event.

Hotel Information for In-Person Training

All courses are scheduled at hotels. Hotel locations are typically finalized 21–28 days prior to the start of the course and will be provided once the course is confirmed.

Session-Specific Links and Login Information for Virtual Learning

Links to and login information for the virtual classroom are provided by email, typically the Friday before the start of the training.

Notice

Oriel STAT A MATRIX prohibits tape or digital recordings of any sessions.

Oriel STAT A MATRIX reserves the right to rearrange course content and is not responsible for typographical errors. Courses may be canceled and locations may be changed at the discretion of Oriel STAT A MATRIX. Oriel STAT A MATRIX is not responsible for airfare, hotel, or other costs incurred by registrants. To ensure an optimal learning environment, Oriel STAT A MATRIX reserves the right to remove disruptive students and not provide a refund. For quality assurance purposes, Oriel STAT A MATRIX may monitor or record our virtual and/or in-person seminars. Recordings will not be shared with learners. By attending the course, you agree to being recorded.

Policy

Oriel STAT A MATRIX does not discriminate on the basis of race, national origin, religion, gender, age, or ability in its policies, procedures, or practices.

Please tell us how we can best accommodate your needs.

EXEMPLAR GLOBAL CERTIFIED COURSES

Oriel STAT A MATRIX is a recognized training provider with Exemplar Global. Our Lead and Internal Auditor Training courses provide evidence of knowledge and skills aligned with their auditor personnel certification schemes. To successfully complete the course, you must earn a passing grade in the course assessments and pass the final examination. To enroll in an Exemplar Global auditor personnel certification program, you will need to register with Exemplar Global and may need to complete additional requirements, such as providing an audit log. Full details of the Exemplar Global QMS Auditor personnel certification requirements and process may be found at www.exemplarglobal.org.

ATTENDEES MUST BRING THEIR OWN LAPTOP COMPUTER (preferred) or TABLET with current web browser and Microsoft Word installed, in order to complete required learning assignments and the final online exam.

Dates and prices are current as of time of publication.
For the latest information, check out our website.

INSTRUCTOR SPOTLIGHT

Our instructors have, on average, 20 years of real-world experience. They teach effectively and keep the classroom atmosphere lively and varied.

Courses may also be taught by other Oriel STAT A MATRIX regulatory and quality experts.

CHRISTINE PARK

Christine has 30+ years of experience in medical device and IVD RA/QA. Christine has served on the working groups authoring ISO 13485:2016; ISO 14971:2019 and ISO/TR 24971:2020; and ISO 20416:2020. Christine brings a pragmatic and common-sense approach to help organizations design and establish good practices and achieve regulatory compliance.

> **Christine** was top-notch and very knowledgeable of the requirements. I can use 100% of this immediately at my organization.
> – CAPA Manager

JOSEPH SILVIA

Joe has extensive experience in medical device software, device security (cybersecurity), mobile apps, wireless technology, wireless coexistence, interoperability, MDDS, and emerging technology. His teaching and consultative approach is collaborative, hands-on, and effective. His deep understanding of software quality and cybersecurity ensures that students stay ahead in this fast-moving area.

> **Joe** brings enormous energy and knowledge to the classroom. Great class.
> – Sr. Manager, Software Design Quality

HARLOW THIELKE

Harlow brings over 20 years of experience to the classroom. From time spent as a college professor to conducting audits in the life sciences sector on a wide array of standards and regulations (including ISO 13485, ISO 9001, and 21 CFR 820) for major device manufacturers, Harlow brings passion, experience, and practical knowledge to each Oriel STAT A MATRIX training class.

> Great instructor. **Harlow** was able to answer all my questions and relate them back to my own organization!
> – RA Manager

JOHN LOVE

John has more than 20 years of training and course development experience that spans production management, quality and regulatory training, document control, root cause investigation, and internal auditing. John is passionate about developing and delivering training to ensure that learning objectives are met during classroom time and that lessons learned are maintained and applied back to the job.

> **John** is effective and engaging — he sure knows how to work a classroom!
> – Sr. Quality Director

CANDICE BETZ

Candice has more than 30 years of experience as a quality and regulatory professional for medical devices, *in vitro* diagnostic (IVD) devices, LDTs, drug/device combination products, and tissue products. As an Oriel STAT A MATRIX instructor, Candice brings her extensive expertise and experience to deliver memorable and useful training.

> **Candice** was great! She had great energy and made the class really fun and enjoyable.
> – Sr. Quality Systems Specialist

GENE REDIG

Gene has more than 25 years of medical device, biotech, and high-tech experience and is responsible for software, quality management systems, and regulatory projects and training. His expertise spans software development, quality systems, risk management, FDA/ISO regulations, qualification/validation, and auditing. This broad experience helps attendees get the most out of his training sessions.

> **Gene** blew the class away with his in-depth knowledge of the subject.
> – Director Software Engineering

OSAM consultants provide our customers with practical interpretations of US, European, and global requirements. They are ready to help your organization start a new program, expand an existing program, or reenergize a stalled initiative.

OMAR GONZALES

Omar has over two decades of medical device and diagnostics RA/QA experience supporting life sciences companies across the globe, as well as serving as an auditor for SGS North America. Leveraging his Notified Body and industry expertise, Omar brings meaningful perspective and insight to each customer engagement. Clients consistently note his extensive knowledge and dedication to success as key distinctions.

> **Omar's** *all-encompassing knowledge was amazing – he's truly at the top of his game!*
> *– VP Quality*

YOGI DELLOW

Yogi has 20+ years of life sciences RA/QA and compliance experience, including medical device and pharmaceutical laws, regulations, and standards. She has served as Response Team Lead for FDA and Notified Body remediation activities regarding EU MDR, vigilance trends, Medwatch inquiries, FDA 483s, and recall reports. She has extensive experience working with manufacturers to understand the new EU MDR and IVDR.

> **Yogi** *is a dynamic instructor whose deep knowledge transfers impactfully to her students.*
> *– RA Director*

CAROLYN TOMLINSON

Carolyn brings more than 20 years of quality engineering experience in life sciences to the classroom. Her focus is on training related to QA, ISO 13485, FDA's QSR, CAPA, auditing, and performance excellence. Carolyn leverages her real-world experiences to ensure that students obtain a practical understanding of classroom topics.

> **Carolyn** *was fabulous – very knowledgeable and supported information with regulatory references and examples from the real world.*
> *– Quality Manager*

ALICIA HEMPHILL

Alicia's regulatory experience spans over 2 decades in negotiating and bringing medical devices from concept through to commercialization. She is responsible for multiple IDEs, PMAs, 510(k)s, direct FDA and NB Q-Sub negotiations, design dossiers, and multiple approvals in Canada, China, Japan, Latin America, and Australia.

> **Alicia** *was great at framing complex regulatory concepts in easy-to-understand terms.*
> *– Director RA*

RICHARD VINCINS

Richard has 25+ years of global medical device, IVD, and pharmaceutical Quality Systems Regulation experience and expertise in submission content, regulatory classifications, risk management, software-driven products, postmarket surveillance, complaint handling, adverse event reporting, inspection readiness, and auditing. Richard is responsible for 30+ FDA 510(k) clearances and has been involved in EC certification for more than 60 tech files varying from Class I to III.

> **Richard's** *ability to pull from his vast experience enhanced my training.*
> *– VP Regulatory Affairs*

KESHU NSO

Keshu has a decade of RA/QA experience, with a special focus on regulatory submissions for the biotech, pharmaceutical, and medical device industries. Her expertise encompasses US, EU, Japanese, and Canadian regulations. As well, Keshu is an experienced auditor to a variety of regulations and standards, including FDA QSR, ISO 13485, ISO 14971, MDSAP, and the EU MDR.

> **Keshu** *was incredible – she streamlined our FDA submission and made the process as painless as possible.*
> *– VP Regulatory Affairs*

Move Beyond Conformance

Medical Device and IVD RA/QA Consulting

WITH AN ORIEL STAT A MATRIX AUDIT – REMOTE OR IN PERSON!

An Oriel STAT A MATRIX **quality management system (QMS)** audit goes beyond surface findings to examine process interactions and efficiency. Whether you need to supplement your internal team for a single audit or require support for a global supplier audit program, choose Oriel STAT A MATRIX to provide an independent, unbiased, and objective view of your quality system and processes.

Because we are consultants, not a certification or regulatory body, we can also provide suggestions on both how to improve your processes and how your suppliers can improve their operations to help them better meet your quality requirements.

PARTNER WITH ORIEL STAT A MATRIX FOR:

- Internal audits
- Baseline assessments
- FDA and MDSAP mock audits
- EU MDR and EU IVDR implementation audits
- Supplier audits
- Preassessment audits
- Practice audits with newly trained auditors to ensure they are correctly applying the tools they learned

Leverage our team's experience to achieve and maintain US FDA and global regulatory compliance with consulting support for the entire product life cycle.

OUR MEDICAL DEVICE AND IVD REGULATORY AND QMS COMPLIANCE EXPERTS CAN HELP WHEN YOU NEED TO:

- Facilitate global regulatory compliance to applicable requirements and standards, such as ISO 13485, FDA GMP, EU MDR, EU IVDR, and other quality system specifications.
- Prepare a global regulatory strategy, 510(k) or PMA submission, STED application, design dossier/technical file, and other product registration documentation for regulatory submission and worldwide product registration.
- Develop/update clinical evaluation reports (CERs), technical documentation, and performance evaluation reports (PERs) for EU MDR/IVDR compliance.
- Obtain independent expert quality and/or regulatory guidance on project teams in commonly known problem areas within a QMS, such as CAPA, complaint handling, design controls, and supplier quality – or when you require assistance with recalls.
- Mitigate serious QMS deficiencies, including development and implementation of corrective action plans to address 483 observations, warning letters, or consent decrees.
- Establish and maintain relationships with regulatory agencies, including Notified Bodies, as well as US, international, and selected registrars.
- Conduct gap analysis and/or risk assessment and take actions to mitigate risks that have been identified.
- Plan, design, and deliver training programs, including evaluating their effectiveness.
- Audit your QMS or a supplier's QMS.
- Ensure that you are prepared and ready for an FDA inspection or an audit.

To learn more,
call **800.472.6477**
or email **info@orielstat.com**.

To schedule a free consultation,
contact us by phone at **800.472.6477**
or by email at **info@orielstat.com**.

GET UP AND RUNNING – FAST!

RA/QA Staff Augmentation for Medical Device and IVD Manufacturers

LICENSE TRAINING MATERIALS FROM ORIEL STAT A MATRIX

Sometimes your company may need some temporary assistance, and we are here to help. Our flexible and cost-effective solutions are designed to address fluctuating resource capability or capacity so you can manage and sustain US FDA, EU, and international regulatory requirements.

OUR TIME-TESTED MATERIALS ARE WELL KNOWN FOR:

- Conveyance of complex topics in simple formats
- Modular design that allows for consistency, scalability, and flexibility in delivery
- Clear flow and structure
- Meaningful artwork and graphics
- Thoroughness of explanations aided by extensive notes
- Industry-specific examples
- Comprehensive skills development for all roles
- Trainer support materials and job aids that facilitate and simplify instructor preparation

ORIEL STAT A MATRIX also can provide train-the-trainer programs and coaching sessions to help your trainers quickly master how to use the materials. The programs go beyond the fundamentals of the subject matter, training participants on the skills essential to teach and coach groups for ongoing quality improvement.

Join the scores of organizations – from Fortune 500 companies to small firms – that rely on Oriel STAT A MATRIX's materials to provide the foundation for their performance improvement and regulatory compliance training programs.

These are some of the ways our highly experienced medical device regulatory affairs and quality assurance experts can help:

- **COVERAGE FOR STAFFING GAPS**. Did someone leave your team recently? We can quickly fill the void until you hire a replacement and train them after they start on the job.
- **PROJECT RAMP-UP**. From clinical evaluation reports (CERs) to SOP overhauls, we can jump-start a project or add capacity to help meet a looming deadline.
- **NICHE PROJECTS**. Don't have the skills in-house to handle a specialized short-term project? We can build a team to help you complete it quickly.
- **START-UP OUTSOURCING**. Not yet able to hire your first RA/QA director? We can fill the void and keep you in compliance until you're ready.

Contact us at **800.472.6477** or **info@orielstat.com** for more information about our flexible licensing plans.

For more information about our RA/QA outsourced services support, contact us by phone at **800.472.6477** or by email at **info@orielstat.com.**

eLearning

PRIVATE TRAINING

Let Oriel STAT A MATRIX enhance your organization's RA/QA learning and development program with our eLearning solutions

Our library of foundation and awareness modules covers important topics like **risk management**, **document control**, **quality management systems**, and **European regulations**. We can also work with you to develop a unique eLearning program specifically for your organization.

MOST POPULAR MODULES
- Overview of ISO 13485:2016, Medical Device Regulations, and Standards
- Quality Management System Basics
- Introduction to the EU IVDR
- EU MDR and Clinical Evaluation

BENEFITS INCLUDE:
- Proven, up-to-the-minute content sourced from the largest library of RA/QA learning assets in the medical device industry
- All the benefits of eLearning – anyone, anytime, anywhere
- Instructional design and development experts utilizing current authoring tools and techniques – seamless integration with today's learning management system platforms
- Objective-based assessments that provide evidence that learners have mastered the desired content

Contact us at **800.472.6477** or **info@orielstat.com** for more information about licensed eLearning solutions from Oriel STAT A MATRIX.

Benefits of private training include:

- **IT'S CUSTOMIZABLE.** **Oriel STAT A MATRIX**'s existing courses can be customized to meet your team's specific business needs. This often includes integrating your specific products, processes, and other critical functions into the training.

- **IT'S COST-EFFECTIVE.** If you need to train 5 or more members of your team, a private class will cost you less per student than a public one.

- **IT'S CONVENIENT.** Private training happens on your schedule. We manage the delivery platform (if virtual), certificates of completion, and training materials.

Oriel STAT A MATRIX can also customize formal certification programs for your organization that cover subject matter areas critical to the medical device and life sciences industries.

For more information on how we can create the perfect training experience for your team, contact us by phone at **800.472.6477** or by email at **info@orielstat.com**.

It's challenging to provide consistent training and get consistent results when you train one person at a time. Training a group together eliminates these problems and also allows the attendees to coalesce as a team, further increasing the value of the training.

All of our instructor-led training classes can be delivered privately to your organization (either as a virtual seminar or as onsite training).

Document Employee Training

TIP TO STAYING COMPLIANT

FAILING TO PROPERLY DOCUMENT TRAINING is a common citation that FDA and Notified Bodies give to companies they are auditing. But this is a citation that can easily be avoided by following just two steps.

THE FIRST STEP is to set up a training matrix to help with the following:

- Identifying job-specific training requirements
- Tracking completed training for individuals and departments
- Demonstrating to an auditor or inspector that training is taking place and being tracked

However, to fulfill this step, you need more than a master Excel spreadsheet listing all employees on one worksheet and a checkbox next to Employee X's name saying they have been trained on SOP #24. FDA inspectors and auditors want to see proof that the employee was actually trained. Simply asking an employee to "read and acknowledge" a document does not cut it as evidence of training!

THE SECOND AND VITAL STEP is to gather and maintain that proof of training. Below is a guide to what documentation is needed based on the type of training given.

DOCUMENTING EMPLOYEE TRAINING

	In-person instructor-led group training	Virtual instructor-led group training	Online self-paced eLearning training modules	SOP or work instructions emailed to an employee	One-on-one training between manager and employee	Third-party instructor-led *(in person, virtual, or eLearning training)*
Acceptable ✓	Employee sign-in sheet, individual attendance sheet, certificate of competency, or certificate of completion	Certificate of competency, certificate of completion, or proof of CEU credit	Confirmation of completion (or passing the test) issued by the learning management system (LMS), or proof of CEU credit	Not acceptable as proof of training	Individual attendance sheet signed by employee	Certificate of competency, certificate of completion, or proof of CEU credit
Unacceptable ✗	Attendee list without signatures	Registration confirmation email or notice	Registration confirmation email or notice	Not acceptable as proof of training	Screenshot of Outlook meeting invitation, or note in personnel file	Registration confirmation email or notice

For more information on training requirements, visit Oriel STAT A MATRIX's blog for the complete article "**A Guide for Managers: Employee Training Requirements for Medical Device and IVD Companies,**" as well as other industry-related posts.

Useful Resources

ORIEL STAT A MATRIX has educational **resources** available on our website that are focused on QMS and regulatory compliance for life sciences companies. These resources include overviews on subjects such as risk management, EU MDR, design control, and process validation.

In addition, our **blog** is packed with informative and insightful articles focused on topics relevant to RA/QA professionals in the life sciences industry. Here are just a few examples of the types of informative articles you can find there:

- **Understanding FDA and EU Medical Device Labeling Requirements**
- **Software as a Medical Device: How to Determine Your SaMD Regulatory Obligations**
- **Understanding ALCOA Principles and FDA & EU Data Integrity Principles for Pharma**
- **How to Evaluate, Select Combination Products Suppliers**

We update our blog (**www.orielstat.com/blog**) regularly with new articles, so be sure to check back often. And if you have any topics that you'd like us to cover, please let us know at **training@orielstat.com**.

ORIEL STAT A MATRIX IS HERE TO HELP

Are you looking to:

- Bring a new medical device to market?
- Implement MDSAP or the new EU regulations?
- Harmonize a quality system across a global organization?
- Enhance your organization's productivity?

More complex products, global supply networks, and changing global requirements make today's regulatory landscape more difficult to navigate than ever. You need a partner with the experience to ensure that you meet your quality and regulatory goals across the full product life cycle.

With our comprehensive library of **RA/QA training content** and **extensive experience with auditing and consulting** that spans a product's full life cycle – **Oriel STAT A MATRIX** is that partner. Contact us at **800.472.6477** or **info@orielstat.com**.

ORIEL STAT A MATRIX is a part of the Validant Group, the leading global consulting firm providing solutions to life sciences companies that are researching, developing, and manufacturing innovative products to serve patients and respond to public health challenges. The Validant Group's companies are able to deliver coordinated services that meet multiple areas of need throughout the product life cycle.

DATAREVIVE is a regulatory strategy and consultancy firm that focuses on supporting pharma and biotech to navigate the regulatory approval pathway for global clients in the US market.

GREENLEAF HEALTH is a leading FDA regulatory consulting firm that provides strategic and technical guidance to pharmaceutical, biotechnology, and medical device companies that are researching, developing, and manufacturing innovative solutions to pressing global public health challenges.

IDEC offers regionally specialized regulatory guidance and end-to-end drug product support for pharmaceutical innovators seeking approval in the Japanese market. IDEC assists with both design and implementation of market entry, commercialization, and product management strategies.

VALIDANT is a full-service life sciences consulting firm serving developers and manufacturers of pharmaceuticals, biologics, medical devices, and diagnostics worldwide. Validant provides strategy, execution, and ongoing support for a range of regulatory, compliance, and quality needs.

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